Mr. Donald A. Flater, Chief
Bureau of Radiological Health
Iowa Department of Public Health
Lucas State Office Building
Des Moines, IA 50319

JAN 14 2000

Dear Mr. Flater:

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Sincerely,

Original signed by:

Frederick C. Combs, Deputy Director
Office of State Programs

Enclosures:
As stated

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DATE	01/05/2000*		01/05/2000*		01/13/2000*		01/11/2000*			

OSP FILE CODE: SP-AG-9

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

January 14, 2000

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COMMENTS ON FINAL IOWA REGULATIONS AGAINST COMPATIBILITY AND HEALTH AND SAFETY CATEGORIES

Category	State Regulation	NRC Regulation	RATS ID	Subject and Comments
A	38.2	35.2(4)(ii)	1995-1	Definition "Misadministration"(teletherapy criteria) The word "or" after the word "fractions" should be changed to "and" to meet the compatibility category.
C	40.75	61.80(l)(1)	1995-3	Transfer for Disposal and Manifests Section 47.75 does not address the requirement for an electronic recordkeeping system for manifests and other information pertaining to receipt and disposal of radioactive waste as addressed in 10 CFR 61.80(l)(1). Consequently, 40.75 needs to be amended to incorporate the essential objectives of the text of 10 CFR 61.80(l)(1) to meet the compatibility category.
B	45.3(4)	34.20(f)	1995-4	Performance Requirements for Radiography Equipment The elimination of an impractical torque test as specified in 10 CFR 34.20(f) is not addressed. This provision is also in RATS 1997-5 and Sec. E.6 of concurred Part E. This provision needs to be essentially identical to meet the compatibility category.
A	38.2	20.1003	1997-3	Definitions "Occupational Dose" and "Public Dose" definitions do not include references to exposure to individuals administered radioactive material and released in accordance with Iowa's equivalent to 10 CFR 35.75. These definitions need to be essentially identical to meet the compatibility category.
A	38.2	20.1003	1997-6	Definitions "Background Radiation" definition does not include radiation from accidents like Chernobyl. The following definitions were not incorporated: "Critical Group" "Decommission" "Distinguishable from Background" "Residual Radioactivity" These definitions need to be essentially identical to meet the compatibility category.

REGULATION ASSESSMENT TRACKING SYSTEM
RATS DATA SHEET

State: Iowa
[12 final amendments (date TBD by IOWA) identified by★]

Tracking Ticket Number: 0-15
Date: January 14, 2000

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed/ Final-Comment (Y/N)[1]	NRC Review Date	Final State Regulation[2] (Effective Date)
Standards for Protection Against Radiation-Part 20	56 FR 23360 plus others (1/1/94)	1991-3	F-N	11/6/97	10/9/96
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843 (1/10/94)	1991-1			
ASNT Certification of Radiographers-Part 34	56 FR 11504 (none)	1991-2			Not required[3]
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980 (10/15/94)	1991-4			
Quality Management Program and Misadministrations - Part 35	56 FR 34104 (1/27/95)	1992-1			
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30,35	57 FR 45566 (none)	1992-2			Not required
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715 (7/1/96)	1993-2			Not applicable SECY-95-112
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886 (7/22/96)	1993-3			Not applicable SECY-95-112
Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628 (10/25/96)	1993-1			
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726 59 FR 1618 (none)	1994-1			Not required
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40	59 FR 28220 (7/1/97)	1994-2			Not applicable
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026 (8/15/97)	1994-3			
★Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use-Parts 30, 32, 35	59 FR 61767 59 FR 65243 60 FR 322 (1/1/98)	1995-1	F-Y	1/14/00	
★Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900 (3/13/98)	1995-2	P-Y F-N	2/27/98 1/14/00	
★Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649 60 FR 25983 (3/1/98)	1995-3	F-Y	1/14/00	

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★Performance Requirements for Radiography Equipment- Part 34	60 FR 28323 (6/30/98)	1995-4	F-Y	1/14/00	
★Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038 (8/14/98)	1995-5	F-N	1/14/00	
★Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235 (11/24/98)	1995-6	F-N	1/14/00	
★Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623 (10/20/98)	1995-7	F-N	1/14/00	
10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248 61 FR 28724 (4/1/99)	1996-1			
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses-Parts 30, 40, 70	61 FR 1109 (none)	1996-2			Not required
★Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669 (6/17/99)	1996-3	F-N	1/14/00	
★Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61 FR 65119 (1/9/00)	1997-1	F-N	1/14/00	
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907 (none)	1997-4			Not required
Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State-Part 150	62 FR 1662 (2/27/00)	1997-2			
★Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120 (5/29/00)	1997-3	F-Y	1/14/00	
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150	62 FR 28948 (6/27/00)	1997-5			
★Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057 (8/20/00)	1997-6	F-Y	1/14/00	
★Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea-Part 30	62 FR 63634 (1/02/01)	1997-7	F-N	1/14/00	
Deliberate Misconduct by Unlicensed Persons- Parts 30, 40, 61, 70, 150	63 FR 1890 63 FR 13773 (2/12/01)	1998-1			
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees-Parts 30, 40, 70	63 FR 29535 (none)	1998-2			Not required
License Term for Medical Use Licenses- Part 35	63 FR 31604 (none)	1998-3			Not required
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059 (7/9/01)	1998-4			

NRC Chronology Identification	FR Notice (State Due Date)	RATS ID	Proposed/ Final-Comment (Y/N)[1]	NRC Review Date	Final State Regulation[2] (Effective Date)
Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36	63 FR 39347 63 FR 45393 (10/26/01)	1998-5			
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127 (11/20/01)	1998-6			
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506 (6/11/02)	1999-1			Not applicable

1. (Y/N) Y means "Yes," there are comments in the review letter that the State needs to address. N means "No," there are no comments in the review letter.

2. Or other generic Legally Binding Requirement.

3. Not required means these regulations are not required for purposes of compatibility.

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DCD (SP07) PDR (YES)

no legal objection

*See previous concurrence

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Iowa Department of Public Health
Promoting and protecting the health of Iowans

Stephen C. Gleason, D. O., Director
Lucas State Office Building
Des Moines, IA 50319-0075
515-281-5787

chapter 38
GENERAL PROVISIONS

641—38.1(136C) Purpose and scope.

38.1(1) Except as otherwise specifically provided, these rules apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in these rules shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission. Attention is directed to the fact that regulation by the state of source material, by–product material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the state and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.

38.1(2) All references to Code of Federal Regulations (CFR) in this chapter are those in effect as of July 1, 1999.

38.1(3) The provisions of Chapter 38 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 39 to 45.

641—38.2(136C) Definitions. As used in these rules, these terms have the definitions set forth below and are adopted by reference and included herein for 641—Chapters 39 to 45.

"A_1" means the maximum activity of special form radioactive material permitted in a Type A package.

"A_2" means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are either listed in Appendix E of 641—Chapter 39, Table I, or may be derived in accordance with the procedure prescribed in Appendix E of 641—Chapter 39.

"Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. It is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the gray (Gy). The units of absorbed dose are the gray (Gy) and the rad.

"Absorbed dose rate" means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

"Accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV. For purposes of this definition, "particle accelerator" is an equivalent term.

"Accelerator–produced material" means any material made radioactive by a particle accelerator.

"Act" means 1984 Iowa Acts, chapter 1286, relating to regulation of radiation machines and radioactive materials. (Iowa Code chapter 136C)

"Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).

"Adult" means an individual 18 years of age or older.

"Agency" means the Iowa department of public health.

"Agreement state" means any state with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under Subsection 274b of the Atomic Energy Act of 1954 as amended (73 Stat. 689).

"Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particles, mists, vapors, or gases.

"Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive material exists in concentrations (1) in excess of the derived air concentrations (DACs) specified in Appendix A of 641—Chapter 40; or (2) to such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC–hours.

"Air kerma (K)" means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

"Annually" means at least once every 365 days.

"As low as is reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these rules as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

"Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an X–ray system or subsystem. The term includes the owner of an X–ray system or the employee or agent who assembles components into an X–ray system that is subsequently used to provide professional or commercial services.

"Background radiation" means radiation from cosmic sources, naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include sources of radiation from radioactive materials regulated by the agency.

"Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

"Becquerel" (Bq) means the SI unit of activity. One becquerel is equal to 1 disintegration or transformation per second (dps or tps).

"Bioassay" means the determination of kinds, quantities or concentrations and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these rules, "radiobioassay" is an equivalent term.

"Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

"By–product material" means (1) any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material, and (2) the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "by–product material" within this definition.

"Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet shielded so that radiation levels at every location on the exterior meet the limitations specified in 641—40.26(136C).

"Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method of determining calendar quarters for purposes of these rules except at the beginning of a year.

"Calibration" means the determination of (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or (2) the strength of a source of radiation relative to a standard.

"CFR" means Code of Federal Regulations.

"Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

"Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

"Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50–year period following the intake.

"Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = Sw_T,H_{T,50}$).

"Constraint" or *"Dose constraint"* means a value above which specified licensee actions are required.

"Curie" means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7E+10 transformations per second (tps).

"Decay–in–storage" means the holding of radioactive material having half–lives of less than 65 days, except Cobalt–57, until it decays to background levels. Before disposal in ordinary trash, the material must have been held for a minimum of ten half–lives and its radioactivity is indistinguishable from background as indicated by a survey meter set on its most sensitive scale with no interposing shielding.

"Deep dose equivalent" (H_d), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

"Depleted uranium" means the source material uranium in which the isotope uranium–235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

"Diagnostic clinical procedures manual" means a collection of written procedures that describes each

method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

"Diagnostic X-ray imaging system" means an assemblage of components for the generation, emission and reception of X-rays and the transformation, storage and visual display of the resultant X-ray image which are designed and used for irradiation of any part of the human body for the purpose of diagnosis or visualization.

"Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these rules, "radiation dose" is an equivalent term.

"Dose equivalent (H_T)" means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

"Dose limits" means the permissible upper bounds of radiation doses established in accordance with these rules. For purposes of these rules, "limits" is an equivalent term.

"Effective dose equivalent (H_E)" means the sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = Sw_T H_T$).

"Embryo/fetus" means the developing human organism from conception until the time of birth.

"Entrance or access point" means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

"Exposure" means being exposed to ionizing radiation or to radioactive material.

"Exposure" means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. (The special unit of exposure is the roentgen (R) (see 38.2(136C) for SI equivalent coulomb per kilogram). When not underlined as above or when indicated as 'exposure' or (X), the term "exposure" has a more general meaning in these rules.

"Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

"External dose" means that portion of the dose equivalent received from any source of radiation outside the body.

"Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

"Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/cm^2).

"Facility" means the location, building, vehicle, or complex under one administrative control, at which radioactive material is stored or used or at which one or more radiation machines are installed, located or used.

"Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants,

or critical mass experimental facilities where AEC or NRC licenses have been terminated.

"Generally applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

"Gray (Gy)" means the SI unit of absorbed dose, kerma, and specific energy imparted equal to 1 joule per kilogram. (1 Gy=100 rad).

"Half–value layer (HVL)" means the thickness of a specified material which attenuates X–radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one–half of the value measured without the material at the same point.

"Hazardous waste" means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part 261.

"Healing arts" means the occupational fields of diagnosing or treating disease, providing health care and improving health by the practice of medicine, osteopathy, chiropractic, podiatry, dentistry, nursing, veterinary medicine, and supporting professions, such as physician assistants, nurse practitioners, radiologic technologists, and dental hygienists.

"High radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or from any surface that the radiation penetrates.

"Human use" means the internal or external administration of radiation or radioactive material to human beings.

"Individual" means any human being.

"Individual monitoring" means the assessment of:

1. Dose equivalent by the use of individual monitoring devices or by the use of survey data; or

2. Committed effective dose equivalent by bioassay or by determination of the time–weighted air concentrations to which an individual has been exposed, that is, DAC–hours. See the definition of DAC–hours in 641—Chapter 40.

"Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these rules, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, optically stimulated luminescent (OSL) devices, and personal air sampling devices.

"Industrial radiography" means a nondestructive testing method using ionizing radiation, such as gamma rays or X–rays, to make radiographic images.

"Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the agency.

"Instrument traceability" means, for ionizing radiation measurements, the ability to show that an instrument has been calibrated at specified time intervals using a national standard or a transfer standard. If a transfer standard is used, the calibration must be from a laboratory accredited by a program which required continuing participation in measurement quality assurance with the National Institute of

Standards and Technology or other equivalent national or international program.

"Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

"Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

"Ionizing radiation." See "Radiation."

"Irradiation" means the exposure of matter to ionizing radiation.

"License" means a license issued by the agency in accordance with the rules adopted by the agency.

"Licensed (or registered) material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license (or registration) issued by the agency.

"Licensed practitioner" means a person licensed or otherwise authorized by law to practice medicine, osteopathy, chiropractic, podiatry, dentistry, or certification as a physician assistant as defined in Iowa Code section 148C.1, subsection 6, and is authorized to prescribe X–ray tests for the purpose of diagnosis or treatment.

"Licensee" means any person who is licensed by the agency in accordance with these rules and the Act.

"Licensing state" means any state with regulations equivalent to the suggested state regulations for control of radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

"Limits." See "Dose limits."

"Lost or missing licensed (or registered) source of radiation" means licensed (or registered) source of radiation whose location is unknown. This definition includes licensed (or registered) material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

"Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in 641—subrule 39.5(2).

"Medical use" means the intentional internal or external administration of radioactive material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user.

"Member of the public" means any individual except when that individual is receiving an occupational dose.

"Minor" means an individual less than 18 years of age.

"Misadministration" means the administration of:

1. A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I–125 or I–131:

Involving the wrong patient or human research subject, or wrong radiopharmaceutical; or

When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries.

2. A therapeutic radiopharmaceutical dosage, other than sodium iodide I–125 or I–131:

Involving the wrong patient or human research subject, wrong radiopharmaceutical, or wrong route of administration; or

When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

3. A gamma stereotactic radiosurgery radiation dose:

Involving the wrong patient or human research subject, or wrong treatment site; or

When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.

4. Radiation doses received from teletherapy, linear accelerator therapy, deep X–ray machine therapy or superficial therapy; involving the wrong patient or human research subject, wrong mode of treatment or wrong treatment site;

When the treatment consists of three or fewer fractions or the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

When the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose; or

When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

5. A brachytherapy radiation dose:

Involving the wrong patient or human research subject, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);

Involving a sealed source that is leaking;

When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

6. A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodide I–125 or I–131, both:

Involving the wrong patient or human research subject, wrong radiopharmaceutical, wrong route of administration; or when the administered dosage differs from the prescribed dosage; and

When the dose to the patient or human research subject exceeds 5 rem effective dose equivalent or 50 rem dose equivalent to any individual organ.

"Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

"NARM" means any naturally occurring or accelerator–produced radioactive material. It does not include

by–product, source, or special nuclear material.

"Natural radioactivity" means radioactivity of naturally occurring nuclides. For the purpose of meeting the definition of a licensing state by the Conference of Radiation Control Program Directors, Inc., (CRCPD), NARM refers only to discrete sources of NARM. Diffuse sources of NARM are excluded from consideration by the CRCPD for licensing state designation purposes.

"Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

"Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation from licensed or unlicensed and registered or unregistered sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received from background radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the public.

"Package" means the packaging together with its radioactive contents as presented for transport.

"Particle accelerator." See "Accelerator."

"Patient" means an individual or animal subjected to healing arts examination, diagnosis or treatment.

"Peak tube potential" means the maximum value of the potential difference across the X–ray tube during an exposure.

"Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, but shall not include federal government agencies.

"Personnel monitoring equipment." See "Individual monitoring devices."

"Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

"Pharmacist" means an individual licensed by this state to compound and dispense drugs, prescriptions, and poisons.

"Physician" means a person who is currently licensed in Iowa to practice medicine and surgery, osteopathic medicine and surgery, or osteopathy.

"Prescribed dosage" means the quantity of radiopharmaceutical activity as documented:

1. In a written directive; or

2. Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

"Prescribed dose" means:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

2. For teletherapy, particle accelerators and X–ray systems, the total dose and dose per fraction as documented in the written directive; or

3. For brachytherapy, either the total source strength and exposure time or the total doses, as

documented in the written directive.

"Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been acquired.

"Principal activities," as used in this part, means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

"Public dose" means the dose received by a member of the public from exposure to sources of radiation possessed by a licensee, registrant, or other person, or to any other source of radiation under the control of a licensee, registrant, or other person. It does not include occupational dose or doses received from background radiation, as a patient from medical practices, or from voluntary participation in medical research programs.

"Pyrophoric material" means any liquid that ignites spontaneously in dry or moist air at or below 130° F (54.4° C) or solid, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water–reactive materials.

"Qualified expert" means an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs. For example, individuals certified in the appropriate field by the American Board of Radiology, the American Board of Medical Physics, or the American Board of Health Physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, for example, individuals certified in Therapeutic Radiological Physics or X–Ray and Radium Physics by the American Board of Radiology, or those having equivalent qualifications.

"Quality factor" (Q) means the modifying factor, listed in Tables I and II of 38.4(4), that is used to derive dose equivalent from absorbed dose.

"Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray).

"Radiation" means alpha particles, beta particles, gamma rays, X–rays, neutrons, high–speed electrons, high–speed protons, and other particles capable of producing ions. For purposes of these rules, ionizing radiation is an equivalent term. Radiation, as used in these rules, does not include nonionizing radiation, such as radiowaves, visible, infrared, or ultraviolet light.

"Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

"Radiation dose." See "Dose."

"Radiation machine" means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.

"Radiation safety officer" means an individual who has the knowledge and responsibility to apply appropriate radiation protection regulations and has been assigned such responsibility by the licensee or registrant.

"Radioactive material" means any solid, liquid, or gas which emits radiation spontaneously.

"Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

"Radiobioassay." See "Bioassay."

"Recordable event" means the administration of:

1. A radiopharmaceutical or radiation without a written directive where a written directive is required;

2. A radiopharmaceutical or radiation dose where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate rec–ord;

3. A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I–125 or I–131 when both:

a. The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and

b. The difference between the administered dosage and prescribed dosage exceeds 15 microcuries;

4. A therapeutic radiopharmaceutical dosage, other than sodium iodide I–125 or I–131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;

5. A teletherapy, particle accelerator or X–ray radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose; or

6. A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

"Registrant" means any person who is registered with the agency or is legally obligated to register with the agency pursuant to these rules and the Act.

"Registration" means registration with the agency in accordance with the rules adopted by the agency.

"Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100–189.

"Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

"Research and development" means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

"Restricted area" means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. A restricted area shall not include any areas used for residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

"Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs/kilogram of air (see "Exposure" and 38.4(4)).

"Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation

means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

"Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

"Shallow dose equivalent" (H_s), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of 1 square centimeter.

"SI" means the abbreviation for the International System of Units.

"Sievert" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

"Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

"Source" means the focal spot of the X–ray tube.

"Source material" means:

1. Uranium or thorium, or any combination thereof, in any physical or chemical form; or

2. Ores that contain by weight one–twentieth of 1 percent (0.05 percent) or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

"Source material milling" means any activity that results in the production of by–product material as defined by definition (2) of by–product material.

"Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

"Source traceability" means the ability to show that a radioactive source has been calibrated either by the national standards laboratory of the National Institute of Standards and Technology or by a laboratory which participates in continuing measurement quality assurance programs with the NationalInstitute of Standards and Technology or other equivalent national or international program.

"Special form radioactive material" means radioactive material which satisfies the following conditions:

1. It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

2. The piece or capsule has at least one dimension not less than 5 millimeters (0.2 inch); and

3. It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this definition applicable at the time of its design or construction.

"Special nuclear material" means:

1. Plutonium, uranium–233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the agency declares by order to be special nuclear material after the U.S. Nuclear

Regulatory Commission, pursuant to the provisions of Section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

2. Any material artificially enriched by any of the foregoing but does not include source material.

"Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U–235 in quantities not exceeding 350 grams of contained U–235; uranium–233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{\text{175 (grams contained U–235)}}{350} + \frac{\text{50 (grams U–233)}}{200} + \frac{\text{50 (grams Pu)}}{200} = 1$$

"Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

"Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"Test" means the process of verifying compliance with an applicable regulation.

"These rules" means 641—Chapters 38 to 45.

"Total effective dose equivalent" (TEDE) means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

"Total organ dose equivalent" (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in 641—40.86(1) *"f."*

"Traceable to a national standard." See "Instrument traceability" or "Source traceability."

"Tube" means an X–ray tube unless otherwise specified. See "X–ray tube."

"Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

"Unrestricted area" means an area to which access is neither limited nor controlled by the licensee or registrant. For purposes of these rules, "uncontrolled area" is an equivalent term.

"U.S. Department of Energy" means the Department of Energy established by Public Law 95–91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the department exercises functions formerly vested in the U.S. Atomic Energy Commission, its chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the administrator thereof pursuant to Sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93–438, October 11, 1974, 88 Stat. 1233 at 1237, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to Section 301(a) of the Department of Energy Organization Act (Public Law 95–91, August 4, 1977, 91 Stat. 565 at 577–578, 42 U.S.C. 7151, effective October 1, 1977).

"Waste" means those low–level radioactive wastes that are acceptable for disposal in a land disposal

facility. For the purposes of this definition, low–level waste has the same meaning as in the Low–Level Radioactive Waste Policy Act, P.L. 96–573, as amended by P.L. 99–240, effective January 15, 1986; that is, radioactive waste (1) not classified as high–level radioactive waste, spent nuclear fuel, or by–product material as defined in Section 11e(2) of the Atomic Energy Act (uranium or thorium tailings and waste) and (2) classified as low–level radioactive waste consistent with existing law and in accordance with (1) by the U.S. Nuclear Regulatory Commission.

"Waste handling licensees" means persons licensed to receive and store radioactive wastes prior to disposal or persons licensed to dispose of radioactive waste.

"Wedge filter" means an added filter effecting continuous progressive attenuation on all or part of the useful beam.

"Week" means seven consecutive days starting on Sunday.

"Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

"Worker" means an individual engaged in work under a license or registration issued by the agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

"Working level" (WL) means any combination of short–lived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3E+5 MeV of potential alpha particle energy. The short–lived radon daughters are—for radon–222: polonium–218, lead–214, bismuth–214, and polonium–214; and for radon–220: polonium–216, lead–212, bismuth–212, and polonium–212.

"Working level month" (WLM) means an exposure to 1 working level for 170 hours—2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

"Written directive" means an order in writing for a specific patient or human research subject, dated and signed by an authorized user or individual qualified by training and experience to conduct particle accelerator or X–ray therapy prior to the administration of a radiopharmaceutical or radiation, except as specified in paragraph "6" of this definition, containing the following information:

1. For any administration of quantities greater than 30 microcuries of either sodium iodide I–125 or I–131: the dosage;

2. For a therapeutic administration of a radiopharmaceutical other than sodium iodide I–125 or I–131: the radiopharmaceutical, dosage, and route of administration;

3. For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

4. For teletherapy, particle accelerator or X–ray: the total dose, dose per fraction, treatment site, and overall treatment period;

5. For high–dose–rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

6. For all other brachytherapy:

a. Prior to implantation: the radioisotope, number of sources, and source strengths; and

b. After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

"X–ray tube" means any electron tube which is designed to be used primarily for the production of X–rays.

"Year" means the period of time beginning in January used to determine compliance with the provisions of these rules. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

641—38.3(136C) Exemptions from the regulatory requirements.

38.3(1) *General provision.* The agency may, upon application therefor or upon its own initiative, grant such exemptions or exceptions from the requirements of these rules as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

38.3(2) *U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors.* Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this state is exempt from these rules to the extent that such contractor or subcontractor under contract receives, possesses, uses, transfers or acquires sources of radiation:

a. Prime contractors performing work for the U.S. Department of Energy at U.S. government–owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

b. Prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

c. Prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States government–owned vehicle or vessel; and

d. Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the state and the U.S. Nuclear Regulatory Commission jointly determine:

(1) That the exemption of the prime contractor or subcontractor is authorized by law; and

(2) That under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

641—38.4(136C) General regulatory requirements.

38.4(1) *Records.* Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in these rules.

38.4(2) *Inspections.*

a. Each licensee and registrant shall afford the agency at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

b. Each licensee and registrant shall make available to the agency for inspection, upon reasonable notice, records maintained pursuant to these rules.

38.4(3) *Tests.* Each licensee and registrant shall perform upon instructions from the agency, or shall permit the agency to perform, such reasonable tests as the agency deems appropriate or necessary including, but not limited to, tests of:

a. Sources of radiation;

b. Facilities wherein sources of radiation are used or stored;

c. Radiation detection and monitoring instruments; and

d. Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

38.4(4) *Units of exposure and dose.*

a. As used in these rules, the quality factors for converting absorbed dose to dose equivalent are shown in Table I.

TABLE I

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent[a]
X, gamma, or beta radiation and high–speed electrons	1	1
Alpha particles, multiple–charged	20	0.05
Particles, fission fragments and Heavy particles of unknown charge		
Neutrons of unknown energy	10	0.1
High–energy protons	10	0.1

[a] Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

b. If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in 38.4(4)*"c,"* 1 rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of these rules, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table II to convert a measured tissue

dose in gray or rad to dose equivalent in sievert or rem.

TABLE II

MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE

EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron Energy (MeV)	Quality Factor[a] (Q)	Fluence per Unit Dose Equivalent[b] (neutrons cm^{-2} rem^{-1})	Fluence per Unit Dose Equivalent[b] (neutrons cm^{-2} Sv^{-1})
(thermal)	2.5E–8	2	980E+6	980E+8
	1E–7	2	980E+6	980E+8
	1E–6	2	810E+6	810E+8
	1E–5	2	810E+6	810E+8
	1E–4	2	840E+6	840E+8
	1E–3	2	980E+6	980E+8
	1E–2	2.5	1010E+6	1010E+8
	1E–1	7.5	170E+6	170E+8
	5E–1	11	39E+6	39E+8
	1	11	27E+6	27E+8
	2.5	9	29E+6	29E+8
	5	8	23E+6	23E+8
	7	7	24E+6	24E+8
	10	6.5	24E+6	24E+8
	14	7.5	17E+6	17E+8
	20	8	16E+6	16E+8
	40	7	14E+6	14E+8
	60	5.5	16E+6	16E+8
	1E+2	4	20E+6	20E+8
	2E+2	3.5	19E+6	19E+8
	3E+2	3.5	16E+6	16E+8
	4E+2	3.5	14E+6	14E+8

[a] Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30–centimeter diameter cylinder tissue–equivalent phantom.

[b] Monoenergetic neutrons incident normally on a 30–centimeter diameter cylinder tissue–equivalent phantom.

38.4(5) *Units of activity.* Rescinded IAB 4/8/98, effective 7/1/98.

38.4(6) *Additional requirements.* The agency may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in these rules as it deems appropriate or necessary to minimize danger to public health and safety or property.

641—38.5(136C) Administrative actions.

38.5(1) *Enforcement requirements.* Upon determination by the agency that Iowa Code chapter 136C or any rule adopted pursuant to that chapter has been or is being violated, the agency may implement the policies and procedures specified in Bureau of Radiological Health Enforcement Program (BRH–EP–1).

38.5(2) *Impounding.* Sources of radiation shall be subject to impoundment pursuant to the Bureau of Radiological Health Enforcement Program (BRH–EP–1).

641—38.6(136C) Prohibited uses. A hand–held fluoroscopic screen shall not be used with X–ray equipment unless it has been accepted for certification by the U.S. Food and Drug Administration, Center for Devices and Radiological Health. A shoe–fitting fluoroscopic device shall not be used.

38.7(1) All communications and reports concerning these rules, and applications filed thereunder, should be addressed to the agency at its office located at the Iowa Department of Public Health, Bureau of Radiological Health, Lucas State Office Building, Des Moines, Iowa 50319.

38.7(2) Drafts of proposed regulations released to the department from the federal government which constitute essential information needed by the department to ensure compliance with federal regulations are not available for public examination. Therefore, pursuant to Iowa Code section 22.9, the department waives the provision of Iowa Code section 22.2 as it applies to these proposed draft regulations.

641—38.8(136C) Fees.

38.8(1) *Radiation machines.*

a. Each registrant shall, at the time of registration and the anniversary date thereafter, as long as the registrant owns the radiation machine, remit to the agency a fee sufficient to defray the cost of registering the equipment with the department. All fees shall be paid annually in the form of a check or money order made payable to the Iowa Department of Public Health. The fees to be paid shall be in the amount computed by the following schedule:

ANNUAL FEE SCHEDULE

Type of X–ray machine	Fee per tube	Maximum fee
1. Medical	$51	$1500
2. Osteopathy	$51	$1500
3. Chiropractic	$51	$1500
4. Dentistry	$39	$1000
5. Podiatry	$39	$1000
6. Veterinary Medicine	$25	—
7. (Industrial/Nonmedical Use)	$50	—
8. Sterilization	$80	—
9. Accelerators	$100	—
10. Electron Microscope	$20	—

Fees for radiation machines not listed in the above schedule shall not be less than $50 per unit/tube.

b. Each registrant shall, where appropriate, pay the following special inspections/interpretation fee at the written request of the department:

(1) Mammography unit inspections fees:

• $850 for the first unit and, if the facility has additional units at the address of the first unit, a fee of $300 for each additional unit; or

• $850 per portable unit for each site where the unit is off–loaded and used and where the processing and patient films are stored; or

• Dollar amount to be determined and justified by the department on a case–by–case basis for facilities which do not meet the above criteria.

(2) Mammography interpretation fees of $100 per mammography examination provided to the department for the purpose of determining film diagnostic quality.

(3) Industrial and oncology accelerator registrants shall pay for each inspection a fee of $400 for the first and $100 for each additional unit.

(4) Industrial radiography X–ray units/walk–in cabinet radiography X–ray unit registrants shall pay for each inspection a fee of $250 for the first unit and $75 for each additional unit.

c. Each person who is engaged in the business of installing or offering to furnish radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or service in the state shall apply for registration of such service with the agency prior to furnishing or offering to furnish any such service. Application shall be on a form provided by the department and include an annual nonrefundable fee of $100.

38.8(2) *Radioactive material licensing, inspection and registration fee.*

a. Licensing.

(1) Fees associated with licensing of the possession and use of radioactive materials in Iowa are identical to those specified in 10 CFR 170.31 entitled "Schedule of Fees for Materials Licenses and Other Regulatory Services."

(2) All required fees for new radioactive materials licenses, amendments to licenses, or renewal of licenses shall accompany the application for the requested action.

b. Inspections.

(1) After completion of an inspection, an inspection fee shall be assessed to a facility based on the fees for inspection found in 10 CFR 170.32 entitled "Schedule of Fees for Health and Safety, and Safeguards Inspections for Materials Licenses."

(2) All required fees for inspections conducted by the agency shall be paid within 30 days after receipt of the agency notification following the inspection.

c. Registration. Each person having generally licensed radioactive materials shall annually register with the department and pay a nonrefundable annual fee of $150.

38.8(3) *Industrial radiography testing and certification.*

a. A nonrefundable fee of $100 shall be submitted with each application for taking an industrial radiography examination to become certified by the agency.

b. A fee of $25 shall be submitted in order to replace lost identification cards issued to industrial radiographers by the agency pursuant to 641—subrule 45.11(3).

38.8(4) *Owner–assessed expenses.* In cases in which the agency determines that the cost of regulating or inspecting registered radiation machine facilities or radioactive materials licensees significantly exceeds the fees charged to the facility, it may assess an additional fee to the owner or user of the source(s) of radiation to cover the actual expenses incurred by the agency.

38.8(5) *Environmental surveillance fee.* A fee may be levied against any licensee for environmental surveillance activities which are necessary to access the radiological impact of activities conducted by the registrant or licensee. This fee shall be sufficient to defray actual costs incurred by the agency, including, but not limited to, salaries of agency employees, per diem, travel, and costs of laboratory analysis of samples, when required.

38.8(6) *Certification fees.* Diagnostic radiographers, radiation therapists, and nuclear medicine technologists, other than licensed practitioners of the healing arts, are required to pay fees sufficient to defray the cost of administering 641—Chapter 42. Fees are as follows:

a. Annual fee. Each individual must submit a $45 initial fee for the first year and $35 annually.

b. Examination fee.

(1) Each individual making application to take an examination given by the agency as a general diagnostic radiographer, or general radiation therapist as defined in 641—Chapter 42 must pay a nonrefundable fee of $25 each time the individual takes the examination required by 641—Chapter 42. Effective January 1, 2000, each individual must pay a nonrefundable fee of $80 each time the individual takes the examination.

(2) Each individual making application to take an examination given by the agency as a limited diagnostic radiographer, limited nuclear medicine technologist, or limited radiation therapist as defined in 641—Chapter 42 must pay a nonrefundable fee of $35 each time the individual takes the examination required by 641—Chapter 42. Effective January 1, 2001, each individual must pay a nonrefundable fee of $85 each time the individual takes the examination.

(3) Each individual making application to take an examination given by the agency as a general nuclear medicine technologist as defined in 641—Chapter 42 must pay a nonrefundable fee of either $80 or $145, depending upon the testing facility chosen, effective January 1, 2000.

c. Recertification fees. Once certification has been terminated for failure to complete continuing education requirements, any individual who requests permission to reestablish certification within six months of the initial continuing education due date must meet the training and testing requirements of 641—Chapter 42, submit proof of continuing education hours and shall submit a late fee of $30 in addition to the annual fee in order to obtain reinstatement of certification.

38.8(7) *Returned check and late fees.* Persons who fail to pay required fees to the agency are subject to the following penalties:

a. $15 for each payment received by the agency in accordance with these rules, for which insufficient funds are available to fulfill the obligation of such payment to the agency.

b. $25 for each month for failure to pay annual radiation machine registration or diagnostic radiation operator fee starting the first day of the month after the expiration of the facility's registration or operator's permit to practice. This fee is added to the unpaid annual fee.

38.8(8) *Reciprocity.* Fees paid for reciprocal recognition of out–of–state persons wishing to utilize radiation machines or radioactive materials in Iowa shall allow the out–of–state person to operate for a total of 180 days during the 365–day reciprocity period starting the date the fee is received by the agency.

a. Radiation machines. Any out–of–state person who wishes to bring an X–ray machine or linear accelerators into the state to perform work or services shall pay a reciprocity fee of $100 for each source of radiation pursuant to 38.8(7).

b. Radioactive materials. Out–of–state persons wishing to bring sources of radioactive material into Iowa for business purposes may be subject to a reciprocity fee depending on the type of activity to be performed and the type of radioactive materials license possessed (refer to 641—subrule 39.4(90)). If a reciprocity fee is applicable, it shall be assessed at the rate for reciprocity specified in 38.8(2) for each 365–day reciprocity period. In addition, if the agency performs an inspection of the out–of–state person's activities while in Iowa, the appropriate inspection fee as specified in 38.8(2) will be assessed.

c. Industrial radiographers wishing to operate in Iowa under an identification card from a jurisdiction recognized by Iowa that charges Iowa card holders a fee will be assessed and must pay a $100 fee prior to conducting industrial radiography in Iowa.

38.8(9) ***Radon certification.*** Any person wishing to become certified as a radon measurement specialist or radon measurement laboratory is required to pay fees sufficient to defray the cost of administering this chapter. Fees which must be submitted are as follows:

a. Application fee.

(1) Each person with Iowa residency wishing certification under the provisions of 641—43.1(136B) shall pay a nonrefundable $25 application fee.

(2) Each person without Iowa residency wishing certification under 641—43.1(136B) shall pay a nonrefundable $100 application fee.

b. Examination fee. Each person taking the EPA radon proficiency examination shall pay a fee of $125. The fee must be submitted prior to testing.

c. Annual certification fee.

(1) Each individual requesting certification and renewing certification as a radon measurement specialist must pay a nonrefundable annual fee of $250.

(2) Each person requesting certification and renewing certification as a radon measurement laboratory must pay a nonrefundable annual fee of $500.

d. Each person wishing to give reciprocal recognition of credentials from another jurisdiction must pay the appropriate fees as outlined in subrule 38.8(9), paragraphs *"a," "b,"* and *"c."*

e. Returned check and late fees. Persons who fail to pay required fees to the department are subject to the following penalty(ies):

(1) $15 for each insufficient funds check submitted for payment of radon testing or mitigation fees.

(2) $25 per month for failure to pay annual radon testing or mitigation fees starting after the annual renewal month.

38.8(10) ***Radon mitigation credentialing.*** Any person wishing to become credentialed as a radon mitigation specialist shall be required to pay fees sufficient to defray the cost of administering 641—Chapter 44. Fees which must be submitted are as follows:

a. Application fee.

(1) Each person with Iowa residency wishing certification under the provisions of 641—Chapter 44 shall pay a nonrefundable $25 application fee.

(2) Each person without Iowa residency wishing certification under 641—Chapter 44 shall pay a nonrefundable $100 application fee.

b. Annual credentialing fee.

(1) Each individual requesting credentialing must:

1. Pay an initial fee of $150 which is refundable if credentialing is not completed.

2. Pay annually a renewal fee of $150 or $40 per mitigation system installed (as defined in 641—44.2(136B)) costing more than $200, whichever is larger. With each renewal, a credentialed person must submit legal documentation of the number of mitigation systems installed the previous credentialing year. This number will be used to calculate the renewal fee.

(2) Each person wishing to receive reciprocal recognition of credentialing from another jurisdiction must pay the appropriate fees as outlined in subrule 38.8(9), paragraphs *"a"* and *"b."*

c. Examination fee. Each person taking the EPA Radon Proficiency Examination, if it is administered by the Iowa department of public health, shall pay a fee of $125. The fee must be submitted prior to testing.

38.8(11) Tanning facility registration/permit fees. Rescinded IAB 3/25/98, effective 4/29/98.

641—38.9(136C) Procedure for imposing requirements by order, or for modification, suspension, or revocation of a license, registration, or certificate or for imposing civil penalties.

38.9(1) *Scope.*

a. This rule prescribes the procedure in cases initiated by the staff, or upon a request by any person, to impose requirements by order, or to modify, suspend, or revoke a license, registration, or certificate or to take other action as may be proper against any person subject to the jurisdiction of the agency. The term "regulated entity" as used in this rule refers to any facility, person, partnership, corporation or other organization which is regulated by the agency by virtue of these rules, the Iowa Code, licensing documents, registrations, certificates, or other official regulatory promulgation. "Authorization" means license, registration, certificate, permit, or any other document issued or received by the agency that authorizes specific activities related to the possession and use of radioactive materials or radiation–producing machines in Iowa.

b. This rule also prescribes the procedures in cases initiated by the staff to impose civil penalties pursuant to Iowa Code section 136C.4, to impose serious misdemeanor penalties pursuant to Iowa Code section 136B.5 or to impose simple misdemeanor penalties pursuant to Iowa Code section 136D.8.

38.9(2) *Notice of violation.*

a. In response to an alleged violation of any provision of the Iowa Code, these rules, the conditions of an authorization issued by the agency or any order issued by the agency, the agency may serve on the regulated entity a written notice of violation; a separate notice may be omitted if an order pursuant to 38.9(3) or demand for information pursuant to 38.9(5) is issued that otherwise identifies the apparent violation. The notice of violation will concisely state the alleged violation(s) and will require that the regulated entity submit, within 30 days of the date of the notice or other specified time, a written explanation or statement in reply including:

(1) Corrective steps which have been taken by the regulated entity and the results achieved;

(2) Corrective action which will be taken to prevent recurrence; and

(3) The date when full compliance will be achieved.

b. The notice may require the regulated entity subject to the jurisdiction of the agency to admit or deny the violation and to state the reasons for the violation, if admitted. It may provide that, if an adequate reply is not received within the time specified in the notice, the agency may issue an order or a demand for information as to why the authorization should not be modified, suspended, or revoked or why such other action as may be proper should not be taken.

38.9(3) *Orders.*

a. The agency may institute a proceeding to modify, suspend, or revoke an authorization or to take other action as may be proper by serving on the regulated entity an order which will:

(1) Allege the violations with which the regulated entity is charged, or the potentially hazardous conditions or other facts deemed to be sufficient grounds for the proposed action;

(2) Provide that the regulated entity may file a written answer to the order under oath or affirmation within 20 days of its date, or such other time as may be specified in the order;

(3) Inform the regulated entity of its right, within 20 days of the date of the order, or such other time as may be specified in the order, to demand a hearing on all or part of the order, except in a case where the regulated entity has consented in writing to the order;

(4) Specify the issues for hearing; and

(5) State the effective date of the order; if the agency finds that the public health, safety, or interest so requires or that the violation or conduct causing the violation is willful, the order may provide, for stated reasons, that the proposed action be immediately effective pending further order.

b. A regulated entity who receives an order may respond to an order under this subrule by filing a written answer under oath or affirmation. The answer shall specifically admit or deny each allegation or charge made in the order and may set forth the matters of fact and law on which the regulated entity relies, and, if the order is not consented to, the reasons as to why the order should not have been issued. Except as provided in paragraph *"d"* of this subrule, the answer may demand a hearing.

c. If the answer demands a hearing, the agency will issue an order designating the time and place of hearing.

d. An answer or stipulation may consent to the entry of an order in substantially the form proposed in the order with respect to all or some of the actions proposed in the order. The consent, in the answer or other written document, of the regulated entity to whom the order has been issued shall constitute a waiver by the regulated entity of a hearing, findings of fact and conclusions of law, and of all right to seek agency and judicial review or to contest the validity of the order in any forum as to those matters which have been consented to or agreed to or on which a hearing has not been requested. An order that has been consented to shall have the same force and effect as an order made after hearing by a presiding officer or the agency, and shall be effective as provided in the order.

38.9(4) *Settlement and compromise.* At any time after the issuance of an order designating the time and place of hearing in a proceeding to modify, suspend, or revoke an authorization, the staff and a regulated entity may enter into a stipulation for the settlement of the proceeding or the compromise of a civil penalty. The stipulation or compromise shall be subject to approval by the designated presiding officer or, if none has been designated, by the chief administrative law judge, according due weight to the position of the staff. The presiding officer, or if none has been designated, the chief administrative law judge, may order such adjudication of the issues as deemed to be required in the public interest to dispose of the proceeding. If approved, the terms of the settlement or compromise shall be embodied in a decision or order settling and discontinuing the proceeding.

38.9(5) *Demand for information.*

a. The agency may issue to a regulated entity a demand for information for the purpose of determining whether an order under 38.9(3) should be issued, or whether other action should be taken, which demand will:

(1) Allege the violations with which the regulated entity is charged, or the potentially hazardous conditions or other facts deemed to be sufficient ground for issuing the demand; and

(2) Provide that the regulated entity must file a written answer to the demand for information under oath or affirmation within 20 days of its date, or such time as may be specified in the demand for information.

b. A regulated entity to whom the agency has issued a demand for information under this subrule must respond to the demand by filing a written answer under oath or affirmation. The regulated entity's answer shall specifically admit or deny each allegation or charge made in the demand for information, and shall set forth the matters of fact and law on which the licensee relies. A person other than a licensee may answer as described above, or by setting forth its reasons why the demand should not have been issued and, if the requested information is not provided, the reasons why it is not provided.

c. Upon review of the answer filed pursuant to 38.9(5)*"a"*(2), or if no answer is filed, the agency may institute a proceeding pursuant to 38.9(3) to take such action as may be proper.

d. An answer may consent to the entry of an order pursuant to 38.9(3) in substantially the form proposed in the demand for information. Such consent shall constitute a waiver as provided in 38.9(3) *"d."*

38.9(6) *Civil penalties.*

a. Before instituting any proceeding to impose a civil penalty under Iowa Code section 136C.4, the agency shall serve a written notice of violation upon the person charged. This notice may be included in a notice issued pursuant to 38.9(2). The notice of violation shall specify the date or dates, facts, and the nature of the alleged act or omission with which the person is charged and shall identify specifically the particular provision or provisions of the law, rule, regulation, license, permit, or cease and desist order involved in the alleged violation and must state the amount of each proposed penalty. The notice of violation shall also advise the person charged that the civil penalty may be paid in the amount specified therein, or the proposed imposition of the civil penalty may be protested in its entirety or in part, by a written answer, either denying the violation or showing extenuating circumstances. The notice of violation shall advise the person charged that upon failure to pay a civil penalty subsequently determined by the agency, if any, unless compromised, remitted, or mitigated, the fee shall be collected by civil action, pursuant to Iowa Code section 136C.4.

b. Within 20 days of the date of a notice of violation or other time specified in the notice, the person charged may either pay the penalty in the amount proposed or answer the notice of violation. The answer to the notice of violation shall state any facts, explanations, and arguments denying the charges of violation, or demonstrating any extenuating circumstances, error in the notice of violation, or other reason why the penalty should not be imposed and may request remission or mitigation of the penalty.

c. If the person charged with violation fails to answer within the time specified in 38.9(6)*"b,"* an order may be issued imposing the civil penalty in the amount set forth in the notice of violation described in 38.9(6)*"a."*

d. If the person charged with violation files an answer to the notice of violation, the agency, upon consideration of the answer, will issue an order dismissing the proceeding or imposing, mitigating, or remitting the civil penalty. The person charged may, within 20 days of the date of the order or other time specified in the order, request a hearing.

e. If the person charged with violation requests a hearing, the agency will issue an order designating the time and place of hearing.

f. If a hearing is held, an order will be issued after the hearing by the presiding officer or the agency dismissing the proceeding or imposing, mitigating, or remitting the civil penalty.

g. The agency may compromise any civil penalty, subject to the provisions of 38.9(4).

h. If the civil penalty is not compromised, or is not remitted by the presiding officer or the agency, and if payment is not made within ten days following either the service of the order described in 38.9(6)*"c"* or *"f,"* or the expiration of the time for requesting a hearing described in 38.9(6)*"d,"* the agency may refer the matter to the attorney general for collection.

i. Except when payment is made after compromise or mitigation by the Department of Justice or as ordered by a court of the state, following reference of the matter to the attorney general for collection, payment of civil penalties imposed under Iowa Code section 136C.4 shall be made by check, draft, or money order payable to the Iowa Department of Public Health.

38.9(7) Requests for action under this rule.

a. Any person may file a request to institute a proceeding pursuant to 38.9(3) to modify, suspend, or revoke an authorization as may be proper. Such a request shall be addressed to the Chief, Bureau of Radiological Health, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319. The requests shall specify the action requested and set forth the facts that constitute the basis for the request. The bureau chief will discuss the matter with staff to determine appropriate action in accordance with 38.9(7)*"b."*

b. Within a reasonable time after a request pursuant to 38.9(7)*"a"* has been received, the bureau chief shall either institute the requested proceeding in accordance with this rule or shall advise the person who made the request in writing that no proceeding will be instituted, in whole or in part, with respect to the request, and the reasons for the decision.

c.(1) The bureau chief's decisions under this rule will be filed and within 25 days after the date of the bureau chief's decision under this rule that no proceeding will be instituted or other action taken in whole or in part, the agency may on its own motion review that decision, in whole or in part, to determine if the bureau chief has abused discretion. This review power does not limit in any way either the agency's supervisory power over delegated staff actions or the agency's power to consult with the staff on a formal or informal basis regarding institution of proceedings under this rule.

(2) No petition or other request for agency review of a bureau chief's decision under this rule will be entertained by the agency.

These rules are intended to implement Iowa Code chapter 136C.

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Iowa Department of Public Health
Promoting and protecting the health of Iowans

Stephen C. Gleason, D. O., Director
Lucas State Office Building
Des Moines, IA 50319-0075
515-281-5787

chapter 39
REGISTRATION OF RADIATION MACHINE FACILITIES, LICENSURE OF RADIOACTIVE MATERIALS AND TRANSPORTATION OF RADIOACTIVE MATERIALS

641—39.1(136C) Purpose and scope.

39.1(1) All persons possessing radiation machines within the state shall be registered in accordance with this chapter, except as specifically exempted.

39.1(2) No person shall receive, possess, use, transfer, own, or acquire radioactive material except as authorized in a specific or general license issued pursuant to this chapter or as otherwise provided in these rules.

39.1(3) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of July 1, 1999.

39.1(4) In addition to the requirements of this chapter, all registrants are subject to the requirements of 641—Chapters 38 and 40. Furthermore, registrants engaged in healing arts are subject to the requirements of 641—Chapters 41 and 42; registrants engaged in industrial/nonmedical radiographic operations are subject to the requirements of 641—Chapter 45.

641—39.2(136C) Definitions. For the purpose of this chapter, the definitions in 641—Chapter 38 may also apply to this chapter.

641—39.3(136C) Requirements for registration of X-ray and other electronic machines that produce radiation.

39.3(1) *Exemptions.*

a. Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this chapter, provided that the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 millirem (5 μSv) per hour at 5 centimeters from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

b. Radiation machines while in transit or storage incident thereto are exempt from the requirements of this chapter.

c. Domestic television receivers are exempt from the requirements of this chapter.

39.3(2) *Application for registration of radiation machine facilities.* Each person having a radiation machine facility shall:

a. Apply for registration of such facility with the agency prior to the operation of a radiation machine facility. In order to register equipment, the person must have a permanent office located in Iowa that has a telephone, employee and equipment, and storage for records regarding the equipment and operator certification. Application for registration shall be completed on forms furnished by the

agency and shall include the appropriate fee from 641—38.8(136C).

b. Designate on the application form an individual to be responsible for radiation protection.

c. Each registrant shall prohibit any person from furnishing radiation machine servicing or services as described in 39.3(3)*"d"* to the registrant's radiation machine facility until such person provides evidence that the person has been registered with the agency as a provider of services in accordance with 39.3(3).

39.3(3) *Application for registration of servicing and services.*

a. Each person who is engaged in the business of installing or offering to install radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this state shall apply for registration of such services with the agency prior to furnishing or offering to furnish any such services.

b. Application for registration shall be completed on forms furnished by the agency and shall contain all information required by the agency as indicated on the forms and accompanying instructions and include the fee required in 641—paragraph 38.8(1)*"c."*

c. Each person applying for registration under this chapter shall specify:

(1) That the person has read and understands the requirements of these rules;

(2) The services for which the person is applying for registration;

(3) The training and experience that qualify the person to discharge the services for which the person is applying for registration;

(4) The type of measurement instrument to be used, frequency of calibration, and source of calibration; and

(5) The type of personnel dosimeters supplied, frequency of reading, and replacement or exchange schedule.

d. For the purpose of 39.3(3), services may include but shall not be limited to:

(1) Installation and servicing of radiation machines and associated radiation machine components;

(2) Calibration of radiation machines or radiation measurement instruments or devices;

(3) Radiation protection or health physics consultations or surveys; and

(4) Personnel dosimetry services.

e. No individual shall perform services which are not specifically stated for that individual on the notice of registration issued by the agency.

39.3(4) *Issuance of notice of registration.*

a. Upon a determination that an applicant meets the requirements of this chapter, the agency shall issue a notice of registration.

b. The agency may incorporate in the notice of registration at the time of issuance or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of radiation machines as it deems appropriate or necessary.

39.3(5) *Expiration of notice of registration.* Except as provided by 39.3(6)*"b,"* each notice of registration shall expire within 12 months of issuance or at the end of the specified day in the month and year stated therein.

39.3(6) *Renewal of notice of registration.*

a. Application for renewal of registration shall be filed in accordance with 39.3(2) or 39.3(3).

b. In any case in which a registrant has properly filed an application for renewal of current registration within 90 days prior to the expiration of the existing registration, such existing registration shall not expire until the application status has been finally determined by the agency.

39.3(7) *Report of changes.* The registrant shall notify the agency in writing before making any change which would render the information contained in the application for registration or the notice of registration no longer accurate.

39.3(8) *Approval not implied.* No person, in any advertisement, shall refer to the fact that the person or the person's facility is registered with the agency pursuant to the provisions of 39.3(2) or 39.3(3), and no person shall state or imply that any activity under such registration has been approved by the agency.

39.3(9) *Assembler and transfer obligation.*

a. Any person who sells, leases, transfers, lends, disposes of, assembles, or installs radiation machines in this state shall notify the agency in writing within 15 days of:

(1) The name and address of persons who have received these machines;

(2) The manufacturer, model, and serial number of each radiation machine transferred; and

(3) The date of transfer of each radiation machine.

b. No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment, when properly placed in operation and used, shall meet the requirements of 641—Chapters 38, 39, 40 and 41.

c. In the case of diagnostic X–ray systems which contain certified components, a copy of the assembler's report prepared in accordance with the requirements of the federal diagnostic X–ray standard (21 CFR 1020.30(d)) shall be submitted to the agency within 15 days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler.

39.3(10) *Reciprocity—out–of–state radiation machines.*

a. Whenever any radiation machine is to be brought into the state, for any temporary use, the person proposing to bring such machine into the state shall give written notice to the agency at least two working days before such machine is to be used in the state. The notice shall include:

(1) The type of radiation machine;

(2) The nature, duration, and scope of use;

(3) The exact location(s) where the radiation machine is to be used; and

4. States in which this machine is registered.

b. If, for a specific case, the two–working–day period would impose an undue hardship on the person, upon application to the agency, permission to proceed sooner may be granted.

c. The person referred to in 39.3(10)*"a"* shall:

(1) Comply with all applicable rules of the agency;

(2) Supply the agency with such other information as the agency may reasonably request; and

(3) Not operate within the state on a temporary basis in excess of 180 calendar days in a 365–day reciprocity period. The 365–day reciprocity period starts on the day the agency receives the appropriate fee, as specified in 641—subrule 38.8(8), and ends exactly 365 days later. It is the registrant's responsibility to ensure the 180–day limit is not exceeded during the 365–day reciprocity period and to ensure that the reciprocal recognition is renewed 30 days prior to the expiration of the 365–day reciprocity period.

39.3(11) *Exemption.* Rescinded IAB 4/8/98, effective 7/1/98.

641—39.4(136C) Requirements for licensing of radioactive materials.

39.4(1) *In addition to the requirements of this chapter, all licensees are subject to the requirements of 641—Chapters 38, 40 and 41.* Furthermore, licensees engaged in industrial/nonmedical radiographic operations are subject to the requirements of 641—Chapter 45; licensees using radionuclides in the healing arts are subject to the requirements of 641—41.2(136C) and 641—Chapter 42; andlicensees engaged in land disposal of radioactive material are subject to the requirements of 641—Chapter 40.

39.4(2) *Source material.*

a. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.

b. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

c. Any person is exempt from this chapter to the extent that such person receives, possesses, uses, or transfers:

(1) Any quantities of thorium contained in:

1. Incandescent gas mantles,

2. Vacuum tubes,

3. Welding rods,

4. Electric lamps for illuminating purposes, provided that each lamp does not contain more than 50 milligrams of thorium,
5. Germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting, provided that each lamp does not contain more than 2 grams of thorium,

6. Rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these, or

7. Personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium.

(2) Source material contained in the following products:

1. Glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material,

2. Glassware containing not more than 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction,

3. Glass enamel or glass enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983, or

4. Piezoelectric ceramic containing not more than 2 percent by weight source material.

(3) Photographic film, negatives, and prints containing uranium or thorium.

(4) Any finished product or part fabricated of, or containing, tungsten–thorium or magnesium–thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part.

(5) Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:

1. The counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee pursuant to 10 CFR Part 40,

2. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM,"

3. Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED," and

4. This exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.

(6) Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

1. The shipping container is conspicuously and legibly impressed with the legend "CAUTION—RADIOACTIVE SHIELDING—URANIUM," and

2. The uranium metal is encased in mild steel or equally fire–resistant metal of minimum wall thickness of 1/8 inch (3.2 mm).

(7) Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and that this exemption shall not be deemed to authorize either:

1. The shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens, or

2. The receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

(8) Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of uranium.

(9) Thorium contained in any finished aircraft engine part containing nickel–thoria alloy, provided that:

1. The thorium is dispersed in the nickel–thoria alloy in the form of finely divided thoria (thorium dioxide), and

2. The thorium content in the nickel–thoria alloy does not exceed 4 percent by weight.

d. The exemptions in 39.4(2) do not authorize the manufacture of any of the products described.

e. The requirements specified in 39.4(2) *"c"* (5)"2" and "3" need not be met by counterweights manufactured prior to December 31, 1969, provided that such counterweights are impressed with the legend, "CAUTION—RADIOACTIVE MATERIAL—URANIUM," as previously required by the rules.

39.4(3) *Radioactive material other than source material.*

a. Exempt concentrations.

(1) Except as provided in 39.4(3)*"a"*(2), any person is exempt from this chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in Appendix A of this chapter.

(2) No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under 39.4(3)*"a"*(1) or equivalent regulations of the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, except in accordance with a specific license issued pursuant to 39.4(29) or the general license provided in 39.4(90).

(3) An exemption is granted to persons who receive, possess, use, process, transfer, distribute, and dispose of materials containing or contaminated at concentrations less than 20 picocuries per gram of radium.

b. Exempt quantities.

(1) Except as provided in 39.4(3)*"b"*(3) and (4), any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities, each of which does not exceed the applicable quantity set forth in Appendix B of this chapter.

(2) Any person who possesses radioactive material received or acquired under the general license issued for manufacture of devices and equipment under special license from NRC is exempt from the requirements for a license set forth in this chapter to the extent that such person possesses, uses, transfers or owns such radioactive material. Such exemption does not apply for radium–226.

(3) This paragraph (39.4(3) *"b"*) does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

(4) No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Appendix B of this chapter, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under 39.4(3) or equivalent regulations of the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR 32 or by the agency pursuant to 39.4(29)*"b,"* which license states that the radioactive material may be transferred by the licensee to persons exempt under 39.4(3)*"b"* or the equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state, or licensing state. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing by–product material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(1) Certain items containing radioactive material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products, any person is exempt from these rules to the extent that the person receives, possesses, uses, transfers, owns, or acquires the following products:

1. Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rate:

• 25 millicuries (925 MBq) of tritium per timepiece;

• 5 millicuries (185 MBq) of tritium per hand;

• 15 millicuries (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial);

• 100 microcuries (3.7 MBq) of promethium–147 per watch or 200 microcuries (7.4 MBq) of promethium–147 per any other timepiece;

• 20 microcuries (0.74 MBq) of promethium–147 per watch hand or 40 microcuries (1.48 MBq) of promethium–147 per other timepiece hand;

• 60 microcuries (2.22 MBq) of promethium–147 per watch dial or 120 microcuries (4.44 MBq) of promethium–147 per other timepiece dial (bezels when used shall be considered as part of the dial).

2. The radiation dose rate from hands and dials containing promethium–147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

• For wrist watches, 0.1 millirad (1 m Gy) per hour at 10 centimeters from any surface.

• For pocket watches, 0.1 millirad (1 m Gy) per hour at 1 centimeter from any surface.

• For any other timepiece, 0.2 millirad (2 m Gy) per hour at 10 centimeters from any surface.

• One microcurie (37 kBq) of radium–226 per timepiece in timepieces acquired prior to the effective date of this rule.

3. Lock illuminators containing not more than 15 millicuries (555 MBq) of tritium or not more than 2 millicuries (74 MBq) of promethium–147 installed in automobile locks. The radiation dose rate from each lock illuminator containing promethium–147 will not exceed 1 millirad (10 mGy) per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.

4. Precision balances containing not more than 1 millicurie (37 MBq) of tritium per balance or not more than 0.5 millicurie (18.5 MBq) of tritium per balance part.

5. Automobile shift quadrants containing not more than 25 millicuries (925 MBq) of tritium.

6. Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas.

7. Thermostat dials and pointers containing not more than 25 millicuries (925 MBq) of tritium per thermostat.

8. Electron tubes, provided that each tube does not contain more than one of the following specified quantities of radioactive material:

• 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 MBq) of tritium per any other electron tube;

• 1 microcurie (37 kBq) of cobalt–60;

• 5 microcuries (185 kBq) of nickel–63;

• 30 microcuries (1.11 MBq) of krypton–85;

• 5 microcuries (185 kBq) of cesium–137; and

• 30 microcuries (1.11 MBq) of promethium–147.

9. Ionizing radiation measuring or detection devices containing one or more sources of radioactive material, provided that:

• Each source contains no more than one exempt quantity set forth in Appendix B of this chapter;

• Each device contains no more than ten exempt quantities. For purposes of this requirement, a device's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Appendix B of this chapter, provided that the sum of such fractions shall not exceed unity; or

• For americium–241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under 39.4(3)*"c"*(1)"9."

10. Spark gap irradiators containing not more than 1 microcurie (37 kBq) of cobalt–60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons(11.4 l) per hour.

(2) Self–luminous products containing radioactive material.

1. Tritium, krypton–85, or promethium–147. Except for persons who manufacture, process, or produce self–luminous products containing tritium, krypton–85, or promethium–147, any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton–85 or promethium–147 in self–luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in 39.4(3)*"c"*(2) does not apply to tritium, krypton–85, or promethium–147 used in products primarily for frivolous purposes or in toys or adornments.

2. Radium–226. Any person is exempt from these rules to the extent that suchperson receives, possesses, uses, transfers, or owns articles containing less than 0.1 microcurie (3.7 kBq) of radium–226 which were acquired prior to the effective date of these rules.

(3) Gas and aerosol detectors containing radioactive material.

1. Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, any person is exempt from 641—Chapters 38, 39, 40, and 41 to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, provided that detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.27 of 10 CFR Part 32; or a licensing state pursuant to 39.4(29) *"c,"* which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

2. Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an agreement state shall be considered exempt under 39.4(3)*"c"*(3)"1," provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device, and provided further that they meet the requirements of 39.4(29) *"c."*

3. Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific license issued by a licensing state shall be considered exempt under 39.4(3)*"c"*(3)"1," provided that the device is labeled in accordance with the specific license authorizing distribution, and

provided further that they meet the requirements of 39.4(29)*"c."*

(4) Resins containing scandium–46 and designed for sand consolidation in oil wells. Any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium–46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license issued by the agency or any agreement state to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Sections 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission. This exemption does not authorize the manufacture of any resins containing scandium–46.

(5) Radioactive drug: capsules containing carbon–14 urea for "in vivo" diagnostic use for humans.

1. Except as provided in paragraphs *"b"* and *"c"* of this subrule, any person is exempt from the requirements for a license set forth in this chapter and in 641—41.2(136C) provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq 1μCi carbon–14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

2. *Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to 641—41.2(136C).

3. Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to 39.4(20) of this rule.

4. Nothing in this subrule relieves persons from complying with applicable FDA or other federal or state requirements governing receipt, administration, and use of drugs.

39.4(4) to **39.4(19)** Reserved.

39.4(20) *Types of licenses.* There are two types of licenses for radioactive materials: general and specific.

a. General licenses provided in this chapter are effective without the filing of applications with the agency or the issuance of licensing documents to the particular persons, although the filing of a certificate with the agency may be required by the particular general license. The general licensee is subject to all other applicable portions of these rules and any limitations of the general license.

b. Specific licenses require the submission of an application to the agency and the issuance of a licensing document by the agency. The licensee is subject to all applicable portions of these rules as well as any limitations specified in the licensing document.

c. The applicant must have a permanent office located in Iowa that has a telephone, employee and equipment, and storage for records regarding the equipment and operator certification.

d. All licensees and registrants must submit the appropriate fee in 641—subrule 38.8(2).

39.4(21) *General licenses—source material.*

a. A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to use and transfer not more than 15 pounds (6.82 kg) of source material at any one time for research, development, educational, commercial, or operational purposes. A person authorized to use or transfer source material, pursuant to this general license, may not receive more than a total of 150 pounds (68.2 kg) of source material in any one calendar year.

b. Persons who receive, possess, use, or transfer source material pursuant to the general license issued in 39.4(21) *"a"* are exempt from the provisions of 641—Chapter 40 to the extent that such receipt, possession, use, or transfer is within the terms of such general license; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to this chapter.

c. Persons who receive, possess, use, or transfer source material pursuant to the general license in 39.4(21) *"a"* are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the agency in a specific license.

d. A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use, or transfer source material.

e. Depleted uranium in industrial products and devices.

(1) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 39.4(21) *"e"*(2), (3), (4), and (5), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(2) The general license in 39.4(21)*"e"*(1) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 39.4(29)*"m"* or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an agreement state which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an agreement state.

(3) 1. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 39.4(21) *"e"* (1) shall file Agency Form "Registration Certificate—Use of Depleted Uranium Under General License" with the agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The general licensee shall furnish on the Agency Form "Registration Certificate—Use of Depleted Uranium Under a General License" the following information and such other information as may be required by that form:

• Name and address of the general licensee;

• A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 39.4(21)*"e"*(1) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

• Name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in 39.4(21) *"e"* (3)"1."

2. The general licensee possessing or using depleted uranium under the general license established by 39.4(21)*"e"*(1) shall report in writing to the agency any changes in information furnished by the general licensee in Agency Form "Registration Certificate—Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of such change.

(4) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 39.4(21)*"e"*(1):

1. Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

2. Shall not abandon such depleted uranium;

2. Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 39.4(41). In the case where the transferee receives the depleted uranium pursuant to the general license established by 39.4(21)*"e"*(1), the transferor shall furnish the transferee a copy of 641—Chapter 39 and a copy of Agency Form "Registration Certificate—Use of Depleted Uranium Under General License." In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's or agreement state's regulation equivalent to 39.4(21)*"e"*(1), the transferor shall furnish the transferee a copy of 641—Chapter 39 and a copy of the Agency Form "Registration Certificate—Use of Depleted Uranium Under General License" accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or agreement state under requirements substantially the same as those in 641—Chapters 38, 39, 40, 41 and 45;

4. Within 30 days of any transfer, shall report in writing to the agency the name and address of the person receiving the depleted uranium pursuant to such transfer; and

5. Shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(5) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 39.4(21)*"e"*(1) is exempt from the requirements of 641—Chapter 40 with respect to the depleted uranium covered by that general license.

39.4(22) *General licenses—radioactive material other than source material.* (Note: Different general licenses are issued in this subrule, each of which has its own specific conditions and requirements.)

a. Certain devices and equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to Section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(3) *"a"* (2), 39.4(32), 39.4(41), 39.4(51), 641—39.5(136C), and 641—Chapter 40. Attention is directed particularly to the provisions of 641—Chapter 40, which relate to the labeling of containers.

(1) Static elimination device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium–210 per device.

(2) Ion generating tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium–210 per device or a total of not more than 50 millicuries (1.85 GBq) of hydrogen–3 (tritium) per device.

b. Reserved.

c. Reserved.

d. Certain measuring, gauging or controlling devices.

(1) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use or transfer, in accordance with the provisions of 39.4(22) *"d"* (2), (3), and (4), radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(2) The general license in 39.4(22)*"d"*(1) applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the agency pursuant to 39.4(29) *"d"* or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, which authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state. Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.

(3) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in 39.4(22)*"d"*(1):

1. Shall ensure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;

2. Shall ensure that the device is tested for leakage of radioactive material and proper operation of the "on–off" mechanism and indicator, if any, at no longer than six–month intervals or at such other intervals as are specified in the label; however, devices containing only krypton need not be tested for leakage of radioactive material, and devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta/gamma–emitting material or 10 microcuries (0.37 MBq) of alpha–emitting material, and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

3. Shall ensure that other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed in accordance with the instructions provided by the labels, or by a person holding an applicable specific license from the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to perform such activities;

4. Shall maintain records showing compliance with the requirements of 39.4(22)*"d"*(3)"2" and "3." The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by 39.4(22) *"d"*(3)"2" shall be maintained for one year after the next required leak test is performed or until the sealed source is transferred or disposed of. Records of tests of the "on–off" mechanism and indicator required by 39.4(22)*"d"*(3)"2" shall be maintained for one year after the next required test of the "on–off" mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records which are required by 39.4(22)*"d"*(3)"3" shall be maintained for a period of two years from the date of the recorded event or until the device is transferred or disposed of;

5. Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the "on–off" mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the agency a report containing a brief description of the event and the remedial action taken;

6. Shall not abandon the device containing radioactive material;

7. Except as provided in 39.4(22)*"d"*(3)"8," shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state whose specific license authorizes the person to receive the device and, within 30 days after transfer of a device to a specific licensee, shall furnish to the agency a report

containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;

8. Shall transfer the device to another general licensee only:

• Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this regulation and any safety documents identified in the label on the device and, within 30 days of the transfer, report to the agency the manufacturer's name and model number of the device transferred, the name and address of the transferee, and the name and position of an individual who may constitute a point of contact between the agency and the transferee; or

• Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee; and

9. Shall comply with the provisions of 641—Chapter 40.

(4) The general license in 39.4(22)*"d"*(1) does not authorize the manufacture of devices containing radioactive material.

(5) The general license provided in 39.4(22)*"d"*(1) is subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(32), 39.4(41), 39.4(51), and 641—39.5(136C).

e. Luminous safety devices for aircraft.

(1) A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium–147 contained in luminous safety devices for use in aircraft, provided:

1. Each device contains not more than 10 curies (370 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium–147; and

2. Each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the agency or any agreement state to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in 39.4(22)*"e"*(1) are exempt from the requirements of 641—Chapter 40 except that they shall comply with the provisions of 641—40.95(136C) and 40.96(136C).

(3) This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium–147.

(4) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium–147 contained in instrument dials.

(5) This general license is subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(32), 39.4(41), 39.4(51), and 641—39.5(136C).

f. Ownership of radioactive material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this chapter, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

g. Calibration and reference sources.

(1) A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of 39.4(22)*"g"*(4) and (5), americium–241 in the form of calibration or reference sources:

1. Any person who holds a specific license issued by the agency which authorizes the person to receive, possess, use, and transfer radioactive material; and

2. Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes the person to receive, possess, use, and transfer special nuclear material.

(2) A general license is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of 39.4(22)*"g"*(4) and (5) to any person who holds a specific license issued by the agency which authorizes the person to receive, possess, use, and transfer radioactive material.

(3) A general license is hereby issued to own, receive, possess, use, and transfer radium–226 in the form of calibration or reference sources in accordance with the provisions of 39.4(22)*"g"*(4) and (5) to any person who holds a specific license issued by the agency which authorizes the person to receive, possess, use, and transfer radioactive material.

(4) The general licenses in 39.4(22)*"g"*(1), (2), and (3) apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the agency, any agreement state or licensing state pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70.

(5) The general licenses provided in 39.4(22)*"g"*(1), (2), and (3) are subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(32), 39.4(41), 39.4(51), 641—39.5(136C), and 641—Chapter 40. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general licenses:

1. Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries (185 kBq) of americium–241, 5 microcuries (185 kBq) of plutonium, or 5 microcuries (185 kBq) of radium–226 in such sources;

2. Shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:

• The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS (AMERICIUM–241).

(PLUTONIUM) (showing only the name of the appropriate material) DO NOT TOUCH

RADIOACTIVE PORTION OF THIS SOURCE.

_____

Name of manufacturer or importer

OR

• The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of a licensing state. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS RADIUM–226.

DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

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4. Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium–241, plutonium, or radium–226 which might otherwise escape during storage; and

5. Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(6) These general licenses do not authorize the manufacture of calibration or reference sources containing americium–241, plutonium, or radium–226.

h. Reserved.

i. General license for use of radioactive material for certain in vitro clinical or laboratory testing. The New Drug Provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

(1) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of 39.4(22)*"i"*(2), (3), (4), (5), and (6), the following radioactive materials in prepackaged units for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

1. Carbon–14, in units not exceeding 10 microcuries (370 kBq) each.

2. Cobalt–57, in units not exceeding 10 microcuries (370 kBq) each.

3. Hydrogen–3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each.

4. Iodine–125, in units not exceeding 10 microcuries (370 kBq) each.

5. Mock iodine–125 reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of iodine–129 and 0.005 microcurie (1.85 Bq) of americium–241 each.

6. Iodine–131, in units not exceeding 10 microcuries (370 kBq) each.

7. Iron–59, in units not exceeding 20 microcuries (740 kBq) each.

8. Selenium–75, in units not exceeding 10 microcuries (370 kBq) each.

(2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by 39.4(22)*"i"*(1) until the person has filed an Agency Form "Certificate—In Vitro Testing with Radioactive Material Under General License" with the agency and received from the agency a validated copy of the form with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish the following information on the form and such other

information as may be required by the form:

1. Name and address of the physician, veterinarian, clinical laboratory or hospital;

2. The location of use; and

3. A statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general license in 39.4(22)*"i"*(1) and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by 39.4(22)*"i"*(1) shall comply with the following:

1. The general licensee shall not possess at any one time, pursuant to the general license in 39.4(22) *"i"* (1), at any one location of storage or use, a total amount of iodine–125, iodine–131, selenium–75, iron–59, or cobalt–57 in excess of 200 microcuries (7.4 MBq).

2. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

3. The general licensee shall use the radioactive material only for the uses authorized by 39.4(22)*"i"*(1).

4. The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the agency, the U.S. Nuclear Regulatory Commission, any agreement state or licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

5. The general licensee shall dispose of the mock iodine–125 reference or calibration sources described in 39.4(22)*"i"*(1)"8" as required by 641—subrule 40.70(1).

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to 39.4(22)*"i"*(1):

1. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 39.4(29)*"h"* or in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, any agreement state or licensing state which authorizes the manufacture and distribution of iodine–125, iodine–131, carbon–14, hydrogen–3 (tritium), iron–59, selenium–75, cobalt–57, or mock iodine–125 to persons generally licensed under 39.4(22)*"i"* or its equivalent, and

2. Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

• This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

• This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings

or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a licensing state.

Name of manufacturer

(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of 39.4(22)*"i"*(1) shall report in writing to the agency any changes in the information furnished in the "Certificate—In Vitro Testing with Radioactive Material Under General License," Agency Form V. The report shall be furnished within 30 days after the effective date of such change.

(6) Any person using radioactive material pursuant to the general license of 39.4(22)*"i"*(1) is exempt from the requirements of 641—Chapter 40 with respect to radioactive material covered by that general license, except that such persons using the mock iodine–125 described in 39.4(22)*"i"*(1)"8" shall comply with the provisions of 641—subrule 40.70(1) and rules 40.95(136C) and 40.96(136C).

j. Ice detection devices.

(1) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium–90 contained in ice detection devices, provided each device contains not more than 50 microcuries (1.85 MBq) of strontium–90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license issued by the agency or an agreement state to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32.

(2) Persons who own, receive, acquire, possess, use, or transfer strontium–90 contained in ice detection devices pursuant to the general license in 39.4(22)*"j"*(1):

1. Shall, upon occurrence of visually observable damage such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an agreement state to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of 641—subrule 40.70(1);

2. Shall ensure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

3. Are exempt from the requirements of 641—Chapter 40 except that such persons shall comply with the provisions of 641—subrule 40.70(1), and rules 40.95(136C) and 40.96(136C).

(3) This general license does not authorize the manufacture, assembly, disassembly or repair of strontium–90 in ice detection devices.

(4) This general license is subject to the provisions of 641—38.4(136C) to 641—38.5(136C), 39.4(32), 39.4(41), 39.4(51), and 641—39.5(136C).

39.4(23) Reserved.

39.4(24) *Filing application for specific licenses.*

a. Applications for specific licenses shall be filed on a form prescribed by the agency and include the fee required in 641—subrule 38.8(2).

b. The agency may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

c. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on the applicant's or licensee's behalf.

d. An application for a license may include a request for a license authorizing one or more activities.

e. In the application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the agency, provided such references are clear and specific.

f. Applications and documents submitted to the agency may be made available for public inspection except that the agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

g. (1) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Appendix G of this chapter, must contain either:

1. An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or

2. An emergency plan for responding to a release of radioactive material.

(2) One or more of the following factors may be used to support an evaluation submitted under 39.4(24)"*g*"(1)"1" of this subrule:

1. The radioactive material is physically separated so that only a portion could be involved in an accident;

2. All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

3. The release fraction in the respirable size range would be lower than the release fraction shown in Appendix G due to the chemical or physical form of the material;

4. The solubility of the radioactive material would reduce the dose received;

5. Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Appendix G;

6. Operating restrictions or procedures would prevent a release fraction as large as that shown in Appendix G; or

7. Other factors appropriated for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted under 39.4(24)"*g*"(1)"2" must include the following information:

1. Facility description. A brief description of the licensee's facility and area near the site.

2. Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

3. Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

4. Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

5. Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

6. Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

7. Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the agency; also, responsibilities for developing, maintaining, and updating the plan.

8. Notification and coordination. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the agency immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

9. Information to be communicated. A brief description of the types of information of facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the agency.

10. Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical, and other emergency personnel. The training shall familiarize personnel with site–specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

11. Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.

12. Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

13. Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right–to–Know Act of 1986, Title III, Pub.L.No. 99–499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the agency. The licensee shall provide any comments received within the 60 days to the agency with the emergency plan.

39.4(25) *General requirements for the issuance of specific licenses.* A license application will be approved if the agency determines that:

a. The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with 641—Chapters 38, 39, 40, 41 and 45 in such a manner as to minimize danger to public health and safety or property;

b. The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

c. The issuance of the license will not be inimical to the health and safety of the public; and

d. The applicant satisfies any applicable special requirements in 39.4(26), 39.4(27), 39.4(28), 641—41.2(136C), or 641—Chapter 45.

e. In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, or for the conduct of any other activity which the agency determines will significantly affect the quality of the environment, the agency, before commencement of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. As used in this paragraph, the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

f. Reserved.

39.4(26) ***Financial assurance and record keeping for decommissioning.***

a. Each applicant for a specific license authorizing the possession and use of unsealed radioactive material of half–life greater than 120 days and in quantities exceeding $1.0E^5$ times the applicable quantities set forth in Appendix F of 641—Chapter 40 shall submit a decommissioning funding plan as described in 39.4(26) *"e."* The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix F.

b. Each applicant for a specific license authorizing possession and use of radioactive material of half–life greater than 120 days and in quantities specified in 39.4(26)*"d"* shall either:

(1) Submit a decommissioning funding plan as described in 39.4(26)*"e"*; or

(2) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 39.4(26) *"d"* using one of the methods described in 39.4(26) *"f."* For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of 39.4(26)*"f"* is submitted to the agency.

c. (1) Each holder of a specific license issued on or after July 1, 1993, which is of a type described in 39.4(26) *"a"* or *"b,"* shall provide financial assurance for decommissioning in accordance with the criteria set forth in this subrule.

(2) Each holder of a specific license issued before July 1, 1993, and of a type described in 39.4(26)*"a,"* shall submit, on or before July 1, 1993, a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount at least equal to $750,000 in accordance with the criteria

set forth in this subrule. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

3. Each holder of a specific license issued before September 30, 1992, and of a type described in 39.4(36)*"b,"* shall submit, on or before July 1, 1993, a certificate of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in this subrule.

d. Table of required amounts of financial assurance for decommissioning by quantity of material.

Greater than 10^4 but less than or

equal to 10^5 times the applicable

quantities of Appendix F of 641—Chapter

40 in unsealed form. (For a combi–

nation of isotopes, if R, as defined

in 39.4(26)*"a,"* divided by 10^4 is

greater than 1, but R divided by 10^5

is less than or equal to 1.) 750,000

Greater than 10^3 but less than or equal

to 10^4 times the applicable quantities

of Appendix F of 641—Chapter 40 in unsealed

form. (For a combination of isotopes,

if R, as defined in 39.4(26)*"a,"* divided

by 10^3 is greater than 1, but R divided by

10^4 is less than or equal to 1.) 150,000

Greater than 10^{10} times the applicable

quantities of Appendix F or 641—Chapter 40

in sealed sources or plated foils. (For

a combination of isotopes, if R, as defined

in 39.4(26)*"a,"* divided by 10^{10} is greater

than 1.) 75,000

e. Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from 39.4(26)*"f,"* including means of

adjusting cost estimates and associated funding levels periodically over the life of the facility.

f. Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

(2) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix F of this chapter. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this subrule. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

1. The surety method or insurance must be open–ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the agency, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the agency within 30 days after receipt of notification of cancellation.

2. The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the agency. An acceptable trustee includes an appropriate state or federal government agency or an entity which has authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

3. The surety method or insurance must remain in effect until the agency has terminated the license.

(3) An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provisions must be as stated in 39.4(26)*"f"*(2).

(4) In the case of federal, state, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the table in 39.4(26)*"d,"* and indicating that funds for decommissioning will be obtained when necessary.

g. Each person licensed under this chapter shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the agency. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the agency considers important to decommissioning consists of:

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As–built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used, stored, or both, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(3) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

(4) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or byproduct materials having only half–lives of less than 65 days, a list contained in a single document and updated every two years, of the following:

1. All areas designated as restricted areas as defined under 641—38.2(136C);

2. All areas outside of restricted areas that require documentation under 641—39.4(26) *"g"* (1);

3. All areas outside of restricted areas where current and previous wastes have been buried as documented under 641—40.88(136C); and

4. All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal in accordance with 641—40.71(136C).

39.4(27) ***Special requirements for issuance of certain specific licenses for radioactive material.***

a. to *d.* Reserved.

e. Use of sealed sources in industrial radiography. In addition to the requirements set forth in 39.4(25), a specific license for use of sealed sources in industrial radiography will be issued if:

(1) The applicant will have an adequate program for training radiographic personnel and submits to the agency a schedule or description of such program which specifies the:

1. Initial training,

2. Periodic training,

3. On–the–job training, and

4. Means to be used by the licensee to determine the radiographic personnel's knowledge and understanding of and ability to comply with agency regulations and licensing requirements, and the operating and emergency procedures of the applicant.

(2) The applicant has established and submits to the agency satisfactory written operating and emergency procedures described in 641—Chapter 45.

(3) The applicant will have an internal inspection system adequate to ensure that 641—Chapters 38, 39, 40, 41 and 45, license provisions, and the applicant's operating and emergency procedures are followed by radiographic personnel. The inspection system shall include the performance of internal inspections at intervals not to exceed three months and the retention of records of such inspections for two years.

(4) The applicant submits to the agency a description of the overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program.

(5) The applicant who desires to conduct leak tests has established adequate procedures to be followed in testing sealed sources for possible leakage and contamination and submits to the agency a description of

such procedures including:

1. Instrumentation to be used,

2. Method of performing tests, and

3. Pertinent experience of the individual who will perform the test.

(6) The licensee shall conduct a program for inspection and maintenance of radiographic exposure devices and storage containers to ensure proper functioning of components important to safety.

39.4(28) *Special requirements for specific licenses of broad scope.* This subrule prescribes requirements for the issuance of specific licenses of broad scope for radioactive material and certain rules governing holders of such licenses. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containingby–product material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

a. The different types of broad scope licenses are set forth below:

(1) A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

(2) A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Appendix D of this chapter, for any authorized purpose. The possession limit for a Type B license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Appendix D, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Appendix D, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

(3) A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in Appendix D of this chapter, for any authorized purpose. The possession limit for a Type C license of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Appendix D, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Appendix D, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

b. An application for a Type A specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in 39.4(25);

(2) The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

(3) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to ensure safe operations, including:

1. The establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of

radioactive material;

2. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

3. The establishment of appropriate administrative procedures to ensure:

• Control of procurement and use of radioactive material;

• Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

• Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 39.4(28) *"b"* (3)"3" prior to use of the radioactive material.

c. An application for a Type B specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in 39.4(25); and

(2) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to ensure safe operations, including:

1. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters, and

2. The establishment of appropriate administrative procedures to ensure:

• Control of procurement and use of radioactive material;

• Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

• Review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared in accordance with 39.4(28)*"c"*(2)"2" prior to use of the radioactive material.

d. An application for a Type C specific license of broad scope will be approved if:

(1) The applicant satisfies the general requirements specified in 39.4(25).

(2) The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

1. A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; and

2. At least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used.

(3) The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to ensure safe operations.

e. Specific licenses of broad scope are subject to the following conditions:

(1) Unless specifically authorized, persons licensed pursuant to 39.4(28) shall not:

1. Conduct tracer studies in the environment involving direct release of radioactive material;

2. Receive, acquire, own, possess, use, or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;

3. Conduct activities for which a specific license issued by the agency under 39.4(27), 39.4(29) or 641—41.2(136C) is required; or

4. Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

(2) Each Type A specific license of broad scope issued under this chapter shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

(3) Each Type B specific license of broad scope issued under this chapter shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

(4) Each Type C specific license of broad scope issued under this chapter shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of 39.4(28)*"d."*

39.4(29) *Special requirements for a specific license to manufacture, assemble, repair, or distribute commodities, products, or devices which contain radioactive material.*

a. Licensing the introduction of radioactive material into products in exempt concentrations.

(1) In addition to the requirements set forth in 39.4(25), a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under 39.4(3)*"a"*(1) will be issued if:

1. The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to ensure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and

2. The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Appendix A of this chapter, that reconcentration of the radioactive material in concentrations exceeding those in Appendix A is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(2) Each person licensed under 39.4(29) *"a"* shall file an annual report with the agency which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to 39.4(29)*"a"*

during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within 30 days thereafter.

b. Licensing the distribution of radioactive material in exempt quantities. Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing by–product material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(1) An application for a specific license to distribute NARM to persons exempted from these rules pursuant to 39.4(3)*"b"* will be approved if:

1. The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

2. The radioactive material is in the form of processed chemical elements, compounds, mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

3. The applicant submits copies of prototype labels and brochures and the agency approves such labels and brochures.

(2) The license issued under 39.4(29) *"b"* (1) is subject to the following conditions:

1. No more than ten exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

2. Each exempt quantity shall be separately and individually packaged. No more than ten such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to 39.4(3)*"b."* The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem (5 mSv) per hour.

3. The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

• Identifies the radionuclide and the quantity of radioactivity, and bears the words "Radioactive Material."

4. In addition to the labeling information required by 39.4(29) *"b"* (2)"3," the label affixed to the immediate container, or an accompanying brochure, shall:

• State that the contents are exempt from licensing state requirements,

• Bear the words "Radioactive Material—Not for Human Use—Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited—Exempt Quantities Should Not Be Combined," and

• Set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

(3) Each person licensed under 39.4(29)*"b"* shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under 39.4(3) *"b"* or the equivalent regulations of a licensing state, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the agency. Each report shall cover the year ending June 30, and shall be filed

within 30 days thereafter. If no transfers of radioactive material have been made pursuant to 39.4(29)*"b"* during the reporting period, the report shall so indicate.

c. Licensing the incorporation of naturally occurring and accelerator–produced radioactive material into gas and aerosol detectors. An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under 39.4(3)*"c"*(3) will be approved if the application satisfies requirements equivalent to those contained in Section 32.26 of 10 CFR Part 32. The maximum quantity of radium–226 in each device shall not exceed 0.1 microcurie (3.7 kBq).

d. Licensing the manufacture and distribution of devices to persons generally licensed under 39.4(22)*"d."*

(1) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under 39.4(22) *"d"* or equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state will be approved if:

1. The applicant satisfies the general requirements of 39.4(25);

2. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

• The device can be safely operated by persons not having training in radiological protection,

• Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of 1 calendar quarter a dose in excess of 10 percent of the limits specified in 641—40.15(136C), and

• Under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood–forming

organs; gonads; or lens of eye 15 rems (150 mSv)

Hands and forearms; feet and ankles; localized

areas of skin averaged over areas no larger than 1 square centimeter 200 rems (2 Sv)

Other organs 50 rems (500 mSv)

3. Each device bears a durable, legible, clearly visible label or labels approved by the agency, which contains in a clearly identified and separate statement:

• Instructions and precautions necessary to ensure safe installation, operation, and servicing of the device. Documents such as operating and service manuals may be identified in the label and used to provide this information;

• The requirement, or lack of requirement, for leak testing, or for testing any "on–off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive

material by isotope, quantity of radioactivity, and date of determination of the quantity; and

• The information called for in one of the following statements, as appropriate, in the same or substantially similar form:
The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, (the model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device) are subject to a general license or the equivalent and the chapter of the U.S. Nuclear Regulatory Commission or a state with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION—RADIOACTIVE MATERIAL

_____

Name of manufacturer or distributor

The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent, and the regulations of a licensing state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION—RADIOACTIVE MATERIAL

_____

Name of manufacturer or distributor

(2) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the "on–off" mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on–off" mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the agency will consider information which includes, but is not limited to:

1. Primary containment or source capsule;

2. Protection of primary containment;

3. Method of sealing containment;

4. Containment construction materials;

5. Form of contained radioactive material;

6. Maximum temperature withstood during prototype tests;

7. Maximum pressure withstood during prototype tests;

8. Maximum quantity of contained radioactive material;

9. Radiotoxicity of contained radioactive material; and

10. Operating experience with identical devices or similarly designed and constructed devices.

(3) In the event the applicant desires that the general licensee under 39.4(22)*"d,"* or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of

radioactive material, service the device, test the "on–off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10 percent of the limits specified in 641—40.15(136C).

(4) Each person licensed under 39.4(29)*"d"* to distribute devices to generally licensed persons shall:

1. Furnish a copy of the general license contained in 39.4(22)*"d"* to each person to whom that person directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in 39.4(22)*"d"*;

2. Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's, agreement state's, or licensing state's regulation equivalent to 39.4(22)*"d,"* or alternatively, furnish a copy of the general license contained in 39.4(22)*"d"* to each person to whom that person directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission, the agreement state, or the licensing state. If a copy of the general license in 39.4(22)*"d"* is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear Regulatory Commission, agreement state, or licensing state under requirements substantially the same as those in 39.4(22)*"d"*;

3. Report to the agency all transfers of such devices to persons for use under the general license in 39.4(22)*"d."* Such report shall identify each general licensee by name and address, an individual by name and position who may constitute a point of contact between the agency and the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under 39.4(22)*"d"* during the reporting period, the report shall so indicate. The report shall cover each calender quarter and shall be filed within 30 days thereafter;

4. Furnish reports to other agencies.

• Report to the U.S. Nuclear Regulatory Commission all transfers of such devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 31.5 of 10 CFR Part 31.

• Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to 39.4(29) *"d"* for use under a general license in that state's regulations equivalent to 39.4(22) *"d."*

• Such reports shall identify each general licensee by name and address, an individual by name and position who may constitute a point of contact between the agency and the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person.

• If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.

• If no transfers have been made to general licensees within a particular state during the reporting period, this information shall be reported to the responsible state agency upon request of that agency; and

5. Keep records showing the name, address, and the point of contact for each general licensee to whom

the person directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general license provided in 39.4(22) *"d,"* or equivalent regulations of the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of 39.4(29) *"d"* (4).

e. Special requirements for the manufacture, assembly, or repair of luminous safety devices for use in aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium–147 for use in aircraft, for distribution to persons generally licensed under 39.4(22)*"e,"* will be approved if:

(1) The applicant satisfies the general requirements specified in 39.4(25); and

(2) The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, 32.56, and 32.101 of 10 CFR Part 32, or their equivalent.

f. Special requirements for license to manufacture calibration sources containing americium–241, plutonium or radium–226 for distribution to persons generally licensed under 39.4(22) *"g."* An application for a specific license to manufacture calibration and reference sources containing americium–241, plutonium or radium–226 to persons generally licensed under 39.4(22) *"g"* will be approved if:

(1) The applicant satisfies the general requirements of 39.4(25); and

(2) The applicant satisfies the requirements of Sections 32.57, 32.58, 32.59, and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70, or their equivalent.

g. Reserved.

h. Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license. An application for a specific license to manufacture or distribute radioactive material for use under the general license of 39.4(22)*"i"* will be approved if:

(1) The applicant satisfies the general requirements specified in 39.4(25).

(2) The radioactive material is to be prepared for distribution in prepackaged units of:

1. Carbon–14 in units not exceeding 10 microcuries (370 kBq) each.

2. Cobalt–57 in units not exceeding 10 microcuries (370 kBq) each.

3. Hydrogen–3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.

4. Iodine–125 in units not exceeding 10 microcuries (370 kBq) each.

5. Mock iodine–125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine–129 and 0.005 microcurie (185 Bq) of americium–241 each.

6. Iodine–131 in units not exceeding 10 microcuries (370 kBq) each.

7. Iron–59 in units not exceeding 20 microcuries (740 kBq) each.

8. Selenium–75 in units not exceeding 10 microcuries (370 kBq) each.

(3) Each prepackaged unit bears a durable, clearly visible label:

1. Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the

amount of radioactivity does not exceed 10 microcuries (370 kBq) of iodine–125, iodine–131, carbon–14, cobalt–57, or selenium–75; 50 microcuries (1.85 MBq) of hydrogen–3 (tritium); 20 microcuries (740 kBq) of iron–59; or mock iodine–125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine–129 and 0.005 microcurie (185 Bq) of americium–241 each; and

2. Displaying the radiation caution symbol described in 641—subrule 40.60(1) and the words, "CAUTION—RADIOACTIVE MATERIAL," and "Not for Internal or External Use in Humans or Animals."

(4) One of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

1. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

2. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a licensing state.

Name of manufacturer

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock iodine–125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in 641—subrule 40.70(1).

i. *Licensing the manufacture and distribution of ice detection devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under 39.4(22)*"j" *will be approved if:*

(1) The applicant satisfies the general requirements of 39.4(25); and

(2) The criteria of Sections 32.61, 32.62, and 32.103 of 10 CFR Part 32 are met.

j. Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing by–product material for material use under 641—41.2(136C).

(1) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing by–product material for use by persons authorized pursuant to 641—41.2(136C) will be approved if:

1. The applicant satisfies the general requirements specified in subrule 39.4(25);

2. The applicant submits evidence that the applicant is at least one of the following:

• Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;

• Registered or licensed with a state agency as a drug manufacturer; or

• Licensed by the Iowa board of pharmacy examiners as a nuclear pharmacy.

3. The applicant submits the following: the chemical and physical form of the radionuclide; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

4. The applicant satisfies the following labeling requirements:

• A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half–life greater than 100 days, the time may be omitted.

• A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(2) A licensee as described by 39.4(29)*"j"*(1)"2":

1. May prepare radioactive drugs for medical use, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in 39.4(29)*"j"*(2)"2" and 39.4(29)*"j"*(2)"3" or an individual under the supervision of an authorized nuclear pharmacist as specified in 641—paragraph 41.2(11)*"c."*

2. May allow a pharmacist to work as an authorized nuclear pharmacist if the individual qualifies as an authorized nuclear pharmacist as defined in 641—subrule 41.2(2).

3. May designate a pharmacist (as defined in 641—subrule 41.2(2)) as an authorized nuclear pharmacist if the individual is identified as of July 9, 1997, as an "authorized user" on a nuclear pharmacy license issued by the agency, the Nuclear Regulatory Commission or an Agreement State.

(3) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha–, beta–, or photon–emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

1. Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument, and make adjustments when necessary; and

2. Check each instrument for constancy and proper operation at the beginning of each day of use.

(4) Nothing in this subrule relieves the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

k. Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceu–ticals containing radioactive material. Although the agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for

the preparation of radiopharmaceuticals containing radioactive material as part of its licensing and regulation of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have their reagent kits approved by the agency for use by persons licensed pursuant to 641—subrule 41.2(33) may submit the pertinent information specified in 39.4(29)*"k."* An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to this chapter for the uses listed in 641—subrule 41.2(33) will be approved if:

(1) The applicant satisfies the general requirements specified in 39.4(25);

(2) The applicant submits evidence that:

1. The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA, or

2. The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

(3) The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

(4) The label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

(5) The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

1. Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

2. A statement that this generator or reagent kit, as appropriate, is approved for use by persons licensed by the agency pursuant to 641—subrule 41.2(33) or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state. The labels, leaflets, or brochures required by 39.4(29)*"k"* are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of the FDA, may be combined with the labeling required by the FDA.

l. Manufacture and distribution of sources or devices containing radioactive material for medical use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to 641—41.2(136C) for use as a calibration or reference source or for the uses listed in 641—subrules 41.2(41) and 41.2(43) will be approved if:

(1) The applicant satisfies the general requirements in 39.4(25);

(2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

1. The radioactive material contained, its chemical and physical form, and amount,

2. Details of design and construction of the source or device,

3. Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

4. For devices containing radioactive material, the radiation profile of a prototype device;

5. Details of quality control procedures to ensure that production sources and devices meet the standards of the design and prototype tests,

6. Procedures and standards for calibrating sources and devices,

7. Legend and methods for labeling sources and devices as to their radioactive content, and

8. Instructions for handling and storing the source or device from the radiation safety standpoint. These instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device, provided that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the source or device is licensed by the agency for distribution to persons licensed pursuant to 641—41.2(136C) and 641—subrules 41.2(41) and 41.2(43) or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state, provided that such labeling for sources which do not require long–term storage may be on a leaflet or brochure which accompanies the source;

(4) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

(5) In determining the acceptable interval for test of leakage of radioactive material, the agency will consider information that includes, but is not limited to:

1. Primary containment or source capsule,

2. Protection of primary containment,

3. Method of sealing containment,

4. Containment construction materials,

5. Form of contained radioactive material,

6. Maximum temperature withstood during prototype tests,

7. Maximum pressure withstood during prototype tests,

8. Maximum quantity of contained radioactive material,

9. Radiotoxicity of contained radioactive material, and

10. Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

m. Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass–volume applications.

(1) An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 39.4(21) *"d"* or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state will be approved if:

1. The applicant satisfies the general requirements specified in 39.4(25);

2. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of 10 percent of the limits specified in 641—40.15(136C) of these rules; and

3. The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass–volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

(2) In the case of an industrial product or device whose unique benefits are questionable, the agency will approve an application for a specific license under 39.4(29)*"m"* only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

(3) The agency may deny any application for a specific license under 39.4(29)*"m"* if the end use(s) of the industrial product or device cannot be reasonably foreseen.

(4) Each person licensed pursuant to 39.4(29)*"m"*(1) shall:

1. Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

2. Label or mark each unit to:

• Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

• State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an agreement state;

3. Ensure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "Depleted Uranium";

4. Furnish a copy of the general license contained in 39.4(21)*"d"* and a copy of the agency form used to register the device to each person to whom the person transfers depleted uranium in a product or device for use pursuant to the general license contained in 39.4(21)*"d,"* or furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or agreement state's regulation equivalent to 39.4(21)*"d"* and a copy of the U.S. Nuclear Regulatory Commission's or agreement state's certificate, or alternatively, furnish a copy of the general license contained in 39.4(21)*"d"* and a copy of the agency form used to register to each person to whom the person transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an agreement state, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an agreement state under requirements substantially the same as those in 39.4(21)*"d"*;

5. Report to the agency all transfers of industrial products or devices to persons for use under the general

license in 39.4(21) *"d."* Such report shall identify each general licensee by name and address, an individual by name and position who may constitute a point of contact between the agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under 39.4(21) *"d"* during the reporting period, the report shall so indicate;

6. Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 40.25 of 10 CFR Part 40; and shall report to the responsible state agency all transfers of devices manufactured and distributed pursuant to 39.4(29) *"m"* for use under a general license in that state's regulations equivalent to 39.4(21) *"d."* Such report shall identify each general licensee by name and address, an individual by name and position who may constitute a point of contact between the agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person. If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission. If no transfers have been made to general licensees within a particular agreement state during the reporting period, this information shall be reported to the responsible agreement state agency upon the request of that agency; and

7. Keep records showing the name, address, and point of contact for each general licensee to whom the person transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 39.4(21) *"d"* or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of 641—Chapters 39 and 40.

39.4(30) Reserved.

39.4(31) *Issuance of specific licenses.*

a. Upon a determination that an application meets the requirements of the Iowa Code and the rules of the agency, the agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

b. The agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this chapter as it deems appropriate or necessary in order to:

(1) Minimize danger to public health and safety or property;

(2) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(3) Prevent loss or theft of material subject to this chapter.

39.4(32) *Specific terms and conditions of licenses.*

a. Each license issued pursuant to this chapter shall be subject to all the provisions of the Iowa Code, now or hereafter in effect, and to all rules, regulations, and orders of the agency.

b. No license issued or granted under this chapter and no right to possess or utilize radioactive material granted by any license issued pursuant to this chapter shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any

license to any person unless the agency shall, after securing full information, find that the transfer is in accordance with the provisions of the Iowa Code, now or hereafter in effect, and to all valid rules, regulations, and orders of the agency, and shall give its consent in writing.

c. Each person licensed by the agency pursuant to this chapter shall confine use and possession of the material licensed to the locations and purposes authorized in the license.

d. Each licensee shall notify the agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

e. Each licensee shall notify the agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(1) The licensee;

(2) An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

(3) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

f. The notification specified in 39.4(32)"e" shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

39.4(33) Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.

a. Each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under 39.4(33) not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days before the expiration date stated in the existing license, the existing license expires at the end of the day on which the agency makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

b. Each specific license revoked by the agency expires at the end of the day on the date of the agency's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by agency order.

c. Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of by–product material until the agency notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

(1) Limit actions involving by–product material to those related to decommissioning; and

(2) Continue to control entry to restricted areas until they are suitable for release in accordance with state of Iowa requirements.

d. Within 60 days of the occurrence of any of the following, each licensee shall provide notification to the agency in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with the state of Iowa requirements, or submit within 12 months of notification a decommissioning plan, if required by 39.4(33) *"j"* and begin decommissioning upon approval of that plan if:

(1) The license has expired pursuant to 39.4(33)*"a"* or *"b"*;

(2) The licensee has decided to permanently cease principal activities, as defined in 641—38.2(136C) at

the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with state of Iowa requirements;

(3) No principal activities under the license have been conducted for a period of 24 months; or

(4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area suitable for release in accordance with State of Iowa requirements.

e. Coincident with the notification required by 39.4(33) *"d,"* the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to subrule 39.4(26) in conjunction with a license issuance or renewal or as required by this subrule. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to paragraph 39.4(33)*"g."*

(1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this rule becomes effective on July 9, 1997.

(2) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the agency.

f. The agency may grant a request to extend the time periods established in 39.4(33)"d" if the agency determines that this request is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to 39.4(33)"d." The schedule for decommissioning set forth in 39.4(33)"d" of this subrule may not commence until the agency has made a determination on the request.

g. A decommissioning plan must be submitted if required by license conditions or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the agency and these procedures could increase the potential health and safety impacts to workers or to the public.

(1) Procedures having potential health and safety impacts include, but are not limited to:

1. Procedures that would involve techniques not applied routinely during cleanup or maintenance operations;

2. Workers that would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

3. Procedures that could result in significantly greater airborne concentrations of radioactive material than are present during operation;

4. Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(2) The agency may approve an alternate schedule for submittal of a decommissioning plan required pursuant to 39.4(33)*"d"* of this subrule if the agency determines that the alternate schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(3) Procedures such as those listed in 39.4(33)*"g"* with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(4) The proposed decommissioning plan for the site or separate building or outdoor area must include:

1. A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

2. A description of planned decommissioning activities;

3. A description of the methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

4. A description of the planned final radiation survey; and

5. An updated detailed cost estimate for decommissioning, and a plan for ensuring the availability of adequate funds for completion of decommissioning.

6. For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include justification for the delay based on the criteria in paragraph *"i"* of this subrule.

(5) The proposed decommissioning plan will be approved by the agency if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

h. Except as provided in 39.4(33)"i," licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

i. The agency may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the agency determines that the alternative is warranted by consideration of the following:

(1) It is technically feasible to complete decommissioning within the allotted 24–month period;

(2) Sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24–month period;

(3) A significant volume reduction exposure to workers can be achieved by allowing short–lived radionuclides to decay;

(4) A significant reduction in radiation exposure to workers can be achieved by allowing short–lived radionuclides to decay; and

(5) Other site–specific factors which the agency may consider appropriate on a case–by–case basis, such as the regulatory requirements of other government agencies, lawsuits, groundwater treatment activities, monitored natural groundwater restoration, actions that could result in more environmental harm than a deferred cleanup, and other factors beyond the controls of the licensee.

j. As the final step in decommissioning, the licensee shall:

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed IDPH Form 588–2793 or equivalent information; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner. The licensee shall, as appropriate:

1. Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report the level of radioactivity, including alpha and beta, in units of disintegrations per minute or microcuries (megabecquerels) per 100 square centimeters (removable and fixed) for surfaces, microcuries (megabecquerels) per liter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

2. Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

k. Specific licenses, including expired licenses, will be terminated by written notice to the licen–see

when the agency determines that:

(1) By–product material has been properly disposed;

(2) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with state of Iowa requirements; or other information submitted by the licensee is sufficient for release in accordance with state of Iowa requirements.

(4) Records required by 39.4(52)*"e"* and 39.4(52)*"g"* have been received.

l. Prior to license termination, each licensee authorized to possess radioactive material with a half–life greater than 120 days, in an unsealed form, shall forward the following records to the agency:

(1) Disposal of licensed material (including burials authorized before January 28, 1981), made under 641—40.71(136C) through 40.74(136C); and

(2) Records required by 641—paragraph 40.82(2)*"d."*

m. If licensed activities are transferred or assigned in accordance with 39.4(32) *"b,"* each licensee authorized to possess radioactive material with a half–life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material (including burials authorized before January 28, 1981), made under 641—40.71(136C) through 40.74(136C); and

(2) Records required by 641—paragraph 40.82(2)*"d."*

n. Prior to license termination, each licensee shall forward the records required by 39.4(26) *"g"* to the agency.

39.4(34) *Renewal of licenses.*

a. Applications for renewal of specific licenses shall be filed in accordance with 39.4(24) and include the fees required in 641—subrule 38.8(2).

b. In any case in which a licensee, not less than 30 days prior to expiration of an existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the agency.

39.4(35) *Amendment of licenses at request of licensee.* Applications for amendment of a license shall be filed in accordance with 39.4(24), include the fees required in 641—subrule 38.8(2), and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

39.4(36) *Agency action on applications to renew or amend.* In considering an application by a licensee to renew or amend the license, the agency will apply the criteria set forth in 39.4(25), 39.4(27), 39.4(28), and 39.4(29) and in 641—Chapters 38, 40, 41, 42, 43, 44 and 45, as applicable.

39.4(37) *Persons possessing a license for source, by–product, or special nuclear material in quantities not sufficient to form a critical mass on effective date of these rules.* Any person who, on the effective date of these rules, possesses a general or specific license issued by the U.S. Nuclear Regulatory Commission for source, by–product, or special nuclear material in quantities not sufficient to form a critical mass, shall be deemed to possess a like license issued under this chapter and the Iowa Code, such license to expire either 90 days after receipt from the agency of a notice of expiration of such license, or

on the date or expiration specified in the U.S. Nuclear Regulatory Commission license, whichever is earlier.

39.4(38) *Persons possessing naturally occurring and accelerator–produced radioactive material on effective date of these rules.* Any person who, on the effective date of these rules, possesses NARM for which a specific license is required by the Iowa Code or this chapter shall be deemed to possess such a license issued under the Iowa Code and this chapter. Such license shall expire 90 days after the effective date of these rules; provided, however, that if within the 90 days the person possessing such material files an application in proper form for a license, such existing license shall not expire until the application has been finally determined by the agency.

39.4(39) and **39.4(40)** Reserved.

39.4(41) *Transfer of material.*

a. No licensee shall transfer radioactive material except as authorized pursuant to 39.4(41).

b. Except as otherwise provided in the license and subject to the provisions of 39.4(41)*"c"* and *"d,"* any licensee may transfer radioactive material:

(1) To the agency (a licensee may transfer material to the agency only after receiving prior approval from the agency);

(2) To the U.S. Department of Energy;

(3) To any person exempt from these rules to the extent permitted under such exemption;

(4) To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the agency, the U.S. Nuclear Regulatory Commission, any agreement state or any licensing state, or to any person otherwise authorized to receive such material by the federal government or any agency thereof, the agency, an agreement state, or a licensing state; or

(5) As otherwise authorized by the agency in writing.

c. Before transferring radioactive material to a specific licensee of the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state, or to a general licensee who is required to register with the agency, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

d. Any of the following methods for the verification required by 39.4(41) *"c"* is acceptable:

(1) The transferor may possess and read a current copy of the transferee's specific license or registration certificate.

(2) The transferor may possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date.

(3) For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date, provided that the oral certification is confirmed in writing within ten days.

(4) The transferor may obtain other information compiled by a reporting service from official rec–ords

of the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state regarding the identity of licensees and the scope and expiration dates of licenses and registration.

(5) When none of the methods of verification described in 39.4(41) *"d"* (1) through (4) are readily available or when a transferor desires to verify that information received by one of such methods is correct or up to date, the transferor may obtain and record confirmation from the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state that the transferee is licensed to receive the radioactive material.

e. Shipment and transport of radioactive material shall be in accordance with the provisions of 641—39.5(136C).

39.4(42) to **39.4(50)** Reserved.

39.4(51) *Modification and revocation of licenses.*

a. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Iowa Code, or by reason of rules, regulations, and orders issued by the agency.

b. Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Iowa Code, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Iowa Code, or of the license, or of any rule, regulation, or order of the agency.

c. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

39.4(52) *Records.*

a. Each person who receives by–product material pursuant to a license shall keep records showing the receipt, transfer, and disposal of the by–product material as follows:

(1) The licensee shall retain each record of receipt of by–product material as long as the material is possessed and for three years following transfer or disposal of material.

(2) The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a specific requirement in another part of these rules dictates otherwise.

(3) The licensee who disposed of the material shall retain each record of disposal of by–product material until the agency terminates each license that authorizes disposal of the material.

b. The licensee shall retain each record that is required by these rules or by license condition for the period specified by the appropriate rule or license condition; the record must be retained until the agency terminates each license that authorizes the activity that is subject to the record–keeping requirements.

c. Records which must be maintained may be the original or a reproduced copy or microfilm if such reproduced copy or microfilm is duly authenticated by authorized personnel and the microfilm is capable of producing a clear and legible copy after storage for the period specified by agency regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings and specifications must include all pertinent information such as stamps, initials, and signatures. The

licensee shall maintain adequate safeguards against tampering with and loss of records.

d. If there is a conflict between the agency's rules or other written agency approval or authorization pertaining to the retention period for the same type of record, the retention period specified in these rules for such records shall apply unless the agency has granted a specific exemption from the record retention requirements specified in agency rules.

e. Prior to license termination, each licensee authorized to possess radioactive material with a half–life greater than 120 days, in an unsealed form, shall forward the following records to the agency:

(1) Records of disposal of licensed material made under 641—40.71(136C) (including burials authorized before January 28, 1981) to 641—40.74(136C); and

(2) Records required by 641—paragraph 40.82(2)*"d."*

f. If licensed activities are transferred or assigned, each licensee authorized to possess radioactive material, with a half–life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material made under 40.71(136C) (including burials authorized before January 28, 1981) to 641—40.74(136C); and

(2) Records required by 641—paragraph 40.82(2)*"d."*

g. Prior to license termination, each licensee shall forward the records required by subrule 39.4(26) to the agency.

39.4(53) to **39.4(89)** Reserved.

39.4(90) *Reciprocal recognition of licenses.*

a. Licenses of by–product, source, and special nuclear material in quantities not sufficient to form a critical mass.

(1) Subject to 641—Chapter 39, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in a one–year period. The one–year period starts on the day the licensee's reciprocity fee, as specified in 641—subrule 38.8(8), is received by the agency and ends exactly 365 days later. Licensees are responsible for ensuring they do not exceed the 180–day limit within the one–year period and must apply for renewal 30 days prior to the expiration date of the one–year reciprocal recognition period. Out–of–state persons wishing to operate in the state in excess of 180 calendar days must obtain an Iowa radioactive materials license, which requires that the person have a permanent office in Iowa where records are maintained pertaining to licensed activities and where material can be stored, and must have at least one full–time employee and a telephone.

(2) The licensing document referenced in 39.4(90)*"a"*(1) shall not limit the activity authorized by such document to specified installations or locations.

(3) The out–of–state licensee shall notify the agency in writing at least three days prior to engaging in activities in the state. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document initially. If, for a specific case, the three–day period would impose an undue hardship on the out–of–state licensee, the licensee may, upon application to the agency, obtain permission to proceed

sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the one–year reciprocity period following the receipt of the initial notification from a person engaging in activities under the general license provided by 39.4(90) *"a."*

(4) The out–of–state licensee shall comply with all applicable rules of the agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the agency.

(5) The out–of–state licensee shall supply other information as the agency may request.

(6) The out–of–state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided by 39.4(90) *"a"* except by transfer to a person:

1. Specifically licensed by the agency, another agreement state or the U.S. Nuclear Regulatory Commission to receive such material, or

2. Exempt from the requirements for a license for such material under 39.4(3) *"a."*

(7) Notwithstanding the provisions of 39.4(90)*"a"*(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state authorizing the holder to manufacture, transfer, install, or service a device described in 39.4(22)*"d"*(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state provided that:

1. Such person shall file a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

2. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an agreement state;

3. Such person shall ensure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

4. The holder of the specific license shall furnish to each general licensee to whom the holder transfers such device or on whose premises the holder installs such device a copy of the general license contained in 39.4(22)*"d"* or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

(8) The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an agreement state, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(9) The agency may revoke or suspend an out–of–state radiographer's ID card issued by the U.S. Nuclear Regulatory Commission, a licensing state, or another agreement state in accordance with the provisions of 641—45.1(10)*"h."*

b. Licenses of naturally occurring or accelerator–produced radioactive material.

(1) Subject to 641—Chapter 39, any person who holds a specific license from the U.S. Nuclear Regulatory Commission or an agreement state, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such

licensing document within this state for a period not in excess of 180 days in a one–year period. The one–year period starts on the day the licensee's reciprocity fee, as specified in 641—subrule 38.8(8), is received by the agency and ends exactly 365 days later. Licensees are responsible for ensuring they do not exceed the 180–day limit within the one–year period and must apply for renewal 30 days prior to the expiration date of the one–year reciprocal recognition period. Out–of–state persons wishing to operate in the state in excess of 180 calendar days must obtain an Iowa radioactive materials license, which requires that the person have a permanent office in Iowa where records are maintained pertaining to licensed activities and where material can be stored, and must have at least one full–time employee and a telephone.

(2) The licensing document referenced in 39.4(90)*"a"*(1) shall not limit the activity authorized by such document to specified installations or locations.

(3) The out–of–state licensee shall notify the agency in writing at least three days prior to engaging in activities in the state. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document initially. If, for a specific case, the three–day period would impose an undue hardship on the out–of–state licensee, the licensee may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the one–year reciprocity period following the receipt of the initial notification from a person engaging in activities under the general license provided by 39.4(90) *"b."*

(4) The out–of–state licensee shall comply with all applicable rules of the agency and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the agency.

(5) The out–of–state licensee shall supply other information as the agency may request.

(6) The out–of–state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided by 39.4(90) *"b"* except by transfer to a person:

1. Specifically licensed by the agency, another agreement state or the U.S. Nuclear Regulatory Commission to receive such material, or

2. Exempt from the requirements for a license for such material under 39.4(3) *"a."*

(7) Notwithstanding the provisions of 39.4(90)*"b"*(1), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission or an agreement state authorizing the holder to manufacture, transfer, install, or service a device described in 39.4(22)*"d"*(1) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this state provided that:

1. Such person shall file a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

2. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission or an agreement state;

3. Such person shall ensure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and

4. The holder of the specific license shall furnish to each general licensee to whom the holder transfers such device or on whose premises the holder installs such device a copy of the general license contained

in 39.4(22)*"d"* or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.

(8) The agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an agreement state, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

(9) The agency may revoke or suspend an out–of–state radiographer's ID card issued by the U.S. Nuclear Regulatory Commission, a licensing state, or another agreement state in accordance with the provisions of 641—45.1(10)*"h."*

39.4(91) to **39.4(104)** Reserved.

641—39.5(136C) Transportation of radioactive material.

39.5(1) *Purpose and scope.* This rule establishes requirements for packaging, preparation for shipment, and transportation of radioactive material and applies to any person who transports radioactive material or delivers radioactive material to a carrier for transport. All references to Code of Federal Regulations(CFRs) in this rule are those in effect as of September 1, 1992.

39.5(2) *Definitions.* As used in this rule, the following definitions apply:

"Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

"Closed transport vehicle" means a transport vehicle equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons to the cargo space containing the radioactive material. The enclosure may be either temporary or permanent but shall limit access from top, sides, and ends. In the case of packaged materials, it may be of the "see–through" type.

"Exclusive use" means the sole use of a conveyance by a single consignor and for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The term "exclusive use" is used interchangeably with the terms "sole use" or "full load" in other regulations, such as Title 49 of the Code of Federal Regulations.

"Fissile material" means any special nuclear material consisting of or containing one or more fissile radionuclides. Fissile radionuclides are plutonium–238, plutonium–239, plutonium–241, uranium–233, and uranium–235. Neither natural nor depleted uranium is fissile material. Agency jurisdiction extends only to special nuclear material if quantities are not sufficient to form a critical mass as defined in 641—Chapter 38.

a. Fissile Class I: A package which may be transported in unlimited numbers and in any arrangement, and which requires no nuclear criticality safety controls during transportation. A transport index is not assigned for purposes of nuclear criticality safety but may be required because of external radiation levels.

b. Fissile Class II: A package which may be transported together with other packages in any arrangement but, for criticality control, in numbers which do not exceed an aggregate transport index of 50. These shipments require no other nuclear criticality safety control during transportation. Individual packages may have a transport index not less than 0.1 and not more than 10.

"Low specific activity material" means any of the following:

a. Uranium or thorium ores and physical or chemical concentrates of those ores;

b. Unirradiated natural or depleted uranium or unirradiated natural thorium;

c. Tritium oxide in aqueous solutions provided the concentration does not exceed 5.0 millicuries (185 MBq) per milliliter;

d. Material in which the radioactivity is essentially uniformly distributed and in which the estimated average concentration per gram of contents does not exceed:

(1) 0.0001 millicurie (3.7 kBq) of radionuclides for which the A_2 quantity in Appendix E of this chapter is not more than 0.05 curie (1.85 GBq);

(2) 0.005 millicurie (185 kBq) of radionuclides for which the A_2 quantity in Appendix E of this chapter is more than 0.05 curie (1.85 GBq) but not more than 1 curie (37 GBq); or

(3) 0.3 millicurie (11.1 MBq) of radionuclides for which the A_2 quantity in Appendix E of this chapter is more than 1 curie (37 GBq);

e. Objects of nonradioactive material externally contaminated with radioactive material, provided that the radioactive material is not readily dispersible, and the surface contamination, when averaged over an area of 1 square meter, does not exceed 0.0001 millicurie per square centimeter (3.7 kBq/cm^2) of radionuclides for which the A_2 quantity in Appendix E of this chapter is not more than 0.05 curie (1.85 GBq) or 0.001 millicurie per square centimeter (37 kBq/cm^2) for other radionuclides.

"Normal form radioactive material" means radioactive material which has not been demonstrated to qualify as special form radioactive material.

"Packaging" means the assembly of components necessary to ensure compliance with the packaging requirements of this chapter. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie–down system, and auxiliary equipment may be designated as part of the packaging.

"Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100–189.

"Specific activity" of a radionuclide means the radioactivity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

"Transport index" (TI) means the dimensionless number, rounded up to the first decimal place, placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number expressing the maximum radiation level in millirem per hour at one meter from the external surface of the package.

"Type A quantity" means a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in Appendix E of this chapter or may be determined by procedures described in Appendix E of this chapter.

"Type B package" means a Type B packaging together with its radioactive contents. A Type B package design is designated as B(U) or B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval. There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, refer to 49 CFR Part 173. A Type B package approved prior to September 6, 1983, was designated only as Type B. Limitations on its use are specified in 39.5(8).

"Type B packaging" means a packaging designed to retain the integrity of containment and shielding when subjected to the normal conditions of transport and hypothetical accident test conditions set forth in 10 CFR Part 71.

"Type B quantity" means a quantity of radioactive material greater than a Type A quantity.

39.5(3) *Requirement for license.* No person shall transport radioactive material or deliver radioactive material to a carrier for transport except as authorized in a general or specific license issued by the agency or as exempted in 39.5(4).

39.5(4) *Exemptions.*

a. Common and contract carriers, freight forwarders, and warehousers which are subject to the requirements of the U.S. Department of Transportation in 49 CFR 170 through 189 or the U.S. Postal Service in the Postal Service Manual (Domestic Mail Manual), Section 124.3 incorporated by reference, 39 CFR 111.11 (1974), and the U.S. Postal Service are exempt from the requirements of this chapter to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers who are not subject to the requirements of the U.S. Department of Transportation or U.S. Postal Service are subject to 39.5(3) and other applicable requirements of 641—Chapters 38 to 46.

b. Any licensee is exempt from the requirements of this chapter to the extent that the licensee delivers to a carrier for transport a package containing radioactive material having a specific activity not greater than 0.002 microcurie per gram (74 Bq/gm).

c. With the exception of 39.5(5) and 39.5(16), a licensee is exempt from all requirements of this chapter, with respect to shipment or carriage of the following:

(1) A package containing no more than a Type A quantity of radioactive material if the package contains no fissile material; or

(2) Packages transported between locations within the United States which contain only americium or plutonium in special form with an aggregate radioactivity not to exceed 20 curies (740 GBq).

39.5(5) *Transportation of licensed material.*

a. Each licensee who transports licensed material outside the confines of the licensee's plant or other place of use, or who delivers licensed material to a carrier for transport, shall:

(1) Comply with the applicable requirements, appropriate to the mode of transport, of the regulations of the U.S. Department of Transportation; and

(2) Ensure that any special instructions needed to safely open the package are sent to or have been made available to the consignee.

b. If, for any reason, the regulations of the U.S. Department of Transportation are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of those regulations to the same extent as if the shipment was subject to the regulations.

39.5(6) *General licenses for carriers.*

a. A general license is hereby issued to any common or contract carrier not exempt under 39.5(4) to receive, possess, transport, and store radioactive material in the regular course of their carriage for others or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle,

and incident reporting. Any notification of incidents referred to in those U.S. Department of Transportation requirements shall be filed with, or made to, the agency.

b. A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting. Any notification of incidents referred to in those U.S. Department of Transportation requirements shall be filed with, or made to, the agency.

c. Persons who transport radioactive material pursuant to the general licenses in 39.5(6)*"a"* or *"b"* are exempt from the requirements of 641—Chapter 40 to the extent that they transport radioactive material.

39.5(7) *General license—approved packages.*

a. A general license is hereby issued to any licensee of the agency to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance, or other approval has been issued by the U.S. Nuclear Regulatory Commission.

b. This general license applies only to a licensee who:

(1) Has a copy of the specific license, certificate of compliance, or other approval of the package and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

(2) Complies with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of this chapter;

(3) Prior to the licensee's first use of the package, has registered with the U.S. Nuclear Regulatory Commission; and

(4) Has a quality assurance program required by 39.5(20) and approved by the agency.

c. The general license in 39.5(7)*"a"* applies only when the package approval authorizes use of the package under this general license.

d. For previously approved Type B packages which are not designated as either B(U) or B(M) in the certificate of compliance, this general license is subject to additional restrictions of 39.5(8).

39.5(8) *General license—previously approved Type B packages.* A Type B package previously approved by the U.S. Nuclear Regulatory Commission, but not designated as B(U) or B(M) in the certificate of compliance, may be used under the general license of 39.5(7) with the following additional limitations:

a. Fabrication of the packaging was satisfactorily completed before August 31, 1986, as demonstrated by application of its model number in accordance with U.S. Nuclear Regulatory Commission regulations; and

b. The package may not be used for a shipment to a location outside the United States after August 31, 1986, except approved under special arrangement in accordance with 49 CFR 173.471.

39.5(9) *General license—specification container.*

a. A general license is issued to any licensee of the agency to transport, or to deliver to a carrier for transport, licensed material in a specification container for a Type B quantity of radioactive material as specified in 49 CFR Parts 173 and 178.

b. This general license applies only to a licensee who has a quality assurance program required by

39.5(20) and approved by the agency.

c. This general license applies only to a licensee who:

(1) Has a copy of the specification; and

(2) Complies with the terms and conditions of the specification and the applicable requirements of this chapter.

d. The general license in 39.5(9)*"a"* is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States after August 31, 1986, except approved under special arrangements in accordance with 49 CFR 173.472.

39.5(10) *General license—use of foreign approved package.*

a. A general license is issued to any licensee of the agency to transport, or to deliver to a carrier for transport, licensed material in a package, the design of which has been approved in a foreign national competent authority certificate which has been revalidated by the U.S. Department of Transportation as meeting the applicable requirements of 49 CFR 171.12.

b. This general license applies only to international shipments.

c. This general license applies only to a licensee who:

(1) Has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment; and

(2) Complies with the terms and conditions of the certificate and revalidation and with the applicable requirements of 641—Chapter 39.

39.5(11) *General license—Type A, fissile Class II package.*

a. A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped as a fissile Class II package.

b. This general license applies only when a package contains no more than a Type A quantity of radioactive material, including only one of the following:

(1) Up to 40 grams of uranium–235; or

(2) Up to 30 grams of uranium–233; or

(3) Up to 25 grams of the fissile radionuclides of plutonium, except that for encapsulatedplutonium–beryllium neutron sources in special form, an A_1 quantity of plutonium may be present; or

(4) A combination of fissile radionuclides in which the sum of the ratios of the amount of each radionuclide to the corresponding maximum amounts in 39.5(11)*"b"*(1), (2), and (3) does not exceed unity.

c. (1) Except as specified in 39.5(11)*"c"*(2), this general license applies only when a package containing more than 15 grams of fissile radionuclides is labeled with a transport index not less than the number given by the following equation:

$$\text{Minimum Transport Index} = (0.4x + 0.67y + z)\left(1 - \frac{15}{\ }\right)$$

x+y+z

where the package contains x grams of uranium–235, y grams of uranium–233, and z grams of the fissile radionuclides of plutonium.

(2) For a package in which the only fissile material is in the form of encapsulated plutonium–beryllium neutron sources in special form, the transport index based on criticality considerations may be taken as 0.026 times the number of grams of the fissile radionuclides of plutonium in excess of 15 grams.

(3) In all cases, the transport index must be rounded up to one decimal place and may not exceed 10.0.

39.5(12) *General license—restricted, fissile Class II package.*

a. A general license is hereby issued to any licensee to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped as a fissile Class II package.

b. This general license applies only when all of the following requirements are met:

(1) The package contains no more than a Type A quantity of radioactive material.

(2) Neither beryllium nor hydrogenous material enriched in deuterium is present.

(3) The total mass of graphite present does not exceed 150 times the total mass of uranium–235 plus plutonium.

(4) Substances having a higher hydrogen density than water are not present, except that polyethylene may be used for packing or wrapping.

(5) Uranium–233 is not present, and the amount of plutonium does not exceed 1 percent of the amount of uranium–235.

(6) The amount of uranium–235 is limited as follows:

1. If the fissile radionuclides are not uniformly distributed, the maximum amount of uranium–235 per package may not exceed the value given in the following table:

Table 1

Uranium enrichment in weight percent of uranium–235 not exceeding		Permissible maximum grams of uranium–235 per package
24		40
20		42
15		45
11		48
10		51
9.5		52
9		54
8.5		55
8		57
7.5		59
7		60
6.5		62
6		65
5.5		68
5		72
4.5		76
4		80
3.5		88
3		100
2.5		120
2		164
1.5		272
1.35		320
1		680*
0.92		1200*

*Pursuant to the agency's agreement with the U.S. Nuclear Regulatory Commission, jurisdiction extends only to 350 grams of uranium–235.

2. If the fissile radionuclides are distributed uniformly, the maximum amount of uranium–235 per package may not exceed the value given in the following table:

Table 2

Uranium enrichment in weight percent of uranium–235 not exceeding		Permissible maximum grams of uranium–235 per package
4		84
3.5		92
3		112
2.5		148
2		240
1.5		560*
1.35		800*

*Pursuant to the agency's agreement with the U.S. Nuclear Regulatory Commission, jurisdiction extends only to 350 grams of uranium–235.

(7) The transport index of each package based on criticality considerations is taken as ten times the number of grams of uranium–235 in the package divided by the maximum allowable number of grams per package in accordance with Table 1 or 2 above as applicable.

39.5(13) *Fissile material—assumptions as to unknown properties.* When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties had credible values that would cause the maximum nuclear reactivity.

39.5(14) *Preliminary determinations.* Prior to the first use of any packaging for the shipment of radioactive material:

a. The licensee shall ascertain that there are no defects which could significantly reduce the effectiveness of the packaging;

b. Where the maximum normal operating pressure will exceed 34.3 kilopascal (5 psi) gauge, the licensee shall test the containment system at an internal pressure at least 50 percent higher than the maximum normal operating pressure to verify the capability of that system to maintain its structural integrity at that pressure;

c. The licensee shall determine that the packaging has been fabricated in accordance with the design approved by the U.S. Nuclear Regulatory Commission; and

d. The licensee shall conspicuously and durably mark the packaging with its model number, gross weight, and a package identification number assigned by the U.S. Nuclear Regulatory Commission.

39.5(15) *Routine determinations.* Prior to each shipment of licensed material, the licensee shall determine that:

a. The package is proper for the contents to be shipped;

b. The package is in unimpaired physical condition except for superficial defects such as marks or dents;

c. Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

d. Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

e. Any pressure relief device is operable and set in accordance with written procedures;

f. The package has been loaded and closed in accordance with written procedures;

g. Any structural part of the package which could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements specified by the U.S. Nuclear Regulatory Commission;

h. (1) The level of removable radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable. The level of removable radioactive contamination may be determined by wiping an area of 300 square centimeters of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the wiping material. Sufficient measurements must be taken in the most appropriate locations to yield a representative assessment of the removable contamination levels. Except as provided in 39.5(15) *"h"*(2), the amount of radioactivity measured on any single wiping material, when averaged over the surface wiped, must not exceed the limits given in Table 3 below at any time during transport. Other methods of assessment of equal or greater efficiency may be used. When other methods are used, the detection efficiency of the method used must be taken into account and in no case may the removable contamination on the external surfaces of the package exceed ten times the limits listed in Table 3.

Table 3

Removable External Radioactive

Contamination Wipe Limits

Contaminant	μ Ci/cm^2*	Maximum Permissible Limits dpm/cm^2
Beta–gamma–emitting radionuclides; all radionuclides with half–lives less than ten days; natural uranium; natural thorium; uranium–235; uranium–238; thorium–232; thorium–228 and thorium–230 when contained in ores or physical concentrates	10^{-5}	22
All other alpha–emitting radionuclides	10^{-6}	2.2

*To convert microcuries (m Ci) to SI units of megabecquerels, multiply the values by 37.

(2) In the case of packages transported as exclusive use shipments by rail or highway only, the removable radioactive contamination at any time during transport must not exceed ten times the levels prescribed in 39.5(15) *"h"*(1). The levels at the beginning of transport must not exceed the levels in 39.5(15)*"h"*(1);

i. External radiation levels around the package and around the vehicle, if applicable, will not exceed 200 millirems per hour (2 mSv/h) at any point on the external surface of the package at any time during transportation. The transport index shall not exceed ten;

j. For a package transported in exclusive use by rail, highway or water, radiation levels external to the package may exceed the limits specified in 39.5(15) *"i"* but shall not exceed any of the following:

(1) 200 millirems per hour (2 mSv/h) on the accessible external surface of the package unless the following conditions are met, in which case the limit is 1000 millirems per hour (10 mSv/h):

1. The shipment is made in a closed transport vehicle,

2. Provisions are made to secure the package so that its position within the vehicle remains fixed during transportation, and

3. There are no loading or unloading operations between the beginning and end of the transportation;

(2) 200 millirems per hour (2 mSv/h) at any point on the outer surface of the vehicle, including the upper and lower surfaces, or, in the case of a flat–bed style vehicle, with a personnel barrier,** at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load (or enclosure, if used) and on the lower external surface of the vehicle;

(3) 10 millirems per hour (0.1 mSv/h) at any point two meters from the vertical planes represented by the outer lateral surfaces of the vehicle, or, in the case of a flat–bed style vehicle, at any point two meters from the vertical planes projected from the outer edges of the vehicle; and

(4) 2 millirems per hour (0.02 mSv/h) in any normally occupied positions of the vehicle, except that this provision does not apply to private motor carriers when persons occupying these positions are provided with special health supervision, personnel radiation exposure monitoring devices, and training in accordance with 641—40.111(136C); and

**A flat–bed style vehicle with a personnel barrier shall have radiation levels determined at vertical planes. If no personnel barrier, the package cannot exceed 200 millirems per hour (2 mSv/h) at the surface.

k. A package must be prepared for transport so that in still air at 100 degrees Fahrenheit (38 degrees Celsius) and in the shade, no accessible surface of a package would have a temperature exceeding 122 degrees Fahrenheit (50 degrees Celsius) in a nonexclusive use shipment or 180 degrees Fahrenheit (82 degrees Celsius) in an exclusive use shipment. Accessible package surface temperatures shall not exceed these limits at any time during transportation.

39.5(16) *Air transport of plutonium.* Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this subrule or included indirectly by citation of the U.S. Department of Transportation regulations, as may be applicable, the licensee shall ensure that plutonium in any form is not transported by air, or delivered to a carrier for air transport, unless:

a. The plutonium is contained in a medical device designed for individual human application; or

b. The plutonium is contained in a material in which the specific activity is not greater than 0.002 microcuries per gram (74 Bq/gm) of material and in which the radioactivity is essentially uniformly distributed; or

c. The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form and is shipped in accordance with 39.5(5); or

d. The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the certificate of compliance for that package issued by the U.S. Nuclear Regulatory Commission.

39.5(17) *Shipment records.* Each licensee shall maintain for a period of two years after shipment a

record of each shipment of licensed material not exempt under 39.5(4), showing, where applicable:

a. Identification of the packaging by model number;

b. Verification that there were no significant defects in the packaging, as shipped;

c. Volume and identification of coolant;

d. Type and quantity of licensed material in each package, and the total quantity of each shipment;

e. Date of the shipment;

f. Name and address of the transferee;

g. Address to which the shipment was made; and

h. Results of the determinations required by 39.5(15).

39.5(18) *Reports.* The licensee shall report to the agency within 30 days:

a. Any instance in which there is significant reduction in the effectiveness of any authorized packaging during use; and

b. Details of any defects with safety significance in the packaging after first use, with the means employed to repair the defects and prevent their recurrence.

39.5(19) *Advance notification of transport of nuclear waste.*

a. Prior to the transport of any nuclear waste outside the confines of the licensee's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each licensee shall provide advance notification of such transport to the governor, or governor's designee, of each state through which the waste will be transported. A list of the mailing addresses of the governors and governors' designees is available upon request from the Director, State Programs, Office of Governmental and Public Affairs, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

b. Advance notification is required only when:

(1) The nuclear waste is required to be in Type B packaging for transportation;

(2) The nuclear waste is being transported to, through, or across state boundaries to a disposal site or to a collection point for transport to a disposal site; and

(3) The quantity of licensed material in a single package exceeds:

1. 5,000 curies (185 TBq) of special form radionuclides;

2. 5,000 curies (185 TBq) of uncompressed gases of argon–41, krypton–85m, krypton–87, xenon–131m, or xenon–135;

3. 50,000 curies (1.85 PBq) of argon–37, or of uncompressed gases of krypton–85 or xenon–133, or of hydrogen–3 as a gas, as luminous paint, or absorbed on solid material;

4. 20 curies (740 GBq) of other nonspecial form radionuclides for which A_2 is less than or equal to 4 curies (148 GBq); or

5. 200 curies (7.4 TBq) of other nonspecial form radionuclides for which A_2 is greater than 4 curies (148

GBq).

c. Each advance notification required by 39.5(19) *"a"* shall contain the following information:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the shipment;

(2) A description of the nuclear waste contained in the shipment as required by 49 CFR 172.202 and 172.203(d);

(3) The point of origin of the shipment and the seven–day period during which departure of the shipment is estimated to occur;

(4) The seven–day period during which arrival of the shipment at state boundaries is estimated to occur;

(5) The destination of the shipment, and the seven–day period during which arrival of the shipment is estimated to occur; and

(6) A point of contact with a telephone number for current shipment information.

d. The notification required by 39.5(19) *"a"* shall be made in writing to the office of each appropriate governor, or governor's designee, and to the agency. A notification delivered by mail must be postmarked at least seven days before the beginning of the seven–day period during which departure of the shipment is estimated to occur. A notification delivered by messenger must reach the office of the governor, or governor's designee, at least four days before the beginning of the seven–day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the licensee for one year.

e. The licensee shall notify each appropriate governor, or governor's designee, and the agency of any changes to schedule information provided pursuant to 39.5(19) *"a."* Such notification shall be by telephone to a responsible individual in the office of the governor, or governor's designee, of the appropriate state or states. The licensee shall maintain for one year a record of the name of the individual contacted.

f. Each licensee who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice to the governor, or governor's designee, of each appropriate state and to the agency. A copy of the notice shall be retained by the licensee for one year.

39.5(20) *Quality assurance requirements.*

a. Each licensee shall establish, maintain, and execute a quality assurance program to verify by procedures such as checking, auditing, and inspection that deficiencies, deviations, and defective material and equipment relating to the shipment of packages containing radioactive material are promptly identified and corrected.

b. The licensee shall identify the material and components to be covered by the quality assurance program.

c. Each licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which packaging is used.

d. Prior to the use of any package for the shipment of radioactive material, each licensee shall obtain approval by the agency of its quality assurance program.

e. The licensee shall maintain sufficient written records to demonstrate compliance with the quality assurance program. Records of quality assurance pertaining to the use of a package for shipment of radioactive material shall be maintained for a period of two years after shipment.

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Stephen C. Gleason, D. O., Director
Lucas State Office Building
Des Moines, IA 50319-0075
515-281-5787

chapter 40
STANDARDS FOR PROTECTION AGAINST RADIATION

GENERAL PROVISIONS

641—40.1(136C) Purpose and scope.

40.1(1) This chapter establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Agency. These rules are issued pursuant to the authority in Iowa Code section 136C.3 and 136C.4.

40.1(2) The requirements of this chapter are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this chapter. However, nothing in this chapter shall be construed as limiting actions that may be necessary to protect health and safety.

40.1(3) In addition to complying with the requirements set forth in this chapter, every reasonable effort should be made to maintain radiation exposures and releases of radioactive material in effluents to unrestricted areas as low as is reasonably achievable (ALARA). The term "as low as is reasonably achievable" means as low as is reasonably achievable taking into account the state of technology and the economics of improvements in relation to benefits to the public health and safety, other societal and socioeconomic considerations, and in relation to the utilization of ionizing radiation in the public interest.

40.1(4) Except as specifically provided in other parts of these rules, this chapter applies to persons licensed or registered by the Agency to receive, possess, use, transfer, or dispose of sources of radiation. The limits in this chapter do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs.

40.1(5) All references to Code of Federal Regulations (CFR) in this chapter are those in effect on or before July 1, 1999.

40.1(6) The provisions of Chapter 40 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 38 to 45.

641—40.2(136C) Definitions.

40.2(1) For the purposes of this chapter, the definitions of 641—Chapter 38 may also apply.

40.2(2) As used in this chapter, these terms have the definitions set forth below.

"Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference person that would result in a committed effective dose equivalent of 5 rem (0.05 Sv) or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B.

"Class" means a classification scheme for inhaled material according to its rate of clearance from the

pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half–times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of these rules, "lung class" and "inhalation class" are equivalent terms.

"Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

"Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference person for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these rules, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of Appendix B.

"Derived air concentration–hour" (DAC–hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC–hours to represent one ALI, equivalent to a committed dose equivalent of 5 rem (0.05 Sv).

"Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

"Inhalation class" (see "Class.")

"Lung class" (see "Class.")

"Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation–induced cataract formation is an example of a nonstochastic effect. For purposes of these rules, "deterministic effect" is an equivalent term.

"Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

"Quarter" means a period of time equal to one–fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

"Reference person" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of the reference person is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man."

"Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

"Sanitary sewerage" means a system of public sewers for carrying off wastewater and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

"Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these rules, "probabilistic effect" is an equivalent term.

"Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 500 rad (5 Gy) in 1 hour at 1 meter from a

source of radiation or from any surface that the radiation penetrates.

"Weighting factor" w_T for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

	ORGAN DOSE WEIGHTING FACTORS		
	Organ or Tissue	w_T	
	Gonads	0.25	
	Breast	0.15	
	Red bone marrow	0.12	
	Lung	0.12	
	Thyroid	0.03	
	Bone surfaces	0.03	
	Remainder	0.30[a]	
	Whole Body	1.00[b]	

[a] 0.30 results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

[b] For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case–by–case basis until such time as specific guidance is issued.

641—40.3(136C) Implementation.

40.3(1) Any existing license or registration condition that is more restrictive than this chapter remains in force until there is an amendment or renewal of the license or registration.

40.3(2) If a license or registration condition exempts a licensee or registrant from a provision of this chapter in effect on or before January 1, 1994, it also exempts the licensee or registrant from the corresponding provision of this chapter.

40.3(3) If a license or registration condition cites provisions of this chapter in effect prior to January 1, 1994, which do not correspond to any provisions of this chapter, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

641—40.4 to **40.9** Reserved.

RADIATION PROTECTION PROGRAMS

641—40.10(136C) Radiation protection programs.

40.10(1) Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this chapter. See 40.81(136C) forrecord–keeping requirements relating to these programs.

40.10(2) The licensee or registrant shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

40.10(3) The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

40.10(4) To implement the ALARA requirements of 40.10(2), and notwithstanding the requirements in 641—40.26(136C), a constraint on air emissions of radioactive material to the environment, excluding radon–222 and its daughters, shall be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in 641—40.97(136C) and promptly take appropriate corrective action to ensure against recurrence.

641—40.11 to 40.14 Reserved.

OCCUPATIONAL DOSE LIMITS

641—40.15(136C) Occupational dose limits for adults.

40.15(1) The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to 40.20(136C), to the following dose limits:

a. An annual limit, which is the more limiting of:

(1) The total effective dose equivalent being equal to 5 rem (0.05 Sv); or

(2) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rem (0.5 Sv).

b. The annual limits to the lens of the eye, to the skin, and to the extremities which are:

(1) An eye dose equivalent of 15 rem (0.15 Sv), and

(2) A shallow dose equivalent of 50 rem (0.5 Sv) to the skin or to any extremity.

40.15(2) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See 40.20(5)*"a"* and *"b."*

40.15(3) The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure determined as follows:

The deep dose equivalent, eye dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

40.15(4) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of Appendix B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See 40.86(136C).

40.15(5) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of Appendix B.

40.15(6) The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See 40.19(5).

641—40.16(136C) Compliance with requirements for summation of external and internal doses.

40.16(1) If the licensee or registrant is required to monitor pursuant to both 40.19(1) and 40.19(2), the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to 40.19(1), or only pursuant to 40.19(2), then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to 40.16(2), 40.16(3) and 40.16(4). The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

40.16(2) Intake by inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

a. The sum of the fractions of the inhalation ALI for each radionuclide, or

b. The total number of derived air concentration–hours (DAC–hours) for all radionuclides divided by 2,000, or

c. The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10 percent of the maximum weighted value of H_{50}, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

40.16(3) Intake by oral ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.

40.16(4) Intake through wounds or absorption through skin. The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen–3 and does not need to be evaluated or accounted for pursuant to this subrule.

641—40.17(136C) Determination of external dose from airborne radioactive material.

40.17(1) Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, eye dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See Appendix B, footnotes 1 and 2.

40.17(2) Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

641—40.18(136C) Determination of internal exposure.

40.18(1) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required pursuant to 40.37(136C), take suitable and timely measurements of:

a. Concentrations of radioactive materials in air in work areas; or

b. Quantities of radionuclides in the body; or

c. Quantities of radionuclides excreted from the body; or

d. Combinations of these measurements.

40.18(2) Unless respiratory protective equipment is used, as provided in 40.50(136C), or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

40.18(3) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee may:

a. Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record; and

b. Upon prior approval of the Agency, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and

c. Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See Appendix B.

40.18(4) If the licensee chooses to assess intakes of Class Y material using the measurements given in 40.8(1) *"b"* or 40.8(1) *"c,"* the licensee may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by 40.96(136C) or 40.97(136C). This delay permits the licensee to make additional measurements basic to the assessments.

40.18(5) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC–hours shall be either:

a. The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix B for each radionuclide in the mixture; or

b. The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

40.18(6) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

40.18(7) When a mixture of radionuclides in air exists, a licensee may disregard certain radionuclides in the mixture if:

a. The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in 40.15(136C) and in complying with the monitoring requirements in 40.37(136C), and

b. The concentration of any radionuclide disregarded is less than 10 percent of its DAC, and

c. The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed

30 percent.

40.18(8) When determining the committed effective dose equivalent, the following information may be considered:

a. In order to calculate the committed effective dose equivalent, the licensee or registrant may assume that the inhalation of one ALI, or an exposure of 2,000 DAC–hours, results in a committed effective dose equivalent of 5 rem (0.05 Sv) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

b. For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 50 rem (0.5 Sv), the intake of radionuclides that would result in a committed effective dose equivalent of 5 rem (0.05 Sv), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B. The licensee or registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in 40.15(1)*"a"*(2) is met.

641—40.19(136C) Determination of prior occupational dose.

40.19(1) For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to this rule, the licensee or registrant shall:

a. Determine the occupational radiation dose received during the current year; and

b. Attempt to obtain the records of lifetime cumulative occupational radiation dose.

40.19(2) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

a. The internal and external doses from all previous planned special exposures; and

b. All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

c. All lifetime cumulative occupational radiation dose.

40.19(3) In complying with the requirements of 40.19(1), a licensee or registrant may:

a. Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and

b. Accept, as the record of lifetime cumulative radiation dose, an up–to–date IDPH Form 588–2833 or equivalent signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and

c. Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

40.19(4) *a.* The licensee or registrant shall record the exposure history, as required by 40.37(136C), on IDPH Form 588–2833 or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For

each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing IDPH Form 588–2833 or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on IDPH Form 588–2833 or equivalent indicating the periods of time for which data are not available.

b. Licensees or registrants are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the rules in this chapter in effect on or before January 1, 1994. Further, occupational exposure histories obtained and recorded on IDPH Form 588–2833 or equivalent on or before January 1, 1994, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

40.19(5) If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

a. In establishing administrative controls pursuant to 40.15(6) for the current year, that the allowable dose limit for the individual is reduced by 1.25 rem (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

b. That the individual is not available for planned special exposures.

40.19(6) The licensee or registrant shall retain the records on IDPH Form 588–2833 or equivalent until the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing IDPH Form 588–2833 or equivalent for three years after the record is made.

641—40.20(136C) Planned special exposures. A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in 40.15(136C) provided that each of the following conditions is satisfied:

40.20(1) The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical.

40.20(2) The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

40.20(3) Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

a. Informed of the purpose of the planned operation; and

b. Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

c. Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

40.20(4) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by 40.19(2) during the lifetime of the individual for each individual involved.

40.20(5) Subject to 40.15(2), the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

a. The numerical values of any of the dose limits in 40.15(1) in any year; and

b. Five times the annual dose limits in 40.15(1) during the individual's lifetime.

40.20(6) The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with 40.85(136C) and submits a written report in accordance with 40.98(136C).

40.20(7) The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to 40.15(1) but shall be included in evaluations required by 40.20(1) and 40.20(2).

641—40.21(136C) Occupational dose limits for minors. The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in 40.15(136C).

641—40.22(136C) Dose to an embryo/fetus.

40.22(1) The licensee or registrant shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). See 40.86(136C) for record–keeping requirements.

40.22(2) The licensee or registrant shall make efforts to avoid substantial variation[1] above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 40.22(1).

40.22(3) The dose to an embryo/fetus shall be taken as the sum of:

a. The deep dose equivalent to the declared pregnant woman; and

b. The dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

40.22(4) If by the time the woman declares pregnancy to the licensee or registrant, the dose to the embryo/fetus has exceeded 0.45 rem, (4.5 mSv), the licensee or registrant shall be deemed to be in compliance with 40.22(1) if the additional dose to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

641—40.23 to **40.25** Reserved.

[1] The National Council on Radiation Protection and Measurements recommended in NCRP Report No. 91 "Recommendations on Limits for Exposure to Ionizing Radiation" (June 1, 1987) that no more than 0.05 rem (0.5 mSv) to the embryo/fetus be received in any one month.

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

641—40.26(136C) Dose limits for individual members of the public.

40.26(1) Each licensee or registrant shall conduct operations so that:

a. The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 millisievert) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with 641—subrule 41.2(27), from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with 641—40.72(136C); and

b. The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with 641—subrule 41.2(27), does

not exceed 0.002 rem (0.02 millisievert) in any one hour.

40.26(2) If the licensee or registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

40.26(3) A licensee, registrant, or an applicant for a license or registration may apply for prior Agency authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). This application shall include the following information:

a. Demonstration of the need for and the expected duration of operations in excess of the limit in 40.13(1); and

b. The licensee's or registrant's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

c. The procedures to be followed to maintain the dose ALARA.

40.26(4) In addition to the requirements of this chapter, a licensee or registrant subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.

40.26(5) The Agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

641—40.27(136C) Compliance with dose limits for individual members of the public.

40.27(1) The licensee or registrant shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public in 40.26(136C).

40.27(2) A licensee or registrant shall show compliance with the annual dose limit in 40.26(136C) by:

a. Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

b. Demonstrating that:

(1) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B; and

(2) If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.

40.27(3) Upon approval from the Agency, the licensee or registrant may adjust the effluent concentration values in Appendix B, Table II, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

641—40.28(136C) Radiological criteria for license termination.

40.28(1) The criteria in this rule apply to the decommissioning of facilities licensed under 641—Chapter 39 as well as other facilities subject to the agency's jurisdiction under Iowa Code chapter 136C.

40.28(2) The criteria in this rule do not apply to sites which:

a. Have been decommissioned prior to July 1, 1999, in accordance with criteria identified in 641—subrule 39.4(33).

b. Have previously submitted and received agency approval on a license termination plan (LTP) or decommissioning plan that is compatible with the United States Nuclear Regulatory Commission (NRC) Site Decommissioning Management Plan (SDMP) Action Plan criteria; or

c. Submit a sufficient LTP or decommissioning plan prior to July 1, 1999, and such LTP or decommissioning plan is approved by the agency prior to July 1, 1999, except that if an environmental impact statement is required in the submittal, there will be a provision for day–to–day extension.

40.28(3) After a site has been decommissioned and the license terminated in accordance with the criteria in this chapter, the agency will require additional cleanup only if, based on new information, it determines that the criteria of this chapter were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

40.28(4) When calculating TEDE to the average member of the critical group the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

40.28(5) Public notification and public participation. Upon the receipt of an LTP or decommissioning plan from the licensee or a proposal by the licensee for release of a site pursuant to 40.30(136C) or 40.31(136C) or whenever the agency deems such notice to be in the public interest, the agency shall:

a. Notify and solicit comments from:

(1) Local and state governments in the vicinity of the site and any Indian nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and

(2) The Environmental Protection Agency for cases where the licensee proposes to release a site pursuant to 40.31(136C).

b. Publish a notice in the Iowa Administrative Bulletin and in a forum, such as local newspapers, letters to state or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

40.28(6) Minimization of contamination. Applicants for licenses, other than renewals, after July 1, 1999, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

641—40.29(136C) Radiological criteria for unrestricted use. A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

641—40.30(136C) Criteria for license termination under restricted conditions. A site will be considered acceptable for license termination under restricted conditions if:

40.30(1) The licensee can demonstrate that reductions in residual radioactivity necessary to comply with the provisions of 40.29(136C) would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as traffic accidents,

expected to potentially result from decontamination and waste disposal;

40.30(2) The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) per year;

40.30(3) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

a. Funds placed into an account segregated from the licensee's assets and outside the licensee's administrative control as described in 641—subparagraph 39.4(26)*"f"*(1);

b. Surety method, insurance or other guarantee method as described in 641—subparagraph 39.4(26)*"f"*(2);

c. A statement of intent in the case of federal, state, or local government licensees, as described in 641—subparagraph 39.4(26)*"f"*(4); or

d. When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

40.30(4) The licensee has submitted a decommissioning plan or license termination plan (LTP) to the agency indicating the licensee's intent to decommission in accordance with 641—paragraph 39.4(33)*"d"* and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community, who may be affected by the decommissioning, has been sought and incorporated, as appropriate, following analysis of that advice. Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

a. Whether provisions for institutional controls proposed by the licensee:

(1) Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) per year;

(2) Will be enforceable; and

(3) Will not impose undue burdens on the local community or other affected parties.

b. Whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site;

c. In seeking advice on the issues identified in 40.30(4) *"a,"* the licensee shall provide for:

(1) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(2) An opportunity for a comprehensive, collective discussion of the issues by the participants represented; and

(3) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

40.30(5) Residual radioactivity at the site has been reduced so that if the institutional controls were no

longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either:

a. 100 mrem (1 mSv) per year; or

b. 500 mrem (5 mSv) per year provided the licensee:

(1) Demonstrates that further reductions in residual radioactivity necessary to comply with the 100 mrem/yr (1 mSv/yr) value of 40.30(5) *"a"* are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(2) Makes provisions for durable institutional controls; and

(3) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every five years to ensure that the institutional controls remain in place as necessary to meet the criteria of 40.30(2) and to assume and carry out responsibilities for any necessary controls and maintenance of those controls. Acceptable financial assurance mechanisms are those in subrule 40.30(3).

641—40.31(136C) Alternate criteria for license termination.

40.31(1) The agency may terminate a license using alternate criteria greater than the dose criterion of 641—40.29(136C), 40.30(2) and 40.30(4)*"a"*(1) if the licensee:

a. Provides assurance that public health and safety would continue to be protected and that it is unlikely that the dose from all man–made sources combined, other than medical, would be more than the 100 mrem/yr (1 mSv/yr) by submitting an analysis of possible sources of exposure;

b. Has employed, to the extent practical, restrictions on site use according to the provisions of 641—40.30(136C) in minimizing exposures at the site;

c. Reduces doses to ALARA levels taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal; and

d. Has submitted a decommissioning plan or license termination plan (LTP) to the agency indicating the licensee's intent to decommission in accordance with 641—paragraph 39.4(33)*"d,"* and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTP how the advice of individuals and institutions in the community, who may be affected by the decommissioning, has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

(1) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(2) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(3) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

40.31(2) The use of alternate criteria to terminate a license requires the approval of the agency after consideration of the staff's recommendations that will address any comments provided by the Environmental Protection Agency and any public comments submitted pursuant to 40.32(136C).

TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

641—40.32(136C) Testing for leakage or contamination of sealed sources.

40.32(1) The licensee in possession of any sealed source shall ensure that:

a. Each sealed source, except as specified in 40.34(2), is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the licensee.

b. Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six months or at alternative intervals approved by the Agency, after evaluation of information specified by 641—subparagraphs 39.4(29) *"l"* (4) and 39.4(29) *"l"* (5) of these rules, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.

c. Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three months or at alternative intervals approved by the Agency, after evaluation of information specified by 641—subparagraphs 39.4(29) *"l"* (4) and 39.4(29) *"l"* (5) of these rules, an Agreement State, a Licensing State, or the Nuclear Regulatory Commission.

d. For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee or registrant shall ensure that the sealed source is tested for leakage or contamination before further use.

e. Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 0.005 μCi (185 Bq) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position.

f. The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 0.001 μCi (37 Bq) of radon–222 in a 24–hour period when the collection efficiency for radon–222 and its daughters has been determined with respect to collection method, volume and time.

g. Tests for contamination from radium daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 0.005 μCi (185 Bq) of a radium daughter which has a half–life greater than four days.

40.32(2) A licensee need not perform tests for leakage or contamination on the following sealed sources:

a. Sealed sources containing only radioactive material with a half–life of less than 30 days;

b. Sealed sources containing only radioactive material as a gas;

c. Sealed sources containing 100 μCi (3.7 MBq) or less of beta– or photon–emitting material or 10 μCi (370 kBq) or less of alpha–emitting material;

d. Sealed sources containing only hydrogen–3;

e. Seeds of iridium–192 encased in nylon ribbon; and

f. Sealed sources, except those used in teletherapy and brachytherapy and those containing radium, which are stored, not being used and identified as in storage. The licensee shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within six months before the date of

use or transfer.

40.32(3) Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.

40.32(4) Test results shall be kept in units of microcurie or becquerel and maintained for inspection by the Agency.

40.32(5) The following shall be considered evidence that a sealed source is leaking:

a. The presence of 0.005 μCi (185 Bq) or more of removable contamination on any test sample.

b. Leakage of 0.001 μCi (37 Bq) of radon–222 per 24 hours for brachytherapy sources manufactured to contain radium.

c. The presence of removable contamination resulting from the decay of 0.005 μCi (185 Bq) or more of radium.

40.32(6) The licensee shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this chapter.

40.32(7) Reports of test results for leaking or contaminated sealed sources shall be made pursuant to 40.102(136C).

641—40.33 to **40.35** Reserved.

SURVEYS AND MONITORING

641—40.36(136C) Surveys and monitoring—general.

40.36(1) Each licensee or registrant shall make, or cause to be made, surveys that:

a. Are necessary for the licensee or registrant to comply with this chapter; and

b. Are necessary under the circumstances to evaluate:

(1) Radiation levels; and

(2) Concentrations or quantities of radioactive material; and

(3) The potential radiological hazards that could be present.

40.36(2) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured except when a more frequent interval is specified in another applicable part of these rules or a license condition.

40.36(3) All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with 40.15(136C), with other applicable provisions of these rules, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

a. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

b. Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

40.36(4) The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

641—40.37(136C) Conditions requiring individual monitoring of external and internal occupational dose. Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this chapter. As a minimum:

40.37(1) Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

a. Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 40.15(1); and

b. Minors and declared pregnant women likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in 40.21(136C) or 40.22(136C); and

c. Individuals entering a high or very high radiation area.

d. Individuals working with medical fluoroscopic equipment.

40.37(2) Each licensee or registrant shall monitor, to determine compliance with 40.18(136C), the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

a. Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B; and

b. Minors and declared pregnant women likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.05 rem (0.5 mSv).

40.37(3) Location of individual monitoring devices. Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with 40.37(136C) wear individual monitoring devices as follows:

a. An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded portion of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar);

b. An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman shall be located at the waist under any protective apron being worn by the woman;

c. An individual monitoring device used for monitoring the eye dose equivalent, to demonstrate compliance with 40.15(136C) shall be located at the neck (collar), outside any protective apron being worn by the monitored individual; or at an unshielded location closer to the eye;

d. An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with 40.15(136C), shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

641—40.38 to 40.41 Reserved.

CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

641—40.42(136C) Control of access to high radiation areas.

40.42(1) The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

a. A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or

b. A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

c. Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

40.42(2) In place of the controls required by 40.42(1) for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

40.42(3) The licensee or registrant may apply to the Agency for approval of alternative methods for controlling access to high radiation areas.

40.42(4) The licensee or registrant shall establish the controls required by 40.42(1) and 40.42(3) in a way that does not prevent individuals from leaving a high radiation area.

40.42(5) The licensee is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the rules of the U.S. Department of Transportation provided that:

a. The packages do not remain in the area longer than three days; and

b. The dose rate at 1 meter from the external surface of any package does not exceed 0.01 rem (0.1 mSv) per hour.

40.42(6) The licensee is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in this chapter and to operate within the ALARA provisions of the licensee's radiation protection program.

40.42(7) The licensee or registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in 641—40.42(136C) if the registrant has met all the specific requirements for access and control specified in other applicable chapters such as 641—Chapter 45 for industrial radiography, 641—Chapter 41 for X–rays in the healing arts, and 641—Chapter 41 for particle accelerators.

641—40.43(136C) Control of access to very high radiation areas.

40.43(1) In addition to the requirements in 40.42(136C), the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rad (5 Gy) or more in 1 hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic X–ray systems are the only source of radiation, or to non–self–shielded irradiators.

40.43(2) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in 40.43(1) if the registrant has met all the specific requirements for access and control specified in other applicable chapters such as 641—Chapter 45 for industrial radiography, 641—Chapter 41 for X-rays in the healing arts, and 641—Chapter 41 for particle accelerators.

641—40.44(136C) Control of access to very high radiation areas—irradiators.

40.44(1) This rule applies to licensees with sources of radiation in non-self-shielded irradiators. This rule does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

40.44(2) Each area in which there may exist radiation levels in excess of 500 rad (5 Gy) in 1 hour at 1 meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

a. Each entrance or access point shall be equipped with entry control devices which:

(1) Function automatically to prevent any individual from inadvertently entering a very high radiation area; and

(2) Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour; and

(3) Prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of 0.1 rem (1 mSv) in 1 hour.

b. Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by 40.44(2)*"a"*:

(1) The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour; and

(2) Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

c. The licensee shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

(1) The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour; and

(2) Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

d. When the shield for stored sealed sources is a liquid, the licensee shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

e. Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of

40.44(2)*"c"* and 40.44(2)*"d."*

f. Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation.

g. Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

h. Each area shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour.

i. The entry control devices required in 40.44(2) *"a"* shall be tested for proper functioning. See 40.89(136C) for record–keeping requirements.

(1) Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and

(2) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

(3) The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

j. The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

k. Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and to automatically prevent loose radioactive material from being carried out of the area.

40.44(3) Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of 40.44(2) which will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of 40.44(2), such as those for the automatic control of radiation levels, may apply to the Agency for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in 40.44(2). At least one of the alternative measures shall include an entry–preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

40.44(4) The entry control devices required by 40.44(2) and 40.44(3) shall be established in such a way that no individual will be prevented from leaving the area.

641—40.45 to 40.47 Reserved.

RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS

641—40.48(136C) Use of process or other engineering controls. The licensee shall use, to the extent

practical, process or other engineering controls, such as containment or ventilation, to control the concentrati*ons of radioactive material in air.

641—40.49(136C) Use of other controls. When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

40.49(1) Control of access; or

40.49(2) Limitation of exposure times; or

40.49(3) Use of respiratory protection equipment; or

40.49(4) Other controls.

641—40.50(136C) Use of individual respiratory protection equipment.

40.50(1) If the licensee uses respiratory protection equipment to limit intakes pursuant to 40.49(136C):

a. Except as provided in 40.50(1), the licensee shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

b. If the licensee wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration has not had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

c. The licensee or registrant shall implement and maintain a respiratory protection program that includes:

(1) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures; and

(2) Surveys and bioassays, as appropriate, to evaluate actual intakes; and

(3) Testing of respirators for operability immediately prior to each use; and

(4) Written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and record keeping; and

(5) Determination by a physician prior to initial fitting of respirators, and either every 12 months thereafter, or periodically at a frequency determined by a physician, that the individual user is medically fit to use the respiratory protection equipment.

d. The licensee shall issue a written policy statement on respirator usage covering:

(1) The use of process or other engineering controls, instead of respirators; and

(2) The routine, nonroutine, and emergency use of respirators; and

(3) The length of periods of respirator use and relief from respirator use.

e. The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

f. The licensee or registrant shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.

40.50(2) When estimating exposure of individuals to airborne radioactive materials, the licensee may make allowance for respiratory protection equipment used to limit intakes pursuant to 40.49(136C), provided that the following conditions, in addition to those in 40.50(1), are satisfied:

a. The licensee selects respiratory protection equipment that provides a protection factor, specified in Appendix A, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B, Table I, Column 3. However, if the selection of respiratory protection equipment with a protection factor greater than the multiple defined in the preceding sentence is inconsistent with the goal specified in 40.49(136C) of keeping the total effective dose equivalent ALARA, the licensee or registrant may select respiratory protection equipment with a lower protection factor provided that such a selection would result in a total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.

b. The licensee shall obtain authorization from the Agency before assigning respiratory protection factors in excess of those specified in Appendix A. The Agency may authorize a licensee to use higher protection factors on receipt of an application that:

(1) Describes the situation for which a need exists for higher protection factors, and

(2) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

40.50(3) In an emergency, the licensee shall use as emergency equipment only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

40.50(4) The licensee shall notify the agency in writing at least 30 days before the date that respiratory protection equipment is first used pursuant to either 40.50(1) or 40.50(2). The agency may impose restrictions in addition to those listed in these rules in order to limit individual exposures.

641—40.51 to **40.54** Reserved.

STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION

641—40.55(136C) Security and control of licensed or registered sources of radiation.

a. The licensee or registrant shall secure licensed or registered radioactive material from unauthorized removal or access.

b. The licensee or registrant shall maintain constant surveillance and use devices or administrative procedures to prevent unauthorized use of licensed or registered radioactive material that is in an

unrestricted area and that is not in storage.

c. The registrant shall secure registered radiation machines from unauthorized removal.

d. The registrant shall use devices or administrative procedures to prevent unauthorized use of registered radiation machines.

641—40.56(136C) Control of sources of radiation not in storage. Rescinded IAB 4/8/98, effective 7/1/98.

641—40.57 to 40.59 Reserved.

PRECAUTIONARY PROCEDURES

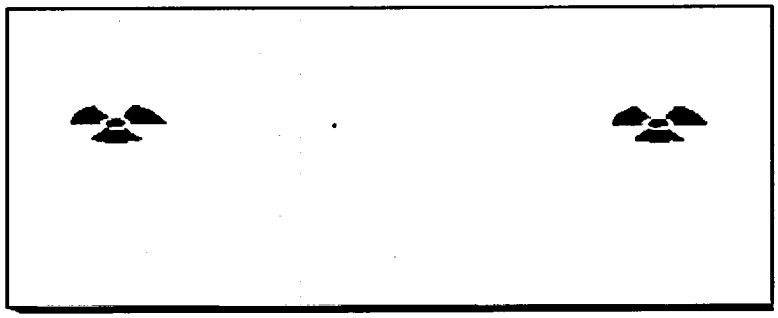
641—40.60(136C) Caution signs.

40.60(1) *Standard radiation symbol.* Unless otherwise authorized by the Agency, the symbol prescribed by this rule shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three–bladed design as follows:

RADIATION SYMBOL

1. Cross–hatched area is to be magenta, or purple, or black, and

2. The background is to be yellow.



40.60(2) *Exception to color requirements for standard radiation symbol.* Notwithstanding the requirements of 40.60(1), licensees are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

40.60(3) *Additional information on signs and labels.* In addition to the contents of signs and labels prescribed in this chapter, the licensee or registrant shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

641—40.61(136C) Posting requirements.

40.61(1) *Posting of radiation areas.* The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA".

40.61(2) *Posting of high radiation areas.* The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA".

40.61(3) *Posting of very high radiation areas.* The licensee or registrant shall post each very high

radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA".

40.61(4) *Posting of airborne radioactivity areas.* The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA".

40.61(5) *Posting of areas or rooms in which licensed or registered material is used or stored.* The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding ten times the quantity of such material specified in Appendix C with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)".

641—40.62(136C) Exceptions to posting requirements.

40.62(1) A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight hours, if each of the following conditions is met:

a. The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this chapter; and

b. The area or room is subject to the licensee's or registrant's control.

40.62(2) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to 40.61(136C) provided that the patient could be released from confinement pursuant to 641—41.29(136C).

40.62(3) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.005 rem (0.05 mSv) per hour.

40.62(4) A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

641—40.63(136C) Labeling containers and radiation machines.

40.63(1) The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL". The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

40.63(2) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

40.63(3) Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

641—40.64(136C) Exemptions to labeling requirements. A licensee is not required to label:

40.64(1) Containers holding licensed materials in quantities less than the quantities listed in Appendix C; or

40.64(2) Containers holding licensed material in concentrations less than those specified in Table III of Appendix B; or

40.64(3) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this chapter; or

40.64(4) Containers when they are in transport and packaged and labeled in accordance with the rules of the U.S. Department of Transportation;[2] or

[2] Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.421–424.

40.64(5) Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water–filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

40.64(6) Installed manufacturing or process equipment, such as piping and tanks.

641—40.65(136C) Procedures for receiving and opening packages.

40.65(1) Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in 641—subrule 39.5(2) and Appendix E of 641—Chapter 39, shall make arrangements to receive:

a. The package when the carrier offers it for delivery; or

b. The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

40.65(2) Each licensee shall:

a. Monitor the external surfaces of a labeled[3] package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in 641—Chapter 38;

b. Monitor the external surfaces of a labeled[3] package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 641—subrule 39.5(2) and Appendix E to 641—Chapter 39; and

c. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

40.65(3) The licensee shall perform the monitoring required by 40.65(2) as soon as practicable after receipt of the package, but not later than three hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.

40.65(4) The licensee shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the Agency when:

a. Removable radioactive surface contamination exceeds the limits of 641—paragraph 39.5(15)*"h"*; or

b. External radiation levels exceed the limits of 641—paragraph 39.5(15) *"i"* and 641—paragraph 39.5(15)*"j."*

40.65(5) Each licensee shall:

a. Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

b. Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

[3] Labeled with a Radioactive e White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 172.436–440.

40.65(6) Licensees transferring special form sources in vehicles owned or operated by the licensee or registrant to and from a work site are exempt from the contamination monitoring requirements of 40.65(2), but are not exempt from the monitoring requirement in 40.65(2), for measuring radiation levels that ensure that the source is still properly lodged in its shield.

641—40.66 to 40.69 Reserved.

WASTE DISPOSAL

641—40.70(136C) General requirements.

40.70(1) A licensee shall dispose of licensed material only:

a. By transfer to an authorized recipient as provided in 40.74(136C) or 641—39.4(136C), or to the U.S. Department of Energy; or

b. By decay in storage; or

c. By release in effluents within the limits in 40.72(1)*"d"*; or

d. As authorized pursuant to 40.71(136C), 40.72(136C), 40.73(136C), or 40.74(136C).

40.70(2) A person shall be specifically licensed to receive waste containing licensed material from other persons for:

a. Treatment prior to disposal; or

b. Treatment or disposal by incineration; or

c. Decay in storage; or

d. Storage until transferred to a storage or disposal facility authorized to receive the waste.

641—40.71(136C) Method for obtaining approval of proposed disposal procedures. A licensee or applicant for a license may apply to the Agency for approval of proposed procedures, not otherwise authorized in these rules, to dispose of licensed material generated in the licensee's operations. Each application shall include:

40.71(1) A description of the waste containing licensed material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal; and

40.71(2) An analysis and evaluation of pertinent information on the nature of the environment; and

40.71(3) The nature and location of other potentially affected facilities; and

40.71(4) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in this chapter.

641—40.72(136C) Disposal by release into sanitary sewerage.

40.72(1) A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

a. The material is readily soluble, or is readily dispersible biological material, in water; and

b. The quantity of licensed radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table III of Appendix B; and

c. If more than one radionuclide is released, the following conditions must also be satisfied:

(1) The licensee shall determine the fraction of the limit in Table III of Appendix B represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table III of Appendix B; and

(2) The sum of the fractions for each radionuclide required by 40.72(1)*"c"*(1) does not exceed unity; and

d. The total quantity of licensed radioactive material that the licensee releases into the sanitary sewerage in a year does not exceed 5 Ci (185 GBq) of hydrogen–3, 1 Ci (37 GBq) of carbon–14, and 1 Ci (37 GBq) of all other radioactive materials combined.

40.72(2) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in 40.72(1).

641—40.73(136C) Treatment or disposal by incineration. A licensee may treat or dispose of licensed materials by incineration only in the amounts and forms specified in 40.74(136C) or as specifically approved by the Agency pursuant to 40.71(136C).

641—40.74(136C) Disposal of specific wastes.

40.74(1) A licensee may dispose of the following licensed material as if it were not radioactive:

a. 0.05 μCi(1.85 kBq), or less, of hydrogen–3 or carbon–14 per gram of medium used for liquid scintillation counting; and

b. 0.05 μCi (1.85 kBq), or less, of hydrogen–3 or carbon–14 per gram of animal tissue, averaged over the weight of the entire animal.

40.74(2) A licensee shall not dispose of tissue pursuant to 40.74(1)*"b"* in a manner that would permit its use either as food for humans or as animal feed.

40.74(3) The licensee shall maintain records in accordance with 40.88(136C).

641—40.75(136C) Transfer for disposal and manifests.

40.75(1) The requirements of this subrule and Appendix D are designed to control transfers of low–level radioactive waste intended for disposal at a licensed low–level radioactive waste disposal facility,

establish a manifest tracking system, and supplement existing requirements concerning transfers and record keeping for those wastes.

40.75(2) Each shipment of radioactive waste designated for disposal at a licensed low–level radioactive waste disposal facility shall be accompanied by a shipment manifest as specified in Section I of Appendix D.

40.75(3) Each shipment manifest shall include a certification by the waste generator as specified in Section II of Appendix D.

40.75(4) Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix D.

641—40.76(136C) Compliance with environmental and health protection regulations. Nothing in 40.70(136C), 40.71(136C), 40.72(136C), 40.73(136C), 40.74(136C), or 40.75(136C) relieves the licensee or registrant from complying with other applicable federal, state and local regulations governing any other toxic or hazardous properties of materials that may be disposed of to 40.70(136C), 40.71(136C), 40.72(136C), 40.73(136C), 40.74(136C), or 40.75(136C).

641—40.77 to 40.79 Reserved.

RECORDS

641—40.80(136C) General provisions.

40.80(1) Each licensee or registrant shall use the special units curie, rad, rem and roentgen, counts per minute (cpm), disintegrations per minute (dpm), or the SI units becquerel, gray, sievert and coulomb per kilogram, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this chapter.

40.80(2) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this chapter, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, eye dose equivalent, deep dose equivalent, or committed effective dose equivalent.

641—40.81(136C) Records of radiation protection programs.

40.81(1) Each licensee or registrant shall maintain records of the radiation protection program, including:

a. The provisions of the program; and

b. Audits and other reviews of program content and implementation.

40.81(2) The licensee or registrant shall retain the records required by 40.81(1) *"a"* until the Agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by 40.81(1) *"b"* for three years after the record is made.

641—40.82(136C) Records of surveys.

40.82(1) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by 40.36(136C) and 40.65(2). The licensee or registrant shall retain these records for three years after the record is made.

40.82(2) The licensee or registrant shall retain each of the following records until the Agency terminates each pertinent license or registration requiring the record:

a. Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

b. Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

c. Records showing the results of air sampling, surveys, and bioassays required pursuant to 40.50(1)*"c"*(1) and 40.50(1)*"c"*(2); and

d. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

40.82(3) Upon termination of the license or registration, the licensee or registrant shall permanently store records on IDPH Form 588–2833 or 588–2834 or equivalent or shall make provisions with the Agency for transfer to the Agency.

641—40.83(136C) Records of tests for leakage or contamination of sealed sources. Records of tests for leakage or contamination of sealed sources required by 40.32(136C) shall be kept in units of microcurie or becquerel and maintained for inspection by the Agency for five years after the records are made.

641—40.84(136C) Records of prior occupational dose.

40.84(1) The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in 40.19(136C) on IDPH Form 588–2833 or equivalent until the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain rec–ords used in preparing IDPH Form 588–2833 or equivalent for three years after the record is made.

40.84(2) Upon termination of the license or registration, the licensee or registrant shall permanently store records on IDPH Form 588–2833 or equivalent or shall make provisions with the Agency for transfer to the Agency.

641—40.85(136C) Records of planned special exposures.

40.85(1) For each use of the provisions of 40.20(136C) for planned special exposures, the licensee or registrant shall maintain records that describe:

a. The exceptional circumstances requiring the use of a planned special exposure; and

b. The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

c. What actions were necessary; and

d. Why the actions were necessary; and

e. What precautions were taken to assure that doses were maintained ALARA; and

f. What individual and collective doses were expected to result; and

g. The doses actually received in the planned special exposure.

40.85(2) The licensee or registrant shall retain the records until the Agency terminates each pertinent license or registration requiring these records.

40.85(3) Upon termination of the license or registration, the licensee or registrant shall permanently store records on IDPH Form 588–2833 or equivalent or shall make provisions with the Agency for transfer to the Agency.

641—40.86(136C) Records of individual monitoring results.

40.86(1) *Record–keeping requirement.* Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to 40.37(136C), and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect on or before January 1, 1994, need not be changed. These records shall include, when applicable:

a. The deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and

b. The estimated intake of radionuclides, see 40.16(136C); and

c. The committed effective dose equivalent assigned to the intake of radionuclides; and

d. The specific information used to calculate the committed effective dose equivalent pursuant to 40.18(3); and

e. The total effective dose equivalent when required by 40.16(136C); and

f. The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

40.86(2) *Record–keeping frequency.* The licensee or registrant shall make entries of the records specified in 40.86(1) at intervals not to exceed one year.

40.86(3) *Record–keeping format.* The licensee or registrant shall maintain the records specified in 40.86(1) on IDPH Form 588–2834, 588–2833, or equivalent in accordance with the instructions for IDPH Form 588–2834, 588–2833, or equivalent or in clear and legible records containing all the information required by IDPH Form 588–2834, 588–2833, or equivalent.

40.86(4) *Embryo/Fetus records.* The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

40.86(5) *Retention during license or registration.* The licensee or registrant shall retain each required form or record until the Agency terminates each pertinent license or registration requiring the record.

40.86(6) *Retention after termination.* Upon termination of the license or registration, the licensee or registrant shall permanently store records on IDPH Form 588–2833, 588–2834, or equivalent or shall make provision with the Agency for transfer to the Agency.

641—40.87(136C) Records of dose to individual members of the public.

40.87(1) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See 40.26(136C).

40.87(2) The licensee or registrant shall retain the records required by this rule until the Agency

terminates each pertinent license or registration requiring the record.

641—40.88(136C) Records of waste disposal.

40.88(1) Each licensee shall maintain records of the disposal of licensed materials made pursuant to 40.71(136C), 40.72(136C), 40.73(136C), 40.74(136C), and disposal or burial in soil.

40.88(2) The licensee shall retain the records required by 40.88(1) until the Agency terminates each pertinent license or registration requiring the record.

641—40.89(136C) Records of testing entry control devices for very high radiation areas.

40.89(1) Each licensee or registrant shall maintain records of tests made pursuant to 40.44(2)*"j"* on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

40.89(2) The licensee or registrant shall retain the records required by 40.89(1) for three years after the record is made.

641—40.90(136C) Form of records.

40.90(1) Each record required by Chapter 40 shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

40.90(2) The licensee shall retain the records required by Chapter 40 until the agency terminates each pertinent license requiring the record.

641—40.91 to **40.94** Reserved.

REPORTS

641—40.95(136C) Reports of stolen, lost, or missing licensed or registered sources of radiation.

40.95(1) Telephone reports. Each licensee or registrant shall report to the Agency by telephone as follows:

a. Immediately after its occurrence becomes known to the licensee, stolen, lost, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C under such circumstances that it appears to the licensee that an exposure could result to individuals in unrestricted areas; or

b. Within 30 days after its occurrence becomes known to the licensee, lost, stolen, or missing licensed radioactive material in quantity greater than ten times the quantity specified in Appendix C that is still missing.

c. Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

d. All other licensees shall make reports by telephone to the bureau of radiological health.

40.95(2) Written reports. Each licensee or registrant required to make a report pursuant to 40.95(1) shall, within 30 days after making the telephone report, make a written report to the Agency setting forth the following information:

a. A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted; and

b. A description of the circumstances under which the loss or theft occurred; and

c. A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

d. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

e. Actions that have been taken, or will be taken, to recover the source of radiation; and

f. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

40.95(3) Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.

40.95(4) The licensee or registrant shall prepare any report filed with the Agency pursuant to 40.95(136C) so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

641—40.96(136C) Notification of incidents.

40.96(1) Immediate notification. Notwithstanding other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

a. An individual to receive:

(1) A total effective dose equivalent of 25 rem (0.25 Sv) or more; or

(2) An eye dose equivalent of 75 rem (0.75 Sv) or more; or

(3) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 250 rad (2.5 Gy) or more; or

b. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot–cells or process enclosures.

c. In addition to the requirements of paragraphs *"a"* and *"b"* above, each licensee shall notify the Iowa department of public health as soon as possible but not later than four hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, and other such events).

40.96(2) Twenty–four–hour notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Agency each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

a. An individual to receive, in a period of 24 hours:

(1) A total effective dose equivalent exceeding 5 rem (0.05 Sv) or

(2) An eye dose equivalent exceeding 15 rem (0.15 Sv) or

(3) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 50 rem (0.5 Sv); or

b. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot–cells or process enclosures.

c. In addition to the requirements of paragraphs *"a"* and *"b"* above, each licensee shall notify the Iowa department of public health within 24 hours after the discovery of any of the following events involving licensed material:

(1) An unplanned contamination event that:

1. Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area;

2. Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B for the material; and

3. Has access to the area restricted for a reason other than to allow isotopes with a half–life of less than 24 hours to decay prior to decontamination.

(2) An event in which equipment is disabled or fails to function as designed when:

1. The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

2. The equipment is required to be available and operable when it is disabled or fails to function; and

3. No redundant equipment is available and operable to perform the required safety function.

(3) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(4) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

1. The quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B for the material; and

2. The damage affects the integrity of the licensed material or its container.

40.96(3) The licensee or registrant shall prepare each report filed with the Agency pursuant to 40.96(136C) so that names of individuals who have received exposure to sources of radiation are stated

in a separate and detachable portion of the report.

40.96(4) Licensees or registrants shall make the reports required by 40.96(1) and 40.96(2) to the agency by telephone, telegram, mailgram, or facsimile.

a. Licensees or registrants making initial reports to the Iowa department of public health shall to the extent that the information is available at the time of notification include:

(1) The caller's name and call–back telephone number;

(2) A description of the event, including date and time;

(3) The exact location of the event;

(4) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(5) Any personnel radiation exposure data available.

b. Each licensee or registrant who makes a report required by 40.96(1) or 40.96(2) shall submit a written follow–up report within 30 days of the initial report. Written reports prepared pursuant to other rules may be submitted to fulfill this requirement if the reports contain all of the necessary information. These written reports must be sent to the Iowa Department of Public Health, Bureau of Radiological Health, Lucas State Office Building, Des Moines, Iowa 50319. The reports must include the following:

(1) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(2) The exact location of the event;

(3) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(4) Date and time of the event;

(5) Corrective actions taken or planned and the results of any evaluations or assessments; and

(6) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

40.96(5) The provisions of 641—40.96(136C) do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to 641—40.98(136C).

641—40.97(136C) Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.

40.97(1) Reportable events. In addition to the notification required by 40.96(136C), each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

a. Incidents for which notification is required by 40.96(136C); or

b. Doses in excess of any of the following:

(1) The occupational dose limits for adults in 40.15(136C); or

(2) The occupational dose limits for a minor in 40.21(136C); or

(3) The limits for an embryo/fetus of a declared pregnant woman in 40.22(136C); or

(4) The limits for an individual member of the public in 40.26(136C); or

(5) Any applicable limit in the license or registration; or

(6) The ALARA constraints for air emissions established under 641—40.10(136C); or

c. Levels of radiation or concentrations of radioactive material in:

(1) A restricted area in excess of applicable limits in the license or registration; or

(2) An unrestricted area in excess of ten times the applicable limit set forth in this chapter or in the license or registration, whether or not involving exposure of any individual in excess of the limits in 40.26(136C); or

d. For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

40.97(2) Contents of reports.

a. Each report required by 40.97(1) shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(1) Estimates of each individual's dose; and

(2) The levels of radiation and concentrations of radioactive material involved; and

(3) The cause of the elevated exposures, dose rates, or concentrations; and

(4) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions. Each report filed pursuant to this paragraph must include the name, social security number, and date of birth for each occupationally overexposed individual. The report must be prepared so that this information is stated in a separate and detachable part of the report.

b. Each report filed pursuant to 40.97(1) shall include for each individual exposed: the name, social security account number, and date of birth. With respect to the limit for the embryo/fetus in 40.22(136C), the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

40.97(3) All licensees or registrants who make reports pursuant to 40.97(1) shall submit the report in writing to the Agency.

641—40.98(136C) Reports of planned special exposures. The licensee or registrant shall submit a written report to the Agency within 30 days following any planned special exposure conducted in accordance with 40.20(136C) informing the Agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by 40.85(136C).

641—40.99 Reserved.

641—40.100(136C) Reports of individual monitoring.

40.100(1) This section applies to each person licensed or registered by the Agency to:

a. Possess or use sources of radiation for purposes of industrial radiography pursuant to 641—39.4(136C) and 641—Chapter 45; or

b. Receive radioactive waste from other persons for disposal pursuant to 10 CFR Part 61 of federal regulations or appropriate other Agreement State regulations; or

c. Possess or use at any time, for processing or manufacturing for distribution pursuant to 641—39.4(136C) or 641—41.2(136C), radioactive material in quantities exceeding any one of the following quantities:

Radionuclide		Activity[a]	
	Ci		GBq
Cesium–137	1		37
Cobalt–60	1		37
Gold–198	100		3,700
Iodine–131	1		37
Iridium–192	10		370
Krypton–85	1,000		37,000
Promethium–147	10		370
Technetium–99m	1,000		37,000

[a] The Agency may require as a license condition, or by rule, regulation, or order pursuant to 40.105(136C), reports from licensees or registrants who are licensed or registered to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

40.100(2) Each licensee or registrant in a category listed in 40.100(1) shall submit an annual report of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by 40.36(136C) during that year. The licensee or registrant may include additional data for individuals for whom monitoring was provided but not required. The licensee or registrant shall use IDPH Form 588–2834 or equivalent or electronic media containing all the information required by IDPH Form 588–2834.

40.100(3) The licensee or registrant shall file the report required by 40.100(2), covering the preceding year, on or before April 30 of each year. The licensee or registrant shall submit the report to the Agency.

641—40.101(136C) Notifications and reports to individuals.

40.101(1) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in 641—40.112(136C).

40.101(2) When a licensee or registrant is required pursuant to 40.97(136C), 40.98(136C), or 40.100(136C) to report to the agency any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee or registrant shall also provide a copy of the report submitted to this agency to the individual. Such notice shall be transmitted at a time not later than the transmittal to the agency, and shall comply with the provisions of 40.112(1).

641—40.102(136C) Reports of leaking or contaminated sealed sources. The licensee shall file a report within five days with the Agency if the test for leakage or contamination required pursuant to 40.32(136C) indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results and the corrective action taken.

641—40.103 and **40.104** Reserved.

ADDITIONAL REQUIREMENTS

641—40.105(136C) Vacating premises. Each specific licensee shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of their activities, notify the Agency in writing of intent to vacate. When deemed necessary by the Agency, the licensee shall decontaminate the premises in such a manner as the Agency may specify.

641—40.106 to 40.109 Reserved.

NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

641—40.110(136C) Posting of notices to workers.

40.110(1) Each licensee or registrant, except those registrants with diagnostic X–ray systems, shall post current copies of the following documents:

a. This subrule and 641—Chapter 40;

b. The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto;

c. The operating procedures applicable to activities under the license or registration; and

d. Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to 641—Chapter 38, and any response from the licensee or registrant.

40.110(2) If posting of a document specified in 40.110(1)*"a,"* 40.110(1)*"b"* and 40.110(1)*"c"* is not practical, the licensee or registrant may post a notice which describes the document and states where it may be examined.

40.110(3) Agency Form "Notice to Employees" shall be posted by each licensee or registrant.

40.110(4) Agency documents posted pursuant to 40.110(1)*"d"* shall be posted within five working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted within five working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

40.110(5) Documents, notices, or forms posted pursuant to 40.110(1) shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

641—40.111(136C) Instructions to workers.

40.111(1) All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv):

a. Shall be kept informed of the storage, transfer, or use of sources of radiation;

b. Shall be instructed in the health protection problems associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

c. Shall be instructed in, and required to observe, to the extent within the worker's control, the applicable

provisions of these rules and licenses for the protection of personnel from exposures to radiation or radioactive material occurring in such areas;

d. Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may constitute, lead to, or cause a violation of the Act, these rules, and licenses or unnecessary exposure to radiation or radioactive material;

e. Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

f. Shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to 641—40.113(136C).

g. The instruction in *"b"* through *"f"* above shall be conducted at least annually.

h. Shall be commensurate with potential radiological health protection problems present in the workplace.

40.111(2) In determining those individuals subject to the requirements of 40.111(1), consideration must be given to assigning activities during normal and abnormal situations involving exposure to sources of radiation which can reasonably be expected to occur during the life of the facility. The extent of these instructions must be commensurate with potential radiological health protection problems present in the workplace.

641—40.112(136C) Notifications and reports to individuals.

40.112(1) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this subrule. The information reported shall include data and results obtained pursuant to these rules, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to 40.86(136C). Each notification and report shall:

a. Be in writing;

b. Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, and the individual's identification number, preferably social security number;

c. Include the individual's exposure information; and

d. Contain the following statement:

"This report is furnished to you under the provisions of 40.112(136C) of Iowa's Radiation Machine and Radioactive Materials rules. You should preserve this report for further reference."

40.112(2) Each licensee or registrant shall advise each worker annually of the worker's dose as shown in records maintained by the licensee or registrant pursuant to 40.86(136C).

40.112(3) Each licensee or registrant shall furnish a report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to 40.37(136C). Such report shall be furnished within 30 days from the date of the request, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

40.112(4) When a licensee or registrant is required pursuant to 40.97(136C) to report to the Agency any

exposure of an individual to sources of radiation, the licensee or the registrant shall also provide the individual a report on the exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the Agency.

40.112(5) At the request of a worker who is terminating employment with the licensee or registrant in work involving exposure to radiation or radioactive material, during the current year, each licensee or registrant shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

641—40.113(136C) Presence of representatives of licensees or registrants and workers during inspection.

40.113(1) Each licensee or registrant shall afford to the Agency at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these rules.

40.113(2) During an inspection, Agency inspectors may consult privately with workers as specified in 40.114(136C). The licensee or registrant may accompany Agency inspectors during other phases of an inspection.

40.113(3) If, at the time of inspection, an individual has been authorized by the workers to represent them during Agency inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

40.113(4) Each worker's representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in 40.111(136C).

40.113(5) Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one worker's representative at a time may accompany the inspectors.
40.113(6) With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany Agency inspectors during the inspection of physical working conditions.

40.113(7) Notwithstanding the other provisions of 40.113(136C), Agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

641—40.114(136C) Consultation with workers during inspections.

40.114(1) Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of these rules and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

40.114(2) During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of the Act, these rules, or license condition, or

any unnecessary exposure of an individual to sources of radiation under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of 40.115(1).

40.114(3) The provisions of 40.114(2) shall not be interpreted as authorization to disregard instructions pursuant to 40.111(136C).

641—40.115(136C) Requests by workers for inspections.

40.115(1) Any worker or representative of workers believing that a violation of the Act, these rules, or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the Bureau of Radiological Health, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319–0075. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the Bureau of Radiological Health, no later than at the time of inspection except that, upon the request of the worker giving such notice, such worker's name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Agency, except for good cause shown.

40.115(2) If, upon receipt of such notice, the Bureau of Radiological Health determines that the complaint meets the requirements set forth in 40.116(1), and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to 40.116(136C) need not be limited to matters referred to in the complaint.

40.115(3) No licensee, registrant, or contractor or subcontractor of a licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these rules or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of such worker or others of any option afforded by this chapter.

641—40.116(136C) Inspections not warranted—informal review.

40.116(1) *a.* If the Bureau of Radiological Health determines, with respect to a complaint under this rule, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Bureau of Radiological Health shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the Attorney General's Office. Such Agency will provide the licen–see or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the Attorney General's Office. Such Agency will provide the complainant with a copy of such statement by certified mail.

b. Upon the request of the complainant, the Attorney General's Office may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Attorney General's Office shall affirm, modify, or reverse the determination of the Radiation Control Program and furnish the complainant and the licensee or registrant a written notification of the decision and the reason therefor.

40.116(2) If the Bureau of Radiological Health determines that an inspection is not warranted because the requirements of 40.116(1) have not been met, the complainant shall be notified in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of 40.116(1).

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Iowa Department of Public Health
Promoting and protecting the health of Iowans

Stephen C. Gleason, D. O., Director
Lucas State Office Building
Des Moines, IA 50319-0075
515-281-5787

Chapter 41
SAFETY REQUIREMENTS FOR THE USE OF
RADIATION MACHINES AND CERTAIN USES
OF RADIOACTIVE MATERIALS

641—41.1(136C) X–rays in the healing arts.

41.1(1) *Scope.* This rule establishes requirements, for which a registrant is responsible, for use of X–ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provisions of this rule are in addition to, and not in substitution for, any other applicable provisions of these rules. The provisions of Chapter 41 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 38 to 42. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of July 1, 1999.

41.1(2) *Definitions.* For the purpose of this chapter, the definitions of 641—Chapter 38 may also apply. The following are specific to rule 41.1(136C).

"Accessible surface" means the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer.

"Added filtration" means any filtration which is in addition to the inherent filtration.

"Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

"Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

"Automatic exposure control (AEC)" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (see also "Phototimer"). (Includes devices such as phototimers and ion chambers.)

"Barrier" (see "Protective barrier").

"Beam–limiting device" means a device which provides a means to restrict the dimensions of the X–ray field.

"Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

"C–arm X–ray system" means an X–ray system in which the image receptor and X–ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

"Cephalometric device" means a device intended for the radiographic visualization and measurement of

the dimensions of the human head.

"Certified components" means components of X–ray systems which are subject to regulations promulgated under Public Law 90–602, the "Radiation Control for Health and Safety Act of 1968," the Food and Drug Administration.

"Certified system" means any X–ray system which has one or more certified component(s).

"Coefficient of variation" or *"C"* means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} \qquad s = \left[\frac{1}{n-1}\sum_{i=1}^{n}(x_i - \bar{x})^2\right]^{1/2}$$

where:

$\underline{s}$ = Estimated standard deviation of the population.

$\bar{X}$ = Mean value of observations in sample.

X_i = i^{th} observation in sample.

N = Number of observations in sample.

"Computed tomography" means the production of a tomogram by the acquisition and computer processing of X–ray transmission data.

"Control panel" (see X–ray control panel).

"Cooling curve" means the graphical relationship between heat units stored and cooling time.

"CT" (see "Computed tomography").

"Dead–man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

"Detector" (see "Radiation detector").

"Diagnostic source assembly" means the tube housing assembly with a beam–limiting device attached.

"Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (see "Scattered radiation").

"Entrance exposure rate" means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

"Equipment" (see "X–ray equipment").

"Field emission equipment" means equipment which uses an X–ray tube in which electron emission from the cathode is due solely to the action of an electric field.

"Filter" means material placed in the useful beam to preferentially absorb selected radiations.

"Fluoroscopic imaging assembly" means a subsystem in which X–ray photons produce a visual image. It includes the image receptor(s) such as the image intensifier and spot–film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

"Focal spot (actual)" means the area projected on the anode of the X–ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

"General purpose radiographic X–ray system" means any radiographic X–ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

"Gonad shield" means a protective barrier for the testes or ovaries.

"Healing arts screening" means the testing of human beings using X–ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by an individual authorized under 41.1(3)"a"(7).

"Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp × mA × second.

"Image intensifier" means a device, installed in its housing, which instantaneously converts an X–ray pattern into a corresponding light image of higher energy intensity.

"Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident X–ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

"Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

"Kilovolts peak" (see "Peak tube potential").

"kV" means kilovolts.

"kVp" (see "Peak tube potential").

"kWs" means kilowatt second.

"Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

"Leakage radiation" means radiation emanating from the diagnostic or therapeutic source assembly except for:

a. The useful beam, and

b. Radiation produced when the exposure switch or timer is not activated.

"Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

a. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum–rated peak tube potential and the maximum–rated number of exposures in an hour for operation at the maximum–rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

b. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum–rated peak tube potential and the maximum–rated number of X–ray pulses in an hour for operation at the maximum–rated peak tube potential.

c. For all other diagnostic or therapeutic source assemblies, the maximum–rated peak tube potential and the maximum–rated continuous tube current for the maximum–rated peak tube potential.

"Light field" means that area of the intersection of the light beam from the beam–limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one–fourth of the maximum in the intersection.

"Linear attenuation coefficient" or "m" means the quotient of dN/N divided by dl when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traversing a distance dl in a specified material.

"Line–voltage regulation" means the difference between the no–load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

Percent line–voltage regulation = $100\ (V_n – V_l)/V_l$

where

V_n = No–load line potential and

V_l = Load line potential.

"mA" means milliampere.

"mAs" means milliampere second.

"Maximum line current" means the root–mean–square current in the supply line of an X–ray machine operating at its maximum rating.

"Mobile X–ray equipment" (see "X–ray equipment").

"PBL" (see "Positive beam limitation").

"Phototimer" means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation–monitoring device(s). The radiation–monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (see "Automatic exposure control").

"PID" (see "Position indicating device").

"Portable X–ray equipment" (see "X–ray equipment").

"Position indicating device" means a device on dental X–ray equipment used to indicate the beam position and to establish a definite source–surface (skin) distance. It may or may not incorporate or serve as a beam–limiting device.

"Positive beam limitation" means the automatic or semiautomatic adjustment of an X–ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

"Primary protective barrier" (see "Protective barrier").

"Protective apron" means an apron made of radiation–absorbing materials used to reduce radiation exposure.

"Protective barrier" means a barrier of radiation–absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

a. "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.

b. "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

"Protective glove" means a glove made of radiation–absorbing materials used to reduce radiation exposure.

"Radiation detector" means a device which, in the presence of radiation, provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

"Radiation therapy simulation system" means a radiographic or fluoroscopic X–ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

"Radiograph" means an image receptor on which the image is created directly or indirectly by an X–ray pattern and results in a permanent record.

"Rating" means the operating limits as specified by the component manufacturer.

"Recording" means producing a permanent form of an image resulting from X–ray photons.

"Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation–sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

"Secondary protective barrier" (see "Protective barrier").

"Shutter" means a device attached to the tube housing assembly which can intercept the entire cross–sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

"SID" (see "Source–image receptor distance").

"Source" means the focal spot of the X–ray tube.

"Source–image receptor distance" means the distance from the source to the center of the input surface of the image receptor.

"Spot check" means a procedure which is performed to ensure that a previous calibration continues to be valid.

"Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

"Spot–film device" means a device intended to transport or position a radiographic image receptor between the X–ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

"SSD" means the distance between the source and the skin entrance plane of the patient.

"Stationary X–ray equipment" (see "X–ray equipment").

"Stray radiation" means the sum of leakage and scattered radiation.

"Technique factors" means the following conditions of operation:

a. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

b. For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of X–ray pulses;

c. For CT X–ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, X–ray pulse width in seconds, and the number of X–ray pulses per scan, or the product of tube current, X–ray pulse width, and the number of X–ray pulses in mAs;

d. For CT X–ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

e. For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

"Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

"Tomogram" means the depiction of the X–ray attenuation properties of a section through the body.

"Tube housing assembly" means the tube housing with tube installed. It includes high–voltage, or filament transformers, or both, and other appropriate elements when such are contained within the tube housing.

"Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

"Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam–limiting device when the exposure controls are in a mode to cause the system to produce radiation.

"Variable–aperture beam–limiting device" means a beam–limiting device which has capacity for stepless adjustment of the X–ray field size at a given SID.

"Visible area" means that portion of the input surface of the image receptor over which incident X–ray photons are producing a visible image.

"X–ray control" means a device, switch, button or similar means by which an operator initiates or terminates the radiation exposure. The X–ray exposure control may include such associated equipment as timers and backup timers.

"X–ray control panel" means a device which controls input power to the X–ray high–voltage generator and the X–ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an X–ray exposure.

"X–ray equipment" means an X–ray system, subsystem, or component thereof. Types of X–ray equipment are as follows:

a. "Mobile X–ray equipment" means X–ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

b. "Portable X–ray equipment" means X–ray equipment designed to be hand–carried.

c. "Stationary X–ray equipment" means X–ray equipment which is installed in a fixed location.

"X–ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one–fourth of the maximum in the intersection.

"X–ray high–voltage generator" means a device which transforms electrical energy from the potential supplied by the X–ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the X–ray tube(s), high–voltage switches, electrical protective devices, and other appropriate elements.

"X–ray system" means an assemblage of components for the controlled production of X–rays. It includes minimally an X–ray high–voltage generator, an X–ray control, a tube housing assembly, a beam–limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

"X–ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky); cassette tunnel, image intensifier, or spot–film device beneath the tabletop.

41.1(3) *Administrative controls.*

a. Registrant. The registrant shall be responsible for maintaining and directing the operation of the X–ray system(s) under the registrant's administrative control and for having the following minimum tests performed every two years by a registered service facility:

1. Medical/chiropractic: timer accuracy, exposure reproducibility, kVp accuracy as set forth in 41.1(6), and light field/X–ray field alignment as set forth in 41.1(6).

2. Dental/podiatry: timer accuracy, exposure reproducibility and kVp accuracy as set forth in 41.1(7).

3. Fluoroscopic: entrance exposure rate (641—41.1(5) *"c"*), minimum SSD (641—41.1(5) *"f"*).

4. Veterinary systems are exempt from the above testing requirements.

All service and installation shall be performed by persons registered under 641—subrule 39.3(3). The registrant or the registrant's agent shall ensure that the requirements of these rules are met in the operation of the X–ray system(s).

(1) An X–ray system which does not meet the provisions of these rules shall not be operated for diagnostic or therapeutic purposes unless so directed by the agency.

(2) Individuals who will be operating the X–ray systems shall be adequately instructed in safe operating

procedures and be competent in the safe use of the equipment in accordance with 641—Chapter 42 as applicable. The individual's permit to practice shall be posted in the immediate vicinity of the general work area and visible to the public.

(3) A chart shall be provided in the vicinity of the diagnostic X–ray system's control panel which specifies, for all examinations performed with that system, the following information:

1. Patient's anatomical size versus technique factors to be utilized;

2. Type and size of the film or film–screen combination to be used;

3. Type and focal distance of the grid to be used, if any;

4. Source to image receptor distance to be used, except for dental intra–oral radiography; and

5. Type and location of placement of human patient shielding to be used (e.g., gonad).

(4) Written safety procedures shall be provided to each individual operating X–ray equipment, including patient holding and any restrictions of the operating technique required for the safe operation of the particular X–ray system. The operator shall be able to demonstrate familiarity with these procedures.

(5) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

1. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.

2. Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

3. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

(6) Gonad shielding of not less than 0.25 millimeter lead equivalent shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(7) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts or a licensed registered nurse who is registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152. This provision specifically prohibits deliberate exposure for the following purposes:

1. Exposure of an individual for training, demonstration, or other nonhealing arts purposes; and

2. Exposure of an individual for the purpose of healing arts screening except as authorized by 41.1(3)*"a"*(11).

(8) When a patient or film must be provided with auxiliary support during a radiation exposure:

1. Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by 41.1(3)*"a"*(4), shall list individual projections where holding devices cannot be utilized;

2. Written safety procedures, as required by 41.1(3)*"a"*(4), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

3. The human holder shall be protected as required by 41.1(3)*"a"*(5)"2";

4. No individual shall be used routinely to hold film or patients; and

5. In those cases where the human patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.

6. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with X–ray operations and who are otherwise not shielded.

(9) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

1. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intra–oral use in dental radiography.

2. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

3. Portable or mobile X–ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary X–ray installation.

4. X–ray systems subject to 41.1(6) shall not be utilized in procedures where the source to human patient distance is less than 30 centimeters.

5. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

• Be positioned properly, i.e., tube side facing the correct direction, and the grid centered to the central ray;

• If of the focused type, be at the proper focal distance for the SIDs being used.

(10) All individuals who are associated with the operation of an X–ray system are subject to the requirements of 641—subrule 40.36(3) and rules 641—40.15(136C) and 641—40.37(136C). In addition:

1. When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is present, it (they) shall be worn in accordance with the recommendations found in Chapter 4 of the National Council of Radiation Protection and Measurements Report No. 57.

2. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

(11) Healing arts screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the agency. When requesting such approval, that person shall submit the information outlined in Appendix C of this chapter. If any information submitted to the agency becomes invalid or outdated, the agency shall be immediately notified.

(12) Fluoroscopic equipment shall be used only under the direct supervision of a licensed practitioner.

b. Information and maintenance record and associated information. The registrant shall maintain the following information for each X–ray system for inspection by the agency:

(1) Model and serial numbers of all major components and user's manual for those components;

(2) Tube rating charts and cooling curves;

(3) Records of surveys, calibrations, maintenance, and modifications performed on the X–ray system(s) with the names of persons who performed such services;

(4) A copy of all correspondence with this agency regarding that X–ray system.

c. X–ray utilization log. Except for veterinary facilities, each facility shall maintain an X–ray log containing the patient's name, the type of examinations, the dates the examinations were performed, the name of the individual performing the X–ray procedure, and the number of exposures and retakes involved. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

d. Plan review.

(1) Prior to construction of all new installations, or modifications of existing installations, or installation of equipment into existing facilities utilizing X–rays for diagnostic or therapeutic purposes, the floor plans and equipment arrangements shall be submitted to the agency for review and approval. The required information is denoted in Appendices A and B of this chapter.

(2) The agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

(3) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 641—Chapter 40.

e. Federal performance standards. All X–ray equipment shall comply with the applicable performance standards of 21 CFR 1020.30 to 1020.40 which were in effect at the time the unit was manufactured. All equipment manufactured before the effective date of 21 CFR 1020.30 to 1020.40 shall meet the requirements of the Iowa rules. Persons registered to possess the affected radiation–emitting equipment in Iowa shall be responsible for maintaining the equipment in compliance with the appropriate federal performance standards.

f. X–ray film processing facilities and practices (except for mammography). Each installation using a radiographic X–ray system and using analog image receptors (e.g., radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

(1) Manually developed film.

1. Processing tanks shall be constructed of mechanically rigid, corrosion–resistant material; and

2. The temperature of solutions in the tanks shall be maintained within the range of 60°F to 80°F (16°C to 27°C). Film shall be developed in accordance with the time–temperature relationships recommended by the film manufacturer or, in the absence of such recommendations, with the time–temperature chart available from the agency.

3. Devices shall be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

(2) Automatic processors and other closed processing systems.

1. Films shall be developed in accordance with the time–temperature relationships recommended by the

film manufacturer; in the absence of such recommendations, the film shall be developed using the chart available from the agency.

2. Processing deviations from the requirements of 41.1(3)*"f"* shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing and special rapid chemistry).

(3) Other requirements.

1. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

2. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to X–radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.1 when exposed out of the cassette in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

3. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

4. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

5. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best ensure radiographs of good diagnostic quality.

6. Outdated X–ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

7. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

41.1(4) *General requirements for all diagnostic X–ray systems.* In addition to other requirements of this chapter, all diagnostic X–ray systems shall meet the following requirements:

a. Warning label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X–ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

b. Battery charge indicator. On battery–powered X–ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

c. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens (25.8 μC/kg) in one hour when the X–ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

d. Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens (0.516 μC/kg) in one hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled X–ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

e. Beam quality.

(1) Half–value layer.

1. The half–value layer of the useful beam for a given X–ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half–value layer at an X–ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

Table I

Design operating range (kVp)	Measured potential (kVp)		Half–value layer (mm of aluminum)
Below 50 30			0.3
	40		0.4
	49		0.5
50 to 70 50			1.2
	60		1.3
	70		1.5
Above 70 71			2.1
	80		2.3
	90		2.5
	100		2.7
	110		3.0
	120		3.2
	130		3.5
	140		3.8
	150		4.1

2. and 3. Rescinded IAB 4/8/98, effective 7/1/98.

4. For capacitor energy storage equipment, compliance with the requirements of 41.1(4) *"e"* shall be determined with the system fully charged and a setting of 10 mAs for each exposure.

5. The required minimal half–value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.

(2) Filtration controls. For X–ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by 41:1(4) *"e"*(1)"1" is in the useful beam for the given kVp

which has been selected.

f. Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X–ray control panel and at or near the tube housing assembly which has been selected.

g. Mechanical support of tube head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the X–ray system.

h. Technique indicators.

(1) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

(2) The requirement of 41.1(4)*"h"*(1) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(3) The technique indicators shall be accurate to within manufacturer's standards.

i. Locks. All position locking, holding, and centering devices on X–ray system components and systems shall function as intended.

41.1(5) *Fluoroscopic X–ray systems except for computed tomography X–ray systems.* All fluoroscopic X–ray systems shall be image intensified and meet the following requirements:

a. Limitation of useful beam.

(1) Primary barrier.

1. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

2. The X–ray tube used for fluoroscopy shall not produce X–rays unless the barrier is in position to intercept the entire useful beam.

(2) Fluoroscopic beam limitation.

1. For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the X–ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

2. For uncertified fluoroscopic systems with a spot film device, the X–ray beam with the shutter fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters from the tabletop to the film plane distance.

3. For uncertified fluoroscopic systems without a spot film device, the requirements of 41.1(5)*"a"*(2)"1" apply.

4. Other requirements for fluoroscopic beam limitation:

• Means shall be provided to permit further limitation of the field. Beam–limiting devices manufactured

after May 22, 1979, and incorporated in equipment with a variable SID or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the X–ray field;

• All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided either with stepless adjustment of the X–ray field or with means to further limit the X–ray field size at the plane of the image receptor to 125 square centimeters or less;

• If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of 5 centimeters by 5 centimeters or less;

• For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X–ray beam is perpendicular to the plane of the image receptor;

• For noncircular X–ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the X–ray field which pass through the center of the visible area of the image receptor.

(3) Spot–film beam limitation. Spot–film devices shall meet the following requirements:

1. Means shall be provided between the source and the patient for adjustment of the X–ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot–film selector. Such adjustment shall be automatically accomplished except when the X–ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot–film devices manufactured after June 21, 1979, if the X–ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

2. Neither the length nor the width of the X–ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4 percent of the SID;

3. It shall be possible to adjust the X–ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters;

4. The center of the X–ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID; and

5. On spot–film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X–ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(4) Override. If a means exists to override any of the automatic X–ray field size adjustments required in 41.1(5)*"a"*(2) and 41.1(5)*"a"*(3), that means:

1. Shall be designed for use only in the event of system failure;

2. Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and

3. Shall have a clear and durable label as follows:

FOR X–RAY FIELD
LIMITATION SYSTEM FAILURE

b. Activation of the fluoroscopic tube. X–ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X–ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

c. Exposure rate limits.

(1) Entrance exposure rate allowable limits.

1. Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, except:

• During recording of fluoroscopic images; or

• When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

2. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient, except:

• During recording of fluoroscopic images; or

• When an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

3. Compliance with the requirements of 41.1(5)*"c"* shall be determined as follows: movable grids and compression devices shall be removed from the useful beam during the measurement;

• If the source is below the table, exposure rate shall be measured 1 centimeter above the tabletop or cradle;

• If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam–limiting device or spacer positioned as closely as possible to the point of measurement;

• All C–arm fluoroscopes, both stationary and mobile, shall meet the entrance exposure rate limits at 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any available SID provided that the end of the spacer assembly or beam–limiting device is not closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.

• For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the X–ray table and in the direction of the X–ray source with the end of the beam–limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral X–ray source, with the end of the beam–limiting device or spacer no closer than 15 centimeters to the centerline of the X–ray table.

4. Periodic measurement of entrance exposure rate shall be performed by a qualified expert for both typical and maximum values as follows: Such measurements shall be made annually or after any maintenance of the system which might affect the entrance exposure rate; results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in 41.1(3)*"b"*(3). The measurement results shall be stated in roentgens per minute (coulombs per kilogram) and include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed shall be included in the results. Conditions of periodic measurements of entrance exposure rate are as follows:

• The measurement shall be made under the conditions that satisfy the requirements of 41.1(5)*"c"*(1)"2";

• The kVp mA, and other selectable parameters shall be adjusted to those settings typical of clinical use on a 23 cm thick abdominal patient;

• The X–ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum entrance exposure rate of the system.

(2) Reserved.

d. Barrier transmitted radiation rate limits.

(1) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens (0.516 μC/kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(2) Measuring compliance of barrier transmission.

1. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

2. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

3. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam–limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

4. Movable grids and compression devices shall be removed from the useful beam during the measurement.

e. Indication of potential and current. During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated.

f. Source–to–skin distance. The SSD shall not be less than:

(1) 38 centimeters on stationary fluoroscopes installed on or after August 1, 1974,

(2) 35.5 centimeters on stationary fluoroscopes which were in operation prior to August 1, 1974,

(3) 30 centimeters on all mobile fluoroscopes, and

(4) 20 centimeters for image–intensified fluoroscopes used for specific surgical application.

(5) The written safety procedures must provide precautionary measures to be adhered to during the use of this device in addition to the procedures provided in 41.1(3)*"a"*(4).

g. Fluoroscopic timer.

(1) Means shall be provided to preset the cumulative on–time of the fluoroscopic X–ray tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

(2) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on–time. Such signal shall continue to sound while X–rays are produced until the timing device is reset.

h. Control of scattered radiation.

(1) Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

(2) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

1. Is at least 120 centimeters from the center of the useful beam, or

2. The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky–slot cover panel, or self–supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 41.1(3)*"a"*(5).

(3) The agency may grant exemptions to 41.1(5)*"h"*(2) where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the agency shall not permit such exemption.

i. Spot–film exposure reproducibility. Fluoroscopic systems equipped with spot–film (radiographic) mode shall meet the exposure reproducibility requirements of 41.1(6) *"d"* when operating in the spot–film mode.

j. Radiation therapy simulation systems. Radiation therapy simulation systems shall be exempt from all the requirements of 41.1(5)*"a," "c," "d,"* and *"g"* provided that:

(1) Such systems are designed and used in such a manner that no individual other than the patient is in the X–ray room during periods of time when the system is producing X–rays; and

(2) Systems which do not meet the requirements of 41.1(5)*"g"* are provided with a means of indicating the cumulative time that an individual patient has been exposed to X–rays. Procedures shall require in such cases that the timer be reset between examinations.

41.1(6) *Radiographic systems other than fluoroscopic, dental intraoral, or computed tomography X–ray systems.*

a. Beam limitation. The useful beam shall be limited to the area of clinical interest. This shall be considered met if a positive beam–limiting device meeting manufacturer's specifications and the requirements of 41.1(6)*"h"*(2) have been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge.)

(1) General purpose stationary and mobile X–ray systems and veterinarian systems (other than portable)

installed after July 1, 1998.

1. Only X–ray systems provided with means for independent stepless adjustment of at least two dimensions of the X–ray field shall be used.

2. A method shall be provided for visually defining the perimeter of the X–ray field.

• Illuminance shall be greater than 7.5 foot–candles or 80.3 LUX at 100 centimeters or maximum SID whichever is less.

• The total misalignment of the edges of the visually defined field with the respective edges of the X–ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X–ray beam.

3. The agency may grant an exemption on noncertified X–ray systems to 41.1(6)*"a"*(1)"1" and "2" provided the registrant makes a written application for such exemption and in that application demonstrates it is impractical to comply with 41.1(6) *"a"* (1)"1" and "2"; and the purpose of 41.1(6)*"a"*(1)"1" and "2" will be met by other methods.

(2) Additional requirements for stationary general purpose X–ray systems. In addition to the requirements of 41.1(6)*"a"*(1), stationary general purpose X–ray systems, both certified and noncertified, shall meet the following requirements:

1. A method shall be provided to indicate when the axis of the X–ray beam is perpendicular to the plane of the image receptor, to align the center of the X–ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

2. The beam–limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

3. Indication of field size dimensions and SIDs shall be specified in inches or centimeters, and shall be such that aperture adjustments result in X–ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam–limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(3) X–ray systems designed for one image receptor size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the X–ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the X–ray field such that the X–ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(4) Systems designed for or provided with special attachments for mammography. Rescinded IAB 4/8/98, effective 7/1/98.

(5) X–ray systems other than those described in 41.1(6)*"a"*(1), (2), and (3), and veterinary systems installed prior to July 1, 1998.

1. Means shall be provided to limit the X–ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the X–ray beam is perpendicular to the plane of the image receptor.

2. Means shall be provided to align the center of the X–ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the X–ray field such that the X–ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the X–ray beam perpendicular to the plane of

the image receptor.

3. 41.1(6)*"a"*(5)"1" and "2" may be met with a system that meets the requirements for a general purpose X–ray system as specified in 41.1(6)*"a"*(1) or, when alignment means are also provided, may be met with either:

• An assortment of removable, fixed–aperture, beam–limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

• A beam–limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

b. Radiation exposure control devices.

(1) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(2) X–ray control.

1. Manual exposure control. An X–ray control shall be incorporated into each X–ray system such that an exposure can be terminated by the operator at any time except for exposure of one–half second or less, or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

2. Each X–ray control shall be located in such a way as to meet the following requirements: Stationary X–ray systems (except podiatry and veterinary units) shall be required to have the X–ray exposure switch permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and mobile and portable X–ray systems which are:

• Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 41.1(6)*"b"*(2)"2"; or

• Used for greater than one hour and less than one week at the same location, i.e., a room or suite, or in a clinical setting for routine extremities only, or where moving the X–ray system from room to room is impractical, shall meet the requirement of the above paragraph or be provided with a 6.5 foot(1.98 m) high protective barrier which is placed at least 2.7 meters (9 feet) from the tube housing assembly.

Stationary podiatric systems which do not meet the above requirements shall be provided with a 9–foot exposure button cord which allows the operator to remain behind a protective barrier during the entire exposure. If the protective barrier is moveable, written procedures must be on file at the facility, which dictate that the operator will remain behind the barrier during the entire exposure.

3. The X–ray control shall provide visual indication observable at or from the operator's protected position whenever X–rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(3) Automatic exposure controls. When an automatic exposure control is provided:

1. Indication shall be made on the control panel when this mode of operation is selected;

2. If the X–ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses;

3. The minimum exposure time for all equipment other than that specified in 41.1(6)*"b"*(3)"2" shall be equal to or less than one–sixtieth second or a time interval required to deliver 5 mAs, whichever is greater;

4. Either the product of peak X–ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of X–ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the X–ray tube potential is less than 50 kVp, the product of X–ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

5. A visible signal shall indicate when an exposure has been terminated at the limits required by 41.1(6)*"b"*(3)"4," and manual resetting shall be required before further automatically timed exposures can be made.

(4) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to five times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when four timer tests are performed:

$$T \geq 5 (T_{max} - T_{min})$$

(5) Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of C $kg^{-1}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average C $kg^{-1}s^{-1}$ (mR/s) values.

c. Source–to–skin distance. All mobile or portable radiographic systems shall be provided with means to limit the source–to–skin distance to equal to or greater than 30 centimeters except for veterinary systems.

d. Exposure reproducibility. The coefficient of variation of exposure shall not exceed 0.05 when all technique factors are held constant. This requirement applies to clinically used techniques. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to five times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}):

$$E \geq 5 (E_{max} - E_{min})$$

e. Radiation from capacitor energy storage equipment in standby status. Radiation emitted from the X–ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens (0.516 μC/kg) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam–limiting device fully open.

f. Accuracy. Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.

g. mA/mAs linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X–ray tube potential within the range of 40 percent to 100 percent of the maximum rated:

(1) Equipment having independent selection of X–ray tube current (mA). The average ratios (X_i) of exposure to the indicated milliampere–seconds product ($C\,kg^{-1}\,mAs^{-1}$ (or mR/mAs)) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \_ 0.10\,(X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

(2) Equipment having a combined X–ray tube current–exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_i) of exposure to the indicatedmilliampere–seconds product, in units of $C\,kg^{-1}\,mAs^{-1}$ (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 \_ 0.10\,(X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) Measuring compliance. Determination of compliance shall be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X–ray tube manufacturer.

h. Additional requirements applicable to certified systems only. Diagnostic X–ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

(1) Beam limitation for stationary and mobile general purpose X–ray systems.

1. There shall be provided a means of stepless adjustment of the X–ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

2. When a light localizer is used to define the X–ray field, it shall provide an average illumination of not less than 160 lux or 15 foot–candles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

3. The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam–limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam–limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of 1 millimeter in diameter.

(2) Beam limitation and alignment on stationary general purpose X–ray systems equipped with PBL. If PBL is being used, the following requirements shall be met:

1. PBL shall prevent the production of X–rays when:

• Either the length or width of the X–ray field in the plane of the image receptor differs, except as permitted by 41.1(6)*"h"*(3), from the corresponding image receptor dimensions by more than 3 percent of the SID; or

• The sum of the length and width differences as stated in 41.1(6)*"h"*(2)"1" above without regard to sign exceeds 4 percent of the SID;

2. Compliance with 41.1(6)*"h"*(2)"1" shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor;

3. The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters;

4. The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in 41.1(6)*"h"*(2)"1," then any change of image receptor size or SID must cause the automatic return.

(3) Beam limitation for portable X–ray systems. Beam limitation for portable X–ray systems shall meet the beam limitation requirements of 41.1(6)*"a"* or 41.1(6)*"h"*(2).

i. Tube stands for portable X–ray systems. A tube stand or other mechanical support shall be used for portable X–ray systems, so that the X–ray tube housing assembly need not be handheld during exposures.

41.1(7) *Intraoral dental radiographic systems.* In addition to the provisions of 41.1(3) and 41.1(4), the requirements of 41.1(7) apply to X–ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in 41.1(6). Only systems meeting the requirements of 41.1(7) shall be used.

a. Source–to–skin distance. X–ray systems designed for use with an intraoral image receptor shall be provided with means to limit source–to–skin distance to not less than:

(1) 18 centimeters if operable above 50 kVp, or

(2) 10 centimeters if not operable above 50 kVp.

b. Beam limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X–ray beam such that:

(1) If the minimum source–to–skin distance (SSD) is 18 centimeters or more, the X–ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 7 centimeters; and

(2) If the minimum SSD is less than 18 centimeters, the X–ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 6 centimeters.

(3) The position indicating device shall be shielded and open–ended. The shielding shall be equivalent to the requirements of 41.1(4)*"c."*

c. Exposure control.

(1) Exposure initiation.

1. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and

2. It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(2) Exposure indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever X–rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(3) Exposure termination.

1. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

2. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

3. An X–ray control shall be incorporated into each X–ray system such that an exposure can be terminated by the operator at any time, except for exposures of one–half (½) second or less.

(4) Exposure duration (timer) linearity. For systems having independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of C $kg^{-2}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \_ 0.1\ (X_1 + X_2)$$

where X_1 and X_2 are the average values.

(5) Each X–ray exposure switch shall be located in such a way as to meet the following requirements:

1. Stationary X–ray systems shall be required to have the X–ray exposure switch so that the operator is required to remain in the protected area during the entire exposure; and

2. Mobile and portable X–ray systems which are:

• Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 41.1(7)*"c"*(5)"1."

• Used for greater than one hour and less than one week at the same location, i.e., a room or suite, shall meet the requirements of the above paragraph or be provided with a 6.5 foot (1.98 m) high protective barrier or means to allow the operator to be at least 9 feet (2.7 meters) from the tube housing assembly while making exposure.

d. Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

e. mA/mS linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed X–ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

(1) Equipment having independent selection of X–ray tube current (mA). The average ratios (X_1) of exposure to the indicated milliampere–seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$(X_1 - X_2) \_ 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

(2) Equipment having a combined X–ray tube current–exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_1) of exposure to the indicated milliampere–seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$(X_1 - X_2) \_ 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) Measuring compliance. Determination of compliance shall be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the X–ray tube manufacturer.

f. Accuracy. Deviation of technique factors from indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.

g. kVp limitations. Dental X–ray machine with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

h. Administrative controls.

(1) Patient and film holding devices shall be used when the techniques permit.

(2) The tube housing and the PID shall not be hand–held during an exposure.

(3) The X–ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of 41.1(7)*"b"*(1).

(4) Dental fluoroscopy without image intensification shall not be used.

41.1(8) Rescinded IAB 6/4/97, effective 7/9/97.

41.1(9) *Bone densitometry units.*

a. No additional shielding for the room is required.

b. Film badges must be issued for the first six months to all personnel operating the unit. If monitoring indicates no exposure, the IDPH may allow discontinuance of monitoring upon written request. When new procedures are started that have not been previously monitored, monitoring must be reinstated for six months.

c. Operators, other than physicians, must possess a health education background to include anatomy and physiology and must complete the manufacturer's training session pertaining to bone densitometry or equivalent. A permit to practice for operators is not required.

d. Specific operating procedures must be prepared and made available at the operator's position.

41.1(10) *Veterinary medicine radiographic installations.*

a. Equipment.

(1) The protective tube housing shall be equivalent to the requirements of 41.1(4) *"c."*

(2) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

(3) The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

b. Operator protection.

(1) All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to ensure compliance with 641—40.15(136C) and 40.21(136C) and subrule 40.26(1).

(2) All stationary, mobile or portable X–ray systems shall be provided with either a 2 meter (6.5 feet) high protective barrier for operator protections during exposures, or shall be provided with means to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during exposures.

c. Operating procedures.

(1) No individual other than the operator shall be in the X–ray room while exposures are being made unless such individual's assistance is required, and

(2) The operator shall stand behind the protective barrier of 9 feet from the useful beam and the animal during radiographic exposures, or

(3) When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and shall be so positioned that no part of the holder's body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

41.1(11) *Computed tomography X–ray systems.*

a. Definitions. In addition to the definitions provided in 641—38.2(136C) and 41.1(2), the following definitions shall be applicable to 41.1(11):

"Computed tomography dose index" means the integral from –7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

	CTDI =	$\frac{1}{nT}$	G	$\int_{-7T}^{+7T}$	D(z) dz

where:

z = Position along a line perpendicular to the tomographic plane.

(z) = Dose at position z.

T = Nominal tomographic section thickness.

n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z = 0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

"*Contrast scale*" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$CS = \frac{m_x - m_w}{(CTN)_x - (CTN)_w}$$

where:

m_x = Linear attenuation coefficient of the material of interest.

= Linear attenuation coefficient of the material of interest.

m_w = Linear attenuation coefficient of water.

$(CTN)_x$ = CTN of the material of interest.

$(CTN)_w$ = CTN of water.

"CS" (see "Contrast scale").

"CT conditions of operation" means all selectable parameters governing the operation of a CT X–ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 41.1(2).

"CTDI" (see "Computed tomography dose index").

"CT gantry" means the tube housing assemblies, beam–limiting devices, detectors, and the supporting structures and frames which hold these components.

"CTN" (see "CT number").

"CT number" means the number used to represent the X–ray attenuation associated with each elemental area of the CT image.

= Linear attenuation coefficient of water.

$(CTN)_x$ = CTN of the material of interest.

$(CTN)_w$ = CTN of water.

"CS" (see "Contrast scale").

"CT conditions of operation" means all selectable parameters governing the operation of a CT X–ray

system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 41.1(2).

"CTDI" (see "Computed tomography dose index").

"CT gantry" means the tube housing assemblies, beam–limiting devices, detectors, and the supporting structures and frames which hold these components.

"CTN" (see "CT number").

"CT number" means the number used to represent the X–ray attenuation associated with each elemental area of the CT image.

$$CTN = \frac{k(m_x - m_w)}{m_w}$$

where:

k = A constant. (The constant has a normal value of 1,000 when the Houndsfield scale of CTN is used.)

m_x = Linear attenuation coefficient of the material of interest.

= Linear attenuation coefficient of the material of interest.

m_w = Linear attenuation coefficient of water.

"Dose profile" means the dose as a function of position along a line.

"Elemental area" means the smallest area within a tomogram for which the X–ray attenuation properties of a body are depicted (see also "Picture element").

"Multiple tomogram system" means a computed tomography X–ray system which obtains X–ray transmission data simultaneously during a single scan to produce more than one tomogram.

"Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

= Linear attenuation coefficient of water.

"Dose profile" means the dose as a function of position along a line.

"Elemental area" means the smallest area within a tomogram for which the X–ray attenuation properties of a body are depicted (see also "Picture element").

"Multiple tomogram system" means a computed tomography X–ray system which obtains X–ray transmission data simultaneously during a single scan to produce more than one tomogram.

"Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \times CS \times s}{m_w}$$

where:

CS = Linear attenuation coefficient of the material of interest.

m_w = Linear attenuation coefficient of water.

s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

"Nominal tomographic section thickness" means the full width at half–maximum of the sensitivity profile taken at the center of the cross–sectional volume over which X–ray transmission data are collected.

"Picture element" means an elemental area of a tomogram.

"Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

"Scan" means the complete process of collecting X–ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

"Scan increment" means the amount of relative displacement of the patient with respect to the CT X–ray system between successive scans measured along the direction of such displacement.

"Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

"Scan time" means the period of time between the beginning and end of X–ray transmission data accumulation for a single scan.

"Single tomogram system" means a CT X–ray system which obtains X–ray transmission data during a scan to produce a single tomogram.

"Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose X–ray attenuation properties are imaged in a tomogram.

b. Requirements for equipment.

(1) Termination of exposure.

1. Means shall be provided to terminate the X–ray exposure automatically by either deenergizing the X–ray source or shuttering the X–ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

2. A visible signal shall indicate when the X–ray exposure has been terminated through the means required by 41.1(11)*"b"*(1)"1."

3. The operator shall be able to terminate the X–ray exposure at any time during a scan, or series of scans under CT X–ray system control, of greater than one–half second duration.

(2) Tomographic plane indication and alignment.

1. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

2. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

3. If a device using a light source is used to satisfy 41.1(11)*"b"*(2)"1" or "2," the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

(3) Beam–on and shutter status indicators and control switches.

1. The CT X–ray control and gantry shall provide visual indication whenever X–rays are produced and, if applicable, whether the shutter is open or closed.

2. Each emergency button or switch shall be clearly labeled as to its function.

(4) Indication of CT conditions of operation. The CT X–ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

(5) Extraneous radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by 41.1(4)*"c."*

(6) Maximum surface CTDI identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

(7) Additional requirements applicable to CT X–ray systems containing a gantry manufactured after September 3, 1985.

1. The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

2. If the X–ray production period is less than one–half second, the indication of X–ray production shall be actuated for at least one–half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

3. The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

4. Premature termination of the X–ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

c. Facility design requirements.

(1) Aural communication. Provision shall be made for two–way aural communication between the patient and the operator at the control panel.

(2) Viewing systems.

1. Windows, mirrors, closed–circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

2. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

d. Surveys, calibrations, spot checks, and operating procedures.

(1) Surveys.

1. All CT X–ray systems installed after the effective date of these rules and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

2. The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the agency upon request.

(2) Radiation calibrations.

1. The calibration of the radiation output of the CT X–ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration.

2. The calibration of a CT X–ray system shall be performed at intervals specified by a qualified expert and after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output.

3. The calibration of the radiation output of a CT X–ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years.

4. CT dosimetry phantom(s) shall be used in determining the radiation output of a CT X–ray system. Such phantom(s) shall meet the following specifications and conditions of use: CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT X–ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode; CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided; any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom; and all dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

5. The calibration shall be required for each type of head, body, or whole–body scan performed at the facility.

6. Calibration shall meet the following requirements: The dose profile along the center axis of the CT

dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness; the CTDI along the two axes specified in 41.1(11)*"d"*(2)"4" shall be measured. (For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.) The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant; and the spot checks specified in 41.1(11)*"d"*(3) shall be made.

7. Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the agency.

(3) Spot checks.

1. The spot–check procedures shall be in writing and shall have been developed by a qualified expert.

2. The spot–check procedures shall incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

3. All spot checks shall be included in the calibration required by 41.1(11)*"d"*(2) and at time intervals and under system conditions specified by a qualified expert.

4. Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by 41.1(11)*"d"*(2). The images shall be retained, until a new calibration is performed, in two forms as follows: photographic copies of the images obtained from the image display device; and images stored in digital form on a storage medium compatible with the CT X–ray system.

5. Written records of the spot checks performed shall be maintained for inspection by the agency.

(4) Operating procedures.

1. The CT X–ray system shall not be operated except by an individual who has been specifically trained in its operation.

2. Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following: dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained; instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system; the distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and a current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.

3. If the calibration or spot check of the CT X–ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified expert, use of the CT X–ray system on patients shall be limited to those uses permitted by established written instructions of the qualified expert.

41.1(12) *X–ray machines used for mammography* . Rescinded IAB 4/8/98, effective 7/1/98.

641—41.2(136C) Use of radionuclides in the healing arts.

41.2(1) *Purpose and scope.* This rule establishes requirements and provisions for the use of

radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this rule are in addition to, and not in substitution for, the applicable portions of 641—Chapters 38 to 40. The requirements and provisions of these rules apply to applicants and licensees subject to this rule unless specifically exempted. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of July 1, 1998.

41.2(2) *Definitions.* For the purpose of this chapter, the definitions of 641—Chapters 38 to 40 may also apply. As used in 41.2(136C), the following definitions apply:

"Area of use" means a portion of a physical structure that has been set aside for the purpose of receiving, using, or storing radioactive material.

"Authorized nuclear pharmacist" means a pharmacist who has met the appropriate requirements of 41.2(78) and who is practicing nuclear pharmacy as authorized by a current Iowa radioactive materials license.

"Authorized user" means a physician, dentist, or podiatrist who has met the appropriate requirements of 41.2(67), 41.2(68), 41.2(69), 41.2(70), 41.2(71), 41.2(72), or 41.2(73) and who uses radioactive materials as authorized by a current medical use Iowa radioactive materials license.

"Dedicated check source" means a radioactive source that is used to ensure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

"Management" means the chief executive officer or that individual's designee.

"Medical institution" means an organization in which several medical disciplines are practiced.

"Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

"Pharmacist" means an individual licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.

"Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on an agency license.

"Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.

41.2(3) *License required.*

a. No person shall manufacture, produce, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a specific license issued pursuant to these rules.

b. Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with these rules under the supervision of an authorized user as provided in 41.2(11).

c. An individual may prepare unsealed radioactive material for medical use in accordance with these rules under the supervision of an authorized nuclear pharmacist or authorized user as provided in 41.2(11) unless prohibited by license condition.

d. A licensee may conduct research involving human subjects using radioactive material provided that

the research is conducted, funded, supported, or regulated by another federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an Institutional Review Board in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

Nothing in this subrule relieves the licensee from complying with applicable FDA, federal, and other state requirements governing radioactive drugs or devices.

e. An applicant that satisfies the requirements of 641—paragraph 39.4(28)*"b"* may apply for a Type A specific license of broad scope.

41.2(4) *License amendments.* A licensee shall apply for and receive a license amendment:

a. Before using radioactive material for a method or type of medical use not permitted by the license issued under this rule;

b. Before permitting anyone, except a visiting authorized user described in 41.2(12), to work as an authorized user or authorized nuclear pharmacist under the license;

c. Before changing a radiation safety officer or teletherapy physicist;

d. Before receiving radioactive material in excess of the amount authorized on the license;

e. Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license; and

f. Before changing statements, representations, and procedures which are incorporated into the license.

41.2(5) *Notifications.*

a. A licensee shall provide to the agency a copy of the board certification, the NRC or Agreement State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user or an authorized nuclear pharmacist pursuant to 41.2(4)*"b"*(1) to 41.2(4)*"b"*(4).

b. A licensee shall notify the agency by letter no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, radiation safety officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change; or

(2) The licensee's mailing address changes.

c. The licensee shall mail the documents required in this subrule to the Iowa Department of Public Health, Des Moines, Iowa.

d. Exemptions regarding Type A specific licenses of broad scope. A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:

(1) The provision of 41.2(4)*"b"*;

(2) The provisions of 41.2(4) *"e"* regarding additions to or changes in the areas of use only at the addresses specified in the license;

(3) The provision of 41.2(5)*"a"*;

(4) The provisions of 41.2(5) *"b"* (1) for authorized user or an authorized nuclear pharmacist.

41.2(6) *Maintenance of records.*

a. Each record required by this rule must be legible throughout the retention period specified by each subrule. The record may be original or reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period.

b. The record may also be stored on electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures.

c. The licensee shall maintain adequate safeguards against tampering with and loss of records specified in 41.2(6)*"a"* and *"b."*

41.2(7) *ALARA program.*

a. Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable in accordance with 641—subrule 40.1(3).

b. To satisfy the requirement of 41.2(7)*"a"*:

(1) The management, radiation safety officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these rules or the radiation safety committee; or

(2) For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the radiation safety officer.

c. The ALARA program shall include an annual review by the radiation safety committee for licensees that are medical institutions, or management and the radiation safety officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

d. The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:

(1) A commitment by management to keep occupational doses as low as reasonably achievable;

(2) A requirement that the radiation safety officer brief management once each year on the radiation safety program;

(3) Personnel exposure investigational levels as established in accordance with 41.2(9)*"b"*(8) that, when exceeded, will initiate an investigation by the radiation safety officer of the cause of the exposure; and

(4) Personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the radiation safety officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

41.2(8) *Radiation safety officer.*

a. A licensee shall appoint a radiation safety officer responsible for implementing the radiation safety program. The licensee, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

b. The radiation safety officer shall:

(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Implement written policy and procedures for:

1. Authorizing the purchase of radioactive material;

2. Receiving and opening packages of radioactive material;

3. Storing radioactive material;

4. Keeping an inventory record of radioactive material;

5. Using radioactive material safely;

6. Taking emergency action if control of radioactive material is lost;

7. Performing periodic radiation surveys;

8. Performing checks and calibrations of survey instruments and other safety equipment;

9. Disposing of radioactive material;

10. Training personnel who work in or frequent areas where radioactive material is used or stored; and

11. Keeping a copy of all records and reports required by the agency rules, a copy of these rules, a copy of each licensing request and license and amendments, and the written policy and procedures required by the rules; and

(3) For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the agency for licensing action; or

(4) For medical use sited at a medical institution, assist the radiation safety committee in the performance of its duties.

41.2(9) *Radiation safety committee.* Each medical institution licensee shall establish a radiation safety committee to oversee the use of radioactive material.

a. The committee shall meet the following administrative requirements:

(1) Membership must consist of at least three individuals and shall include an authorized user of each type of use permitted by the license, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. Other members may be included as the licensee deems appropriate.

(2) The committee shall meet at least once each calendar quarter.

(3) To establish a quorum and to conduct business, one–half of the committee's membership shall be present, including the radiation safety officer and the management's representative.

(4) The minutes of each radiation safety committee meeting shall include:

1. The date of the meeting;

2. Members present;

3. Members absent;

4. Summary of deliberations and discussions;

5. Recommended actions and the numerical results of all ballots; and

6. Document any reviews required in 41.2(7)*"c"* and 41.2(9)*"b."*

(5) The committee shall provide each member with a copy of the meeting minutes and retain one copy until the agency authorizes its disposition.

b. To oversee the use of licensed material, the committee shall:

(1) Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;

(2) Review:

1. Review, on the basis of safety and with regard to the training and experience standards of this rule, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the radiation safety officer, or teletherapy physicist before submitting a license application or request for amendment or renewal;

2. Review, pursuant to 41.2(4)*"b"*(1) to 41.2(4)*"b"*(4), on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist.

(3) Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;

(4) Review on the basis of safety, and approve with the advice and consent of the radiation safety officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the agency for licensing action;

(5) Review quarterly, with the assistance of the radiation safety officer, occupational radiation exposure records of all personnel working with radioactive material;

(6) Review quarterly, with the assistance of the radiation safety officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;

(7) Review annually, with the assistance of the radiation safety officer, the radioactive material program; and

(8) Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the radiation safety officer.

41.2(10) *Statement of authorities and responsibilities.*

a. A licensee shall provide sufficient authority and organizational freedom to the radiation safety officer and the radiation safety committee to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide solutions; and

(3) Verify implementation of corrective actions.

b. A licensee shall establish in writing the authorities, duties, responsibilities, and radiation safety activities of the radiation safety officer and the radiation safety committee.

41.2(11) *Supervision.*

a. A licensee who permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 41.2(3) shall:

(1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material;

(2) Review the supervised individual's use of radioactive material, provide reinstruction as needed and review records kept to reflect this use;

(3) Require the authorized user to be immediately available to communicate with the supervised individual;

(4) Require the authorized user to be able to be physically present and available to the supervised individual on one hour's notice (the supervising authorized user need not be present for each use of radioactive material); and

(5) Require that only those individuals specifically trained, and designated by the authorized user, shall be permitted to administer radionuclides or radiation to patients or human research subjects.

b. A license shall require the supervised individual receiving, possessing, using or transferring radioactive material under 41.2(3) to:

(1) Follow the instructions of the supervising authorized user;

(2) Follow the procedures established by the radiation safety officer; and

(3) Comply with these rules and the license conditions with respect to the use of radioactive material.

c. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by 41.2(3)*"c,"* shall:

(1) Instruct the supervised individual in the preparation of radioactive material for medical use and the principles of and procedures for radiation safety and in the licensee's written quality management program, as appropriate to that individual's use of radioactive material;

(2) Require the supervised individual to follow the instructions given pursuant to 41.2(11)*"c"* and to comply with the regulations of this chapter and license conditions; and

(3) Require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing radioactive material for medical use and the records kept to reflect that work.

d. A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

41.2(12) *Visiting authorized user.*

a. A licensee may permit any visiting authorized user and visiting authorized nuclear pharmacist to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:

(1) The visiting authorized user and visiting authorized nuclear pharmacist has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee;

(2) The licensee has a copy of an agency, agreement state, licensing state or U.S. Nuclear Regulatory Commission license that identifies the visiting authorized user or visiting authorized nuclear pharmacist by name as an authorized user for medical use; and

(3) Only those procedures for which the visiting authorized user or visiting authorized nuclear pharmacist is specifically authorized by an agency [, agreement state, licensing state or U.S. Nuclear Regulatory Commission] license are performed by that individual.

b. A licensee need not apply for a license amendment in order to permit a visiting authorized user or visiting authorized nuclear pharmacist to use licensed material as described in 41.2(12) *"a."*

c. A licensee shall retain copies of the records specified in 41.2(12)*"a"* for five years from the date of the last visit.

41.2(13) *Mobile nuclear medicine service administrative requirements.*

a. The agency will only license mobile nuclear medicine services in accordance with this rule and other applicable requirements of these rules.

b. Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of radioactive material.

c. If a mobile nuclear medicine service provides services that the client is also authorized to provide, the client is responsible for ensuring that services are conducted in accordance with the rules in this chapter while the mobile nuclear medicine service is under the client's direction.

d. A mobile nuclear medicine service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client's address of use.

41.2(14) *Records and reports of misadministrations.*

a. When a misadministration involves any therapy procedure, the licensee shall notify the agency by telephone. The licensee shall also notify the referring physician of the affected patient or human research subject and the patient or human research subject or a responsible relative or guardian, unless the referring physician agrees to inform the patient or human research subject or believes, based on medical judgment, that telling the patient or human research subject or the patient's or human research subject's responsible relative or guardian would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient or human research subject, or the patient's or human research subject's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or human research subject or the patient's or human research subject's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient or human research subject because of this including remedial care as a result of the misadministration because of any delay in notification.

b. Written reports.

(1) The licensee shall submit a written report to the agency within 15 days after discovery of the misadministration. The written report must include the licensee's name, the prescribing physician's name, a brief description of the event, why the event occurred, the effect on the patient or the human research subject, what improvements are needed to prevent recurrence, actions taken to prevent recurrence, whether the licensee notified the patient or the human research subject or the patient's or the human research subject's responsible relative or guardian (this individual will subsequently be referred to as "the patient or the human research subject"), and if not, why not, and if the patient or the human research subject was notified, what information was provided to that individual. The report must not include the patient's or the human research subject's name or other information that could lead to identification of the patient or the human research subject.

(2) If the patient or the human research subject was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the patient or the human research subject by sending either:

1. A copy of the report that was submitted to the agency; or

2. A brief description of both the event and the consequences as they may affect the patient or the human research subject, provided a statement is included that the report submitted to the agency can be obtained from the licensee.

c. When a misadministration involves a diagnostic procedure, the radiation safety officer shall promptly investigate its cause, make a record for agency review, and retain the record as directed in 41.2(14)*"d."* The licensee shall also notify the referring physician and the agency in writing on IDPH Form #588–2608 within 15 days if the misadministration involved the use of radioactive material not intended for medical use, administration of dosage five–fold different from the intended dosage, or administration of radioactive material such that the patient or human research subject is likely to receive an organ dose greater than 2 rems (0.02 Sv) or a whole body dose greater than 500 millirems (5 mSv). Licensees may use dosimetry tables in package inserts, corrected only for amount of radioactivity administered, to determine whether a report is required.

d. Each licensee shall retain a record of each misadministration for ten years. The record shall contain the names of all individuals involved in the event, including the physician, allied health personnel, the patient or human research subject, and the patient's or human research subject's referring physician, the patient's or human research subject's social security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient or human research subject, what improvements are needed to prevent recurrence, and the action taken, if any, to prevent recurrence.

e. Aside from the notification requirement, nothing in 41.2(14)*"a"* to 41.2(14)*"d"* shall affect any rights or duties of licensees and physicians in relation to each other, patients or human research subjects, or responsible relatives or guardians.

f. Written directives. Each licensee shall meet the following objectives:

(1) That, prior to administration, a written directive[1] is prepared for:

1. Any teletherapy radiation dose;

2. Any gamma stereotactic radiosurgery radiation dose;

3. Any brachytherapy radiation dose;

4. Any administration of quantities greater than 30 microcuries of either sodium iodide I–125 or I–131;

or

5. Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I–125 or I–131;

(2) That, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

(3) That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

(4) That each administration is in accordance with the written directive; and

(5) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

(6) The licensee shall retain:

1. Each written directive; and

2. A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in 41.2(14)*"f"*(1) in an auditable form, for three years after the date of administration.

41.2(15) Suppliers. *Suppliers.* A licensee shall use for medical use only:

a. Radioactive material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to these rules or the equivalent regulations of another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission; and

b. Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Food and Drug Administration;

[1] If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the nextteletherapy fractional dose.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

c. Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to these rules, or the equivalent regulations of another agreement state, a licensing state, or the U.S. Nuclear Regulatory Commission.

41.2(16) *Quality control of imaging equipment.* Each licensee shall establish written quality control procedures for all equipment used to obtain images from radionuclide studies. As a minimum, the procedures shall include quality control procedures recommended by equipment manufacturers or procedures which have been approved by the agency. The licensee shall conduct quality control procedures in accordance with written procedures.

41.2(17) *Possession, use, calibration, and check of dose calibrators.*

a. A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient or human research subject.

b. A licensee shall:

(1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this section, the check shall be done on a frequently used setting with a sealed source of not less than 10 microcuries (370 kBq) of radium–226 or 50 microcuries (1.85 MBq) of any other photon–emitting radionuclide with a half–life greater than 90 days;

(2) Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least two sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5 percent of the stated activity, with minimum activity of 10 microcuries (370 kBq) for radium–226 and 50 microcuries (1.85 MBq) for any otherphoton–emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(3) Test each dose calibrator for linearity upon installation and at intervals not to exceed three months thereafter over the range of use between 30 microcuries (1.1 megabequerels) and the highest dosage that will be administered; and

(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

c. A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries (370 kBq) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

d. A licensee shall also perform checks and tests required by 41.2(17)*"b"* following adjustment or repair of the dose calibrator.

e. A licensee shall retain a record of each check and test required by 41.2(17) for three years. The records required by 41.2(17)*"b"* shall include:

(1) For 41.2(17)*"b"*(1), the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

(2) For 41.2(17)*"b"*(2), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, the identity of the individual performing the test, and the signature of the radiation safety officer;

(3) For 41.2(17)*"b"*(3), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, the identity of the individual performing the test, and the signature of the radiation safety officer; and

(4) For 41.2(17)*"b"*(4), the model and serial number of the dose calibrator, the configuration calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, the identity of the individual performing the test, and the signature of the radiation safety officer.

41.2(18) *Calibration and check of survey instruments.*

a. A licensee shall ensure that the survey instruments used to show compliance with this rule have been calibrated before first use, annually, and following repair.

b. To satisfy the requirements of 41.2(18)*"a,"* the licensee shall:

(1) Calibrate all required scale readings up to 1000 millirems (10 mSv) per hour with a radiation source;

(2) For each scale that shall be calibrated, calibrate two readings separated by at least 50 percent of scale

rating; and

(3) Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

c. To satisfy the requirements of 41.2(18)*"b,"* the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent and shall conspicuously attach a correction chart or graph to the instrument.

d. A licensee shall check each survey instrument for proper operation with the dedicated check source before each use. The licensee is not required to keep records of these checks.

e. The licensee shall retain a record of each calibration required in 41.2(18)*"a"* for three years. The record shall include:

(1) A description of the calibration procedure; and

(2) A description of the source used and the certified dose rates from the source, the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

f. To meet the requirements of 41.2(18)*"a," "b,"* and *"c,"* the licensee may obtain the services of individuals licensed by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations which contain information required by 41.2(18)*"e"* shall be maintained by the licensee.

g. Possession, use, calibration, and check of instruments to measure dosages of alpha– or beta–emitting radionuclides.

(1) This subrule does not apply to unit dosages of alpha– or beta–emitting radionuclides that are obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29)*"j,"* the U.S. Nuclear Regulatory Commission or equivalent Agreement State requirements.

(2) For other than unit dosages obtained pursuant to 41.2(18)*"g"*(1) a licensee shall possess and use instrumentation to measure the radioactivity of alpha– or beta–emitting radionuclides. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha– or beta–emitting radionuclides prior to administration to each patient or human research subject. In addition, the licensee shall:

1. Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument, and make adjustments when necessary; and

2. Check each instrument for constancy and proper operation at the beginning of each day of use.

41.2(19) *Assay of radiopharmaceutical dosages.* A licensee shall:

a. Assay, prior to medical use, the activity of each radiopharmaceutical dosage that contains more than 30 microcuries (1.1 megabecquerels) of a photon–emitting radionuclide;

b. Assay, before medical use, the activity of each radiopharmaceutical dosage of a photon–emitting radionuclide to verify that the dosage does not exceed 30 microcuries (1.1 mBq); and

c. Measure, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha– or beta–emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 641—paragraph 39.4(29)*"j"* or equivalent

NRC or Agreement State requirements.

d. Retain a record of the assays required by 41.2(19)*"a"* for three years. To satisfy this requirement, the record shall contain the:

(1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

(2) Patient's or human research subject's name and identification number if one has been assigned;

(3) Prescribed dosage and activity of the dosage at the time of assay, or a notation that the total activity is less than 30 microcuries (1.1 megabecquerels);

(4) Date and time of the assay and administration; and

(5) Initials of the individual who performed the assay.

41.2(20) *Authorization for calibration and reference sources.* Any person authorized by 41.2(3) for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

a. Sealed sources manufactured and distributed by persons specifically licensed pursuant to 641—Chapter 39 or equivalent provisions of the U.S. Nuclear Regulatory Commission, agreement state or licensing state and that do not exceed 15 millicuries (555 MBq) each;

b. Any radioactive material listed in 41.2(31) or 41.2(33) with a half–life of 100 days or less in individual amounts not to exceed 15 millicuries (555 MBq);

c. Any radioactive material listed in 41.2(31) or 41.2(33) with a half–life greater than 100 days in individual amounts not to exceed 200 microcuries (7.4 MBq) each; and

d. Technetium–99m in individual amounts not to exceed 50 millicuries (1.85 GBq).

41.2(21) *Requirements for possession of sealed sources and brachytherapy sources.*

a. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the agency and shall maintain the instructions for the duration of source use in a legible form convenient to users.

b. A licensee in possession of a sealed source shall ensure that:

(1) The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(2) The source is tested for leakage at intervals not to exceed six months or at intervals approved by the agency, another agreement state, a licensing state or the U.S. Nuclear Regulatory Commission.

c. To satisfy the leak test requirements of 41.2(21) *"b,"* the licensee shall ensure that:

(1) Leak tests are capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample or, in the case of radium, the escape of radon at the rate of 0.001 microcurie (37 Bq) per 24 hours;

(2) Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

(3) Test samples are taken when the source is in the "off" position.

d. A licensee shall retain leak test records for five years. The records shall contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries (becque–rels), a description of the method used to measure each test sample, the date of the test, and the signature of the radiation safety officer.

e. If the leak test reveals the presence of 0.005 microcurie (185 Bq) or more of removable contamination, the licensee shall:

(1) Immediately withdraw the sealed source from use and store it in accordance with the requirements of these rules; and

(2) File a report with the agency within five days of receiving the leak test results with the agency describing the equipment involved, the test results, and the action taken.

f. A licensee need not perform a leak test on the following sources:

(1) Sources containing only radioactive material with a half–life of less than 30 days;

(2) Sources containing only radioactive material as a gas;

(3) Sources containing 100 microcuries (3.7 MBq) or less of beta or photon–emitting material or 10 microcuries (370 kBq) or less of alpha–emitting material; [and]

(4) Seeds of iridium–192 encased in nylon ribbon; and

(5) Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been tested for leakage within six months before the date of use or transfer.

g. A licensee in possession of a sealed source or brachytherapy source shall conduct a physical inventory of all such sources at intervals not to exceed three months. The licensee shall retain each inventory record for five years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory, and the signature of the radiation safety officer.

h. A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed three months all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

i. A licensee shall retain a record of each survey required in 41.2(21)*"h"* for three years. The record shall include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the radiation safety officer.

41.2(22) *Syringe shields.*

a. A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.

b. A licensee shall require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindicated for that patient or human research subject.

41.2(23) *Syringe labels.* Unless utilized immediately, a licensee shall conspicuously label each syringe,

or syringe radiation shield that contains a syringe with a radiopharmaceutical, with the radiopharmaceutical name or its abbreviation, the type of diagnostic study or therapy procedure to be performed, or the patient's or human research subject's name.

41.2(24) *Vial shields.* A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

41.2(25) *Vial shield labels.* A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.

41.2(26) *Surveys for contamination and ambient radiation dose rate.*

a. A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

b. A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

c. A licensee shall conduct the surveys required by 41.2(26)*"a"* and *"b"* so as to be able to measure dose rates as low as 0.1 millirem (1 μSv) per hour.

d. A licensee shall establish dose rate action levels for the surveys required by 41.2(26)*"a"* and *"b"* and shall require that the individual performing the survey immediately notify the radiation safety officer if a dose rate exceeds an action level.

e. A licensee shall survey for removable contamination each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered and each week where radioactive materials are stored.

f. A licensee shall conduct the surveys required by 41.2(26)*"e"* so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute (33.3 Bq).

g. A licensee shall establish removable contamination action levels for the surveys required by 41.2(26)*"e"* and shall require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.

h. A licensee shall retain a record of each survey required by 41.2(26)*"a," "b,"* and *"e"* for two years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in millirems (microsieverts) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

41.2(27) *Release of patients or human research subjects containing radiopharmaceuticals or permanent implants.*

a. The licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (5 mSv).

b. The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 0.1 rem (1 mSv). If the dose to a breast-feeding infant or child could exceed 0.1 rem (1 mSv) assuming there were no interruption of breast feeding, the instructions shall also include:

(1) Guidance on the interruption or discontinuation of breast feeding, and

(2) Information on the consequences of failure to follow the guidance.

c. The licensee shall maintain a record of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:

(1) Using the retained activity rather than the activity administered,

(2) Using an occupancy factor less than 0.25 at 1 meter,

(3) Using the biological or effective half–life, or

(4) Considering the shielding by tissue.

d. The licensee shall maintain a record for three years after the date of release that instructions were provided to a breast–feeding woman if the radiation dose to the infant or child from continued breast feeding could result in a total effective dose equivalent exceeding 0.5 rem (5 mSv). IDPH Regulatory Guide, Release of Patients Administered Radioactive Materials describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 mSv).

41.2(28) *Mobile nuclear medicine service technical requirements.* A licensee providing mobile nuclear medicine service shall:

a. Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

b. Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

c. Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a location of use;

d. Check survey instruments and dose calibrators as required in 41.2(17) *"b"* (1) *"d"* and *"e"* and 41.2(18) *"d"* and check all other transported equipment for proper function before medical use at each location of use;

e. Carry a calibrated survey meter in each vehicle that is being used to transport radioactive material and, before leaving a client location of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed; and

f. Retain a record of each survey required by 41.2(28) *"e"* for three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirems (microsieverts) per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.

41.2(29) *Storage of volatiles and gases.*

a. A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.

b. A licensee shall store and use a multidose container in a properly functioning fume hood.

41.2(30) *Decay–in–storage.*

a. A licensee may hold radioactive material with half–lives of less than 65 days, except for Cobalt–57 for decay–in–storage before disposal in ordinary trash and is exempt from the requirements of 641—subrule 40.70(1) if the licensee:

(1) Holds radioactive material for decay a minimum of ten half–lives;

(2) Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

(3) Removes or obliterates all radiation labels; and

(4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

b. For radioactive material disposed in accordance with 41.2(30)*"a,"* the licensee shall retain a record of each disposal for three years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the model and serial number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

41.2(31) *Use of radiopharmaceuticals for uptake, dilution, or excretion studies.* A licensee may use any radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion for which the Food and Drug Administration (FDA) has a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

41.2(32) *Possession of survey instrument.* A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem (1.0 μSv) per hour to 50 millirems (500 μSv) per hour. The instrument shall be operable and calibrated in accordance with 41.2(18).

41.2(33) *Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.*

a. A licensee may use any radioactive material in a diagnostic radiopharmaceutical or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for which the Food and Drug Administration has a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

b. A licensee shall elute generators in compliance with subrule 41.2(34).

c. Provided that the conditions of subrule 41.2(35) are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the agency.

41.2(34) *Permissible molybdenum–99 concentration.*

a. A licensee shall not administer a radiopharmaceutical containing more than 0.15 microcurie of molybdenum–99 per millicurie of technetium–99m (0.15 kilobecquerel of molybdenum–99 per megabecquerel of technetium–99m).

b. A licensee preparing technetium–99m radiopharmaceuticals from molybdenum–99/technetium–99m generators shall measure the molybdenum–99 concentration in each eluate or extract.

c. A licensee who must measure molybdenum concentration shall retain a record of each measurement for three years. The record shall include, for each elution or extraction of technetium–99m, the measured activity of the technetium expressed in millicuries (megabecquerels), the measured activity of molybdenum expressed in microcuries (kilobecquerels), the ratio of the measures expressed as

microcuries of molybdenum per millicurie of technetium (kilobecquerels of molybdenum per megabecquerel of technetium), the date of the test, and the initials of the individual who performed the test.

d. A licensee shall report immediately to the agency each occurrence of molybdenum–99 concentration exceeding the limits specified in 41.2(34)*"a."*

41.2(35) *Control of aerosols and gases.*

a. A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by 641—40.15(136C) and 641—40.26(136C) of these rules.

b. The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

c. A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

d. Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in Appendix B of 641—Chapter 40. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

e. A licensee shall post the time calculated in 41.2(35)*"a"* at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

f. A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six months. Records of these checks and measurements shall be maintained for three years.

g. A copy of the calculations required in 41.2(35)"d" shall be recorded and retained for the duration of the license.

41.2(36) *Possession of survey instruments.* A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μSv) per hour to 50 millirems (500 μSv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μSv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 41.2(18).

41.2(37) *Use of radiopharmaceuticals for therapy.* A licensee may use any radioactive material in a radiopharmaceutical and for a therapeutic use for which the Food and Drug Administration has a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

41.2(38) *Safety instruction.*

a. A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients or human research subjects undergoing radiopharmaceutical therapy. Refresher training shall be provided at intervals not to exceed one year.

b. To satisfy 41.2(38) *"a,"* the instruction shall describe the licensee's procedures for:

(1) Patient or human research subject control;

(2) Visitor control;

(3) Contamination control;

(4) Waste control;

(5) Notification of the radiation safety officer or authorized user in case of the patient's or human research subject's death or medical emergency; and

(6) Training requirements specified in 641—40.110(136C) and 40.116(136C) and adopted by reference and included herein.

c. A licensee shall keep a record of individuals receiving instruction required by 41.2(38) *"a,"* a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the agency for three years.

41.2(39) *Safety precautions.*

a. For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 41.2(27), a licensee shall:

(1) Provide a private room with a private sanitary facility;

(2) Post the patient's or human research subject's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(3) Authorize visits by individuals under 18 years of age only on a case–by–case basis with the approval of the authorized user after consultation with the radiation safety officer;

(4) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 641—subrule 40.26(1) which is adopted by reference and included herein and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirems (μSv) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

(5) Either monitor material and items removed from the patient's or human research subject's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste;

(6) Provide the patient or human research subject with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient or human research subject;

(7) Survey the patient's or human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient or human research subject to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute (3.33 Bq) per 100 square centimeters; and

(8) Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine–131 during the period which starts the first day after administration and ends the fourth day after administering the dosage, and retain for the period required by 641—paragraph 40.82(2) *"c"* which is adopted and included herein a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

b. A licensee shall notify the radiation safety officer or the authorized user immediately if the patient or human research subject dies or has a medical emergency.

41.2(40) *Possession of survey instruments.* A licensee authorized to use radioactive material for radiopharmaceutical therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μSv) per hour to 50 millirems (500 μSv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μSv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 41.2(18).

41.2(41) *Use of sealed sources for diagnosis.* A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:

a. Iodine–125 as a sealed source in a device for bone mineral analysis;

b. Americium–241 as a sealed source in a device for bone mineral analysis;

c. Gadolinium–153 as a sealed source in a device for bone mineral analysis; and

d. Iodine–125 as a sealed source in a portable device for imaging.

41.2(42) *Availability of survey instrument.* A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μ Sv) per hour to 50 millirems (500 μ Sv) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μSv) per hour to 1000 millirems (10 mSv) per hour. The instrument shall be operable and calibrated in accordance with 41.2(18).

41.2(43) *Use of sources for brachytherapy.* A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

a. Cesium–137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

b. Cobalt–60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

c. Gold–198 as a sealed source in seeds for interstitial treatment of cancer;

d. Iodine–125 as a sealed source in seeds for interstitial treatment of cancer;

e. Iridium–192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

f. Radium–226 as a sealed source in needles or applicator cells for topical, interstitial, and intracavitary treatment of cancer;

g. Radon–222 as seeds for interstitial treatment of cancer;

h. Strontium–90 as a sealed source in an applicator for treatment of superficial eye conditions; and

i. Palladium–103 as a sealed source in seeds for the interstitial treatment of cancer.

41.2(44) ***Safety instruction.***

a.

a. The licensee shall provide oral and written radiation safety instruction to all personnel caring for a

patient or human research subject receiving implant therapy. Refresher training shall be provided at intervals not to exceed one year.

b. To satisfy 41.2(44)*"a,"* the instruction shall describe:

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions in case of a dislodged source;

(3) Procedures for patient or human research subject control;

(4) Procedures for visitor control;

(5) Procedures for notification of the radiation safety officer or authorized user if the patient or human research subject dies or has a medical emergency; and

(6) Training requirements specified in 641—40.110(136C) and 40.116(136C) as adopted by reference and included herein.

c. A licensee shall maintain a record of individuals receiving instruction required by 41.2(44)*"a,"* a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for three years.

41.2(45) *Safety precautions.*

a. For each patient or human research subject receiving implant therapy a licensee shall:

(1) Not place the patient or human research subject in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirement of 641—40.26(136C) as adopted by reference and included herein at a distance of 1 meter from the implant;

(2) Post the patient's or human research subject's door with a "Caution: Radioactive Materials" sign and note on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(3) Authorize visits by individuals under 18 years of age only on a case–by–case basis with the approval of the authorized user after consultation with the radiation safety officer;

(4) Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with 641—40.26(136C) as adopted by reference and included herein; and retain for three years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in millirems (mSv) per hour, the instrument used to make the survey, and the initials of the individual who made the survey; and

(5) Provide the patient or human research subject with radiation safety guidance that will help keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient or human research subject if the patient or human research subject was administered a permanent implant.

b. A licensee shall notify the radiation safety officer or authorized user immediately if the patient or human research subject dies or has a medical emergency.

41.2(46) *Brachytherapy sources inventory.*

a. Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee

shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.

b. A licensee shall make a record of brachytherapy source utilization which includes:

(1) The names of the individuals permitted to handle the sources;

(2) The number and activity of sources removed from storage, the room number of use and patient's or human research subject's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

(3) The number and activity of sources returned to storage, the room number of use and patient's or human research subject's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

c. Immediately after implanting sources in a patient or human research subject and immediately after removal of sources from a patient or human research subject, the licensee shall make a radiation survey of the patient or human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

d. A licensee shall maintain the records required in 41.2(46) *"b"* and *"c"* for three years.

41.2(47) *Release of patients or human research subjects treated with temporary implants.*

a. Immediately after removing the last temporary implant source from a patient or human research subject, the licensee shall perform a radiation survey of the patient or human research subject with a radiation detection survey instrument to confirm that all sources have been removed. The licensee shall not release from confinement for medical care a patient or human research subject treated by temporary implant until all sources have been removed.

b. A licensee shall maintain a record of patient or human research subject surveys which demonstrate compliance with 41.2(47)*"a"* for three years. Each record shall include the date of the survey, the name of the patient or human research subject, the dose rate from the patient or human research subject expressed as millirems (microsieverts) per hour and measured within 1 meter from the patient or human research subject, and the initials of the individual who made the survey.

41.2(48) *Possession of survey instruments.* A licensee authorized to use radioactive material for implant therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μSv) per hour to 50 millirems (500 μSv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μSv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 41.2(18).

41.2(49) *Use of a sealed source in a teletherapy unit.* A licensee shall use cobalt–60 or cesium–137 as a sealed source in a teletherapy unit for medical use in accordance with the manufacturer's radiation safety and operating instructions.

41.2(50) *Maintenance and repair restrictions.* Only a person specifically licensed by the agency, the U.S. Nuclear Regulatory Commission, or an agreement state to perform teletherapy unit maintenance and repair shall install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source or maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

41.2(51) *Amendments.* In addition to the requirements specified in 41.2(4), a licensee shall apply for and

receive a license amendment before:

a. Making any change in the treatment room shielding;

b. Making any change in the location of the teletherapy unit within the treatment room;

c. Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

d. Relocating the teletherapy unit; or

e. Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

41.2(52) *Safety instruction.*

a. A licensee shall conspicuously post written instructions at the teletherapy unit console. These instructions shall inform the operator of:

(1) The procedure to be followed to ensure that only the patient or human research subject is in the treatment room before turning the primary beam of radiation "on" to begin a treatment or after a door interlock interruption;

(2) The procedure to be followed if the operator is unable to turn the primary beam of radiation "off" with controls outside the treatment room or any other abnormal operation occurs; and

(3) The names and telephone numbers of the authorized users and radiation safety officer to be immediately contacted if the teletherapy unit or console operates abnormally.

b. A licensee shall provide instruction in the topics identified in 41.2(52) *"a"* to all individuals who operate a teletherapy unit and shall provide appropriate refresher training to individuals at intervals not to exceed one year.

c. A licensee shall maintain a record of individuals receiving instruction required by 41.2(52) *"b,"* a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for three years.

41.2(53) *Doors, interlocks, and warning systems.*

a. A licensee shall control access to the teletherapy room by a door at each entrance.

b. A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:

(1) Prevent the operator from turning the primary beam of radiation "on" unless each treatment room entrance door is closed;

(2) Turn the beam of radiation "off" immediately when an entrance door is opened; and

(3) Prevent the primary beam of radiation from being turned "on" following an interlock interruption until all treatment room entrance doors are closed and the beam "on–off" control is reset at the console.

c. A licensee shall equip each entrance to the teletherapy room with a conspicuously visible beam condition indicator light.

41.2(54) *Possession of survey instrument.* A licensee authorized to use radioactive material in a teletherapy unit shall possess either a portable radiation detection survey instrument capable of detecting

dose rates over the range of 0.1 millirem (1 μSv) per hour to 50 millirems (500 μSv) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 millirem (10 μSv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 41.2(18).

41.2(55) *Radiation monitoring device.*

a. A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

b. Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.

c. Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

d. A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.

e. A licensee shall maintain a record of the check required by 41.2(55)*"d"* for three years. The record shall include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.

f. If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in 41.2(55)*"e."*

g. A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

41.2(56) *Viewing system.* A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or human research subject from the teletherapy unit console during irradiation.

41.2(57) *Dosimetry equipment.*

a. A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:

(1) The system shall have been calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration shall have been performed within the previous two years and after any servicing that may have affected system calibration; or

(2) The system shall have been calibrated within the previous four years; 18 to 30 months after that calibration, the system shall have been intercompared at an inter–comparison meeting with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt–60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt–60 source. When intercomparing dosimetry systems to be used for calibrating cesium–137 teletherapy units, the licensee shall use a teletherapy unit with a cesium–137 source.

b. The licensee shall have available for use a dosimetry system for spot–check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 41.2(57) *"a."* This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot–check system shall be the same system used to meet the requirement in 41.2(57)*"a."*

c. The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 41.2(57)*"a"* and *"b,"* the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.

41.2(58) *Full calibration measurements.*

a. A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

1. Whenever spot–check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

2. Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and

3. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding one year.

b. To satisfy the requirement of 41.2(58)*"a,"* full calibration measurements shall include determination of:

(1) The output within 3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer accuracy, constancy, and linearity;

(5) "On–off" error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

c. A licensee shall use the dosimetry system described in 41.2(57) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 41.2(58)*"b"*(1) may then be made using a dosimetry system that indicates relative dose rates.

d. A licensee shall make full calibration measurements required by 41.2(58)*"a"* in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American

Association of Physicists in Medicine that are described in Physics in Medicine and Biology, Vol. 16, No. 3, 1971, pp. 379–396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics, Vol. 10, No. 6, 1983, pp. 741–771, and Vol. 11, No. 2, 1984, p. 213.

e. A licensee shall correct mathematically the outputs determined in 41.2(58)*"b"*(1) for physical decay for intervals not exceeding one month for cobalt–60 and intervals not exceeding six months for cesium–137.

f. Full calibration measurements required by 41.2(58)*"a"* and physical decay corrections required by 41.2(58)*"e"* shall be performed by a teletherapy physicist named on the licensee's license or authorized by a license issued by the U.S. Nuclear Regulatory Commission or an agreement state to perform such services.

g. A licensee shall maintain a record of each calibration for the duration of the license. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated "on–off" error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.

41.2(59) *Periodic spot checks.*

a. A licensee authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit at intervals not to exceed one month.

b. To satisfy the requirement of 41.2(59) *"a,"* spot checks shall include determination of:

(1) Timer constancy and timer linearity over the range of use;

(2) "On–off" error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions; and

(6) The difference between the measurement made in 41.2(59) *"b"* (5) and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

c. A licensee shall use the dosimetry system described in 41.2(57) to make the spot check required in 41.2(59)*"b"*(5).

d. A licensee shall perform spot checks required by 41.2(59) *"a"* in accordance with procedures established by the teletherapy physicist. The teletherapy physicist does not need to actually perform the output spot–check measurements.

e. A licensee shall have the teletherapy physicist review the results of each output spot check within 15 days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each output spot check. The licensee shall keep a copy of each written notification for three years.

f. A licensee authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility at intervals not to exceed one month.

g. To satisfy the requirement of 41.2(59) *"f,"* safety spot checks shall ensure proper operation of:

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam "on–off" mechanism;

(3) Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off."

h. A licensee shall lock the control console in the "off" position if any door interlock malfunctions. No licensee shall use the unit until the interlock system is repaired unless specifically authorized by the agency.

i. A licensee shall promptly repair any system identified in 41.2(59) *"g"* that is not operating properly. The teletherapy unit shall not be used until all repairs are completed.

j. A licensee shall maintain a record of each spot check required by 41.2(59) *"a"* and *"f"* for three years. The record shall include the date of the spot check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, the timer constancy and linearity, the calculated "on–off" error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the timer constancy and linearity for a typical treatment time, the calculated "on–off" error, the estimated accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot check.

41.2(60) *Radiation surveys for teletherapy facilities.*

a. Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by 41.2(51), the licensee shall perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with 41.2(18) to verify that:

(1) The maximum and average radiation levels at 1 meter from the teletherapy source with the source in the "off" position and the collimators set for a normal treatment field do not exceed 10 millirems (100 μSv) per hour and 2 millirems (20 μSv) per hour, respectively; and

(2) With the teletherapy source in the "on" position with the largest clinically available treatment field, and with a scattering phantom in the primary beam of radiation, that:

1. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 641—40.15(136C); and

2. Radiation levels in unrestricted areas do not exceed the limits specified in 641—40.26(136C).

b. If the results of the surveys required in 41.2(60) *"a"* indicate any radiation levels in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the "off" position and not use the unit:

(1) Except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or

(2) Until the licensee has received a specific exemption from the agency.

c. A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the "off" position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirems (μSv) per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the radiation safety officer.

41.2(61) *Safety spot checks for teletherapy facilities.*

a. A licensee shall promptly check all systems listed in 41.2(59) *"g"* for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by 41.2(51).

b. If the results of the safety spot checks required in 41.2(61)*"a"* indicate the malfunction of any system specified in 41.2(59), the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

c. A licensee shall maintain a record of the safety spot checks following installation of a source for three years. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the radiation safety officer.

41.2(62) *Modification of teletherapy unit or room before beginning a treatment program.* If the survey required by 41.2(60) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 641—40.26(136C) before beginning the treatment program the licensee shall:

a. Either equip the unit with stops or add additional radiation shielding to ensure compliance with 641—40.26(136C);

b. Perform the survey required by 41.2(60) again; and

c. Include in the report required by 41.2(63) the results of the initial survey, a description of the modification made to comply with 41.2(62) *"a,"* and the results of the second survey; or

d. Request and receive a license amendment under 641—40.26(136C) that authorizes radiation levels in unrestricted areas greater than those permitted by 641—40.26(136C).

41.2(63) *Reports of teletherapy surveys, checks, tests, and measurements.* A licensee shall furnish a copy of the records required in 41.2(60), 41.2(61), and 41.2(62) and the output from the teletherapy source expressed as rems (sieverts) per hour at 1 meter from the source as determined during the full calibration required in 41.2(58) to the agency within 30 days following completion of the action that initiated the record requirement.

41.2(64) *Five-year inspection.*

a. A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to ensure proper functioning of the source exposure mechanism.

b. This inspection and servicing shall be performed only by persons specifically licensed to do so by the agency, an agreement state, or the U.S. Nuclear Regulatory Commission.

c. A licensee shall maintain a record of the inspection and servicing for the duration of the license. The record shall contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

41.2(65) *Radiation safety officer.* Except as provided in 41.2(66), an individual fulfilling the responsibilities of the radiation safety officer as provided in 41.2(8) shall:

a. Be certified by the:

(1) American Board of Health Physics in comprehensive health physics;

(2) American Board of Radiology in radiological physics, therapeutic radiological physics, or medical nuclear physics;

(3) American Board of Nuclear Medicine;

(4) American Board of Science in Nuclear Medicine;

(5) Board of Pharmaceutical Specialties in Nuclear Pharmacy;

(6) American Board of Medical Physics in radiation oncology physics;

(7) Royal College of Physicians and Surgeons of Canada in nuclear medicine;

(8) American Osteopathic Board of Radiology; or

(9) American Osteopathic Board of Nuclear Medicine.

b. Have had 200 hours of classroom and laboratory training as follows:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Radiation biology;

(5) Radiopharmaceutical chemistry; and

(6) One year of full–time experience in radiation safety at a medical institution under the supervision of the individual identified as the radiation safety officer on an agency, agreement state, licensing state, or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; or

c. Be an authorized user for those radioactive material uses that come within the radiation safety officer's responsibilities.

41.2(66) *Training for experienced radiation safety officer.* An individual identified as a radiation safety officer on an agency, agreement state, licensing state, or U.S. Nuclear Regulatory Commission license on September 1, 1992, who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of 41.2(65).

41.2(67) *Training for uptake, dilution, or excretion studies.* Except as provided in 41.2(75) and 41.2(76), the licensee shall require the authorized user of a radiopharmaceutical listed in 41.2(31) to be a physician who:

a. Is certified in:

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology; or

(4) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

(5) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

b. Has completed 40 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, and 20 hours of supervised clinical experience.

(1) To satisfy the basic instruction requirement, 40 hours of classroom and laboratory instruction shall include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Radiation biology; and

5. Radiopharmaceutical chemistry.

(2) To satisfy the requirement for 20 hours of supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and shall include:

1. Examining patients or human research subjects and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;

2. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

3. Administering dosages to patients or human research subjects and using syringe radiation shields;

4. Collaborating with the authorized user in the interpretation of radionuclide test results; and

5. Patient or human research subject follow–up; or

c. Has successfully completed a six–month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in 41.2(67)*"b"*;

d. Be identified on a current Agreement State or NRC license as an authorized user for use listed in 41.2(31).

41.2(68) *Training for imaging and localization studies.* Except as provided in 41.2(75) and 41.2(76), the

licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in 41.2(33) to be a physician who:

a. Is certified in:

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology; or

(4) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

(5) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

b. Has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, 500 hours of supervised work experience, and 500 hours of supervised clinical experience.

(1) To satisfy the basic instruction requirement, 200 hours of classroom and laboratory training shall include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Radiopharmaceutical chemistry; and

5. Radiation biology.

(2) To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

2. Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

3. Calculating and safely preparing patient or human research subject dosages;

4. Using administrative controls to prevent the misadministration of radioactive material;

5. Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

6. Eluting technetium–99m from generator systems, assaying and testing the eluate for molybdenum–99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium–99m labeled radiopharmaceuticals.

(3) To satisfy the requirement for 500 hours of supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

1. Examining patients or human research subjects and reviewing their case histories to determine their

suitability for radionuclide diagnosis, limitations, or contraindications;

2. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

3. Administering dosages to patients or human research subjects and using syringe radiation shields;

4. Collaborating with the authorized user in the interpretation of radionuclide test results; and

5. Patient or human research subject follow–up; or

c. Has successfully completed a six–month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in 41.2(68)*"b"*;

d. Be identified on a current Agreement State or NRC license as an authorized user for those uses listed in 41.2(33).

41.2(69) *Training for therapeutic use of radiopharmaceuticals.* Except as provided in 41.2(75), the licensee shall require the authorized user of a radiopharmaceutical listed in 41.2(37) for therapy to be a physician who:

a. Is certified by:

(1) The American Board of Nuclear Medicine; or

(2) The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; or

(3) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(4) The American Osteopathic Board of Radiology after 1984; or

b. Has completed 80 hours of instruction in basic radionuclide handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience.

(1) To satisfy the requirement for instruction, 80 hours of classroom and laboratory training shall include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity; and

4. Radiation biology;

(2) To satisfy the requirement for supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

1. Use of iodine–131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in ten individuals;

2. Use of soluble phosphorus–32 for the treatment of ascites, polycythemia vera, leukemia, or bone metastases in three individuals;

3. Use of iodine–131 for treatment of thyroid carcinoma in three individuals;

4. Use of colloidal chromic phosphorus–32 or of colloidal gold–198 for intracavitary treatment of malignant effusions in three individuals; and

5. Use of strontium–89 for relief of pain in metastatic disease in three individuals; or

c. Be identified on a current Agreement State or NRC license as an authorized user for these uses in 41.2(37).

41.2(70) *Training for therapeutic use of brachytherapy sources.* Except as provided in 41.2(75), the licensee shall require the authorized user using a brachytherapy source specified in 41.2(43) for therapy to be a physician who:

a. Is certified in:

(1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with a specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

b. Is in the active practice of therapeutic radiology, has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience and a minimum of three years of supervised clinical experience.

(1) To satisfy the requirement for instruction, 200 hours of classroom and laboratory training shall include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity; and

4. Radiation biology.

(2) To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

2. Checking survey meters for proper operation;

3. Preparing, implanting, and removing sealed sources;

4. Using administrative controls to prevent the misadministration of radioactive material; and

5. Using emergency procedures to control radioactive material.

(3) To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical

experience shall include:

1. Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

2. Selecting the proper brachytherapy sources, dose, and method of administration;

3. Calculating the dose; and

4. Postadministration follow–up and review of case histories in collaboration with the authorized user; or

c. Be identified on a current Agreement State or NRC license as an authorized user for the uses in 41.2(43).

41.2(71) *Training for ophthalmic use of strontium–90.* Except as provided in 41.2(75), the licensee shall require the authorized user using only strontium–90 for opthalmic radiotherapy to be a physician who:

a. Is certified in radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; or

b. Is in the active practice of therapeutic radiology or ophthalmology, and has completed 24 hours of instruction in basic radionuclide handling techniques applicable to the use of strontium–90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy.

(1) To satisfy the requirement for instruction, the classroom and laboratory training shall include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity; and

4. Radiation biology.

(2) To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training shall be under the supervision of an authorized user at a medical institution and shall include the use of strontium–90 for the ophthalmic treatment of five individuals that includes:

1. Examination of each individual to be treated;

2. Calculation of the dose to be administered;

3. Administration of the dose; and

4. Follow–up and review of each individual's case history; or

c. Be identified on a current Agreement State or NRC license as an authorized user for the use in 41.2(43)"h."

41.2(72) *Training for use of sealed sources for diagnosis.* Except as provided in 41.2(75), the licensee shall require the authorized user using a sealed source in a device specified in 41.2(41) to be a physician, dentist, or podiatrist who:

a. Is certified in:

(1) Radiology, diagnostic radiology with special competence in nuclear radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Nuclear medicine by the American Board of Nuclear Medicine; or

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

b. Has completed eight hours of classroom and laboratory instruction in basic radionuclide handling techniques specifically applicable to the use of the device.

(1) To satisfy the requirements for instruction, the training shall include:

1. Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

2. Radiation biology; and

3. Radiation protection and training in the use of the device for the purposes authorized by the license.

(2) Reserved; or

c. Be identified on a current Agreement State or NRC license as an authorized user for those uses in 41.2(41).

41.2(73) *Training for teletherapy.* Except as provided in 41.2(75), the licensee shall require the authorized user of a sealed source specified in 41.2(49) in a teletherapy unit to be a physician who:

a. Is certified in:

(1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

b. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radionuclide techniques applicable to the use of a sealed source in a teletherapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

(1) To satisfy the requirement for instruction, the classroom and laboratory training shall include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity; and

4. Radiation biology.

(2) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user at an institution and shall include:

1. Review of the full calibration measurements and periodic spot checks;

2. Preparing treatment plans and calculating treatment times;

3. Using administrative controls to prevent misadministrations;

4. Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and

5. Checking and using survey meters.

(3) To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:

1. Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment and any limitations or contraindications;

2. Selecting the proper dose and how it is to be administered;

3. Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and

4. Postadministration follow–up and review of case histories;

c. Be identified on a current Agreement State or NRC license as an authorized user for teletherapy.

41.2(74) *Training for teletherapy physicist.* The licensee shall require the teletherapy physicist to:

a. Be certified by:

(1) The American Board of Radiology in:

1. Therapeutic radiological physics;

2. Roentgen–ray and gamma–ray physics;

3. X–ray and radium physics; or

4. Radiological physics; or

5. The American Board of Medical Physics in radiation oncology physics; or

(2) Reserved; or

b. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full–time training in therapeutic radiological physics and also one year of full–time work experience under the supervision of a teletherapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 41.2(21), 41.2(58), 41.2(59), and 41.2(60) under the supervision of a teletherapy physicist during the year of work experience.

c. Be identified on a current Agreement State or NRC license as a teletherapy physicist.

41.2(75) *Training for experienced authorized users.* Rescinded IAB 8/3/94, effective 9/7/94.

41.2(76) *Physician training in a three–month program.* A physician who, before July 1, 1984, began a three–month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program, is exempted from the requirements of 41.2(67) or 41.2(68).

41.2(77) *Recentness of training.* The training and experience specified in 41.2(65) to 41.2(79) shall have been obtained within the seven years preceding the date of application or the individual shall have had related continuing education and continuing applicable experience since the required training and experience was completed.

41.2(78) *Training for an authorized nuclear pharmacist.* The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

a. Has current board certification as a nuclear pharmacist by the board of pharmaceutical specialties, or

b. Has completed:

(1) 700 hours in a structured educational program consisting of both:

1. Didactic training in the following areas:

• Radiation physics and instrumentation;

• Radiation protection;

• Mathematics pertaining to the use and measurement of radioactivity;

• Chemistry of radioactive material for medical use; and

• Radiation biology; and

2. Supervised experience in a nuclear pharmacy involving the following:

• Shipping, receiving, and performing related radiation surveys;

• Using and performing checks for proper operation of dose calibrators, survey meters, and if appropriate, instruments used to measure alpha– or beta–emitting radionuclides;

• Calculating, assaying, and safely preparing dosages for patients or human research subjects;

• Using administrative controls to avoid mistakes in the administration of radioactive material;

• Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

41.2(79) *Training for experienced nuclear pharmacists.* A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in 41.2(78)*"b"* before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement in 41.2(78)*"b"*(2) and recentness of training in 41.2(77) to qualify as an authorized nuclear pharmacist.

641—41.3(136C) Therapeutic use of radiation machines.

41.3(1) Scope and applicability.

a. This subrule establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines.

b. The use of therapeutic radiation machines shall be by, or under the supervision of, a physician who meets the training/experience criteria established by 41.3(4)*"c."*

c. Unless specifically required otherwise by 641—41.3(136C), all registrants are subject to the requirements of 641—Chapters 38 to 40.

41.3(2) Definitions. The following definitions are specific to 641—41.3(136C).

"Accessible surface" means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

"Added filtration" means any filtration which is in addition to the inherent filtration.

"Beam axis" means the axis of rotation of the beam–limiting device.

"Beam–limiting device" means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

"Beam–scattering foil" means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

"Bent beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

"Contact therapy system" means a therapeutic radiation machine with a short target–to–skin distance (TSD), usually less than 5 centimeters.

"Dose monitor unit (DMU)" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

"External beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"Field flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field.

"Filter" means material placed in the useful beam to change beam quality in therapeutic radiation machines subject to subrule 41.3(6).

"Gantry" means that part of a radiation therapy system supporting and allowing movements of the radiation head around a center of rotation.

"Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

"Isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

"Kilo electron volt (keV)" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1000 volts in a vacuum.

"Megavolt (MV) (mega electron volt (MeV))" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1 million volts in a vacuum. (Note: Current convention is to use MV for photons and MeV for electrons.)

"Monitor unit (MU)." See "Dose monitor unit."

"Moving beam radiation therapy" means radiation therapy with continuous displacement of one or more mechanical axes relative to the patient during irradiation. It includes arc therapy, skip therapy, conformal therapy and rotational therapy.

"Nominal treatment distance" means:

1. For electron irradiation, the distance from the scattering foil, or exit window, of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

2. For X–ray irradiation target to isocenter distance along the central axis of the useful beam. For nonisocentric equipment, this distance shall be that specified by the manufacturer.

"Periodic quality assurance check" means a procedure which is performed to ensure that a previous calibration continues to be valid.

"Practical range of electrons" corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung X–rays. A further explanation may be found in "Clinical Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25" (Medical Physics 18(1): 73–109, Jan/Feb 1991) and ICRU Report 35, "Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV," International Agency on Radiation Units and Measurements, September 15, 1984.

"Radiation detector" means a device which in the presence of radiation provides, by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

"Radiation field." See "Useful beam."

"Radiation head" means the structure from which the useful beam emerges.

"Radiation therapy physicist" means an individual qualified in accordance with 41.3(4) *"d."*

"Redundant beam monitoring system" means a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a preselected number of dose monitor units.

"Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.

"Stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

"Target" means that part of an X–ray tube or accelerator onto which is directed a beam of accelerated particles to produce ionizing radiation or other particles.

"Target–to–skin distance (TSD)" means the distance measured along the beam axis from the center of the front surface of the X–ray target or electron scattering foil to the surface of the irradiated object or patient.

"Tenth–value layer (TVL)" means the thickness of a specified material which attenuates X–radiation or

gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one–tenth of the value measured without the material at the same point.

"Therapeutic radiation machine" means X–ray or electron–producing equipment designed and used for external beam radiation therapy.

"Virtual source" means a point from which radiation appears to originate.

41.3(3) *Registration or license requirements*. No person shall receive, possess, use, transfer, own, or acquire therapeutic radiation machines except as authorized in a registration issued pursuant to 641—39.1(136C) to 39.4(136C).

41.3(4) *General administrative requirements for facilities using therapeutic radiation machines.*

a. Administrative controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines which have been registered with the agency. The registrant or the registrant's agent shall ensure that the requirements of 41.3(136C) are met in the operation of the therapeutic radiation machine(s).

b. A therapeutic radiation machine which does not meet the provisions of these regulations shall not be used for irradiation of patients unless authorized by the agency.

41.3(5) *Training for external beam radiation therapy authorized users*. The registrant for any therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall require the authorized user to be a physician who:

a. Is certified in:

(1) Radiology or therapeutic radiology by the American Board of Radiology; or

(2) Radiation oncology by the American Osteopathic Board of Radiology; or

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

b. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

c. To satisfy the requirement for instruction in 41.3(5)*"b"* above, the classroom and laboratory training shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of ionization radiation; and

(4) Radiation biology.

d. To satisfy the requirement for supervised work experience in 41.3(4)"b" above, training shall be under the supervision of an authorized user and shall include:

(1) Reviewing the full calibration measurements and periodic quality assurance checks;

(2) Evaluating prepared treatment plans and calculation of treatment times/patient treatment settings;

(3) Using administrative controls to prevent misadministrations;

(4) Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

(5) Checking and using radiation survey meters.

e. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

(1) Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;

(2) Selecting proper dose and how it is to be administered;

(3) Calculating the external beam radiation therapy doses and collaborating with the authorized user in the review of patients' progress; consideration of the need to modify originally prescribed doses or treatment plans as warranted by patients' reaction to radiation; and

(4) Postadministration follow–up and review of case histories.

f. Notwithstanding the requirements of 41.3(5)*"b,"* the registrant for any therapeutic radiation machine subject to 41.3(17) and 41.3(18) may also submit the training of the prospective authorized user physician for agency review.

41.3(6) *Training for radiation therapy physicist.* The registrant for any therapeutic radiation machine subject to 41.3(17) or (18) shall require the radiation therapy physicist to:

a. Be registered with the agency, under the provisions of 641—subrule 39.3(3) of these regulations, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and

b. Be certified by the American Board of Radiology in:

(1) Therapeutic radiological physics; or

(2) Roentgen–ray and gamma–ray physics; or

(3) X–ray and radium physics; or

(4) Radiological physics; or

c. Be certified by the American Board of Medical Physics in radiation oncology physics; or

d. Be certified by the Canadian College of Medical Physics; or

e. Hold a master's or doctorate degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full–time training in therapeutic radiological physics and also one year of full–time work experience under the supervision of a radiation therapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 41.3(16) *"a"* (1), 41.3(17) *"c,"* 41.3(17) *"c"*(5), 41.3(18) *"e,"* and 41.3(18) *"f"* under the supervision of a radiation therapy physicist during the year of work experience.

f. Notwithstanding the provisions of 41.3(6)"e," certification pursuant to 41.3(6)"b," 41.3(6)"c" or 41.3(6)"d" shall be required on or before December 31, 1999, for all persons currently qualifying as a radiation therapy physicist pursuant to 41.3(6)"e."

41.3(7) Qualifications of operators.

a.*Qualifications of operators.*

a. Individuals who will be operating a therapeutic radiation machine for medical use shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment in accordance with 641—Chapter 42 as applicable.

b. Each operator's permit to practice under 641—Chapter 42 shall be posted in the immediate vicinity of the general work area and visible to the public.

41.3(8) Written safety procedures and rules shall be developed by a radiation therapy physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine.

41.3(9) Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a physician. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non–healing arts purposes.

41.3(10) *Records of* visiting authorized users. *visiting authorized users.* Notwithstanding the provisions of 41.3(5), a registrant may permit any physician to act as a visiting authorized user under the following conditions:

a. The authorized user has the prior written permission of the registrant's management if the use occurs on behalf of an institution, and

b. The registrant maintains copies of all records specified in 41.3(5) for five years from the date of the last visit.

41.3(11) *Information and maintenance record and associated information.* The registrant shall maintain the following information for each therapeutic radiation machine for inspection by the agency:

a. Report of acceptance testing;

b. Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by 41.3(136C), as well as the name(s) of person(s) who performed such activities;

c. Records of maintenance or modifications, or both, performed on the therapeutic radiation machine after July 9, 1997, as well as the name(s) of person(s) who performed such services;

d. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

e. Records of training specified in 41.3(5) and 41.3(6).

41.3(12) *Records retention.* All records required by 641—41.3(136C) shall be retained until disposal is authorized by the agency unless another retention period is specifically authorized in 41.3(136C).

41.3(13) *Form of records*. Each record required by 41.3(136C) shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or microfilm, provided that the copy or microfilm is authenticated by authorized personnel and that the microfilm is capable of producing a clear copy throughout the required retention period, or the record may also be stored in

electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The registrant shall maintain adequate safeguards against tampering with and loss of records.

41.3(14) *Written directives* . Each registrant shall meet the following objectives:

a. That, prior to each administration, a written directive [1] is prepared for any therapeutic dose;

b. That prior to each initial administration of a treatment series, the patient's identity is verified as the individual named in the written directive;

c. That final plans of treatment and related calculations for the therapy are in accordance with the respective written objectives;

d. That each administration is in accordance with the written directive;

e. That any unintended deviation from the written directive is identified and evaluated, and appropriate action taken.

f. The registrant shall retain:

(1) Each written directive; and

(2) A record of each administered radiation dose, in an auditable form, for three years after the date of administration.

41.3(15) *Misadministration.*

a. When a misadministration involves any therapeutic procedure, the registrant shall notify the agency by telephone. The registrant shall also notify the referring physician of the affected patient and the patient or the responsible relative or guardian, unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or responsible relative or guardian would be medically harmful for the patient. These notifications must be made within 24 hours after the registrant discovers the misadministration. If the referring physician, patient, or patient's responsible relative or guardian cannot be reached within 24 hours, the registrant shall notify all of them as soon as practicable. The registrant is not required to notify the patient or patient's responsible relative or guardian without first consulting the referring physician; however, the registrant shall not delay medical care for the patient because of this.

b. Within 15 days after the initial therapy misadministration report to the agency, the registrant shall report, in writing, to the agency and referring physician, and furnish a copy of the report to the patient or

[1] If, because of the patient's condition, a delay in the order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

Also, a written directive revision to an existing written directive may be made for any therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of thedose.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

the patient's responsible relative or guardian if either was notified by the registrant as required by

41.3(15)*"a."* The written report shall include the registrant's name; the referring physician's name; a brief description of the event causing the misadministration; the effect on the patient; the action to prevent recurrence; and whether the registrant informed the patient or patient's responsible relative or guardian, and if not, why. The report shall not include the patient's name or other information that could

lead to the identification of the patient.

c. Each registrant shall retain records of misadministrations for ten years. The records shall include the names of all individuals involved in the event, including the physician, allied health personnel, the patient, patient's referring physician, the patient's social security number or identification number if assigned, a brief description of the event, the effect on the patient, and action taken, if any, to prevent recurrence.

41.3(16) General technical requirements for facilities using therapeutic radiation machines.

a. *General technical requirements for facilities using therapeutic radiation machines.*

a. Protection surveys.

(1) The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed, are performed with an operable radiation measurement survey instrument calibrated within the past 12 months. The radiation protection survey shall be performed by, or under the direction of, a radiation therapy physicist or a certified health physicist and shall verify that, with the therapeutic radiation machine in a "BEAM–ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:

1. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 641—subrule 40.15(1); and

2. Radiation levels in unrestricted areas do not exceed the limits specified in 641—paragraphs 40.26(1)*"a"* and *"b."*

(2) In addition to the requirements of 41.3(16) *"a"* (1), a radiation protection survey shall also be performed prior to medical use and:

1. After making any change in the treatment room shielding;

2. After installing or relocating of the therapeutic radiation machine;

3. Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

(3) The survey record shall indicate all instances where the facility, in the opinion of the radiation therapy physicist or a certified health physicist, is in violation of applicable regulations. The survey record shall also include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the therapeutic radiation machine, the instrument(s) used to measure radiation levels, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microsieverts or millirems per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the individual responsible for conducting the survey.

(4) If the results of the surveys required by 41.3(16)*"a"*(1) or (2) indicate any radiation levels in excess of the respective limit specified in 41.3(16)*"a"*(1), the registrant shall lock the control in the "OFF" position and not use the unit:

1. Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

2. Until the registrant has received a specific exemption in writing from the agency.

b. Modification of radiation therapy unit or room before beginning a treatment program. If the survey required by 41.3(16)*"a"* indicates that an individual in an unrestricted area may be exposed to levels of

radiation greater than those permitted by 641—paragraphs 40.26(1)*"a"* and *"b,"* before beginning the treatment program the registrant shall:

(1) Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 641—paragraphs 40.26(1)*"a"* and *"b"*;

(2) Perform the survey required by 41.3(16)*"a"* again; and

(3) Include in the report required by 41.3(16)*"d"* the results of the initial survey, a description of the modification made to comply with 41.3(5) *"b"* (1), and the results of the second survey; or

(4) Request and receive written authorization from the agency that authorizes radiation levels in unrestricted areas greater than those permitted by 641—paragraphs 40.26(1) *"a"* and *"b."*

c. *Dosimetry equipment.*

(1) The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration.

1. For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt–60.

2. For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured.

(2) The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 41.3(16)*"c"*(1). This comparison shall have been performed within the previous 12 months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in 41.3(16) *"c"* (1).

(3) The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license or registration. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 41.3(16)*"c"*(1) and (2), the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a radiation therapy physicist.

d. Reports of external beam radiation therapy surveys and measurements. The registrant for any therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall furnish a copy of the records required in 41.3(16)*"a"* and *"b"* to the agency within 30 days following completion of the action that initiated the record requirement.

41.3(17) *Therapeutic radiation machines of less than 500 kV.*

a. Equipment requirements.

(1) Leakage radiation. When the X–ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

1. 5–50 kV systems. The leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly shall not exceed 100 mrad (1 mGy) in any one hour.

2. >50 and <500 kV systems. The leakage air kerma rate measured at a distance of one meter from the target in any direction shall not exceed 1 rad (1 cGy) in any one hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly shall not exceed 30 rad (30 cGy) per hour.

(2) Permanent beam–limiting devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

(3) Adjustable or removable beam–limiting devices.

1. All adjustable or removable beam–limiting devices, diaphragms, cones or blocks shall not transmit more than 5 percent of the useful beam for the most penetrating beam used;

2. When adjustable beam–limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

(4) Filter system. The filter system shall be so designed that:

1. Filters cannot be accidentally displaced at any possible tube orientation;

2. For equipment installed after July 9, 1997, an interlock system prevents irradiation if the proper filter is not in place;

3. The air kerma rate escaping from the filter slot shall not exceed 1 rad (1 cGy) per hour at one meter under any operating conditions; and

4. Each filter shall be marked as to its material of construction and its thickness.

(5) Tube immobilization.

1. The X–ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and

2. The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

(6) Source marking. The tube housing assembly shall be so marked that it is possible to determine the location of the source to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.

(7) Beam block. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(8) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

1. A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time or time remaining indicator;

2. The timer shall be a cumulative timer which activates with an indication of "BEAM–ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a preselected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

4. The timer shall permit accurate presetting and determination of exposure times as short as one second;

5. The timer shall not permit an exposure if set at zero;

6. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

7. Timer shall be accurate to within 1 percent of the selected value or one second, whichever is greater.

(9) Control panel functions. The control panel, in addition to the displays required by other provisions in 41.3(6), shall have:

1. An indication of whether electrical power is available at the control panel and if activation of the X–ray tube is possible;

2. An indication of whether X–rays are being produced;

3. Means for indicating X–ray tube potential and current;

4. The means for terminating an exposure at any time;

5. A locking device which will prevent unauthorized use of the therapeutic radiation machine; and

6. For therapeutic radiation machines manufactured after July 9, 1997, a positive display of specific filter(s) in the beam.

(10) Multiple tubes. When a control panel may energize more than one X–ray tube:

1. It shall be possible to activate only one X–ray tube at any time;

2. There shall be an indication at the control panel identifying which X–ray tube is activated; and

3. There shall be an indication at the tube housing assembly when that tube is energized.

(11) Target–to–skin distance (TSD). There shall be a means of determining the central axis TSD to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

(12) Shutters. Unless it is possible to bring the X–ray output to the prescribed exposure parameters within five seconds after the X–ray "ON" switch is energized, the beam shall be attenuated by a shutter(s) having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter(s) shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

(13) Low filtration X–ray tubes. Each therapeutic radiation machine equipped with a beryllium or other low–filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

b. Facility design requirements for therapeutic radiation machines capable of operating in the range 50 kV to 500 kV. In addition to shielding adequate to meet requirements of 41.3(8), the treatment room shall meet the following design requirements:

(1) Aural communication. Provision shall be made for continuous two–way aural communication between the patient and the operator at the control panel.

(2) Viewing systems. Provision shall be made to permit continuous observation of the patient during

irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(3) Additional requirements. Treatment rooms which contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

1. All protective barriers shall be fixed except for entrance doors or beam interceptors;

2. The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;

3. Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

4. When any door referred to in 41.3(17)*"b"*(3)"3" is opened while the radiation machine is activated, the air kerma rate at a distance of one meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

c. Full calibration measurements.

(1) Full calibration of a therapeutic radiation machine subject to 41.3(17) shall be performed by, or under the direct supervision of, a radiation therapy physicist:

1. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;

2. At intervals not exceeding one year; and

3. Before medical use under the following conditions:

• Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled; and

• Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

4. Notwithstanding the requirements of 41.3(17)*"c"*(1):

• Full calibration of therapeutic radiation machines with multienergy capabilities is required only for those modes or energies that are not within their acceptable range; and

• If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in 41.3(17)*"b"*(3).

(2) To satisfy the requirement of 41.3(17) *"c"* (1), full calibration shall include all measurements recommended for annual calibration by NCRP Report 69, "Dosimetry of X–ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV" (1981).

(3) The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the X–ray tube, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the radiation therapy physicist responsible for performing the calibration.

d. Periodic quality assurance checks.

(1) Periodic quality assurance checks shall be performed on therapeutic radiation machines, subject to 41.3(17), which are capable of operation at greater than or equal to 50 kV.

(2) To satisfy the requirement of 41.3(17) *"d"*(1), quality assurance checks shall meet the following requirements:

1. The registrant shall perform quality assurance checks in accordance with written procedures established by the radiation therapy physicist; and

2. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in 41.3(17)*"c"*(1). The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in 41.3(17)*"c"*(1), shall be stated.

(3) The cause for a parameter exceeding a tolerance set by the radiation therapy physicist shall be investigated and corrected before the system is used for patient or human research subject irradiation;

(4) Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the radiation therapy physicist's quality assurance check procedures, the system shall be recalibrated as required in 41.3(17)*"c"*(1);

(5) The registrant shall use the dosimetry system described in 41.3(16) *"c"* (2) to make the quality assurance check required in 41.3(17)*"d"*;

(6) The registrant shall have the radiation therapy physicist review and sign the results of each radiation output quality assurance check within one month of test completion;

(7) The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to 41.3(17) are performed at intervals not to exceed one month;

(8) Notwithstanding the requirements of 41.3(17) *"d"* (6) and (7), the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by 41.3(17) *"d"* (6) and (7) have been performed within the 30 days prior to administration;

(9) To satisfy the requirement of 41.3(17) *"d"*(7), safety quality assurance checks shall ensure proper operation of:

1. Electrical interlocks at each external beam radiation therapy room entrance;

2. Proper operation of the "BEAM–ON" and termination switches;

3. Beam condition indicator lights on the access door(s), control console, and in the radiation therapy room;

4. Viewing systems;

5. If applicable, electrically operated treatment room doors from inside and outside the treatment room.

(10) The registrant shall maintain a record of each quality assurance check required by 41.3(17) *"d"*(1) and (7) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the

radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

e. Operating procedures.

(1) Therapeutic radiation machines shall not be left unattended unless secured by means identified in 41.3(17)*"a"*(9)"5";

(2) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

(3) The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

(4) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

(5) No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of 641—40.26(136C).

f. Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 41.3(17) shall have at its disposal appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μSv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable and calibrated at intervals not to exceed 12 months for the radiation measured.

41.3(18*)* Therapeutic radiation machines—photon therapy systems (500 kV and above) and electron therapy systems (500 keV and above).

a. ***Therapeutic radiation machines—photon therapy systems (500 kV and above) and electron therapy systems (500 keV and above).***

a. Equipment requirements.

(1) Leakage radiation outside the maximum useful beam in photon and electron modes.

1. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside themaximum–sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e., patient plane), shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;

2. Except for the area defined in 41.3(18) *"a"* (1)"1," the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters;

3. For equipment manufactured after July 9, 1997, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Agency (IEC) Document 601–2–1 (most current revision); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 41.3(18)"a"(1)"1" to "3" for the specified operating conditions. Records of leakage radiation measurements shall be maintained for inspection by the agency.

(2) Leakage radiation through beam–limiting devices.

1. Photon radiation. All adjustable or interchangeable beam–limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam–limiting device(s) shall not exceed 2 percent of the maximum absorbed dose on the central axis of the useful beam measured in a 10–centimeter by 10–centimeter radiation field;

2. Electron radiation. All adjustable or interchangeable electron applicators shall attenuate the radiation including, but not limited to, photon radiation generated by electrons incident on the beam–limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

• A maximum of 2 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and

• A maximum of 10 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.

(3) Measurement of leakage radiation.

1. Photon radiation. Measurements of leakage radiation through the beam–limiting devices shall be made with the beam–limiting devices closed and any residual aperture blocked by at least two–tenth value layers of suitable absorbing material. In the case of overlapping beam–limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector with an area not exceeding ten square centimeters;

2. Electron radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector with an area up to but not exceeding one square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one centimeter of water equivalent buildup material.

(4) Filters/wedges.

1. Each wedge filter which is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined;

2. If the absorbed dose rate information required by 41.3(18)"a"(8) relates exclusively to operation with a field–flattening or beam–scattering filter in place, such filter shall be removable only by the use of tools;

3. For equipment manufactured after July 9, 1997, which utilizes a system of wedge filters, interchangeable field–flattening filters, or interchangeable beam–scattering foils:

• Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has

been made at the treatment control panel, either manually or automatically;

• An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

• A display shall be provided at the treatment control panel showing the wedge filter(s); and

• An interlock shall be provided to prevent irradiation if any filter or beam–scattering foil selection operation carried out in the treatment room does not agree with the filter or beam–scattering foil selection operation carried out at the treatment control panel.

(5) Stray radiation in the useful beam. For equipment manufactured after July 9, 1997, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that X–ray stray radiation in the useful electron beam, absorbed dose at the surface during X–ray irradiation and stray neutron radiation in the useful X–ray beam are in compliance with International Electrotechnical Agency (IEC) Document 601–2–1 (most current revision).

(6) Beam monitors. All therapeutic radiation machines subject to 41.3(18) shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

1. Equipment manufactured after July 9, 1997, shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

2. Equipment manufactured on or before July 9, 1997, shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system. The detector and the system into which that detector is incorporated shall meet the following requirements:

• Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;

• Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;

• Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation; and

3. For equipment manufactured after July 9, 1997, the design of the beam monitoring systems shall ensure that the:

• Malfunctioning of one system shall not affect the correct functioning of the other system(s); and

• Failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation or prevent the initiation of radiation.

4. Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after July 9, 1997, each display shall:

• Maintain a reading until intentionally reset;

• Have only one scale and no electrical or mechanical scale multiplying factors;

• Utilize a design such that increasing dose is displayed by increasing numbers; and

• In the event of power failure, the beam monitoring information required in 41.3(18)*"a"*(6)"4" displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20–minute

period of time.

(7) Beam symmetry.

1. Bent–beam linear accelerators subject to 41.3(18) shall be provided with auxiliary device(s) to monitor beam symmetry;

2. The device(s) referenced in 41.3(18)*"a"*(7)"1" shall be able to detect field asymmetry greater than 10 percent, and shall be configured to terminate irradiation if the specifications in 41.3(18)*"a"*(7)"2" cannot be maintained.

(8) Selection and display of dose monitor units.

1. The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually;

2. After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

3. For equipment manufactured after July 9, 1997, after termination of irradiation, it shall be necessary for the operator to reset the preselected dose monitor units before irradiation can be initiated.

(9) Air kerma rate/absorbed dose rate. For equipment manufactured after July 9, 1997, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. (The radiation detectors specified in 41.3(18) *"a"* (6) may form part of this system.) In addition:

1. The dose monitor unit rate shall be displayed at the treatment control panel;

2. If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

3. If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 400 rad (4 Gy); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in 41.3(18)*"a"*(7)"2" and "3" for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the agency.

(10) Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy.

1. Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system;

2. If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

3. For equipment manufactured after July 9, 1997, an indicator on the control panel shall show which monitoring system has terminated irradiation.

(11) Termination switches. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

(12) Interruption switches. If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change of a preselected value is made during an interruption, irradiation and equipment movements shall be automatically terminated.

(13) Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a preset time interval.

1. A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator;

2. The timer shall be a cumulative timer which activates with an indication of "BEAM–ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

3. The timer shall terminate irradiation when a preselected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

(14) Selection of radiation type. Equipment capable of both X–ray therapy and electron therapy shall meet the following additional requirements:

1. Irradiation shall not be possible until a selection of radiation type (X–rays or electrons) has been made at the treatment control panel;

2. The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

3. An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type which has been selected;

4. An interlock system shall be provided to prevent irradiation with X–rays, except to obtain a verification image, when electron applicators are fitted;

5. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for X–ray therapy are fitted; and

6. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(15) Selection of energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

2. The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation; and

3. Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected

energy is in its proper location.

(16) Selection of stationary beam radiation therapy or moving beam radiation therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

1. Irradiation shall not be possible until a selection of stationary beam radiation therapy or rotational arc radiation therapy has been made at the treatment control panel;

2. The mode of operation shall be displayed at the treatment control panel;

3. An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected;

4. An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

5. Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after July 9, 1997:

• An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees of rotation differs by more than 20 percent from the selected value;

• Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than 5 percent from the dose monitor unit value selected;

• An interlock shall be provided to prevent motion of more than five degrees beyond the selected limits during moving beam radiation therapy;

• An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counterclockwise moving beam radiation therapy.

• Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

6. Where the beam monitoring system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by 41.3(18)*"a"*(10); and

7. For equipment manufactured after July 9, 1997, an interlock system shall be provided to terminate irradiation if movement:

• Occurs during stationary beam radiation therapy; or

• Does not start or stops during moving beam radiation therapy unless such stoppage is a preplanned function.

b. Facility design requirements for therapeutic radiation machines operating above 500 kV. In addition to shielding adequate to meet requirements of 41.3(19), the following design requirements are made:

(1) Protective barriers. All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors.

(2) Control panel. In addition to other requirements specified in 41.3(136C), the control panel shall also:

1. Be located outside the treatment room;

2. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

3. Provide an indication of whether radiation is being produced; and

4. Include an access control (locking) device which will prevent unauthorized use of the therapeutic radiation machine.

(3) Viewing systems. Windows, mirrors, closed–circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

(4) Aural communications. Provision shall be made for continuous two–way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two–way aural communication is possible.

(5) Room entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF".

(6) Entrance interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel.

(7) Beam interceptor interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 641—paragraphs 40.26(1)*"a"* and *"b,"* interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s).

(8) Emergency cutoff switches. At least one emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by 41.3(18)*"a"*(11). All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch.

(9) Safety interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine.

(10) Surveys for residual radiation. Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photoneutron production.

(11) Possession of survey instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with 41.3(18) shall have at its disposal appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μSv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable and calibrated at intervals not to exceed 12 months for the radiation measured.

c. Radiation therapy physicist support.

(1) The services of a radiation therapy physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The radiation therapy physicist shall be responsible for:

1. Full calibration(s) required by 41.3(18) *"e"* and protection surveys required by 41.3(16) *"a"*;

2. Supervision and review of dosimetry;

3. Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

4. Quality assurance, including quality assurance check review required by 41.3(18) *"f"*(5) of these regulations;

5. Consultation with the authorized user in treatment planning, as needed; and

6. Performing calculations/assessments regarding misadministrations.

(2) If the radiation therapy physicist is not a full–time employee of the registrant, the operating procedures required by 41.3(18)*"d"* shall also specifically address how the radiation therapy physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the radiation therapy physicist can be contacted.

d. Operating procedures.

(1) No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

(2) Therapeutic radiation machines shall not be made available for medical use unless the requirements of 41.3(16)*"a,"* 41.3(18)*"e,"* and 41.3(18)*"f"* have been met;

(3) Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

(4) When adjustable beam–limiting devices are used, the position and shape of the radiation field shall be indicated by a light field;

(5) If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and

(6) A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

e. Full calibration measurements.

(1) Full calibration of a therapeutic radiation machine subject to 41.3(18) shall be performed by, or under the direct supervision of, a radiation therapy physicist:

1. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;

2. At intervals not to exceed 12 months; and

3. Before medical use under the following conditions:

• Whenever quality assurance check measurements indicate that the radiation output differs by more than 5 percent from the value obtained at the last full calibration and the difference cannot be reconciled; and

• Following any component replacement, major repair, or modification of components that could

significantly affect the characteristics of the radiation beam.

4. Notwithstanding the requirements of 41.3(18)*"e"*(1)"3":

• Full calibration of therapeutic radiation machines with multienergy or multimode capabilities is required only for those modes or energies that are not within their acceptable range; and

• If the repair, replacement or modification does not affect all modes or energies, full calibration shall be performed on the effected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in 41.3(18)*"e"*(1)"3."

(2) To satisfy the requirement of 41.3(18)*"e"*(1), full calibration shall include all measurements required for annual calibration by Appendix D of 641—Chapter 41.

(3) The registrant shall use the dosimetry system described in 41.3(16) *"c"* to measure the radiation output for one set of exposure conditions. The remaining radiation measurements required in 41.3(18) *"e"*(2) may then be made using a dosimetry system that indicates relative dose rates; and

(4) The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine, and the signature of the radiation therapy physicist responsible for performing the calibration.

f. Periodic quality assurance checks.

(1) Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to 41.3(18) at intervals not to exceed one week;

(2) To satisfy the requirement of 41.3(18)*"f"*(1), quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in Appendix D of 641—Chapter 41. Representative sampling shall include all referenced periodic quality assurance checks at intervals not to exceed 12 consecutive calendar months;

(3) The registrant shall use a dosimetry system which has been compared within the previous 12 months with the dosimetry system described in 41.3(16) *"c"*(1) to make the periodic quality assurance checks required in 41.3(18)*"f"*(2);

(4) The registrant shall perform periodic quality assurance checks required by 41.3(18) *"f"* (1) in accordance with procedures established by the radiation therapy physicist;

(5) The registrant shall review the results of each periodic radiation output check according to the following procedures:

1. The authorized user and radiation therapy physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the radiation therapy physicist has determined that all parameters are within their acceptable tolerances;

2. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or radiation therapy physicist within two weeks of treatment; and

3. The radiation therapy physicist shall review and sign the results of each radiation output quality assurance check within two weeks of completion.

(6) Therapeutic radiation machines subject to 41.3(18) shall have safety quality assurance checks of each external beam radiation therapy machine performed at intervals not to exceed one week;

(7) To satisfy the requirement of 41.3(18)*"f"*(6), safety quality assurance checks shall ensure proper operation of:

1. Electrical interlocks at each external beam radiation therapy room entrance;

2. Proper operation of the "BEAM–ON," interrupt and termination switches;

3. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

4. Viewing systems;

5. Aural systems;

6. Electrically operated treatment room door(s) from inside and outside the treatment room;

(8) Emergency power cutoff switches shall be checked for proper operation at intervals not to exceed three months. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine;

(9) The registrant shall promptly repair any system identified in 41.3(18)*"f"*(7) that is not operating properly; and

(10) The registrant shall maintain a record of each quality assurance check required by 41.3(18)*"f"*(1) and 41.3(18)*"f"*(7) for three years. The record shall include the date of the quality assurance check, the manufacturer's name, model number, and serial number for the therapeutic radiation machine, the manufacturer's name, model number and serial number of the instrument(s) used to measure the radiation output of the therapeutic radiation machine, and the signature of the individual who performed the periodic quality assurance check.

41.3(19) *Shielding and safety design requirements.*

a. Each therapeutic radiation machine subject to 41.3(17) or 41.3(18) shall be provided with such primary or secondary barriers as are necessary to ensure compliance with 641—40.15(136C) and 641—40.26(136C).

b. Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for agency approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in Appendix E of 641—Chapter 41.

641—41.4(136C) Radiation safety requirements for analytical X–ray equipment. Rescinded IAB 4/8/98, effective 7/1/98.

641—41.5(136C) Radiation safety requirements for wireline service operations and subsurface tracer studies. Rescinded IAB 4/8/98, effective 7/1/98.

641—41.6(136C) X–ray machines used for screening and diagnostic mammography.

41.6(1) *Definitions.* In addition to the definitions provided in 41.1(136C), the following definitions shall be applicable to this rule.

"Artifact" means a substance or structure not naturally present in living tissue but of which an authentic image appears in a radiograph.

"Automatic exposure control systems" means automatic exposure control systems, often referred to as phototimers, which are designed to automatically determine and provide the exposure needed to produce an adequate density image by sampling the X–ray intensity after passage through the patient and image receptor.

"Average glandular dose" means the energy deposited per unit mass of glandular tissue averaged over all the glandular tissue in the breast, calculated from values of entrance exposure in air, the X–ray beam quality (half–value layer), and compressed breast thickness. The maximum average glandular dose should be 6 milliGray (0.6 rad) or less for a 2–view examination of the breast. See also: "Dose."

"Base density" means the optical density due to the supporting base of the film alone. The base density of a film is the optical density that would result if an unexposed film were processed through the fixer, wash, and dryer, without first passing through the developer.

"Base plus fog density" means the optical density of a film due to its base density plus any action of the developer on the unexposed silver halide crystals. The base plus fog density can be measured by processing an unexposed film through the entire processing cycle and measuring the resultant optical density.

"Cassette" means a light–tight case, usually made of thin, low X–ray absorption plastic, for holding X–ray film. One or two intensifying screens for the conversion of X–rays to visible light photons are mounted inside the cassette so that they are in close contact to the film.

"Compression device" means a firm plastic paddle used to help hold the breast stationary and eliminate blurring due to motion, to help separate structures within the breast, and to decrease the thickness of breast tissue, minimizing the amount of radiation used and the amount of scattered radiation reaching the film.

"Control chart" means a chart used to record (and control) the results of quality control testing as a function of time.

"Control limit" means the range of variation on a control chart beyond which action must be taken to correct the results of quality control testing.

"Craniocaudal view" means one of two routine views for mammography. The detector system is placed caudad to (below) the breast and the vertical X–ray beam is directed from cranial to caudad (downward) through the breast.

"Dedicated mammography equipment" means X–ray systems designed specifically for breast imaging, providing optimum imaging geometry, a device for breast compression and low dose exposure that can generate reproducible images of high quality.

"Densitometer" means an instrument which measures the degree of blackening (or radiographic density) of film due to radiation or light by measuring the ratio of the light intensity incident on the film to the light intensity transmitted by the film.

"Detents" means mechanical settings that limit or prevent the motion or rotation of an X–ray tube, cassette assembly, or image receptor system.

"Developer" means a chemical solution (alkaline) that changes the latent image (exposed silver halide crystals) on a film to a visible image composed of minute masses of black metallic silver.

"Developer replenishment" means the process, occurring as film travels past a certain point in the

processor, triggering the activation of a pump, whereby fresh developer is added in small amounts to the solution in the developer tank of the processor. The purpose is to maintain the proper alkalinity, chemical activity, and level of solution in the developer tank.

"Diagnostic mammography" means mammography performed on an individual who, by virtue of symptoms or physical findings, is considered to have a substantial likelihood of having breast disease.

"Dose" means the amount of energy deposited per unit mass of tissue due to X–radiation. The newer unit of absorbed dose is the Gray: 1 Gray=1 Joule of energy deposited per kilogram of tissue. The older unit of absorbed dose is the rad: 1 rad=0.01 Gray, 1 centiGray, or 10 milliGray.

"Exposure" means the amount of X–radiation, quantitated by measuring the amount of ionization in air caused by the radiation. The units of exposure are Coulombs of charge ionized per kilogram of air. The older unit of exposure is the Roentgen: 1 Roentgen=2.58 × 10E–4 Coulombs of charge per kilogram of air.

"Fixer" means a chemical solution (acidic) which removes the unexposed and undeveloped silver halide crystals from film so it will not discolor or darken with age or exposure to light. Fixer also hardens the gelatin containing the black metallic silver so film may be dried and resist damage from abrasions.

"Fixer retention" means the inadequate removal of fixer from the film by the water in the wash tank of the processor. Retained fixer causes eventual brown discoloration of the radiograph.

"Focal spot size" means the focal spot is the area of the target or anode that is bombarded by electrons from the cathode of the X–ray tube to produce X–rays. The smaller the focal spot, the better the limited spatial resolution of the X–ray system, especially in magnification mammography.

"Fog" means the density added to a radiograph due to unwanted action of the developer on the unexposed silver halide crystals or by light, radiation, or heat exposure during storage, handling, and processing.

"Grids" means a set of thin lead strips spaced close to one another, interspaced by carbon fiber for mammographic grids. The grid is placed between the breast and the screen–film image receptor to reduce scattered radiation reaching the image receptor.

"Half–value layer (HVL)" means the thickness of a specified substance which, when introduced into the path of a given beam of radiation, reduces the exposure rate by one–half. HVL is a measure of beam quality and is usually specified in millimeters of aluminum for diagnostic units.

"Image contrast" means the amount of radiographic density difference between adjacent areas resulting from a fixed amount of attenuation difference or light exposure difference.

"Image noise." See "Radiographic noise."

"Image quality" means the overall clarity and detail of a radiographic image. Limiting spatial resolution (or resolving power), image sharpness, and image contrast are three common measures of image quality.

"Image sharpness" means the overall impression of detail and clarity in a radiographic image.

"Kilovoltage, peak (kVp)" means the maximum potential difference setting between anode and cathode in an X–ray tube. This setting is also the maximum energy of X–rays emitted by the X–ray tube in kilo–electron volts (keV).

"Mediolateral view" means one of the routine views for mammography in addition to the craniocaudal view. The detector system is placed lateral to the breast and the horizontal X–ray beam is directed from medial to lateral aspect through the breast.

"Milliampere (mA) setting" means the current of electrons passing from cathode to anode in an X–ray tube. For a fixed kVp, the output of X–rays per unit time from the tube is linearly proportional to the mA setting.

"Milliampere–seconds (mAs)" means the product of electron current (mA) and the time over which an X–ray exposure is made (in seconds). For a fixed kVp, total X–ray output is linearly proportional to mAs.

"Oblique mediolateral view" means one of the standard two views of the breast. The detector system (cassette holder assembly) is angled 30–60 degrees from horizontal so that the cassette assembly is parallel to the pectoral muscle and the corner of the cassette holder fits comfortably into the axilla. The X–ray beam is directed from the supero–medial to the infero–lateral aspect of the breast.

"Phantom" means an artificial test object which simulates the average composition of and various structures within the breast. A "good breast phantom" should have an established correlation with clinical image quality, allowing objective rather than subjective analysis, and should be sensitive to small changes in mammographic image quality.

"Physician consultant" means a licensed doctor of medicine or osteopathy who meets the requirements for the interpreting physician as specified in 41.6(3)*"b"* and who is responsible for the operation of the mammography program. This individual is designated by the supplier.

"Processor" means an automated device which transports film in a controlled manner by a system of rollers through specialized sections where developing, fixing, washing, and drying of the film occur.

"Quality assurance" means the overall program of testing and maintaining the highest possible standards of quality in the acquisition and interpretation of radiographic images.

"Quality control" means the actual process of testing and maintaining the highest possible standards of quality in equipment performance and the acquisition and interpretation of radiographic images.

"Quality control technologist" means the technologist assigned the task of testing for and maintaining records of radiographic image quality.

"Radiographic contrast" means the magnitude of optical density difference between structures of interest and their surroundings, or between areas of film receiving different amounts of X–ray or visible light exposure.

"Radiographic noise" means unwanted fluctuations in optical density on the screen–film image.

"Radiographic sharpness" means the distinctness or perceptibility of the boundary or edge of the structure in a mammogram.

"Repeat (or reject) analysis" means a systematic approach to determine the causes for radiographs being discarded or repeated, or both.

"Replenishment rate" means the amount of chemicals added in order to maintain the proper chemical activity of developer and fixer solutions.

"Safelight" means a source of minimal visible light in a darkroom, produced at frequencies (colors) to which the film is insensitive, protecting the film from unwanted exposure (fog) while allowing personnel to function more efficiently and safely.

"Screen" means microscopic phosphor crystals on a plastic support and used in conjunction with either single or double emulsion film; the screen emits visible light when exposed to X–radiation, creating a latent image on X–ray film.

"Screen–film combination" means a particular intensifying screen used with a particular type of film. Care must be taken to match the number of screens (one or two) to the number of emulsions coating the film and to match the light output spectrum of the screen to the light sensitivity of the film.

"Screen–film contact" means the close proximity of the intensifying screen to the emulsion of the film, necessary in order to achieve a sharp image on the film.

"Screen–film mammography" means mammography performed with high–detailed intensifying screen(s) in close contact with the film.

"Screening mammography" means X–ray breast examination of asymptomatic individuals in an attempt to detect breast cancer when it is small, nonpalpable, and confined to the breast.

"Sensitometer" means a device used to reproducibly expose a piece of film to a number of different levels of light intensity.

"Sensitometric strip" means a sheet of film exposed by a sensitometer, resulting in a gray scale range. Such strips are used to measure the range of densities, from minimum to maximum, resulting from a reproducible set of exposures.

"Sensitometry" means a quantitative measurement of the response of film to exposure and development. Sensitometry is used to test the processor setup and stability.

"Supplier" means the individual in control of a mammography facility whose basic responsibility is the overall quality of all mammograms conducted in that particular facility.

"Thermoluminescent dosimeter (TLD)" means a radiation dose measurement device using a crystalline substance (chips or powder) that, when properly prepared (annealed) and exposed to radiation, emits light in proportion to the radiation dose received.

"Viewbox" means a device by which a uniform field of white light is transmitted through an X–ray so that the image on the film may be seen.

"Written report" means interpreting physician's technical narrative of a mammography evaluation.

"Written statement" means interpreting physician's description of a mammography examination written in lay terms.

41.6(2) Registration and application standards and requirements.

a. *Registration and application standards and requirements.*

a. Each radiation machine used to perform mammography shall be registered according to 641—subrule 39.3(2).

b. Each facility wishing to perform mammography shall apply for agency authorization by providing or verifying the following information for each mammography machine:

(1) The mammography unit meets the criteria for the American College of Radiology (ACR) mammography accreditation. An evaluation report issued by the American College of Radiology meets this requirement.

(2) The mammography equipment and facility meet the general requirements of these rules for radiation machines.

(3) The radiation machine is specifically designed to perform mammography.

(4) The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

(5) The radiation machine is operated by individuals meeting the requirements of this subrule.

(6) The entire mammography system is evaluated annually by a radiation physicist.

(7) The equipment, personnel, procedures, and records are evaluated annually by a physician consultant.

c. Withdrawal or denial of mammography authorization.

(1) Mammography authorization may be withdrawn with cause if any machine does not meet one or more of the standards of these rules.

(2) The facility shall have opportunity for a hearing in connection with a denial or withdrawal of mammography authorization.

(3) An emergency order withdrawing authorization may be issued if the agency finds the radiation unit or facility violates rules that seriously affect the health, safety, and welfare of the public. An opportunity for hearing shall be held within five working days after the issuance of the order. The order shall be effective during the proceedings.

(4) If authorization is withdrawn, the radiation machine shall not be used for mammography until reinstated.

d. Reinstatement of mammography authorization.

(1) An application for reinstatement shall be submitted and processed the same as an initial application.

(2) The agency shall inspect the radiation machine within 60 days of the approved reinstatement application.

(3) A certificate of reinstatement shall be issued only after the agency has inspected the radiation machine and determined that it meets the requirements of these rules.

e. Inspections. The agency shall conduct an inspection of each radiation machine no later than 60 days after initial mammography authorization and at least annually thereafter.

f. Determination of the quality of the mammograms produced by facilities. To make the determination each facility will:

(1) Provide at the time of initial registration and at renewal (at least every three years) thereafter, two original (not copies) mammography examinations which meet the following criteria:

1. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with fatty breasts,

2. One mammography examination, including craniocaudal and mediolateral oblique views of each breast, of a patient with at least 75 percent glandular tissue, and

3. Each mammography examination must have been interpreted as a "normal" examination.

(2) Provide randomly (at least every three years), at the request of agency mammography inspectors, two mammography examinations (mammograms) which meet the criteria in 41.6(2) *"f"* (1).

(3) Have the film returned by the agency for inclusion in the patient's file after quality interpretation by agency radiologists.

(4) Be billed the fee for the quality interpretation as set forth in 641—38.8(1) *"b"* (2).

(5) Be provided with a written explanation of the results of the quality evaluation which will accompany the returned mammograms referred to in 41.6(2)*"f"*(3).

g. Federal mammography regulations. All Iowa facilities performing mammography shall comply with the applicable regulations found in 21 CFR Parts 16 and 900 which have an effective date of April 28, 1999. Persons authorized to perform mammography in Iowa shall be responsible for ensuring compliance with the appropriate CFR regulations or Iowa administrative rules, whichever are more stringent.

41.6(3) *Mammography personnel.*

a. Physician consultant.

(1) Must be available either on staff or through arrangement.

(2) Must document in writing annually completion of:

1. Review of the procedural manuals to determine that they are adequate.

2. Verification that equipment and personnel meet applicable state requirements and are performing properly.

3. Verification that the safety procedures are being followed.

4. Verification that all other requirements of these rules are being met.

b. Interpreting physician. All mammograms must be interpreted by a radiologist who meets the following certification, experience, continuing education, and written report requirements:

(1) Be certified by the American Board of Radiology, the American Osteopathic Board of Radiology, or Royal College of Physicians and Surgeons of Canada in Radiology or have had at least two months of documented full–time training from a person recognized by this agency. The training must include interpretation of mammograms, including instructions in radiation physics, radiation effects and radiation protection.

(2) Has interpreted an average of ten or more mammograms per workweek in the prior six months or has completed a radiology residency within the past two years.

(3) Has successfully completed or taught a minimum of 40 hours (includes radiology residency) of postgraduate instruction in mammography interpretation.

(4) Has successfully completed or taught a minimum of 15 hours of postgraduate instruction in mammography interpretation every 36 months thereafter.

(5) Continues to interpret an average of ten or more mammograms per workweek.

(6) Signs a written report, as defined in 41.6(1), a copy of which must be sent to the referring physician or, if a referring physician is not available, directly to the patient.

(7) Provides a copy of the written report and the original images or films to the patient's mammography supplier for inclusion in the patient's medical record.

(8) Provides a written statement to the patient, either through a referring physician or designee or, if a referring physician is not available, directly to the patient. The statement must:

1. Be written in terms easily understood by a lay person.

2. Describe the test results and the importance of the mammogram to the patient's health (including, if the results are positive, a description of the next steps), as well as the patient's responsibility to share with any new physician or supplier of the next mammogram, the date and place of the previous mammogram.

3. Record the date of the procedure, name of the facility, and the name of the physician, if any, to whom the patient wants a copy to be sent.

4. Indicate that the original images of films are being provided to the mammographic supplier, for inclusion in the patient's medical record.

c. Mammography imaging medical physicist. All mammography imaging medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program under the federal "Mammography Quality Standards Act of 1992" (MQSA) shall meet the requirements for initial qualifications as well as the requirements for continuing qualifications.

(1) Initial qualifications. All mammography imaging medical physicists shall be state–approved or be certified by the American Board of Radiology in Radiological Physics/Diagnostic Radiological Physics, the American Board of Medical Physics in Diagnostic Imaging Physics, or the Canadian College of Physicists in Medicine as a Fellow in Diagnostic Radiological Physics or any other body approved by FDA to certify medical physicists; and

1. Have a master's or higher degree in a science from a college or university accredited by one of the regional accreditation bodies of the Commission on Higher Education with not less than 30 semester hours or equivalent of college level physics or radiation science, have two years of experience in conducting performance evaluations of mammography facilities and 20 hours of documented specialized training in conducting performance evaluations of mammography facilities. Complete surveys of five mammography units shall be equal to one year of experience. Two or more years of training while pursuing a master's or higher degree in medical physics may be accepted in lieu of one year of experience. After April 28, 1999, the experience shall be acquired under the direct supervision of amammography imaging medical physicist who meets the requirements in 41.6(3) *"c"* (1) and 41.6(3)*"c"*(2).

2. Prior to October 27, 1997, have a bachelor's degree in a physical science from a college or university accredited by one of the regional accreditation bodies of the Commission on Higher Education with not less than 15 semester hours or equivalent college level physics or radiation sciences and five years of experience in conducting performance evaluations of mammography facilities. The individual shall have surveyed at least five mammography units in each of the five years and have at least 40 hours of documented specialized training in conducting performance evaluations of mammography facilities to comply with the requirements of MQSA.

(2) Continuing qualifications.

1. Continuing education. After the third anniversary of completion of the requirements of 41.6(3)*"c"*(1), the individual shall have taught or completed at least 15 continuing education units in mammographic imaging over the three previous years. This shall include training, if available, appropriate to each mammographic modality evaluated by the mammography imaging medical physicist during the surveys or oversights of quality assurance programs for which the medical physicist is responsible.

2. Continuing experience. After the first anniversary of completion of the requirements of 41.6(3)*"c"*(1), and each year thereafter, the individual shall have surveyed at least three mammography units within the last 12 months. This requirement does not apply to an individual who is employed full–time at a single facility as a diagnostic medical physicist.

(3) All facility survey reports must be signed by a mammography imaging medical physicist who meets the qualification requirements of 41.6(3)*"c"*(1).

(4) A mammography imaging medical physicist who signs a facility survey report must have been present in that facility during the survey.

(5) Mammography imaging medical physicists who fail to maintain the required continuing qualifications stated in 41.6(3)*"c"*(2) shall reestablish their qualifications before independently surveying another facility. To reestablish their qualifications, mammography imaging medical physicists who fail to meet the continuing education requirement of 41.6(3) *"c"*(2) must obtain a sufficient number of continuing education units to bring their total up to the required 15 in the previous three years. Mammography imaging medical physicists who fail to meet the continuing experience requirement of 41.6(3)*"c"*(1) must obtain experience by surveying one mammography unit for each year of not meeting the continuing experience requirements under the supervision of a mammography imaging medical physicist who meets the qualifications stated in 41.6(3)*"c"*(1) and 41.6(3)*"c"*(2). After five years of not meeting the continuing experience requirements, the mammography imaging medical physicist must requalify under 41.6(3)*"c"*(1).

d. Equipment operators. Any individual operating mammography equipment must be a physician as defined in 641—Chapter 38 or must be credentialed as a general radiographer as set forth in 641—Chapter 42.

(1) Each general radiographer must meet one of the following:

1. Have successfully completed a formal training program in radiologic technology in a school that meets the requirements of Appendix A (Standards for Accreditation of Educational Programs for Radiographers) of 42 CFR Part 75; or

2. Have successfully completed a formal training program in radiologic technology that is approved by the Council on Allied Health Education and Accreditation; or

3. Have had at least five years' experience in performing radiologic procedures and at least one year's experience in performing mammography before October 1, 1992.

(2) Each general radiographer must have completed successfully 40 hours of specialized training, approved by the agency, to include a minimum of one hour of hands–on mammographic positioning, quality control, technique factor settings and other areas pertinent to mammography prior to the time the individual begins performing mammography and an average of five hours of specialized training every 12 months thereafter to be averaged over no more than a 36–month period.

Training programs shall be submitted to the agency for approval and shall include demonstrations and practical evaluation by the instructor of the student's performance and documentation describing training, date and length of training, and evaluation of student's performance to be signed and dated by the instructor, and the business address of the supplier of the training.

e. Personnel orientation. The supplier of mammography services must have an orientation program for operators of mammography equipment based on a procedures manual that is available to all staff members and that incorporates relevant documents and instructions concerning the following:

(1) Precautions to protect the operator of the equipment, the patient and individuals in the surrounding area from unnecessary exposure to radiation.

(2) Determination of the area that will receive the primary beam (breast positioning).

(3) Pertinent information on compression, exposure levels, resolution, contrast, noise, examination identification, artifacts, and average glandular dose per view.

(4) Employee responsibilities concerning the proper use of personal radiation monitors.

(5) Proper use and maintenance of equipment, including a discussion of the image receptors appropriate for use with mammography and the kV–target–filter combination to be used with each image receptor.

(6) Proper maintenance of records.

(7) Possible technical problems and solutions.

(8) Protection against electrical hazards.

(9) Hazards of excessive exposures to radiation.

(10) Quality control procedures and those individuals responsible for performing them.

f. Personnel records. Records must be maintained to indicate that each employee is qualified for a specific position by means of appropriate state or other certification, license, training, and experience.

41.6(4) *Obtaining and preserving records.*

a. The supplier of the current mammography examination must make all reasonable efforts to obtain the patient's recent mammography records, including original images or films, copies of written reports prepared by interpreting physicians, and other relevant information pertinent to previous mammograms that might be available from others, for comparison with the current mammography records.

b. The supplier must make, for each patient, a record of the mammography services it provides, including:

(1) The date the mammography procedure was performed and the date of the interpretation.

(2) The name of the patient.

(3) The name of the operator of the equipment and the interpreting physician.

(4) A description of the procedures performed.

(5) The name of the referring physician (if any) or other physician (if any) identified by the patient to receive the interpreting physician's written report.

(6) The date the interpreting physician's written report was sent to the appropriate physician or patient.

c. Preservation of records.

(1) The supplier must provide satisfactory assurances (as documented in its medical records) that the images or films of the first and subsequent mammography procedures and the related written reports of the interpreting physician for each patient are either placed in the patient's medical record kept by the supplier or sent for placement in the patient's medical record as directed by the patient's physician or the patient.

(2) Records retained by the supplier must be retained for at least 60 calendar months following the date of service or not less than ten years, if no additional mammograms of the patient are performed.

(3) If the supplier should cease to exist before the end of the 60–month period, the records must be transferred to the patient or patient's physician.

41.6(5) *Quality assurance program.*

a. The supplier shall ensure that the facility has an equipment quality assurance program specific to mammography and covering all components of the system, to ensure consistently high–quality images with minimum patient exposure.

b. The supplier shall ensure that a general review of the program is conducted at least annually and have available the services of a qualified radiation physicist who is capable of establishing and conducting the program.

c. Under the direction of the physician consultant, the radiation physicist shall have responsibility for establishing and conducting the equipment quality assurance program. The program shall include:

(1) Conducting or training others to conduct equipment performance monitoring functions.

(2) Analyzing the monitoring results to determine if there are any problems requiring correction.

(3) Ensuring that the facility has procedures in place for carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventive maintenance.

d . Calibration of equipment. All variable parameters of the equipment shall be calibrated:

(1) When the equipment is first installed.

(2) After any major changes or replacement of parts.

(3) At least annually during use based on recommendations of the mammography imaging medical physicist.

(4) When quality assurance tests indicate that calibration is needed.

e. Performance monitoring. The supplier shall routinely ensure that the performance of the mammography system is monitored. The parameters to be monitored shall include but not be limited to:

(1) Processor performance (through daily sensitometric–densitometric means).

(2) Half–value layer.

(3) Output reproducibility and linearity.

(4) Automatic exposure control reproducibility and linearity.

(5) Adequacy of film storage (both before use and after exposure if processing does not occur immediately).

(6) Availability and use of technique charts that shall include an indication of the kV–target–filter combination to be used with each image receptor.

(7) Darkroom integrity, to be performed at least semiannually or when conditions have changed, shall include an inspection for light leaks, a fog test, and a safe light test.

(8) Image quality. The minimum image quality achieved at a mammographic facility shall be the ability to observe the image of four 0.75–mm fibriles, three 0.32–mm specks, and three 0.75–mm masses from an ACR–approved phantom (or equivalent) on the standard mammographic film used at the facility. No mammograms shall be performed if this minimum is not met.

f. Frequency of monitoring.

(1) Processor performance shall be accomplished daily before processing patient films.

(2) Image quality shall be monitored at least monthly with a phantom and every time the unit is altered including the replacement of parts.

(3) All other parameters shall be proportional to the expected variability of each parameter, but at least annually.

g. Evaluation of monitoring results.

(1) Standards of image quality giving acceptable ranges of values for each of the parameters tested shall be established to aid in the evaluation. The standards of image quality related to dose shall include a requirement that the mean glandular dose for one craniocaudal view of a 4.5 cm compressed breast (50 percent adipose/50 percent glandular) or equivalent phantom shall not exceed 100 mrad (millirad) for film/screen units with no grids, or 300 mrad for film/screen units with grids.

(2) The monitoring results shall be compared routinely to the standards of image quality in Appendix I. If the results fall outside the acceptable range, the test shall be repeated. If the results continue to be unacceptable, the source of the problem shall be identified and corrected before further examinations are conducted.

h. Retake analysis program.

(1) A program shall be established as a further aid in detecting and correcting problems affecting image quality or exposure.

(2) All retakes shall be logged including date, technologist's name and reason for retake. A retake analysis shall be performed every 250 patients or quarterly, whichever comes first.

i. Medical outcomes audit. Each facility shall establish a system for reviewing outcome data from all mammography performed, including follow–up on the disposition of positive mammograms and correlation of surgical biopsy results with mammogram reports.

j. Responsibility for each requirement for monitoring shall be assigned to qualified personnel and documented in the supplier's records.

41.6(6) *Equipment standards.* The equipment used to perform mammography shall meet the following standards:

a. Be specifically designed for mammography.

b. Meet the Food and Drug Administration (FDA) performance standards for diagnostic X–ray systems and their major components found in 21 CFR 1020.30 and FDA standards for radiographic equipment in 21 CFR 1020.31.

c. Have image receptor systems and individual components which are appropriate for mammography and used according to the manufacturer's recommendations.

d. Have beam limitation which limits the useful beam so that the X–ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated source to image receptor distance (SID). However, the X–ray field may extend beyond the edge of the image receptor which is adjacent to the chest wall provided it does not extend beyond this edge by more than 2 percent of the SID.

e. Check film/screen contact when cassettes are first placed into use and semiannually thereafter.

f. Have limits to provide kV–target–filter combinations appropriate for the image receptors which have met the requirements of 41.6(6)*"c."*

g. The focal spot size, magnification factor and source to image receptor distance (SID) are appropriate for mammography and in the ranges shown below:

SID	Nominal Focal Spot Size
>65 cm	< or = to 0.6 mm
50 to 65 cm	< or = to 0.5 mm
< or = to 50 cm	< or = to 0.4 mm

h. Devices parallel to the imaging plane shall be available to immobilize and compress the breast with a force of at least 25 pounds per square inch and shall be capable of maintaining this compression for at least three seconds.

i. Shall have the capability for using antiscatter grids.

j. Shall have the capability of automatic exposure control.

k. Shall have a control panel that:

(1) Gives a positive indication when X–rays are being produced.

(2) Gives an audible signal indicating termination of exposure.

(3) Includes labeled control settings or appropriate indications that show the physical factors used for exposure such as kilovoltage potential (kVp), milliampere seconds (mAs), exposure time, and whether exposure termination is automatic.

l. Shall indicate, or provide a means of determining, the mAs resulting from each exposure made with automatic exposure control.

m. The viewbox shall be checked periodically to ensure optimal conditions. When the mammogram is placed on the viewbox, the area surrounding the film must be masked to exclude extraneous light which may reduce image contrast.

n. Mobile units and vans.

(1) A phantom image shall be made and processed after each relocation.

(2) If processing is not available, a check of the radiation output shall be made.

(3) Equipment shall be recalibrated as necessary to maintain quality of phantom image.

41.6(7) Safety standards for mammography equipment.

a.*Safety standards for mammography equipment.*

a. Proper safety precautions shall be maintained and shall include, but not be limited to, adequate shielding for patients, personnel, and facilities. The equipment shall be operated only from a shielded position.

b. Equipment operators shall wear personnel monitors to measure their radiation exposure.

c. Annual inspections shall be conducted by an inspector from the agency to ensure compliance with

these rules. Identified hazards shall be promptly corrected.

d. Equipment shall be shockproof and grounded to protect against electrical hazards.

e. Records of all inspections, reports, and consultations shall be maintained for at least seven years.

RULE 41.6(136C)—APPENDIX I

Normally, the frequency of monitoring for each of the following should be no longer than the values given on the following table. The standards of image quality are also given on the table. The surveyor is expected to measure phantom image quality and calculate dose from a measured exposure to confirm that the guidelines meet the desired standards of image quality. The surveyor will determine if the other standards are met by checking the supplier's monitoring records.

ITEMS	FREQUENCY	STDS OF IMAGE QUALITY
Processor	Daily	Mid–density step and density difference (contrast) t _ 0.1 OD of the optimized operating level and base + fog deviation _ 0.03 OD
HVL	Annually	Meas. HVL with compression device in field _ (kVp/100) mm Al and _ (kVp/100 + 0.1 mm Al)
Output reproducibility	*Quarterly	Coefficient of variation _ 0.05 with 4 exposures at the same technique
Output linearity	*Quarterly	mR/mAs values at any two consecutive tube current settings should not vary more than 0.1 times their sum.
Automatic exposure control reproducibility	Annually	The phantom used for measurements related to this and the two following automatic control parameters should be either acrylic or BR–12 and consist of at least three 2–cm–thick slabs to provide thicknesses of 2cm, 4cm, and 6cm (each having linear dimensions of at least 8 × 10 cm). When a

		fixed kVp is used to produce four images of the 4–cm–thick phantom, the maximum value for the coefficient of variation for exposure at the center of the image should be _ 0.05.
kVp response of automatic exposure	Annually	Film density maintained to _ 0.3 OD of the average optical density at the center of an exposure control phantom image over the range of kVp used in the facility. To obtain the average, at least four phantom images should be made, one each with the highest and lowest kVps commonly used in the facility and the other two at intermediate values.
Thickness response of automatic exposure control	Annually	Film density maintained to _ 0.3 OD of the average optical density at the center of a phantom image at each kVp commonly used in the facility. To obtain the average, images with phantom thickness of at least 2 cm, 4 cm, and 6 cm should be used.
Adequacy of unexposed film storage	Quarterly	Increase in base + fog density over storage time maintained to t0.02 OD
Availability and use of technique charts	Monthly	Ensure that charts are available and used
kVp/target/filter combination	Daily	Must be unchanged from that indicated on the technique charts
Darkroom integrity	Clean Daily Fog measured	Minimum dust particles on film. Fog

	when bulbs or filter changed and semiannually	not greater than 0.05 OD with 2–minute test
Phantom image quality	At least monthly	Phantom image scores not less than required ACR MAP (currently specified only using RMI phantoms) and that should not decrease more than one in any category between consecutive tests. Also, they should not have decreased by more than one in any category from the initial baseline phantom image.
Dose	Annually	See Appendix II

*If the supplier can document that the item has remained within limits for at least three consecutive monitoring periods, it may use a longer monitoring interval for any parameters except processor performance and phantom image quality. The period should not be longer than one year in any case. If during the longer monitoring interval the test results fall outside the "Standards of Image Quality" criteria, then the test frequency must revert to the original intervals for at least three consecutive quarters.

RULE 41.6(136C)—APPENDIX II
Glandular Dose (in mrad) for 1 Roentgen Entrance Exposure
4.5–cm Breast Thickness—50% Adipose/50% Glandular Breast Tissue*

Mo/Mo Target Filter X–Ray Voltage (kVp)												W/Al Target Filter Combination
HVL	23	24	25	26	27	28	29	30	31	32	33	
0.23	109											
0.24	113	116										
0.25	117	120	122									
0.26	121	124	126	128								
0.27	126	128	130	132	134							
0.28	130	132	134	136	138	139						
0.29	135	137	139	141	142	143	144					
0.30	139	141	143	145	146	147	148	149				170
0.31	144	146	147	149	150	151	152	153	154			175
0.32	148	150	151	153	154	155	156	158	159	160	160	180
0.33	153	154	155	157	158	159	160	162	163	164	164	185
0.34	157	159	160	161	162	163	164	166	167	168	168	190
0.35		163	164	166	167	168	169	170	171	172	172	194
0.36			168	170	171	172	173	174	175	176	176	199
0.37				174	175	176	177	178	178	179	180	204
0.38					179	180	181	182	182	183	184	208
0.39						184	185	186	186	187	188	213
0.40							189	190	191	192	192	217
0.41								194	195	196	196	221
0.42										200	200	225
0.43											204	230
0.44												234
0.45												238

To convert from entrance exposure in air in Roentgen to mean glandular breast dose in millirads, multiply the entrance exposure by the factor shown in the table for the appropriate kVp and beam quality (HVL) combination. For example, a measured entrance exposure of 0.50 Roentgen from a Mo/Mo Target Filter system at 30 kVp with a measured HVL of 0.36–mm aluminum yields an average glandular dose of (0.50 R) × (174 mrad/R) = 87 mrad or 0.87 mGy.

*Wu X. Breast dosimetry in screen–film mammography. In: Barnes GT, Frey GD (eds), Screen film mammography: Imaging considerations and medical physics responsibilities. Madison, WI: Medical Physics Publishing; 159–175, 1991. W/Al conversion factors are derived from fits to data from Stanton L et al. Dosage evaluation in mammography. Radiology 1984; 150:577–584.

641—41.7(136C) X–ray machines used for mammographically guided breast biopsy.

41.7(1) Definitions. *Definitions.* In addition to the definitions provided in rule 41.1(136C), the following definitions are applicable to this rule.

"Collaborative setting" means a setting in which a qualified radiologist and surgeon (under 41.7(3)*"a"* or 41.7(3)*"c"*) are working together in consultation and in performing mammographically guided breast biopsies with a common goal of the patient's benefit.

"Mammographically guided breast biopsy" means a breast biopsy procedure performed with the utilization of a dedicated system which emits ionizing radiation and is designed specifically for that procedure.

"Supervising physician" means the physician designated by the facility/owner to:

1. Evaluate the equipment, personnel, procedures, and records annually; and

2. Establish and conduct the quality assurance program.

41.7(2) *Registration and application standards and requirements.*

a. Each radiation machine used to perform mammographically guided breast biopsies shall be registered according to 641—subrule 39.3(2).

b. Each facility wishing to perform mammographically guided breast biopsies shall apply to the agency for authorization by providing or verifying the following information for each machine:

(1) The mammographically guided breast biopsy equipment and facility meet the general requirements of these rules for radiation machines.

(2) The radiation machine is specifically designed to perform mammographically guided breast biopsies.

(3) The radiation machine is used according to these rules on patient radiation exposure and radiation dose levels.

(4) The radiation machine is operated by individuals meeting the requirements of this rule.

(5) The entire mammographically guided breast biopsy system is evaluated annually by a radiation physicist who meets the requirements of this rule.

(6) The equipment, personnel, procedures and records are evaluated annually by the supervising physician.

c. Withdrawal or denial of authorization.

(1) Authorization may be withdrawn with cause if any machine does not meet one or more of the standards of these rules.

(2) The facility shall have an opportunity for a hearing in connection with a denial or withdrawal of authorization.

(3) An emergency order withdrawing authorization may be issued if the agency finds the radiation machine or facility violates rules that seriously affect the health, safety and welfare of the public. An opportunity for hearing shall be held within five working days after the issuance of the order. The order shall be effective during the proceedings.

(4) If authorization is withdrawn, the radiation machine shall not be used until reinstated.

d. Reinstatement of authorization.

(1) An application for reinstatement shall be submitted and processed the same as an initial application.

(2) The agency shall inspect the radiation machine within 60 days of the approved reinstatement application.

(3) A certificate of reinstatement shall be issued only after the agency has inspected the radiation machine and facility and determined that they meet the requirements of these rules.

e. Inspections. The agency shall conduct an inspection of each radiation machine no later than 60 days after initial authorization and at least annually thereafter.

41.7(3) *Physicians.* Physicians must be qualified according to the setting and their role in performing mammographically guided breast biopsies as outlined below.

a. Requirements for a radiologist in a collaborative setting are as follows:

(1) Initial training and qualifications.

1. Must be qualified according to 41.6(3)*"b."*

2. Shall have performed at least 12 mammographically guided breast biopsies prior to July 1, 1998, or at least 3 hands–on image–guided breast biopsies under a physician who is qualified under 41.6(3)*"b"* and has performed at least 24 mammographically guided breast biopsies.

3. Shall have at least three hours of Category 1 CME in image–guided breast biopsy.

4. Shall be responsible for mammographic interpretation, be experienced as noted in "2" above and be experienced in recommendations for biopsy and lesion identification at time of biopsy.

5. Shall be responsible for oversight of all quality control and quality assurance activities.

6. Shall be responsible for the supervision of the radiologic technologist and the medical physicist.

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 mammographically guided breast biopsies per year or requalify as specified above in 41.7(3)*"a"*(1).

2. Obtain at least three hours of Category 1 CME in mammographically guided breast biopsy every three years.

b. Requirements for a physician other than a qualified radiologist in a collaborative setting are as follows:

(1) Initial training and qualifications.

1. Must have at least three hours of Category 1 CME in mammographically guided breast biopsy which includes instruction on triangulation for lesion location.

2. Must have performed at least 12 mammographically guided breast biopsies prior to the effective date of these rules, or at least 3 hands–on mammographically guided breast biopsy procedures under a physician who is both qualified to interpret mammography according to 41.6(3)*"b"* and has performed at least 24 mammographically guided breast biopsies.

3. Shall be responsible for postbiopsy management of the patient.

(2) Maintenance of proficiency and CME requirements.

1. Perform or participate in at least 12 mammographically guided breast biopsies per year or requalify by performing 3 supervised procedures.

2. Obtain at least three hours of Category 1 CME in mammographically guided breast biopsy every three years.

c. Requirements for a radiologist performing mammographically guided breast biopsy independently are as follows:

(1) Initial training and requirements.

1. Must be qualified according to 41.6(3)*"b."*

2. Initially, must have at least three hours of Category 1 CME in mammographically guided breast biopsy.

3. Initially, must obtain at least 15 hours of CME in breast imaging including benign and malignant breast diseases.

4. Must have performed at least 12 mammographically guided breast biopsies prior to July 1, 1998, or at least 3 hands–on mammographically guided breast biopsy procedures under a physician who is both qualified according to 41.6(3) *"b"* and has performed at least 24 mammographically guided breast biopsies.

5. Must be responsible for mammographic interpretation.

6. Must be responsible for patient selection.

7. Must be responsible for quality assurance activities including medical audit (tracking of number of biopsies done, cancers found, benign lesions, biopsies needing repeat, and complications).

8. Must be responsible for the oversight of all quality control.

9. Must be responsible for the supervision of the radiologic technologist and the medical physicist.

10. Must be responsible for postbiopsy management of the patient which may include referral to a surgeon for a follow–up on certain lesions.

(2) Maintenance of proficiency and CME requirements.

1. Perform at least 12 mammographically guided breast biopsies per year or requalify by performing 3 supervised procedures.

2. Obtain at least three hours of Category 1 CME in mammographically guided breast biopsy every three years which includes postbiopsy management of the patient.

d. Requirements for a physician other than a qualified radiologist (under 41.7(3) *"c"*) performing mammographically guided breast biopsy independently are as follows:

(1) Initial training and requirements.

1. Must have evaluated at least 480 mammograms per year in the prior two years in consultation with a physician who is qualified according to 41.6(3)*"b."*

2. Initially, must have at least 15 hours of Category 1 CME in mammographically guided breast imaging

and biopsy or three years' experience having performed at least 36 image–guided breast biopsies.

3. Must have four hours of Category 1 CME in medical radiation physics.

4. Must have performed at least 12 mammographically guided breast biopsies prior to the effective date of these rules, or at least 3 hands–on mammographically guided breast biopsy procedures under a physician who is both qualified according to 41.6(3)*"b"* and has performed at least 24 image–guided breast biopsies.

5. Must be responsible for patient selection.

6. Must be responsible for quality assurance activities including medical audit (tracking of number of biopsies, cancers found, benign lesions, biopsies needing repeat and complications).

7. Must be responsible for oversight of all quality control.

8. Must be responsible for the supervision of the radiologic technologist and the medical physicist.

9. Must be responsible for postbiopsy management of the patient.

(2) Maintenance of proficiency and CME requirements.

1. Continue to evaluate at least 480 mammograms per year in consultation with a physician who is qualified according to 41.6(3)*"b."*

2. Perform at least 12 mammographically guided breast biopsies per year or requalify by performing 3 supervised procedures.

3. Obtain at least three hours of Category 1 CME in mammographically guided breast biopsy every three years.

41.7(4) *Medical physicist.*

a. Must be qualified according to 41.6(3)*"c."*

b. Must meet the following initial requirements:

(1) Prior to July 1, 1998, have performed three hands–on mammographically guided breast biopsy physics surveys; or one hands–on mammographically guided breast biopsy physics survey under the guidance of a medical physicist qualified through 41.7(4)*"a"* and 41.7(4)*"b."*

(2) On or after July 1, 1998, have one hands–on image–guided breast biopsy physics survey under the guidance of a medical physicist qualified to perform mammographically guided breast biopsy physics surveys. Have at least one mammographically guided breast biopsy physics survey per year after the initial qualifications are met; and three hours of continuing education in mammographically guided breast biopsy physics every three years after the initial qualifications are met.

41.7(5) *Radiologic technologist.*

a. Must be qualified according to 41.6(3)*"d."*

b. Must meet the following initial requirements:

(1) Five hands–on procedures on patients under the supervision of a qualified physician or technologist.

(2) Three hours of continuing education in mammographically guided breast biopsy.

c. Thereafter, an average of at least 12 mammographically guided breast biopsies per year after initial qualifications are met.

d. Three hours of continuing education in mammographically guided breast biopsy every 3 years after initial qualifications are met.

41.7(6) *Obtaining and preserving records.*

a. The facility must make, for each procedure, a record of the service provided including:

(1) The date of the procedure.

(2) The name of the patient.

(3) The name of the radiologic technologists and physicians performing the procedure.

(4) A description of the service provided.

(5) The name of the referring physician, if any.

b. Records retained by the medical facility must be retained for at least ten years.

41.7(7) *Quality assurance program.*

a. The facility shall have an equipment quality assurance program specific to image–guided breast biopsy systems and covering all components of the system to ensure high–quality images with minimum patient exposure.

b. The facility shall ensure that a general review of the program is conducted at least annually and have available the services of a qualified radiation physicist who is capable of establishing and conducting the program.

c. Under the direction of the supervising physician, the radiation physicist shall have the responsibility for establishing and conducting the equipment quality assurance program. The program shall include:

(1) Conducting equipment performance monitoring functions, at least annually, to include:

1. Evaluation of biopsy unit assembly.

2. Evaluation of focal spot.

3. kVp accuracy/reproducibility.

4. Half–value layer measurement.

5. Exposure reproducibility.

6. Breast entrance exposure, average glandular dose.

7. Image quality evaluation.

8. Artifact evaluation.

9. Digital field uniformity.

10. Localization simulation (gelatin phantom) test.

11. Evaluation of the facility's technologist quality control program.

(2) Analyzing the monitoring results to determine if there are any problems requiring correction.

(3) Ensuring that the facility has procedures in place for carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventative maintenance.

d. The supervising physician shall have the responsibility for establishing and conducting the quality control program in a facility with a fixed unit. In the case of a mobile stereotactic unit, the owner or designee shall assume the responsibility for establishing and conducting the quality assurance program. The program shall include:

(1) Localization accuracy (daily before use and before using the localization unit after it is adjusted).

(2) Visual checklist (weekly).

(3) Phantom image (weekly).

(4) Compression (semiannually).

(5) Processor sensitometry (daily before use with systems utilizing film).

e. Each facility shall establish a medical audit program to ensure the accuracy and appropriateness of the procedures performed. This program shall include an imaging–pathology correlation for each biopsy performed, an ongoing analysis of biopsy results and periodic review of the utilization of the procedure.

41.7(8) *Equipment standards.*

a. Be specifically designed for mammographically guided breast biopsy.

b. Meet the Food and Drug Administration (FDA) standards found in 21 CFR.

41.7(9) *Safety standards.*

a. Proper safety precautions shall be maintained and shall include, but not be limited to, adequate shielding for patients, personnel and facilities. The equipment shall be operated only from a shielded position.

b. Equipment operators shall wear personnel monitors to monitor their radiation exposure.

c. Annual inspections shall be conducted by an inspector from the agency to ensure compliance with these rules. Identified hazards shall be promptly corrected.

d. Equipment shall be shockproof and grounded to protect against electrical hazards.

e. Records of all inspections, reports and consultations shall be maintained for at least seven years.

This rule is intended to implement Iowa Code chapter 136C.

Chapter 41—APPENDIX A

INFORMATION ON RADIATION SHIELDING

REQUIRED FOR PLAN REVIEWS (EXCLUDING THERAPY MACHINES)

In order for the agency to provide an evaluation, technical advice, and official approval on shielding requirements for a radiation installation, the following information shall be submitted.

1. The plans should show, as a minimum, the following:

(a) The normal location of the X–ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the X–ray control panel.

(b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

(c) The dimensions of the room(s) concerned.

(d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

(e) The make and model of the X–ray equipment, the energy waveform (single phase, three phase, etc.) and the maximum technique factors.

(f) The type of examination(s) or treatment(s) which will be performed with the equipment.

2. Information on the anticipated workload of the X–ray system(s) in mA–minutes per week.

3. If the services of a qualified expert have been utilized to determine the shielding requirements, a report, including all basic assumptions used, shall be submitted with the plans.

CHAPTER 41—APPENDIX B

DESIGN REQUIREMENTS FOR AN

OPERATOR'S BOOTH

1. Space requirements:

(a) The operator shall be allotted not less than 7.5 square feet (0.697 m) of unobstructed floor space in the booth.

(b) The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.61 m).

(c) The space shall be allotted excluding any encumbrance by the X–ray control panel, such as overhang, cables, or other similar encroachments.

(d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette will not reach the operator's station in the booth.

2. Structural requirements:

(a) The booth walls shall be permanently fixed barriers of at least 7 feet (2.13 m) high.

(b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.

(c) Shielding shall be provided to meet the requirements of 641—Chapter 40.

3. X–ray control placement:

The X–ray control for the system shall be fixed within the booth; and

(a) Shall be at least 40 inches (1.02 m) from any point subject to direct scatter, leakage or primary beam radiation.

(b) Shall allow the operator to use the majority of the available viewing windows.

4. Viewing system requirements:

(a) Each booth shall have at least one viewing device which will:

(1) Be so placed that the operator can view the patient during any exposure, and

(2) The device shall be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then outside that door there shall be an "X–ray" warning sign that will be lighted anytime the rotor of the X–ray tube is activated. Alternatively, that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.

(b) When the viewing system is a window, the following requirements also apply:

(1) The viewing area shall be at least 1 square foot (0.0929 m^2).

(2) Regardless of size or shape, at least 0.09 m^2 (1 sq ft) of window area must be centered no less than 0.6 m (2 feet) from the open edge of the booth and no less than 1.5 m (5.0 feet) from the floor.

(3) The material constituting the window shall have the same lead equivalence as that required in the booth's wall in which it is mounted.

(c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of Appendix B, 4(a).

(d) When the viewing system is by electronic means:

(1) The camera shall be so located as to accomplish the general requirements of Appendix B, 4(a), and

(2) There shall be an alternate viewing system as a backup for the primary system.

Chapter 41—APPENDIX C

INFORMATION TO BE SUBMITTED BY PERSONS

PROPOSING TO CONDUCT HEALING

ARTS SCREENING

Persons requesting that the agency approve a healing arts screening program shall submit the following information and evaluation:

1. Name and address of the applicant and, where applicable, the names and addresses of agents within this state.

2. Diseases or conditions for which the X–ray examinations are to be used in diagnoses.

3. A detailed description of the X–ray examinations proposed in the screening program.

4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.

5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the X–ray examinations.

6. An evaluation by a qualified expert of the X–ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) does satisfy all requirements of these regulations. The evaluation shall include a measurement of patient exposures from the X–ray examinations to be performed.

7. A description of the diagnostic film quality control program.

8. A copy of the technique chart for the X–ray examination procedures to be used.

9. The qualifications of each individual who will be operating the X–ray system(s).

10. The qualifications of the individual who will be supervising the operators of the X–ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.

11. The name and address of the individual who will interpret the radiograph(s).

12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.

13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the X–ray examinations.

14. An indication of the frequency of screening and the duration of the entire screening program.

APPENDIX D
QA for Therapeutic Radiation Machines

Frequency	Procedure	Tolerance[a]
Daily	Dosimetry	
	X–ray output constancy	3%
	Electron output constancy[b]	3%
	Mechanical	
	Localizing lasers	2mm
	Distance indicator (ODI)	2mm
	Safety	
	Door interlocks	functional
	Audiovisual monitors	functional
Monthly	Dosimetry	
	X–ray output constancy[c]	2%
	Electron output constancy[c]	2%
	Backup monitor constancy	2%
	X–ray central axis dosimetry	2%

parameter (PDD, TAR) constancy	
Electron central axis dosimetry parameter constancy (PDD)	2mm @ therapeutic depth
X–ray beam flatness constancy	2%
Electron beam flatness constancy	3%
X–ray and electron symmetry	3%
Safety Interlocks	
Wedge, electron cone interlocks	functional
Mechanical	
Light/radiation field coincidence	2mm or 1% on a side[d]
Gantry/collimator angle indicators	1 degree
Wedge position	2mm (or 2% change in transmission factor)
Tray position	2mm
Applicator position	2mm
Field size indicators	2mm
Cross–hair centering	2mm diameter
Treatment couch position indicators	2mm/1deg
Latching of wedges, blocking tray	functional
Jaw symmetry[e]	2mm
Field Light intensity	functional

[a] The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under the gantry exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values + the deviation of the parameter with respect to its nominal value; distances are referenced to the isocenter or nominal SSD.

[b] All electron energies need not be checked daily, but all electron energies are to be checked at leastwice weekly.

[c] A constancy check with a field instrument using temperature pressure corrections.

[d] Whichever is greater. Should also be checked after change of light field source.

[e] Jaw symmetry is defined as the difference in distance ofeach jaw from the isocenter.

Frequency	Procedure	Tolerance[a]
Annual	Dosimetry	
	X–ray/electron output calibration constancy	2%
	Field size dependence of X–ray output constancy	2%
	Output factor constancy for electron applicators	2%
	Central axis parameter constancy (PDD, TAR)	2%
	Off–axis factor constancy	2%
	Transmission factor constancy for all treatment accessories	2%
	Wedge transmission factor constancy[f]	2%
	Monitor chamber linearity	1%
	X–ray output constancy vs. gantry angle	2%
	Electron output constancy vs. gantry angle	2%
	Off–axis factor constancy vs. gantry angle	2%
	Arc mode	Mfrs. specs.
	Safety Interlocks	
	Follow manufacturer's test procedures	functional
	Mechanical	
	Collimator rotation isocenter	2mm diameter
	Gantry rotation isocenter	2mm diameter
	Couch rotation isocenter	2mm diameter
	Coincidence of collimetry, gantry, couch axes with isocenter	2mm diameter
	Coincidence of radiation and mechanical isocenter	2mm diameter

[a] The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under the gantry exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values $\pm$ the deviation of the parameter with respect to its nominal

value; distances are referenced to the isocenter or nominal SSD.

[f] Most wedges' transmission factors are field size and depth dependent.

APPENDIX E
INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS FOR THERAPY MACHINES

I. All therapeutic radiation machines.

A. Basic facility information including: name, telephone number and agency registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address (including room number if applicable) of the external beam radiation therapy facility. The plan should also indicate whether this is a new structure or a modification to existing structure(s).

B. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

C. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

II. Therapeutic machines up to 150 kV (photons only).

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors.

B. Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) or air kerma at one meter), total beam–on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. A facility blueprint/drawing indicating: scale (0.25 inch = 1 foot is typical); direction of north; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the external beam radiation therapy treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with 641—40.15(136C).

D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, entry door(s)) and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

III. Therapeutic radiation machines over 150 kV.

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce photons or electrons with a maximum energy in excess of 150 kV or electrons shall submit shielding plans which contain, as a minimum, the following additional information:

A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced (i.e., photon, electron). The target to isocenter distance shall be specified.

B. Maximum design workload for the facility including total weekly radiation output (expressed in gray (rad) at one meter), total beam–on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week.

C. Facility blueprint/drawing (including both floor plan and elevation views) indicating relative orientation of the therapeutic radiation machine, scale (0.25 inch = 1 foot is typical), type(s), thickness and minimum density of shielding material(s), direction of north, the locations and size of all penetrations through each shielding barrier (ceiling, walls and floor), as well as details of the door(s) and maze.

D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

F. Description of all assumptions that were in shielding calculations including, but not limited to, design energy (i.e., room may be designed for 6 MV unit although only a 4 MV unit is currently proposed), workload, presence of integral beam–stop in unit, occupancy and use(s) of adjacent areas, fraction of time that useful beam will intercept each permanent barrier (walls, floor and ceiling) and "allowed" radiation exposure in both restricted and unrestricted areas.

G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary leakage barriers, restricted and unrestricted areas, small angle scatter, entry door(s) and maze) and shielding material in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

IV. Neutron shielding.

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities which are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

A. The structural composition, thickness, minimum density and location of all neutron shielding material.

B. Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluency rate, absorbed dose and dose

equivalent (due to neutrons) in both restricted and unrestricted areas.

C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition (i.e., restricted and unrestricted areas, entry door(s) and maze) and neutron shielding material utilized in the facility.

(1) If commercial software is used to generate shielding requirements, also identify the software used and the version/revision date.

(2) If the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software.

D. The method(s) and instrumentation which will be used to verify the adequacy of all neutron shielding installed in the facility.

V. References.

A. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of X–Rays and Gamma Rays of Energies Up to 10 MeV" (1976).

B. NCRP Report 51, "Radiation Protection Design Guidelines for 0.1–100 MeV Particle Accelerator Facilities" (1977).

C. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerator" (1984).

These rules are intended to implement Iowa Code chapter 136C.

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Iowa Department of Public Health
Promoting and protecting the health of Iowans

Stephen C. Gleason, D. O., Director
Lucas State Office Building
Des Moines, IA 50319-0075
515-281-5787

Chapter 42
MINIMUM CERTIFICATION STANDARDS FOR DIAGNOSTIC RADIOGRAPHERS, NUCLEAR MEDICINE TECHNOLOGISTS, AND RADIATION THERAPISTS

641—42.1(136C) Purpose and scope.

42.1(1) *Applicability.* Except as otherwise specifically provided, these rules apply to all individuals who operate as a diagnostic radiographer, nuclear medicine technologist, or radiation therapist as defined below.

The provisions of this chapter are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 38 to 41.

42.1(2) *Definitions.* For the purpose of this chapter, the definitions of 641—Chapter 38 may also apply.

"Approved course of study" means a curriculum and associated training and testing materials which the department has determined are adequate to train students to meet the requirements of this chapter.

"Chest" is defined as the lung fields including the cardiac shadow, as taught in the approved limited radiography curriculum. Radiography of the shoulder, clavicle, scapula, ribs, thoracic spine and sternum for diagnostic evaluation of these body structures is not allowed under this body part classification for limited diagnostic radiographers.

"Clinical education" means the direct participation of the student in completion of diagnostic studies.

"Continuing education course" means a planned program of continuing education having sufficient scope and depth of a given subject area directly related to the field to form an educational unit that is planned, coordinated, administered, and evaluated in terms of educational objects and provides a defined level of knowledge or specific performance skill. This concept involves the organized presentation of a body of knowledge so that the subject matter is comprehensively covered in sufficient detail to meet the educational objectives of the course.

"Contrast media" means material intentionally administered to the human body to define a part(s) which is not normally visualized radiographically.

"Diagnostic radiographer" means an individual, other than a licensed practitioner or dental radiographer, who applies X–radiation to the human body for diagnostic purposes while under the supervision of a licensed practitioner or registered nurse registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152. The types are as follows:

1. "General diagnostic radiographer" applies X–radiation to any part of the human body.

2. "Limited diagnostic radiographer" applies X–radiation to not more than two body parts. Chest and extremity radiographic examinations are considered as one body part.

3. "Limited in–hospital radiographer" applies X–radiation as permitted in 42.3(1) *"c."*

"Diagnostic radiography" means the science and art of applying X–radiation to human beings for diagnostic purposes other than in dental radiography. It shall include adjustment or manipulation of X–ray equipment and appurtenances including image receptors, positioning of patients and processing of films so as to materially affect the radiation exposure of patients.

"In vitro" means a procedure in which the radioactive material is not administered to a human being.

"In vivo" means a procedure in which the radioactive material is administered to a human being.

"Lower extremities" refers to those body parts from the distal phalanges of the foot to the head of the femur and its articulation with the pelvic girdle as taught in the approved limited radiographer curriculum. True hip radiographs are prohibited under this category for limited diagnostic radiographers.

"Nuclear medicine procedure" means any procedure utilizing radiopharmaceuticals for diagnosis or treatment of disease in human beings and any duties performed by the technologist during sealed source procedures and includes, but is not limited to:

1. Administration of any radiopharmaceutical to human beings for diagnostic purposes.

2. Administration of radioactive material to human beings for therapeutic purposes.

3. Use of radioactive material for diagnostic purposes involving transmission or excitation.

4. Quality control and quality assurance.

"Nuclear medicine technologist" means an individual, other than a licensed physician, who performs nuclear medicine procedures while under the supervision of a physician who is authorized by NRC or Iowa to possess and use radioactive materials.

"Quality assurance" means all aspects of a nuclear medicine program that ensure the quality of imaging and therapy procedures.

"Quality control" means specific tests and measurements that ensure the purity, quantity, product identity, and biologic safety of radiopharmaceuticals.

"Radiation therapist" means a person, other than a licensed physician, who performs radiation therapy technology under the supervision of a radiation oncologist.

"Radiation therapy technology" means the science and art of performing simulation radiography or applying ionizing radiation emitted from X-ray machines, particle accelerators, or radioactive materials to human beings for therapeutic purposes.

"Radionuclide" means a radioactive element or a radioactive isotope.

"Radiopharmaceutical" means a substance defined by the Food and Drug Administration as a radioactive drug.

"Simulation radiography" means the science and art of applying X–radiation to human beings for the purpose of localizing treatment fields and isotopes and for treatment planning.

"Simulation therapist" means an individual, other than a physician, who applies X–radiation to human beings for the purpose of localizing treatment fields and isotopes and for treatment planning.

"Sinus" as used in the limited radiographer curriculum refers to the paranasal sinuses only.

"Special category course" means those programs still related to health care but indirectly related to diagnostic radiography, nuclear medicine technology, or radiation therapy. Such programs are: venipuncture, CPR, educator's programs, management programs, tumor boards, equipment training, personal improvement, for example.

"Spine" refers to the cervical, thoracic (dorsal), lumbar vertebrae and their articulations. It may also

include the sacrum or coccyx and the sacral articulation with the pelvic girdle. True pelvis radiographs performed with the image receptor positioned perpendicular to the long axis of the torso are prohibited under this limited category. Lumbo–pelvic or full spine radiography may be performed if the long axis of the image receptor is positioned parallel with the long axis of the spine as taught in the approved limited radiographer curriculum.

"Student" means an individual enrolled in and participating in an approved course of study.

"Supervision" means responsibility for and control of quality, radiation safety and protection, and technical aspects of the application of ionizing radiation to human beings for diagnostic or therapeutic purposes.

"Upper extremities" refers to those body parts from the distal phalanges of the hand to the head of the humerus. These projections may include the acromioclavicular or glenoid–humeral areas as taught in the approved limited radiographer curriculum. True shoulder radiography that includes both distal and proximal ends of the clavicle is prohibited under this category for limited diagnostic radiographers.

"X–radiation" means penetrating electromagnetic radiation with energy greater than 0.1 kV produced by bombarding a metallic target with fast electrons in a high vacuum.

641—42.2(136C) *General requirements.*

42.2(1) *Minimum eligibility requirements.*

a. Graduation from high school or its equivalent.

b. Attainment of 18 years of age.

c. Ability to adequately perform necessary duties without constituting a hazard to the health or safety of patients or operators.

42.2(2) *Disciplinary grounds and actions.* The following shall be grounds for disciplinary action involving possible suspension or revocation of certification or levying of fines:

a. Operating as a diagnostic radiographer, nuclear medicine technologist, or radiation therapist without meeting the requirements of this chapter.

b. Allowing any individual excluding a licensed physician to operate as a diagnostic radiographer, nuclear medicine technologist, or radiation therapist if that individual cannot provide proof of certification by the department.

c. Failing to report to the department any individual whom the certificate holder knows is in violation of this rule.

d. Submitting false information in order to obtain certification or renewal certification as a diagnostic radiographer, nuclear medicine technologist, or radiation therapist.

e. Any action that the department determines may jeopardize the public, other staff, or certificate holder's health and safety.

42.2(3) *Continuing education.*

a. Each individual who is certified under these rules shall, during a two–year period, obtain continuing education credit as follows:

(1) General diagnostic radiographer: 24 clock hours, 1.0 hour must be in radiation protection.

(2) Limited in–hospital diagnostic radiographer: 24 clock hours, 1.0 hour must be in radiation protection.

(3) Limited diagnostic radiographer: 12 clock hours, 1.0 hour must be in radiation protection.

(4) General nuclear medicine technologist: 24 hours total.

1. One clock hour in principles of radiation protection and exposure each year, a total of two hours each two–year period.

2. One clock hour in quality assurance each year, a total of two hours each two–year period.

3. The remaining 20 clock hours of continuing education in each two–year period may be in any other subjects directly related to nuclear medicine and approved by the department.

(5) Limited nuclear medicine technologists: 12 hours total, 1.0 hour must be radiation protection and 1.0 hour must be in quality assurance.

(6) Radiation therapist: proof of 24.0 clock hours of continuing education courses in subjects directly related to radiation therapy.

(7) Simulation therapist: proof of 24.0 clock hours of continuing education courses with at least 12.0 hours directly related to radiation therapy. 12.0 hours may be in specified diagnostic radiography courses.

b. Continuing education course approval.

(1) Thirty days prior to conducting a continuing education course, the sponsoring individual must submit the following:

1. The course objectives.

2. An outline of the course which sets forth the subject, the course content, and the length of the course in clock hours.

3. The instructor's name and short résumé detailing qualifications.

(2) Following its review, the department may, in consultation with or under predetermined guidance of the technical advisory committee, approve, disapprove, or request additional information on the proposed course.

(3) The department may, from time to time, audit the continuing education course to verify the adequacy of program content and delivery.

(4) Courses must be at least one clock hour in length and if lasting more than one hour, will be assigned credit in half–hour increments to the closest half–hour.

c. Continuing education credit will be awarded under provisions of 42.2(3) by the department to individuals:

(1) Who have successfully completed a continuing education course which has been approved by the department.

(2) Who present a department–approved continuing education course to individuals certified in the presenter's field. Credit granted shall be at a rate of two times the amount of time it takes to present the course up to a maximum of 50 percent of the total hours required.

(3) Only once during a two–year period for the same continuing education course.

d. Continuing education must be directly related to the area of practice of the operator attending the program. Twenty–five percent of the total hours required may be in "special category."

e. It is required that proof of receiving continuing education be retained at each individual's place of employment for review by representatives of the department. Proof of continuing education must be maintained for at least three years.

f. All continuing education requirements shall be completed during the two–year period prior to the certification continuing education due date.

g. Late submission of continuing education requirements.

(1) For any individual who completes the required continuing education before the continuing education due date but fails to submit the required proof within 30 days after the continuing education due date, the certification shall be terminated and the renewal fee will not be refunded.

(2) Any individual who fails to complete the required continuing education before the continuing education due date but submits a written plan of correction to obtain the required hours shall be allowed no more than 60 days after the original continuing education due date to complete the plan of correction and submit the documentation of completion of continuing education requirements. After 60 days, the certification shall be terminated and the individual shall not function as a diagnostic radiographer, radiation therapist, or nuclear medicine technologist in Iowa.

(3) Once certification has been terminated, any individual who requests permission to reestablish certification within six months of the initial continuing education due date must submit proof of continuing education hours and shall submit a late fee as set forth in 641—paragraph 38.8(6) *"c"* in addition to the annual fee set forth in 641—paragraph 38.8(6) *"a"* in order to obtain reinstatement of certification.

42.2(4) *Recertification.*

a. If an individual allows the certification to expire for any reason or if any individual voluntarily terminates certification, the following will apply:

(1) Any individual who wishes to regain certification and makes application within six months of the termination date will be allowed to do so with no additional training or testing required.

(2) Any individual who wishes to regain certification after the six–month period will need to meet the current educational and testing requirements for that particular certification. Proof of possession of a previous certification may satisfy the training portion of this requirement.

(3) Any individual who has not renewed certification for at least five years and wants to regain certification, or who has not applied for certification within five years of the completion date of the original training course, will need to complete a recertification program approved by the department of not less than 24 contact hours for general certifications and 12 contact hours for limited certifications which specifically applies to the area of certification.

b. Recertification programs.

(1) The recertification program must review those basic principles necessary to ensure minimum competency in the certification area and must also include the satisfactory completion of a written examination. Both the program and the examination must acquire prior approval from the department. Courses designed for use in the recertification program will not qualify for continuing education credit for those individuals required to attend in order to recertify.

(2) If no approved programs are available, the department may require attendance for a minimum of 24

contact hours for general certifications and 12 hours for limited certifications at specific continuing education programs. The continuing education must be confined to subjects which apply to the area of certification limitation, if any, and would have to be completed within a specified time period.

c. Exemptions. Any or all of the above–mentioned requirements may be waived for an individual who has been actively employed in the certification area in another state, country, or federal institution or who can prove circumstances above and beyond the norm. These cases will be reviewed on an individual basis and the decision of the department shall be final.

d. Training programs. Any individual submitting a training program to the department for approval must provide the following:

(1) An outline of the didactic and clinical studies to meet the requirements of this subrule.

(2) Proof that the instructor meets the requirements of this rule as a diagnostic radiographer, nuclear medicine technologist, radiation therapist or is a licensed physician trained in the specific area of competence.

(3) A time schedule of the training program.

(4) A description of the mechanism to be used to determine competency.

e. Upon the completion of the training the following must be submitted:

(1) A statement of competency from the trainer.

(2) A statement of permission to allow a representative of the department to comprehensively evaluate whether the individual meets the training standard.

42.2(5) *Fees.* All individuals certified under this rule must pay fees as specified in 641—subrule 38.8(6).

641—42.3(136C) Specific requirements for diagnostic radiographers.

42.3(1) *Training requirements.*

a. General diagnostic radiographer. Successful completion of a Joint Review Committee on Education in Radiologic Technology approved course of study or equivalent to prepare the student to demonstrate competency in the following areas:

(1) Radiation protection of patients and workers, including monitoring, shielding, units of measurement and permissible levels, biological effects of radiation, and technical consideration in reducing radiation exposure and frequency of retakes;

(2) Technique and quality control to achieve diagnostic objectives with minimum patient exposure, including X–ray examinations, X–ray production, films, screens, holders and grids, technique conversions, film processing, artifacts, image quality, film systems and control of secondary radiation for the specified category;

(3) Patient care including, but not limited to, aseptic techniques, emergency procedures and first aid, and contrast media;

(4) Positioning, including normal and abnormal anatomy and projections;

(5) Radiographic equipment and operator maintenance to include X–ray tubes, grids, standardization of equipment, generators, preventive maintenance, basic electricity, film processors and maintenance, collimators, X–ray control consoles, tilt tables, ancillary equipment, fluoroscopes and electrical and mechanical safety;

(6) Special techniques, including stereo, body section radiography, pelvimetry, image intensification, photo timing and mobile units; and

(7) Clinical experience sufficient to demonstrate competency in the application of the above as specified in the revised 1990 edition of the "Essentials and Guidelines of an Accredited Educational Program for the Radiographer" of the American Medical Association's Committee on Allied Health Education and Accreditation.

b. Limited diagnostic radiographer.

(1) Completion of an approved course of study to prepare the student to demonstrate competency in the following areas:

1. Radiation protection of patients and workers including monitoring, shielding, units of measurement and permissible levels, biological effects of radiation, and technical considerations in reducing radiation exposure and frequency of retakes;

2. Technique and quality control to achieve diagnostic objectives with minimum patient exposure to include X–ray examination, X–ray production, films, screens, holders and grids, technique conversions, film processing, artifacts, image quality, film systems and control of secondary radiation for the specified category;

3. Patient care including, but not limited to, aseptic techniques, emergency procedures and first aid;

4. Positioning, including normal and abnormal anatomy and projections for the specific category;

5. Radiographic equipment and operator maintenance to include X–ray tubes, grids, standardization of equipment, generators, preventive maintenance, basic electricity, film processors and maintenance, collimators, X–ray control consoles, tilt tables, ancillary equipment, and electrical and mechanical safety;

6. Special techniques limited to those required by the specific category; and

7. Clinical experience sufficient to demonstrate competency in the application of the above as specified by the department. Clinical experience must be directly supervised by a two–year trained general radiographer, licensed physician, chiropractor, or podiatrist who physically observes and critiques the actual X–ray procedures.

8. Permission for a representative of the Iowa department of public health to comprehensively evaluate whether the individual meets the training standard.

c. Limited in–hospital diagnostic radiographer. An individual employed in a diagnostic radiography facility which has a workload of less than 5000 examinations per year and which provides 24–hour service in a hospital will be permitted to apply X–radiation to any part of the human body at that facility if the individual completes a training program recognized by the department, as outlined in 42.1(4)*"b"*(1) and submits a letter from a board–certified or board–eligible radiologist who verifies in writing the specific procedures the individual is competent to perform. The training program must cover the areas outlined in 42.1(4) *"b,"* the anatomy and physiology of the entire body, positioning and techniques relative to the procedures to be performed, and appropriate clinical training which includes all parts of the human body. Training received under this subrule is specific to the facility and must be reevaluated by the department before an individual may transfer to another facility.

d. Certification by the American Registry of Radiologic Technologists or the American Registry of Clinical Radiography Technologists meets the minimum requirements of 42.3(136C).

42.3(2) *School accreditation.*

a. Graduates of schools accredited by the Joint Review Committee on Education in Radiologic Technology who have successfully completed an appropriate course of study in diagnostic radiography will be considered to meet the requirements of 42.3(1)*"a."*

b. Graduates of programs recognized by the Iowa department of public health in consultation with the professional societies and boards of examiners for appropriate course of study in diagnostic radiography will be considered to meet the requirements of this rule.

42.3(3) *Examinations.*

a. All individuals seeking to perform diagnostic radiography must, in addition to subrule 42.3(1), take and satisfactorily pass a written examination within one year of the date of the initial certification. Examination must include the following subject matter for each category of radiographer:

(1) General diagnostic radiographer and limited in–hospital radiographer: radiation protection, radiation physics, radiographic and fluoroscopic techniques, special procedures, patient care, positioning, equipment maintenance, anatomy, contrast media, physiology, quality control, radiographic processing and clinical experience.

(2) Limited diagnostic radiographer: radiation protection, radiation physics, radiographic techniques, patient care, positioning, equipment maintenance, anatomy, physiology, quality control, and radiographic processing and clinical experience for the specific permit to practice requested.

(3) Contents of the examinations will be established and periodically revised by the department in consultation with the technical advisory committee.

b. Examinations will be given by the department at least annually, or as necessary, at course of study location or other location determined by the department.

c. The department may accept, in lieu of its own examination, evidence of satisfactory performance in an examination given by an appropriate organization or testing service provided that the department finds the organization or service to be competent to examine applicants in the discipline of radiography. For purposes of this subrule, individuals who are registered with the American Registry of Radiologic Technologists or American Registry of Clinical Radiography Technologists meet the testing requirements of 42.3(3).

d. Any individual certified under these rules and exempted from examination is exempted from examination requirements as long as the initial certification remains in effect.

42.3(4) *Exemptions.*

a. Students enrolled in and participating in an approved program or approved course of study for diagnostic radiography, or an approved school of medicine, osteopathy, podiatry, and chiropractic, who as a part of their course of study, apply ionizing radiation to a human being while under the supervision of a licensed practitioner. The projected completion date of the clinical portion of the program or course of study shall be within a time period equal to or less than twice that required for the original program or course of study.

b. Licensed practitioners as defined in 641—Chapter 38.

c. Individuals who operate processors only.

641—42.4(136C) *Specific requirements for nuclear medicine technologists.*

42.4(1) *Specific eligibility requirements.*

a. Any individual who is registered in nuclear medicine technology with the following organizations may meet the education and testing requirements of this rule.

(1) American Registry of Radiologic Technologists.

(2) Nuclear Medicine Technology Certification Board.

(3) American Society of Clinical Pathologists.

b. Any individual, other than a licensed physician, who has completed all educational requirements of this rule but has not yet successfully completed the required examination will be issued temporary certification valid for one year from completion of a training program approved by the department.

42.4(2) *Training requirements.*

a. General nuclear medicine technologist. Successful completion of a Joint Review Committee on Educational Programs in Nuclear Medicine approved course of study or equivalent designed to prepare the student to demonstrate competency in the following:

(1) Basic anatomy, physiology, and pathology.

(2) Intravenous injections and radiopharmaceutical chemistry.

(3) Radiation physics and mathematics.

(4) Nuclear instrumentation.

(5) Radiation biology.

(6) Radiation protection and radiation protection standards and codes.

(7) Laboratory procedures and techniques (in vivo and in vitro).

(8) Clinical application of radiopharmaceuticals used for diagnostic and therapeutic uses and duties performed by the technologist during sealed source procedures.

(9) Records and administrative procedures.

(10) Medical ethics.

(11) Patient care.

b. Limited nuclear medicine technologist. Successful completion of a department–approved training program that prepares the student to demonstrate competency in a specified area. Each program shall include the items in 42.4(2)*"a"* that are specific to the limited area. Included are laboratory technologists who perform nuclear medicine procedures unless the material handled is regulated under 641—paragraph 39.4(22)*"i."*

c. Graduates of programs recognized by the department in consultation with the professional societies and others as being adequate and appropriate courses of study in nuclear medicine technology may be considered to meet the requirements of this subrule.

42.4(3) *Examinations.*

a. Any individual, other than a licensed physician, seeking certification as a general nuclear medicine technologist shall, in addition to the requirements of 42.4(2) successfully complete a written examination including the subject matter specified in 42.4(2) *"a."* The following organizations offer

approved general examinations:

(1) American Registry of Radiologic Technologists.

(2) Nuclear Medicine Technology Certification Board.

b. Any individual certified under these rules shall be exempt from the examination requirements as long as the original certification remains in effect.

c. Any individual, other than a licensed physician, seeking certification as a limited nuclear medicine technologist shall, in addition to the requirements of 42.4(2) *"b,"* successfully complete a written examination approved by the department which includes the subject matter specified in 42.4(2) *"b."*

d. Any individual holding temporary certification must successfully complete an approved examination within one year of the issuance date of the certification.

42.4(4) *Exemptions.*

a. Students enrolled in and participating in an approved program or approved course of study for nuclear medicine technology or an approved school of medicine, osteopathy, podiatry, or chiropractic who, as a part of their course of study, administer radioactive material to a human being while under the supervision of a licensed physician who appears as an authorized user on an Iowa or NRC radioactive materials license. Clinical experience must be directly supervised by a certified nuclear medicine technologist or by a physician who appears as an authorized user on an Iowa or NRC radioactive materials license.

b. A licensed physician who appears as an authorized user on an Iowa or NRC radioactive materials license.

641—42.5(136C) Specific requirements for radiation therapists.

42.5(1) *Specific eligibility requirements.* Each individual shall meet one of the following:

a. Any individual who is registered in radiation therapy with the American Registry of Radiological Technologists in radiation therapy meets the education and testing requirements of this rule.

b. Any individual, other than a licensed physician, who has completed all educational requirements of this rule but has not successfully completed the required examination will be issued temporary certification valid for one year from the date of completion of a training program approved by the department.

42.5(2) *Training requirements.*

a. General radiation therapist. Successful completion of a Joint Committee on Education in Radiologic Technology approved course of study or equivalent designed to prepare the student to demonstrate didactic and clinical competency in radiation therapy including, but not limited to, anatomy, physiology, radiation physics, radiation protection and exposure, quality assurance, radiation oncology treatment techniques, dosimetry, radiation oncology and pathology, radiology, oncologic patient care and management.

b. Limited radiation therapist. Successful completion of a training program approved by the department to prepare the student to demonstrate competency in a specified area only. This includes the simulation therapist. Each program shall include the items in 42.5(2) *"a"* that are specific to the limited area.

c. Graduates of programs recognized by the department in consultation with the professional societies and others as being adequate and appropriate courses of study in radiation therapy technology may be considered to meet the requirements of this subrule.

42.5(3) *Examinations.*

a. Any individual, other than licensed physicians, seeking certification as a radiation therapist shall, in addition to the requirements of 42.5(2), satisfactorily complete a written examination in radiation therapy technology approved by the department. An approved examination is offered by the American Registry of Radiologic Technologists.

b. Any individual certified under these rules and exempted from examination is exempt fromexamination requirements as long as the initial certification remains in effect.

c. Any individual seeking to perform simulation radiography only must successfully complete an approved examination in either diagnostic radiography or radiation therapy.

d. Any individual holding a temporary certification must successfully complete an approved examination within one year of the date of completion of the training.

42.5(4) *Exemptions.*

a.

a. Students enrolled in and participating in an approved program or approved course of study for radiation therapy technology or an approved school of medicine, osteopathy, podiatry, or chiropractic who, as a part of their course of study, administer radiation therapy to a human being while under the supervision of a licensed physician in the state of Iowa. Clinical experience must be directly supervised by a radiation therapist or radiation oncologist who physically observes and critiques the actual radiation therapy procedure.

b. A licensed physician in the state of Iowa.

These rules are intended to implement Iowa Code chapter 136C.

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**Subrule 42.1(4)"b"(4) is rescinded two years subsequent to the effectivedate of rule 42.1(136C).

◊Two or more ARCs.

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Iowa Department of Public Health
Promoting and protecting the health of Iowans

Stephen C. Gleason, D. O., Director
Lucas State Office Building
Des Moines, IA 50319-0075
515-281-5787

Chapter 45
RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

[Prior to 8/5/92, see 641—41.4(136C)]

641—45.1(136C) General requirements for industrial radiography operations.

45.1(1) *Purpose and scope.* The rules in this chapter establish radiation safety requirements for using sources of radiation for industrial radiography. The requirements of this chapter are in addition to, and not in substitution for, other applicable requirements of 641—Chapters 38, 39, and 40. The rules in this chapter apply to all licensees or registrants who use sources of radiation for industrial radiography. All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of July 1, 1999.

The provisions of 641—Chapter 38 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 39 to 45.

45.1(2) *Definitions.* For the purpose of this chapter, the definitions of 641—Chapter 38 may also apply. As used in this chapter, the following definitions apply:

"Cabinet X–ray system" means an X–ray system with the X–ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. The cabinet X–ray system is intended to:

1. Contain at least that portion of a material being irradiated;

2. Provide radiation attenuation; and

3. Exclude personnel from its interior during generation of radiation. Included are all X–ray systems designed primarily for the inspection of carry–on baggage at airline, railroad, and bus terminals, and in similar facilities. An X–ray tube used within a shielded part of a building, or X–ray equipment which may temporarily or occasionally incorporate portable shielding, is not considered a cabinetX–ray system.

"Certifiable cabinet X–ray system" means an existing uncertified X–ray system that has been modified to meet certification requirements specified in 21 CFR 1020.40.

"Certified cabinet X–ray system" means an X–ray system which has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

"Collimator" means a small radiation shield of lead or other heavy metal that is placed on the end of a guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

"Crank–out device" means the cable, protective sheath, and handcrank used to move the sealed source from the shielded to the unshielded position to make an industrial radiographic exposure.

"Enclosed radiography" means industrial radiography conducted in an enclosed cabinet or room and

includes cabinet radiography and shielded–room radiography.

"Fluoroscopic imaging assembly" means a subsystem in which X–ray photons produce a fluoroscopic image. It includes the image receptors such as the image intensifier and spot–film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and source assembly.

"GED" means general educational development.

"I.D. card" means the document issued by the agency, another Agreement State, a licensing state, or third–party certification to industrial radiographers following completion of requirements stated in 45.1(10)*"b."*

"Lay–barge radiography" means industrial radiography performed on any water vessel used for laying pipe.

"Lixiscope" means a portable light–intensified imaging device using a sealed source.

"Lock–out survey" means a radiation survey performed to verify that a sealed source is in its shielded position. The lock–out survey is performed before moving the radiographic exposure device or source changer to a new location or when securing the radiographic exposure device or source changer.

"Minimal threat" means that during the operations of electronic devices capable of generating or emitting fields of radiation:

a. No deliberate exposure of an individual occurs;

b. The radiation is not emitted in an open beam configuration; and

c. No known physical injury to an individual has occurred.

"Offshore" means within the territorial waters of the United States.

"Permanent radiographic installation" means a shielded installation or structure designed or intended for performing enclosed radiography, not located at a temporary job site, and in which radiography is performed.

"Personal supervision" means guidance and instruction provided to a radiographer trainee by a radiographer instructor who is present at the site, in visual contact with the trainee while the trainee is using sources of radiation, and in such proximity that immediate assistance can be given if required.

"Platform radiography" means industrial radiography performed on an offshore platform or other structure.

"Radiation safety officer" means an individual named by the licensee or registrant who has a knowledge of, responsibility for, and authority to enforce appropriate radiation protection rules, standards, and practices on behalf of the licensee or registrant and who meets the requirements of 45.1(10) *"d."*

"Radiographer" means any individual who has successfully completed the training, testing, and documentation requirements of 45.1(10) *"b,"* who performs or personally supervises industrial radiographic operations, and is responsible to the licensee or registrant for ensuring compliance with the requirement of these rules and all license and certificate of registration conditions.

"Radiographer trainee" means any individual who has successfully completed the training, testing, and documentation requirements of 45.1(10)*"a"* and who uses sources of radiation and related handling tools or radiation survey instruments under the personal supervision of a radiographer trainer.

"Radiographer trainer (instructor)" means any individual who instructs and supervises radio–grapher trainees during on–the–job training and who meets the requirements of 45.1(10) *"c."*

"Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved or otherwise changed from a shielded to unshielded position for purposes of making a radiographic exposure (e.g., camera).

"Radiographic personnel" means any radiographer or radiographer trainee.

"Residential location" means any area where structures in which people lodge or live are located, and the grounds on which such structures are located including, but not limited to, houses, apartments, condominiums, and garages.

"Shielded position" means the location within the radiographic exposure device or storage container which, by manufacturer's design, is the proper location for the sealed source during storage.

"Shielded–room radiography" means industrial radiography conducted in a room shielded so that radiation levels at every location on the exterior meet the limitations specified in 641—40.26(136C).

"Source assembly" means a component to which the sealed source is affixed or in which the sealed source is contained. The source assembly includes the sealed source (pigtail).

"Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources.

"Source container" means a shielded device in which sealed sources are secured, transported, and stored.

"Storage area" means any location, facility, or vehicle which is used to store, to transport, or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

"Storage container" means a shielded device in which sealed sources are secured, transported, and stored.

"Temporary job site" means any location where industrial radiography is performed other than the location(s) listed in a specific license or certificate of registration.

"Trainee status card" means the document issued by the agency following completion of the requirements of 45.1(10)*"a"*(1) and (2).

"Transport container" means a package that is designed to provide radiation safety and security when sealed sources are transported and which meets all applicable requirements of the U.S. Department of Transportation.

"Underwater radiography" means industrial radiography performed when the radiographic exposure device and related equipment are beneath the surface of the water.

45.1(3) *Exemptions.*

a. Uses of certified and certifiable cabinet X–ray systems designed to exclude individuals are exempt from the requirements of this chapter, except for the requirements of 45.2(6) *"b"* and *"c."*

b. Industrial uses of lixiscopes are exempt from the requirements in this chapter.

c. Radiation machines determined by the agency to constitute a minimal threat to human health and

safety in accordance with 641—subrule 38.3(1) are exempt from the rules in this chapter, except for the requirements of this subrule.

45.1(4) *Receipt, transfer, and disposal of sources of radiation*. Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of sources of radiation. These records shall include the date the individual made the record, the radionuclide, number of curies, and the make, model, and serial number of each source of radiation and device, as appropriate. Records shall be maintained for agency inspection until disposal is authorized by the agency.

45.1(5) *Radiation survey instruments.*

a. The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each location where sources of radiation are present to make physical radiation surveys as required by this chapter and 641—subrule 40.36(1). Instrumentation required by this subrule shall have a range such that 2 millirems (0.02 millisievert) per hour through 1 rem (0.01 sievert) per hour can be measured.

b. Notwithstanding the requirements of 641—subrule 40.36(2) each radiation survey instrument shall be calibrated:

(1) At energies appropriate for use and at intervals not to exceed six months and after each instrument servicing;

(2) Such that accuracy within plus or minus 20 percent can be demonstrated;

(3) At 2 points located approximately 1/3 and 2/3 of full–scale on each scale for linear scale instruments; at midrange of each decade, and at 2 points of at least 1 decade for logarithmic scale instruments; and at 3 points between 2 and 1000 mrem per hour for digital instruments; and

(4) By a person licensed or registered by the agency, another agreement state, or the U.S. Nuclear Regulatory Commission to perform such service.

c. Records of these calibrations shall be maintained for two years after the calibration date for inspection by the agency.

d. Each radiation survey instrument shall be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is operating properly.

45.1(6) *Quarterly inventory.* Each licensee shall conduct a physical inventory at intervals not to exceed three months to account for all sealed sources and radiography exposure devices received and possessed by the licensee. Sources of radiation include radiographic exposure devices containing depleted uranium. The records of the inventories shall be maintained for two years from the date of the inventory for inspection by the agency and shall include: the manufacturer, model number, serial number, radionuclide, number of curies, and location of each source of radiation; number of kilograms of depleted uranium shielding; date of the inventory; and name of the individual making the inventory.

45.1(7) *Utilization logs.*

a. Each licensee or registrant shall maintain current logs of the use of each source of radiation. The logs shall include:

(1) A unique identification, such as a serial number, of each radiation machine, each radiographic exposure device containing a sealed source, and each sealed source;

(2) The identity of the radiographer using the source of radiation;

(3) Locations where each source of radiation is used; and

(4) The date(s) each source of radiation is removed from storage and returned to storage. For fixed installations, the date(s) each source of radiation is energized or used and the number of exposures made.

b. Utilization logs may be kept on IDPH Form 588–2693, Utilization Log, or on clear, legible records containing all the information required by 45.1(7)"a." Copies of utilization logs shall be maintained for agency inspection for two years from the date of the recorded event. The records shall be kept at the location specified by the license or certificate of registration.

45.1(8) *Inspection and maintenance.*

a. Each licensee or registrant shall ensure that visual and operability checks for obvious defects, proper working order, adequate shielding, and required labeling of radiation machines, radiographic exposure devices, storage containers, and source changers, and survey instruments are performed prior to each day or shift of use.

b. Each licensee or registrant shall conduct a program, at intervals not to exceed three months, or prior to the first use thereafter, of inspection and maintenance of radiation machines, radiographic exposure devices, storage containers, and source changers to ensure proper functioning of components important to safety. All appropriate parts shall be maintained in accordance with manufacturer's specifications. Records of inspection and maintenance shall be maintained for inspection by the agency for two years from the date of the recorded event. This program shall cover, as a minimum, the items in Appendix B.

c. If any inspection conducted pursuant to 45.1(8)*"a"* or *"b"* reveals damage to components critical to radiation safety, the device shall be removed from service and labeled as defective until repairs have been made.

45.1(9) *Permanent radiographic installations.* Permanent radiographic installations having high radiation area entrance controls of the type described in 641—paragraphs 40.42(1)*"b"* and *"c"* shall also meet the following requirements:

a. Each entrance that is used for personnel access to the high radiation area shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation. The audible signal shall be activated when an attempt is made to enter the installation while the source is exposed.

b. The control device or alarm system shall be tested for proper operation at the beginning of each day of equipment use. If a control device or alarm system is operating improperly, it shall be immediately labeled as defective and repaired before industrial radiographic operations are resumed. Records of these tests shall be maintained for inspection by the agency for two years from the date of the event.

45.1(10) *Training and testing for radiographic personnel.*

a. Radiographer trainee requirements. No licensee or registrant shall permit any individual to act as a radiographer trainee, as defined in this chapter, until:

(1) It has been documented on the appropriate agency form or equivalent that such individual has received copies of and has demonstrated an understanding of:

1. The subjects outlined in Appendix A, presented in a course approved by the agency, another agreement state, or the U.S. Nuclear Regulatory Commission;

2. The rules contained in this chapter and the applicable sections of 641—Chapters 38, 39, and 40;

3. The appropriate conditions of license(s) or certificate(s) of registration; and

4. The licensee's or registrant's operating and emergency procedures.

(2) The individual possesses a current agency–issued trainee status card issued after completion of 45.1(10)*"a"*(1). Trainee status will be granted only once for each individual and is valid for no longer than two years.

b . Radiographer requirements. No licensee or registrant shall permit any individual to act as a radiographer:

(1) Until it has been documented to the agency that such individual:

1. Has completed the requirements of 45.1(10)*"a"*(1);

2. Has completed at least two months of on–the–job training as a radiographer trainee supervised by one or more radiographic trainers authorized on a license or registration certificate. The on–the–job training shall be documented on the appropriate agency form or equivalent and shall include at least 200 hours of active participation in industrial radiographic operations and does not include safety meetings or classroom training (this requirement does not apply to individuals designated as radio–graphers prior to January 1, 1992);

3. Has demonstrated competence in the use of sources of radiation, radiographic exposure devices, related handling tools, and radiation survey instruments which may be employed in industrial radiographic assignments;

(2) Unless the individual has successfully completed within the last five years the appropriate agency–administered examination prescribed in 45.1(10) *"f"* (2) or equivalent examination; and

(3) Unless the individual possesses a current I.D. card.

c. Radiographer trainer. No individual shall act as a radiographer trainer unless such individual:

(1) Has met the requirements of 45.1(10)*"a"*(1) and *"b"*;

(2) Has one year of documented experience as an industrial radiographer; and

(3) Is named on the specific license or certificate of registration issued by the agency and under which an individual is acting as a radiographer trainer, or

(4) Possesses a valid radiographer trainer card issued by the agency.

d. Radiation safety officer.

(1) A radiation safety officer (RSO) shall be designated for every industrial radiography license and certificate of registration issued by the agency.

(2) The RSO's qualifications shall include:

1. Possession of a high school diploma or a certificate of high school equivalency based on the GED test;

2. Completion of the training and testing requirements of 45.1(10)*"a"*(1) and 45.1(10)*"b"*(1)"3," (2), and (3); and

3. Two years of documented radiation protection experience, including knowledge of industrial radiographic operations with at least 40 hours of active participation in industrial radiographic operations.

(3) The specific duties of the RSO include, but are not limited to, the following:

1. To establish and oversee operating, emergency, and ALARA procedures and to review them regularly to ensure that the procedures are current and conform with these rules;

2. To oversee and approve all phases of the training program for radiographic personnel so that appropriate and effective radiation protection practices are taught;

3. To ensure that required radiation surveys and leak tests are performed and documented in accordance with these rules, including any corrective measures when levels of radiation exceed established limits;

4. To ensure that personnel monitoring devices are calibrated and used properly by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by 641—Chapter 40;

5. To ensure that any required interlock switches and warning signals are functioning and that radiation signs, ropes, and barriers are properly posted and positioned;

6. To investigate and report to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by these rules and each theft or loss of source(s) of radiation, to determine the cause, and to take steps to prevent its recurrence;

7. To have a thorough knowledge of management policies and administrative procedures of the licensee or registrant;

8. To assume control and have the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;

9. To maintain records as required by these rules (see Appendix C);

10. To ensure the proper storing, labeling, transport, and use of exposure devices and sources of radiation;

11. To ensure that quarterly inventory and inspection and maintenance programs are performed in accordance with 45.1(6), 45.1(8), 45.2(3), and 45.3(6)*"b"*; and

12. To ensure that personnel are complying with these rules, the conditions of the license or the registration, and the operating and emergency procedures of the licensee or registrant.

e. Training and testing records. Each licensee and registrant shall maintain, for agency inspection, training and testing records which demonstrate that the applicable requirements of 45.1(10)*"a"* and *"b"* are met for all industrial radiographic personnel. Records shall be kept on IDPH Form 588–2692 or on clear, legible records containing all the information required by IDPH Form 588–2692. Records shall be maintained until disposal is authorized by the agency.

f. Applications and examinations.

(1) Application.

1. An application for taking the examination shall be on forms prescribed and furnished by the agency along with the fee required in 641—38.8(3).

2. An individual whose I.D. card has been suspended or revoked shall obtain prior approval from the agency to apply to take the examination.

(2) Examination. The examination shall be given for the purpose of determining the qualifications of applicants.

1. A written examination shall be held at such times and places as the agency shall determine. The scope of the examination and the methods of procedure, including determination of the passing score, shall be prescribed by the agency. The examination will emphasize the applicant's ability to safely use sources of radiation and related equipment and the applicant's knowledge of these rules.

2. A candidate failing an examination may apply for reexamination in accordance with 45.1(10)*"f"*(1) and will be reexamined. A candidate shall not retake the same version of the agency–administered examination.

3. The examination will be held at locations designated by the agency. The examination shall normally be offered quarterly. Dates, times, and locations of the examinations will be provided by the agency.

4. The examination will be in the English language.

5. To take the examination, an individual shall have a picture identification card (such as an Iowa driver's license) at the time of the examination.

6. Calculators will be permitted during the examination; however, calculators or computers with preprogrammed data or formulas, including exposure calculations, will not be permitted.

7. The examination will be a "closed book" examination.

8. Examination material shall be returned to the agency at the end of the examination. No photographic or other copying of examination questions or materials shall be permitted. Disclosure by any individual of the contents of any examination prior to the administration is prohibited.

9. Any individual observed by an agency proctor to be compromising the integrity of the examination shall be required to surrender the examination, the answer sheet, and any work paper. Such individual will not be allowed to complete the examination, will forfeit the examination fee, and will leave the examination site to avoid disturbing other examinees. Such individual may resubmit an application and an additional examination fee to take the examination not earlier than three months later.

10. The names and scores of individuals taking the examination shall be a public record.

g. Identification procedures.

(1) I.D. card.

1. An I.D. card shall be issued to each person who successfully completes the requirements of 45.1(10) *"b"* and the examination prescribed in 45.1(10) *"f"* (2) or equivalent exam.

2. Each person's I.D. card shall contain the person's photograph.

3. The I.D. card remains the property of the state of Iowa and may be revoked or suspended under the provisions of 45.1(10)*"h."*

4. Any individual who wishes to replace the I.D. card shall submit to the agency a written request for a replacement I.D. card, stating the reason a replacement I.D. card is needed and the fee required in 641—subrule 38.8(3). The individual shall maintain in possession a copy of the request while performing industrial radiographic operations until a replacement I.D. card is received from the agency.

(2) Expiration of I.D. card. Each I.D. card expires at the end of the day, in the month and year stated on the I.D. card.

(3) Renewal of I.D. card.

1. Applications for examination to renew an I.D. card shall be filed in accordance with 45.1(10)*"f"*(1).

2. The examination for renewal of an I.D. card shall be administered in accordance with 45.1(10)*"f"*(2).

3. A renewed I.D. card shall be issued in accordance with 45.1(10)*"g"*(1).

h. Revocation or suspension of an I.D. card.

(1) Any radiographer who violates these rules may be required to show cause at a formal hearing why the I.D. card should not be revoked or suspended.

(2) When an agency order has been issued for an industrial radiographer to cease and desist from the use of radioactive material or revoking or suspending the I.D. card, the industrial radiographer shall surrender the I.D. card to the agency until such time as the order is changed or the suspension expires.

(3) An agency's inspector may, in certain instances, confiscate any radiographer's I.D. card on the spot while conducting an inspection or investigation. If the inspector determines that the activities being conducted by the radiographer are significant enough to be classified as severity I, II, or III, as specified in 641—38.5(136C), and after obtaining the approval of agency management, the inspector may take any radiographer's I.D. card. The agency will then issue a cease and desist order to the radio–grapher's employer, forward the I.D. card(s) to the issuing entity, and notify the U.S. Nuclear Regulatory Commission and other agreement states.

i. Exemptions. Any person using a source of radiation to determine the presence of explosives in a package or the authenticity of a piece of art is exempt from the provisions of 45.1(10) *"a"* to *"h."*

45.1(11) *Internal audits.* Each licensee or registrant shall conduct an internal audit program to ensure that the radioactive material license conditions and the licensee's or registrant's operating and emergency procedures are followed by each radiographer. Each radiographer's, radiographer trainee's, and accelerator operator's performance during an actual radiographic operation shall be audited at intervals not to exceed three months. If a radiographer or a radiographer trainee has not participated in a radiographic operation for more than three months since the last audit, that individual's performance shall be observed and recorded the next time the individual participates in a radiographic operation. Records of audits shall be maintained by the registrant for agency inspection for two years from the date of the audit.

45.1(12) *Personnel monitoring control.*

a. The personnel monitoring program shall meet the applicable requirements of 641—Chapter 40.

b. When performing industrial radiographic operations:

(1) No licensee or registrant shall permit an individual to act as a radiographer, radiographer trainee, or radiographer trainer unless the individual wears a direct–reading pocket dosimeter, an alarm ratemeter, and either a film badge or a thermoluminescent dosimeter (TLD) at all times during the radiographic operations. For permanent radiographic installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarm ratemeter is not required.

(2) Pocket dosimeters shall meet the criteria in ANSI N322–1977 and shall have a range of zero to at least 200 milliroentgens.

(3) Pocket dosimeters shall be recharged at the start of each work shift.

(4) Pocket dosimeters shall be read and exposures recorded at least once daily, at the end of each work shift, and before each recharging.

(5) If an individual's pocket dosimeter is discharged beyond its range (i.e., goes "off scale"), industrial radiographic operations by that individual shall cease and the individual's film badge or TLD shall be

within 24 hours sent for processing. The individual shall not return to work with sources of radiation until a determination of the radiation exposure has been made.

(6) Each film badge or TLD shall be assigned to and worn by only one individual.

(7) Film badges and TLDs must be replaced at least monthly. After replacement, each film badge or TLD must be returned to the supplier for processing within 14 calendar days of the exchange date specified by the personnel monitoring supplier.

(8) If a film badge or TLD is lost or damaged, the worker shall cease work immediately until a replacement film badge or TLD is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge or TLD.

c. Records of pocket dosimeter readings of personnel exposures shall be maintained for two years by the licensee or registrant for agency inspection. If the dosimeter readings were used to determine external radiation dose (i.e., no TLD or film badge exposure records exist), the records shall be maintained until the agency authorizes disposal.

d. Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed one year. Acceptable dosimeters shall read within plus or minus 20 percent of the true radiation exposure. Records of this check shall be maintained for inspection by the agency for two years from the date of the event.

e. Reports received from the film badge or TLD processor shall be kept for inspection by the agency until the agency authorizes disposition.

f. Each alarm ratemeter must:

(1) Be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift. Records of alarm function checks shall be maintained for two years by the licensee or registrant for agency inspection;

(2) Be set to give an alarm signal at a preset dose rate of 500 mR/hr;

(3) Require special means to change the preset alarm function; and

(4) Be calibrated at periods not to exceed one year for correct response to radiation: Acceptable ratemeters must alarm within plus or minus 20 percent of the true radiation dose rate. Records of the alarming ratemeter calibrations shall be maintained for two years by the licensee or registrant for agency inspection.

45.1(13) *Supervision of radiographer trainee.* Whenever a radiographer trainee uses radiographic exposure devices, sealed sources or related source handling tools or conducts radiation surveys required by 45.2(5) or 45.3(7) to determine that the sealed source has returned to the shielded position after an exposure, the radiographer trainee shall be under the personal supervision of a radiographer instructor.

45.1(14) *Access control.*

a. During each industrial radiographic operation, a radiographer shall maintain visual surveillance of the operation to protect against unauthorized entry into a restricted area, radiation area or high radiation area, except:

(1) Where the high radiation area is equipped with a control device or an alarm system as described in 641—subrule 40.42(1); or

(2) Where the high radiation area is locked to protect against unauthorized or accidental entry.

b. Radiographic exposure devices shall not be left unattended except when in storage or physically

secured against unauthorized removal.

45.1(15) *Posting.*

a. Notwithstanding any provisions in 641—subrule 40.62(1) areas in which radiography is being performed shall be conspicuously posted as required by 641—subrules 40.61(1) and 40.61(2).

b. Whenever practicable, ropes or barriers shall be used in addition to appropriate signs to designate areas in accordance with 641—subrule 40.26(1) and to help prevent unauthorized entry.

c. During pipeline industrial radiography operations, sufficient radiation signs and other barriers shall be posted to prevent unmonitored individuals from entering the radiation area.

d. Notwithstanding the requirements of 45.1(15)*"a,"* a restricted area may be established in accordance with 641—subrule 40.26(1) and may be posted in accordance with 40.61(1) and 40.61(2), i.e., both signs may be posted at the same location at the boundary of the restricted area.

45.1(16) *Temporary job site requirements.*

a. Documents and records. Each licensee or registrant conducting industrial radiography at a temporary job site shall have the following records available at that site for inspection by the agency:

(1) Appropriate license or certificate of registration or equivalent document;

(2) The appropriate operating and emergency procedures;

(3) The applicable agency rules;

(4) Survey records required pursuant to 45.2(5)*"d"* and 45.3(7)*"j"* for the period of operation at the site;

(5) Daily pocket dosimeter records for the period of operation at the site;

(6) The daily alarming ratemeter records for the period of operation at the site; and

(7) The latest radiation survey instrument calibration and leak test records for specific devices and sealed sources in use at the site. Acceptable records include tags or labels which are affixed to the device or survey meter and decay charts for sources which have been manufactured within the last six months.

b. Reserved.

45.1(17) *Specific requirements for radiographic personnel performing industrial radiography.*

a. At a job site, the following shall be supplied by the licensee or registrant:

(1) At least one operable, calibrated radiation survey instrument;

(2) A current whole body personnel monitor (TLD or film badge) for each individual;

(3) An operable, calibrated pocket dosimeter with a range of 0 to 200 milliroentgens (5.16×10^{-5} C/kg) for each worker; and

(4) An operable, calibrated alarm ratemeter for each worker; and

(5) The appropriate barrier ropes and signs.

b. Each radiographer at a job site shall possess a valid I.D. card.

c. Each radiographer trainee at a job site shall possess a valid trainee status card issued by the agency.

d. Industrial radiographic operations shall not be performed if any of the items in 45.1(17)*"a," "b,"* and *"c"* are not available at the job site or are inoperable.

e. No individual other than a radiographer or a radiographer trainee who is under the personal supervision of a radiographer trainer shall manipulate controls or operate equipment used in industrial radiographic operations.

f. During an inspection by the agency, the agency inspector may terminate an operation if any of the items in 45.1(17)*"a"* are not available and operable or if the required number of radiographic personnel are not present. Operations shall not be resumed until such conditions are met.

45.1(18) *Notification of incidents.*

a. The agency shall be notified of thefts or losses of sources of radiation, overexposures, and excessive levels in accordance with 641—40.95(136C) and 40.97(136C).

b. Each licensee or registrant shall submit a written report within 30 days to the agency whenever one of the following events occurs:

(1) The source assembly cannot be returned to the fully shielded position and properly secured;

(2) The source assembly becomes disconnected from the drive cable;

(3) The failure of any component (critical to safe operation of the radiographic exposure device) to properly perform its intended function; or

(4) An indicator on a radiation–producing machine fails to show that radiation is being produced or an exposure switch fails to terminate production of radiation when turned to the off position.

c. The licensee or registrant shall include the following information in each report submitted in accordance with 45.1(18)*"b"*:

(1) A description of the equipment problem;

(2) Cause of each incident, if known;

(3) Manufacturer and model number of equipment involved in the incident;

(4) Location, time, and date of the incident;

(5) Actions taken to establish normal operations;

(6) Corrective actions taken or planned to prevent recurrence; and

(7) Names of personnel involved in the incident.

641—45.2(136C) Radiation safety requirements for the use of radiation machines in industrial radiography.

45.2(1) *Locking of sources of radiation.* The control panel of each radiation machine shall be equipped with a locking device that will prevent the unauthorized use of an X–ray system or the accidental production of radiation. The radiation machine shall be kept locked and the key removed at all times except when under the direct visual surveillance of a radiographer.

45.2(2) *Permanent storage precautions.* Radiation machines shall be secured while in storage to prevent

tampering or removal by unauthorized individuals.

45.2(3) *Requirements for radiation machines used in industrial radiographic operations.*

a. Equipment used in industrial radiographic operations involving radiation machines manufactured after January 1, 1992, shall be certified at the time of manufacture to meet the criteria set forth by ANSI N537–1976.

b. The registrant's name and city or town where the main business office is located shall be prominently displayed with a durable, clearly visible label(s) on all vehicles used to transport radiation machines for temporary job site use.

45.2(4) *Operating and emergency procedures.*

a. The registrant's operating and emergency procedures shall include instructions in at least the following:

(1) Operation and safety instruction on the radiation machine(s) to be used;

(2) Methods and occasions for conducting radiation surveys;

(3) Methods for controlling access to radiographic areas;

(4) Methods and occasions for locking and securing sources of radiation;

(5) Personnel monitoring and the use of personnel monitoring equipment, including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off–scale;

(6) Minimizing exposure of individuals in the event of an accident;

(7) The procedure for notifying proper personnel in the event of an accident;

(8) Maintenance of records; and

(9) Inspection and maintenance of radiation machines.

b. Each registrant shall provide, as a minimum, two radiographic personnel when radiation machines are used for any industrial radiography conducted other than at a permanent radiographic installation (shielded room, bay, or bunker). If one of the personnel is a radiographer trainee the other shall be a radiographer trainer authorized by the certificate of registration.

c. No individual other than a radiographer or a radiographer trainee who is under the personal supervision of a radiographer trainer shall manipulate controls or operate equipment used in industrial radiographic operations.

d. Rescinded IAB 4/8/98, effective 7/1/98.

45.2(5) *Radiation surveys and survey records.*

a. No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation, as described in 45.1(5), is available and used at each site where radiographic exposures are made.

b. A physical radiation survey shall be made after each radiographic exposure using radiation machines to determine that the machine is "off."

c. All potential radiation areas where industrial radiographic operations are to be performed shall be

posted in accordance with 45.1(15), based on calculated dose rates, before industrial radiographic operations begin. An area survey shall be performed during the first radiographic exposure to confirm that 45.1(15) requirements have been met and that unrestricted areas do not have radiation levels in excess of the limits specified in 641—subrule 40.26(1).

d. Records shall be kept of the surveys required by 45.2(5)*"b"* and *"c."* Such records shall be maintained for inspection by the agency for two years after completion of the survey. If the survey was used to determine an individual's exposure, however, the records of the survey shall be maintained until the agency authorizes their disposition.

45.2(6) *Special requirements and exemptions for enclosed radiography.*

a. Systems for enclosed radiography, including shielded-room radiography and cabinet radiography, designed to allow admittance of individuals shall:

(1) Comply with all applicable requirements of this chapter and 641—subrule 40.26(1). If such a system is a certified cabinet X-ray system, it shall comply with all applicable requirements of this chapter and 21 CFR 1020.40.

(2) Be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements as specified in 641—subrule 40.26(1). Records of these evaluations shall be maintained for inspection by the agency for a period of two years after the evaluation.

b. Certified and certifiable cabinet X-ray systems designed to exclude individuals from the interior of the cabinet are exempt from the requirements of this chapter except that:

(1) Operating personnel must be provided with either a film badge or a thermoluminescent dosimeter in accordance with the appropriate provisions of 641—40.37(136C).

(2) No registrant shall permit any individual to operate a cabinet X-ray system until such individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with this subparagraph shall be maintained for inspection by the agency until disposition is authorized by the agency.

(3) Tests for proper operation of interlocks used to control entry to the high radiation area or alarm systems, where applicable, shall be conducted and recorded every three months. Records of these tests shall be maintained for agency inspection until disposal is authorized by the agency.

(4) The registrant shall perform an evaluation, at intervals not to exceed one year, to determine conformance with 641—subrule 40.26(1). If such a system is a certified cabinet X-ray system, it shall be evaluated at intervals not to exceed one year to determine conformance with 21 CFR 1020.40.Records of these evaluations shall be maintained for inspection by the agency for a period of two years after the evaluation.

c. Certified cabinet X-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the agency pursuant to 641—38.3(136C).

45.2(7) *Registration for industrial radiographic operations.*

a. Radiation machines used in industrial radiographic operations shall be registered in accordance with 641—Chapter 39.

b. In addition to the registration requirements in 641—Chapter 39, an application for a certificate of registration shall include the following information:

(1) A schedule or description of the program for training radiographic personnel which specifies:

1. Initial training,

2. Periodic training,

3. On–the–job training, and

4. Methods to be used by the registrant to determine the knowledge, understanding, and ability of radiographic personnel to comply with agency rules, registration requirements, and the operating and emergency procedures of the applicant.

(2) Written operating and emergency procedures, including all items listed in Appendix D.

(3) A description of the internal inspection system or other management control to ensure that radiographic personnel follow registration provisions, rules of the agency, and the applicant's operating and emergency procedures.

(4) A list of permanent radiographic installations and descriptions of permanent storage and use locations.

(5) A description of the organization of the industrial radiographic program, including delegations of authority and responsibility for operation of the radiation safety program.

c. A certificate of registration will be issued if the requirements of 641—Chapter 39 and this subrule are met.

641—45.3(136C) ***Radiation safety requirements for use of sealed sources of radiation in industrial radiography.***

45.3(1) Limits on external radiation levels from storage containers and source changers. The maximum exposure rate limits for storage containers and source changers are 200 millirems (2 millisieverts) per hour at any surface, and 10 millirem (0.1 millisieverts) per hour at any surface, and 10 millirem (0.1 millisieverts) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

45.3(2) ***Locking of sources of radiation.***

a. Each source of radiation shall be provided with a lock or lockable outer container designed to prevent unauthorized or accidental removal or exposure of a sealed source and shall be kept locked at all times except when under the direct surveillance of a radiographer or radiographer trainee, or as may be otherwise authorized pursuant to 45.3(6). Each storage container and source changer likewise shall be provided with a lock and shall be kept locked when containing sealed sources except when the container is under the direct surveillance of a radiographer or radiographer trainee.

b. Radiographic exposure devices, source changers, and storage containers, prior to being moved from one location to another and also prior to being secured at a given location, shall be locked and surveyed to ensure that the sealed source is in the shielded position.

c. The sealed source shall be secured in its shielded position by locking the exposure device or securing the remote control each time the sealed source is returned to its shielded position. Then a survey shall be performed to determine that the sealed source is in the shielded position pursuant to 45.3(7) *"b."*

45.3(3) ***Storage precautions.***

a. Locked radiographic exposure devices, source changers, transport packages, and storage containers shall be physically secured to prevent tampering, accidental loss, or removal by unauthorized personnel and stored to minimize danger from explosion or fire.

b. Radiographic exposure devices, source changers, or storage containers that contain radioactive material shall not be stored in residential locations. This requirement does not apply to storage of radioactive material in a vehicle in transit for use at temporary job sites, if the licensee complies with 45.3(3)*"c,"* and if the vehicle does not constitute a permanent storage location as described in 45.1(9).

c. If a vehicle is to be used for storage of radioactive material, a vehicle survey shall be performed after securing radioactive material in the vehicle and before transport to ensure that radiation levels do not exceed the limits specified in 641—subrule 40.26(1) at the exterior surface of the vehicle.

d. A storage or use location is permanent if radioactive material is stored at the location for more than 90 days and any one or more of the following applies to the location:

(1) Telephone service is established by the licensee;

(2) Industrial radiographic services are advertised for or from the location;

(3) Industrial radiographic operations are conducted at other sites due to arrangements made from the location.

45.3(4) *Performance requirements for radiography equipment.* Equipment used in industrial radiographic operations must meet the following minimum criteria:

a. Each radiographic exposure device and all associated equipment must meet the requirements specified in American National Standard N432–1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography" (published as NBS Handbook 136, issued January 1981). This publication has been approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a). This publication may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, and from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018, telephone (212)642–4900. Copies of the document are available for inspection at the Iowa Department of Public Health, Bureau of Radiological Health, Lucas State Office Building, Des Moines, Iowa 50319.

b. In addition to the requirements specified in paragraph *"a"* of this subrule, the following requirements apply to radiographic exposure devices and associated equipment.

(1) Each radiographic exposure device must have attached to it by the user a durable, legible, clearly visible label bearing the:

1. Chemical symbol and mass number of the radionuclide in the device;

2. Activity and the date on which this activity was measured;

3. Model number and serial number of the sealed source;

4. Manufacturer of the sealed source; and

5. Licensee's name, address, and telephone number.

(2) Radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of 641—39.5(136C).

(3) Modification of any exposure devices and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

c. In addition to the requirements specified in paragraphs *"a"* and *"b"* of this subrule, the following requirements apply to radiographic exposure devices and associated equipment that allow the source to

be moved out of the device for radiographic operation or source changing:

(1) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions;

(2) The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device;

(3) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand, or other foreign matter;

(4) Each sealed source or source assembly must have attached to it or engraved in it, a durable, legible, visible label with the words: "DANGER—RADIOACTIVE." The label must not interfere with safe operation of the exposure device or associated equipment;

(5) The guide tube must have passed the crushing tests for the control tube as specified in ANSI N432 and a kinking resistance test that closely approximates the kinking forces likely to be encountered during use;

(6) Guide tubes must be used when moving the source out of the device;

(7) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during radiographic operations;

(8) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432;

(9) Source changers must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

d. All newly manufactured radiographic exposure devices and associated equipment acquired by licensees after January 10, 1992, must comply with the requirements of this subrule.

e. All radiographic exposure devices and associated equipment in use after January 10, 1996, must comply with the requirements of this subrule.

45.3(5) *Leak testing, repair, tagging, opening, modification, and replacement of sealed sources.*

a. The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening, or any other modification of any sealed source shall be performed only by persons specifically authorized to do so by the agency, the U.S. Nuclear Regulatory Commission, or an agreement state.

b. Each sealed source shall be tested for leakage at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within the six–month period prior to the transfer, the sealed source shall not be put into use until tested.

c. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of removable contamination on the sealed source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed source storage position, or other appropriate measuring point, by a procedure to be approved pursuant to 641—subparagraph

39.4(27) *"e"*(5). Records of leak test results shall be kept in units of microcuries (becquerels) and maintained for inspection by the agency for six months after the next required leak test is performed or until the sealed source is transferred or disposed.

d. Any test conducted pursuant to 45.3(5)*"b"* and *"c"* which reveals the presence of 0.005 microcurie (185 Bq) or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with rules of the agency. Within five days after obtaining results of the test, the licensee shall file a report with the agency describing the equipment involved, the test results, and the corrective action taken.

e. Each radiographic exposure device shall have permanently attached to it a durable label which has, as a minimum, the instruction: "Danger—Radioactive Material—Do Not Handle—Notify Civil Authorities if Found."

45.3(6) *Operating and emergency procedures.*

a. The licensee's operating and emergency procedures shall include instructions in at least the following:

(1) Handling and use of sources of radiation to be employed such that no individual is likely to be exposed to radiation doses in excess of the limits established in 641—Chapter 40;

(2) Methods and occasions for conducting radiation surveys;

(3) Methods for controlling access to radiographic areas;

(4) Methods and occasions for locking and securing sources of radiation;

(5) Personnel monitoring and the use of personnel monitoring equipment, including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off–scale;

(6) Transportation to field locations, including packing of sources of radiation in the vehicles, posting of vehicles, and control of sources of radiation during transportation;

(7) Minimizing exposure of individuals in the event of an accident;

(8) The procedure for notifying proper personnel in the event of an accident;

(9) Maintenance of records; and

(10) The inspection and maintenance of radiographic exposure devices, source changers, storage containers, and radiation machines.

b. Rescinded IAB 4/8/98, effective 7/1/98.

c. Each licensee shall provide, as a minimum, two radiographic personnel when sources of radiation are used for any industrial radiography conducted other than at a permanent radiographic installation (shielded room, bay, bunker). If one of the personnel is a radiographer trainee, the other shall be a radiographer trainer authorized by the license.

d. Collimators shall be used in industrial radiographic operations which use crank–out devices except when physically impossible.

e. No individual other than a radiographer or a radiographer trainee who is under the personal supervision of a radiographer trainer shall manipulate controls or operate equipment used in industrial radiographic operations.

45.3(7) *Radiation surveys and survey records.*

a. No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation, as described in 45.1(5), is available and for each exposure device used at each site where radiographic exposures are made.

b. A survey with a calibrated and operable radiation survey instrument shall be made after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall also include the entire length of the guide tube and collimator.

c. (1) All potential radiation areas where industrial radiographic operations are to be performed shall be posted in accordance with 641—40.61(136C), based on calculated dose rates, before industrial radiographic operations begin. An area survey shall be performed during the first radiographic exposure (i.e., with the sealed source in the exposed position) to confirm that 641—40.61(136C) requirements have been met and that unrestricted areas do not have radiation levels in excess of the limits specified in 641—subrule 40.26(1).

(2) Each time the exposure device is relocated or the exposed position of the sealed source is changed, the requirements of 45.3(7)*"c"*(1) shall be met.

(3) The requirements of 45.3(7)*"c"*(2) do not apply to pipeline industrial radiographic operations when the conditions of exposure include, but are not limited to, the radiographic exposure device, duration of exposure, source strength, pipe size, and pipe thickness remain constant.

d. A lock–out survey, in which all accessible surfaces of the radiographic exposure device or source changer are surveyed, shall be made to determine that each sealed source is in its shielded position before securing the radiographic exposure device or source changer.

e. The sealed source shall be secured in its shielded position by locking the radiographic exposure device or source changer each time the sealed source is returned to its shielded position.

f. Each radiographic exposure device and source changer shall be locked and the key removed from any keyed lock prior to being moved or transported from one location to another and also prior to being stored at a given location.

g. If a vehicle is to be used for storage of radioactive material, a vehicle survey shall be performed after securing radioactive material in the vehicle and before transport to ensure that radiation levels do not exceed the limits specified in 641—subrule 40.26(1) at the exterior surface of the vehicle.

h. Surveys shall be performed on storage containers to ensure that radiation levels do not exceed the limits specified in 641—40.15(136C). These surveys shall be performed initially with the maximum amount of radioactive material present in the storage location and thereafter at the time of the quarterly inventory and whenever storage conditions change.

i. A survey meeting the requirements of 45.3(7)*"b"* shall be performed on the radiographic exposure device and the source changer after every sealed source exchange. A survey shall be made of the storage area as defined in 641—45.2(136C) whenever a radiographic exposure device is being placed in storage.

j. Records shall be kept of the surveys required by 45.3(7)*"c," "d," "g," "h,"* and *"i."* Such records shall be maintained for inspection by the agency for two years after completion of the survey. If the survey was used to determine an individual's exposure, however, the records of the survey shall be maintained until the agency authorizes their disposition.

45.3(8) *Requirements for enclosed radiography.*

a. Systems for enclosed radiography, including shielded–room radiography designed to allow admittance of individuals shall comply with all applicable requirements of this chapter.

b. Procedures shall be evaluated at intervals not to exceed one year to ensure compliance with the applicable requirements as specified in 641—subrule 40.26(1). Records of these evaluations shall be maintained for inspection by the agency for a period of two years after the evaluation.

c. Tests for proper operation of high radiation area control devices or alarm systems, where applicable, shall be conducted, recorded, and maintained in accordance with 45.1(9)*"b."*

45.3(9) *Underwater, offshore platform, and lay–barge radiography.*

a. Underwater, offshore platform, or lay–barge radiography shall not be performed unless specifically authorized in a license issued by the agency in accordance with 45.3(11).

b. In addition to the other rules of this chapter, the following rules apply to the performance of lay–barge or offshore platform radiography:

(1) Cobalt–60 sources with activities in excess of 20 curies (nominal) and iridium–192 sources with activities in excess of 100 curies (nominal) shall not be used in the performance of lay–barge or offshore platform industrial radiography.

(2) Collimators shall be used for all industrial radiographic operations performed on lay–barge or offshore platforms.

45.3(10) *Prohibitions.* Industrial radiography performed with a sealed source which is not fastened to or contained in a radiographic exposure device (fishpole technique) is prohibited unless specifically authorized in a license issued by the agency.

45.3(11) *Licensing for industrial radiographic operations.*

a. Sealed sources used in industrial radiographic operations shall be licensed in accordance with 641—Chapter 39.

b. In addition to the licensing requirements in 641—Chapter 39, an application for a license shall include the following information:

(1) A schedule or description of the program for training radiographic personnel which specifies:

1. Initial training,

2. Periodic training,

3. On–the–job training, and

4. Methods to be used by the licensee to determine the knowledge, understanding, and ability of radiographic personnel to comply with agency rules, licensing requirements, and the operating and emergency procedures of the applicant;

(2) Written operating and emergency procedures, including all items listed in Appendix D;

(3) A description of the internal inspection system or other management control to ensure that radiographic personnel follow license provisions, rules of the agency, and the applicant's operating and emergency procedures;

(4) A list of permanent radiographic installations and descriptions of permanent storage and use locations. Radioactive material shall not be stored at a permanent storage location or used at a permanent

use location unless such storage or use location is specifically authorized by the license. A storage or use location is permanent if radioactive material is stored at the location for more than 90 days and any one or more of the following applies to the location:

1. Telephone service is established by the licensee;

2. Industrial radiographic services are advertised for or from the location;

3. Industrial radiographic operations are conducted at other sites due to arrangements made from the location;

(5) A description of the organization of the industrial radiographic program, including delegations of authority and responsibility for operation of the radiation safety program;

(6) A description of the program for inspection and maintenance of radiographic exposure devices and transport and storage containers (including applicable items in 45.1(8) and Appendix A); and

(7) If a license application includes underwater radiography, a description of:

1. Radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;

2. Radiographic equipment and radiation safety equipment unique to underwater radiography; and

3. Methods for gas–tight encapsulation of equipment;

(8) If a license application includes offshore platform or lay–barge radiography, a description of:

1. Transport procedures for radioactive material to be used in industrial radiographic operations;

2. Storage facilities for radioactive material; and

3. Methods for restricting access to radiation areas.

641—45.4(136C) Radiation safety requirements for the use of particle accelerators for nonhuman use.

45.4(1) *Purpose and scope.*

a. This rule establishes procedures for the registration or licensing and the use of particle accelerators.

b. Unless specifically required otherwise by this rule, all registrants or licensees performing operations with a particle accelerator are subject to the requirements of 641—Chapters 38 to 40 and 641—45.1(136C). The requirements of 45.1(10) do not apply.

45.4(2) *Definitions.* For purposes of this subrule, definitions in 641—Chapter 38 may also apply. As used in this rule, the following definitions apply:

"Self–shielded particle accelerator" means a particle accelerator with the accelerator installed in an enclosure independent of the existing architectural structures except the floor on which it may be placed. The enclosure must have been evaluated by a qualified expert and that evaluation approved by an appropriate regulatory authority through a device evaluation. The self–shielded accelerator is intended to contain at least that portion of material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. A particle accelerator used within a shielded part of a building, or which may temporarily or occasionally incorporate portable shielding, is not a self–shielded particle accelerator.

"Shielded facility" means an accelerator facility where shielding is required to be constructed on site in order to assure compliance with the requirements of 641—Chapter 40, or where shielding supplied with the accelerator has been evaluated by qualified experts and that evaluation approved by an appropriate regulatory authority through a device evaluation.

45.4(3) *Registration or license requirements.* No person shall receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration or license issued pursuant to 641—39.1(136C) to 39.4(136C) and the following requirements:

a. Accelerator facilities whose operations result in nuclear transformations that produce or are likely to produce radioactive material more than the exempt quantities and concentrations listed in Appendices A and B of 641—Chapter 39 shall be authorized by the issuance of a radioactive material license in accordance with 641—Chapter 39.

b. For accelerator facilities required to be licensed in accordance with 45.4(3), those operations that would require personnel monitoring, pursuant to 641—40.37(136C), due to the presence of radioactive material, shall be performed only by a specific licensee. Such operations would normally include installation, testing and maintenance as well as routine operations.

45.4(4) *General requirements for the issuance of a registration or license for particle accelerators.* Along with the requirements of 641—39.1(136C) to 39.4(136C), an application for use of a particle accelerator will be approved only if the agency determines that:

a. The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this rule and 641—Chapter 40 in such a manner as to minimize danger to public health and safety or property;

b. The applicant's proposed or existing equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

c. The issuance of the registration or license will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in 45.4(4);

d. The applicant has appointed a radiation safety officer responsible for the day–to–day operation of the radiation safety program;

e. The applicant and the applicant's staff have experience in the use of particle accelerators and training sufficient for application to its intended uses;

f. The applicant has an adequate training program for operators of particle accelerators.

45.4(5) *Personnel monitoring.* In addition to the requirements of 641—Chapter 40, personnel monitoring shall be provided to and used by all individuals entering any area for which interlocks are required unless a survey of the area has determined that radiation levels are below that of a high radiation area; and

a. Power to an accelerator cannot be activated; or

b. An accelerated beam cannot be directed to the area.

45.4(6) *Operations.*

a. No registrant shall permit any individual to act as an operator of a particle accelerator until such individual:

(1) Has been instructed in radiation safety and shall have demonstrated an understanding thereof;

(2) Has received copies of and instruction in this rule and the applicable requirements of 641—Chapter 40, pertinent registration and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

(3) Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed.

b. The radiation safety officer or radiation safety committee, if applicable, shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to minimize danger to public health and safety or property.

c. Along with the audit required in 641—subrule 40.10(3), each operator's performance during an actual accelerator operation shall be audited by the radiation safety officer or designee at intervals not to exceed 12 months. If an operator has not participated in an accelerator operation for more than 12 months since the last audit, the individual's performance shall be observed and recorded at the first opportunity the individual participates in an accelerator operation. Records of the audits shall be maintained by the registrant for the agency inspection for three years from the date of the audit.

45.4(7) *Shielding and safety design requirements.*

a. A qualified expert acceptable to the agency shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation.

b. Each particle accelerator installation shall be provided with such primary and secondary barriers as are necessary to ensure compliance with 641—40.15(136C) and 641—40.26(136C).

c. In addition to the requirements of 45.4(8) *"a"* and *"b,"* shielded facilities or self–shielded particle accelerators shall meet the following requirements:

(1) Authorization, by issuance of a construction permit, shall be granted upon a determination of adequacy being made pursuant to the review of an initial application of the shielding design, physical plant, and site specifications, and of the applicant's proposed equipment, uses and workloads. For a shielded facility, the applicant shall submit an evaluation of the shielding design by a qualified expert. For a self–shielded particle accelerator, the applicant need not submit an evaluation of a shielding design if an evaluation by an appropriate regulatory authority has been performed. The applicant may instead reference this evaluation. The applicant shall maintain a copy of the evaluation of shielding design for agency review.

(2) Authorization for installation and testing of an accelerator shall be given only after a determination of adequacy of testing protocols, testing safety procedures, staff training, and radiation detection instrumentation has been made; and

(3) Operational use of an accelerator shall be authorized only after determination of adequacy of the items listed in 45.4(4) has been made by the agency.

45.4(8) *Particle accelerator controls and interlock systems.*

a. Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified, easily discernible and located outside the high radiation area.

b. Each entrance into a target area or other high radiation area shall be provided with two safety interlocks that shut down the machine when the barrier is breached.

c. Each safety interlock shall be on a circuit that allows it to operate independently of all other safety interlocks.

d. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents operation of the accelerator.

e. When a safety interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the safety interlock has been tripped and, lastly, at the main control console.

f. A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

45.4(9) *Warning devices.*

a. Each location designated as a high radiation area, and each entrance to such location, shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

b. Each high radiation area shall have an audible warning device that shall be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning device shall be clearly discernible in all high radiation areas.

c. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted in accordance with 641—40.61(136C).

45.4(10) *Operating and emergency procedures.*

a. Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

b. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

c. All safety and warning devices, including interlocks, shall be checked for proper operation intervals not to exceed three months. Results of such tests shall be maintained at the accelerator facility for inspection by the agency.

d. All incidents whereby the interlock system fails to operate properly or where the operation is terminated by the interlock system shall be investigated and reported to the radiation safety officer or, if applicable, the radiation safety committee. Documentation shall be maintained for inspection by the agency.

e. If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

(1) Authorized by the radiation safety officer and, if applicable, the radiation safety committee;

(2) Recorded in a permanent log and a notice posted at the accelerator control console; and

(3) Terminated as soon as possible.

f. The registrant's operating and emergency procedures shall include the following:

(1) Operation and safety instructions on the accelerator(s) to be used;

(2) Methods for controlling access to restricted areas;

(3) Methods and occasions for locking and securing sources of radiation;

(4) Use of personnel monitoring equipment;

(5) The procedure for notifying proper personnel in the event of an accident;

(6) Maintenance of records;

(7) Inspections and maintenance of the accelerator; and

(8) Steps to be taken in the case of an emergency.

g. A copy of the current operating and emergency procedures shall be maintained at the accelerator control panel.

45.4(11) Radiation monitoring requirements.

a. *Radiation monitoring requirements.*

a. A radiation protection survey shall be performed and documented by a qualified expert, acceptable to the agency, when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

b. Accelerator facilities registered pursuant to 45.4(3) *"a"* shall survey with a radiation detection instrument at intervals not to exceed three months. Records of this survey shall be maintained for agency review for three years.

c. Accelerator facilities registered pursuant to 45.4(3) *"a"* shall survey for removable contamination at intervals not to exceed three months to determine the degree of contamination.

d. Each time removable shields on self–shielded particle accelerators are opened, a visual survey of the shielding must be performed to observe physical damage. In addition, when these shields are returned to the closed position, a physical radiation survey shall be conducted upon initial reactivating of the accelerator. Records of this survey shall be maintained for agency review for three years.

e. Accelerator facilities registered pursuant to 45.4(3) *"a"* shall perform a survey with a radiation detection instrument and surveys for removable contamination before maintenance or servicing of its particle accelerator(s) or associated equipment located in the high radiation area.

f. Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

g. Upon installation, all area monitoring equipment shall be tested to assure proper operation under operating conditions of the particle accelerator. All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair.

h. Whenever applicable, accelerator facilities registered pursuant to 45.4(3) *"a"* shall perform surveys at intervals not to exceed six months to determine the amount of airborne particulate radioactivity present.

i. All surveys shall be made in accordance with the written procedures established by the radiation safety officer or a qualified expert who is acceptable to the agency.

j. Records of all radiation protection surveys, calibrations, and instrumentation tests shall be maintained at the accelerator facility for inspection by the agency.

45.4(12) *Radiation safety officer.*

a. Each registrant shall appoint a radiation safety officer that meets the following requirements:

(1) Possesses a high school diploma or a certificate of high school equivalency based on the GED test;

(2) Documents two years of radiation protection experience.

b. The specific duties of the RSO include, but are not limited to, the following:

(1) To establish and oversee operating, emergency, and ALARA procedures and to review them regularly to ensure that the procedures are current and conform with these rules;

(2) To oversee and approve all phases of the training program for accelerator operators so that appropriate and effective radiation protection practices are taught;

(3) To ensure that required radiation surveys are performed and documented in accordance with these rules, including any corrective measures when levels of radiation exceed established limits;

(4) To ensure that personnel monitoring devices are calibrated and used properly by occupationally exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by 641—Chapter 40;

(5) To ensure that any required interlock switches and warning signals are functioning and that radiation signs, ropes, and barriers are properly posted and positioned;

(6) To investigate and report to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by these rules and each theft or loss of source(s) of radiation, to determine the cause, and to take steps to prevent its recurrence;

(7) To have a thorough knowledge of management policies and administrative procedures of the licensee or registrant;

(8) To assume control and have the authority to institute corrective actions including shutdown of operations when necessary in emergency situations or unsafe conditions;

(9) To maintain records as required by these rules;

(10) To ensure the proper storing, labeling, and use of the accelerator;

(11) To ensure that inspection and maintenance programs are performed in accordance with 45.1(6), 45.1(8), 45.4(10)*"c"*; and

(12) To ensure that personnel are complying with these rules and the operating and emergency procedures of the registrant.

641—45.5(136C) Radiation safety requirements for analytical X-ray equipment.

45.5(1) *Purpose and scope.* This rule provides special requirements for analytical X-ray equipment. The requirements of this rule are in addition to, and not in substitution for, 641—Chapters 38, 39, and 40. The requirements of rules 641—45.1(136C) to 641—45.4(136C) do not apply.

45.5(2) *Definitions.* For the purpose of this subrule, definitions in 641—Chapter 38 may also apply. As used in this rule, the following definitions apply:

"Analytical X-ray equipment" means equipment used for X-ray diffraction or fluorescence analysis.

"Analytical X-ray system" means a group of components utilizing X-rays or gamma rays to determine the elemental composition or to examine the microstructure of materials.

"Fail-safe characteristics" means a design feature which causes beam port shutters to close, or

otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

"Local components" means part of an analytical X–ray system and includes X–ray areas that are struck by X–rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but does not include power supplies, transformers, amplifiers, readout devices, and control panels.

"Normal operating procedures" means step–by–step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant or licensee, and data recording procedures, which are related to radiation safety.

"Open–beam configuration" means an analytical X–ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

"Primary beam" means radiation which passes through an aperture of the source housing by a direct path from the X–ray tube or a radioactive source located in the radiation source housing.

45.5(3) *Equipment requirements.*

a. Safety device. A device which prevents the entry of any portion of an individual's body into the primary X–ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open–beam configurations. A registrant or licensee may apply to the agency for an exemption from the requirement of a safety device. Such application shall include:

(1) A description of the various safety devices that have been evaluated;

(2) The reason each of these devices cannot be used; and

(3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to ensure that operators and others in the area will be informed of the absence of safety devices.

b. Warning devices.

(1) Open–beam configurations shall be provided with a readily discernible indication of:

1. X–ray tube "on–off" status located near the radiation source housing, if the primary beam is controlled in this manner; or

2. Shutter "open–closed" status located near each port on the radiation source housing, if the primary beam is controlled in this manner.

(2) An easily visible warning light labeled with the words "X–RAY ON," or words having a similar intent, shall be located:

1. Near any switch that energizes an X–ray tube and shall be illuminated only when the tube is energized; or

2. In the case of a radioactive source, near any switch that opens a housing shutter and shall be illuminated only when the shutter is open.

(3) Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after the effective date of these rules, warning devices shall have fail–safe characteristics.

c. Ports. Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

d. Labeling. All analytical X–ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

(1) "CAUTION—HIGH INTENSITY X–RAY BEAM," or words having a similar intent, on the X–ray source housing; and

(2) "CAUTION—RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an X–ray tube if the radiation source is an X–ray tube; or

(3) "CAUTION—RADIOACTIVE MATERIAL," or words having a similar intent, on the source housing in accordance with 641—40.63(136C) if the radiation source is a radionuclide.

e. Shutters. On open–beam configurations, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

f. Radiation source housing. Each radiation source housing shall be subject to the following requirements:

(1) Each X–ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.

(2) Each radioactive source housing or port cover or each X–ray tube housing shall be so constructed that, with all shutters closed, the radiation measured at a distance of 5 centimeters from its surface is not capable of producing a dose in excess of 2.5 millirems (0.025 mSv) in one hour. For systems utilizing X–ray tubes, this limit shall be met at any specified tube rating.

g. Generator cabinet. Each X–ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 centimeters from its surface such that it is not capable of producing a dose in excess of 0.25 millirem (2.5 mSv) in one hour.

45.5(4) *Area requirements.*

a. Radiation levels. The local components of an analytical X–ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in 641—40.26(136C). For systems utilizing X–ray tubes, these levels shall be met at any specified tube rating.

b. Surveys.

(1) Radiation surveys, as required by 641—40.36(136C), of all analytical X–ray systems sufficient to show compliance with 45.5(4)*"a"* shall be performed:

1. Upon installation of the equipment, and at least once every 12 months thereafter;

2. Following any change in the initial arrangement, number, or type of local components in the system;

3. Following any maintenance requiring the disassembly or removal of a local component in the system;

4. During the performance of maintenance and alignment procedures if the procedures require the presence of a primary X–ray beam when any local component in the system is disassembled or removed;

5. Anytime a visual inspection of the local components in the system reveals an abnormal condition; and

6. Whenever personnel monitoring devices show a significant increase over the previous monitoring

period or the readings are approaching the limits specified in 641—40.15(136C).

(2) Radiation survey measurements shall not be required if a registrant or licensee can demonstrate compliance with 45.5(4)*"a"* to the satisfaction of the agency.

c. Posting. Each area or room containing analytical X–ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION—X–RAY EQUIPMENT" or words having a similar intent in accordance with 641—subrule 40.61(1).

45.5(5) *Operating requirements.*

a. Procedures. Normal operating procedures shall be written and available to all analytical X–ray equipment workers. No individual shall be permitted to operate analytical X–ray equipment in any manner other than that specified in the procedures unless such individual has obtained written approval of the radiation safety officer.

b. Bypassing. No individual shall bypass a safety device or interlock unless such individual has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words having a similar intent, shall be placed on the radiation source housing.

c. Repair or modification of X–ray tube systems. Except as specified in 45.5(5) *"b,"* no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

d. Radioactive source replacement, testing, or repair. Radioactive source housings shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state.

45.5(6) *Personnel requirements.*

a. Instruction. No individual shall be permitted to operate or maintain analytical X–ray equipment unless such individual has received instruction in and demonstrated competence as to:

(1) Identification of radiation hazards associated with the use of the equipment;

(2) Significance of the various radiation warnings, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

(3) Proper operating procedures for the equipment;

(4) Recognition of symptoms of an acute localized exposure; and

(5) Proper procedures for reporting an actual or suspected exposure.

b. Personnel monitoring.

(1) Finger or wrist dosimetry devices shall be provided to and shall be used by:

1. Analytical X–ray equipment workers using systems having an open–beam configuration and not equipped with a safety device; and

2. Personnel maintaining analytical X–ray equipment if the maintenance procedures require the presence of a primary X–ray beam when any local component in the analytical X–ray system is disassembled or removed.

(2) Reported dose values shall not be used for the purpose of determining compliance with 641—subrule 40.2(1) unless evaluated by a qualified expert.

641—45.6(136C) Radiation safety requirements for wireline service operations and subsurface tracer studies.

45.6(1) *Purpose.* This rule establishes radiation safety requirements for using sources of radiation for wireline service operations including mineral–logging, radioactive markers, and subsurface tracer studies. The requirements of this rule are in addition to, and not in substitution for, the requirements of 641—Chapters 38, 39, and 40. The requirements of 641—45.1(136C) to 641—45.5(136C) do not apply.

45.6(2) *Scope.* This rule applies to all licensees or registrants who use sources of radiation for wireline service operations including mineral–logging, radioactive markers, or subsurface tracer studies.

45.6(3) *Definitions.* For the purpose of this subrule, the definitions of 641—Chapter 38 may also apply. As used in this rule, the following definitions apply:

"Field station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary job sites.

"Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

"Logging assistant" means any individual who, under the personal supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by 45.6(22).

"Logging supervisor" means the individual who uses sources of radiation or provides personal supervision of the utilization of sources of radiation at the well site.

"Logging tool" means a device used subsurface to perform well–logging.

"Mineral–logging" means any logging performed for the purpose of mineral exploration other than oil or gas.

"Personal supervision" means guidance and instruction by the supervisor who is physically present at the job site and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required.

"Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

"Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well–logging operations.

"Subsurface tracer study" means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well–bore or adjacent formation.

"Temporary job site" means a location where radioactive materials are present for the purpose of performing wireline service operations or subsurface tracer studies.

"Uranium sinker bar" means a weight containing depleted uranium used to pull a logging tool down toward the bottom of a well.

"Well–bore" means a drilled hole in which wireline service operations or subsurface tracer studies are performed.

"Well–logging" means all operations involving the lowering and raising of measuring devices or tools which may contain sources of radiation into well–bores or cavities for the purpose of obtaining information about the well or adjacent formations.

"Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well–bore.

"Wireline service operation" means any evaluation or mechanical service which is performed in the well–bore using devices on a wireline.

45.6(4) *Prohibition.* No licensee shall perform wireline service operations with a sealed source(s) unless, prior to commencement of the operation, the licensee has a written agreement with the well operator, well owner, drilling contractor, or landowner that:

a. In the event a sealed source is lodged downhole, a reasonable effort at recovery will be made; and

b. In the event a decision is made to abandon the sealed source downhole, the requirements of 45.6(25) *"c"* and the name of any other state agency having applicable regulations shall be met.

45.6(5) *Limits on levels of radiation.* Sources of radiation shall be used, stored, and transported in such a manner that the transportation requirements of 641—39.5(136C) and the dose limitation requirements of 641—Chapter 40 are met.

45.6(6) *Storage precautions.*

a. Each source of radiation, except accelerators, shall be provided with a storage or transport container. The container shall be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of, or exposure to, the source of radiation.

b. Sources of radiation shall be stored in a manner which will minimize danger from explosion or fire.

45.6(7) *Transport precautions.* Transport containers shall be physically secured to the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

45.6(8) *Radiation survey instruments.*

a. The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each field station to make physical radiation surveys as required by this subrule and by 641—40.36(136C). Instrumentation shall be capable of measuring 0.1 milliroentgen (25.8 nanocoulombs/kg) per hour through at least 50 milliroentgens (12.9 microcoulombs/kg) per hour.

b. Each radiation survey instrument shall be calibrated:

(1) At intervals not to exceed six months and after each instrument servicing;

(2) For linear scale instruments, at two points located approximately 1/3 and 2/3 of full–scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two points of at least one decade; and for digital instruments, at appropriate points; and

(3) So that accuracy within 20 percent of the true radiation level can be demonstrated on each scale.

c. Calibration records shall be maintained for a period of two years for inspection by the agency.

45.6(9) Leak testing of sealed sources.

a. Requirements. *Leak testing of sealed sources.*

a. Requirements. Each licensee using sealed sources of radioactive material shall have the sources tested for leakage. Records of leak test results shall be kept in units of microcuries (Bq) and maintained for inspection by the agency for six months after the next required leak test is performed or until transfer or disposal of the sealed source.

b. Method of testing. Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state. The test sample shall be taken from the surface of the source, source holder, or from the surface of the device in which the source is stored or mounted and on which one might expect contamination to accumulate. The test sample shall be analyzed for radioactive contamination, and the analysis shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample.

c. Interval of testing. Each sealed source of radioactive material shall be tested at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source shall not be put into use until tested. If, for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

d. Leaking or contaminated sources. If the test reveals the presence of 0.005 microcurie (185 Bq) or more of leakage or contamination, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired, or disposed of in accordance with these rules. A report describing the equipment involved, the test results, and the corrective action taken shall be filed with the agency within five days of receiving the test results.

e. Exemptions. The following sources are exempted from the periodic leak test requirements of 45.6(9)*"a"* to *"d"*:

(1) Hydrogen–3 sources;

(2) Sources of radioactive material with a half–life of 30 days or less;

(3) Sealed sources of radioactive material in gaseous form;

(4) Sources of beta– or gamma–emitting radioactive material with an activity of 100 microcuries (3.7 MBq) or less; and

(5) Sources of alpha–emitting radioactive material with an activity of 10 microcuries (0.370 MBq) or less.

45.6(10) *Quarterly inventory.* Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation. Records of inventories shall be maintained for two years from the date of the inventory for inspection by the agency and shall include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory, and the name of the individual conducting the inventory.

45.6(11) *Utilization records.* Each licensee or registrant shall maintain current records, which shall be kept available for inspection by the agency for two years from the date of the recorded event, showing the following information for each source of radiation:

a. Make, model number, and a serial number or a description of each source of radiation used;

b. The identity of the well–logging supervisor or field unit to whom assigned;

c. Locations where used and dates of use; and

d. In the case of tracer materials and radioactive markers, the utilization record shall indicate the radionuclide and activity used in a particular well.

45.6(12) Design, performance, and certification criteria for sealed sources used in downhole operations.

a. *Design, performance, and certification criteria for sealed sources used in downhole operations.*

a. Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations shall be certified by the manufacturer, or other testing organization acceptable to the agency, to meet the following minimum criteria:

(1) Be of doubly encapsulated construction;

(2) Contain radioactive material whose chemical and physical forms are as insoluble and nondispersible as practical; and

(3) Has been individually pressure tested to at least 24,656 pounds per square inch absolute (170 MN/m^2) without failure.

b. For sealed sources, except those containing radioactive material in gaseous form, in the absence of a certificate from a transferor certifying that an individual sealed source meets the requirements of 45.6(12)*"a,"* the sealed source shall not be put into use until such determinations and testing have been performed.

c. Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations, shall be certified by the manufacturer, or other testing organization acceptable to the agency, as meeting the sealed source performance requirements for oil well–logging as contained in the American National Standard Institute (ANSI) N542–1977 or United States of American Standards Institute (USASI) N5.10–1968.

d. Certification documents shall be maintained for inspection by the agency for a period of two years after source disposal. If the source is abandoned downhole, the certification documents shall be maintained until the agency authorizes disposition.

45.6(13) *Labeling.*

a. Each source, source holder, or logging tool containing radioactive material shall bear a durable, legible, and clearly visible marking or label, which has, as a minimum, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

DANGER[1]

RADIOACTIVE

This labeling shall be on the smallest component transported as a separate piece of equipment.

b. Each transport container shall have permanently attached to it a durable, legible, and clearly visible label which has, as a minimum, the standard radiation caution symbol and the following wording:

DANGER[1]

RADIOACTIVE

NOTIFY CIVIL AUTHORITIES

[OR NAME OF COMPANY]

[1]or CAUTION

45.6(14) *Inspection and maintenance.*

a. Each licensee or registrant shall conduct, at intervals not to exceed six months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools to ensure proper labeling and physical condition. Records of inspection and maintenance shall be maintained for a period of two years for inspection by the agency.

b. If any inspection conducted pursuant to 45.6(14)*"a"* reveals damage to labeling or components critical to radiation safety, the device shall be removed from service until repairs have been made.

c. If a sealed source is stuck in the source holder, the licensee shall not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the licensee is specifically approved by the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state to perform this operation.

d. The repair, opening, or modification of any sealed source shall be performed only by persons specifically authorized to do so by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state.

45.6(15) *Training requirements.*

a. No licensee or registrant shall permit any individual to act as a logging supervisor as defined in this rule until such individual has:

(1) Received, in a course recognized by the agency, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state, instruction in the subjects outlined in Appendix D of this chapter and demonstrated an understanding thereof;

(2) Read and received instruction in the rules contained in this chapter and the applicable sections of 641—Chapters 38, 39, and 40 or their equivalent, conditions of appropriate license or certificate of registration, and the licensee's or registrant's operating and emergency procedures, and demonstrated an understanding thereof; and

(3) Demonstrated competence to use sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

b. No licensee or registrant shall permit any individual to assist in the handling of sources of radiation until such individual has:

(1) Read or received instruction in the licensee's or registrant's operating and emergency procedures and demonstrated an understanding thereof; and

(2) Demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

c. The licensee or registrant shall maintain employee training records for inspection by the agency for two years following termination of the individual's employment.

45.6(16) *Operating and emergency procedures.* The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

a. Handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in 641— Chapter 40;

b. Methods and occasions for conducting radiation surveys;

c. Methods and occasions for locking and securing sources of radiation;

d. Personnel monitoring and the use of personnel monitoring equipment;

e. Transportation to temporary job sites and field stations, including the packaging and placing of sources of radiation in vehicles, placarding of vehicles, and securing sources of radiation during transportation;

f. Minimizing exposure of individuals in the event of an accident;

g. Procedure for notifying proper personnel in the event of an accident;

h. Maintenance of records;

i. Use, inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools;

j. Procedure to be followed in the event a sealed source is lodged downhole;

k. Procedures to be used for picking up, receiving, and opening packages containing radioactive material;

l. For the use of tracers, decontamination of the environment, equipment, and personnel;

m. Maintenance of records generated by logging personnel at temporary job sites;

n. Notifying proper persons in the event of an accident; and

o. Actions to be taken if a sealed source is ruptured, including actions to prevent the spread of contamination and minimize inhalation and ingestion of radioactive material and actions to obtain suitable radiation survey instruments as required by 45.6(8).

45.6(17) *Personnel monitoring.*

a. No licensee or registrant shall permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears either a film badge or a thermoluminescent dosimeter (TLD). Each film badge or TLD shall be assigned to and worn by only one individual. Film badges must be replaced at least monthly and TLDs replaced at least quarterly. After replacement, each film badge or TLD must be promptly processed.

b. Personnel monitoring records shall be maintained for inspection until the agency authorizes disposition.

45.6(18) *Security.* During each logging or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized or unnecessary entry into a restricted area, as defined in 641—Chapter 38.

45.6(19) *Handling tools.* The licensee shall provide and require the use of tools that will ensure remote handling of sealed sources other than low activity calibration sources.

45.6(20) *Subsurface tracer studies.*

a. Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel handling radioactive tracer material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.

b. No licensee shall cause the injection of radioactive material into potable aquifers without prior written authorization from the agency and any other appropriate state agency.

45.6(21) *Particle accelerators.* No licensee or registrant shall permit aboveground testing of particle accelerators, designed for use in well–logging, which results in the production of radiation, except in areas or facilities so controlled or shielded that the requirements of 641—40.15(136C) and 641—40.26(136C), as applicable, are met.

45.6(22) *Radiation surveys.*

a. Radiation surveys or calculations shall be made and recorded for each area where radioactive materials are used and stored.

b. Radiation surveys shall be made and recorded for the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys shall include each source of radiation or combination of sources to be transported in the vehicle.

c. If the sealed source assembly is removed from the logging tool before departing the job site, the logging tool detector shall be energized, or a survey meter used, to ensure that the logging tool is free of contamination.

d. Radiation surveys shall be made and recorded at the job site or wellhead for each tracer operation, except those using hydrogen–3, carbon–14, and sulfur–35. .These surveys shall include measurements of radiation levels before and after the operation.

e. Records required pursuant to 45.6(22)" *a"* to *"d"* shall include the dates, the identification of individual(s) making the survey, the identification of survey instrument(s) used, and an exact description of the location of the survey. Records of these surveys shall be maintained for inspection by the agency for two years after completion of the survey.

45.6(23) *Documents and records required at field stations.* Each licensee or registrant shall maintain, for inspection by the agency, the following documents and records for the specific devices and sources used at the field station:

a. Appropriate license, certificate of registration, or equivalent document(s);

b. Operating and emergency procedures;

c. Applicable regulations;

d. Records of the latest survey instrument calibrations pursuant to 45.6(8);

e. Records of the latest leak test results pursuant to 45.6(9);

f. Records of quarterly inventories required pursuant to 45.6(10);

g. Utilization records required pursuant to 45.6(11);

h. Records of inspection and maintenance required pursuant to 45.6(14);

i. Survey records required pursuant to 45.6(22); and

j. Training records required pursuant to 45.6(15).

45.6(24) *Documents and records required at temporary job sites.* Each licensee or registrant conducting operations at a temporary job site shall have the following documents and records available at that site for inspection by the agency:

a. Operating and emergency procedures;

b. Survey records required pursuant to 45.6(22) for the period of operation at the site;

c. Evidence of current calibration for the radiation survey instruments in use at the site;

d. When operating in the state under reciprocity, a copy of the appropriate license, certificate of registration, or equivalent document(s); and

e. Shipping papers for the transportation of radioactive material.

45.6(25) *Notification of incidents, abandonment, and lost sources.*

a. Notification of incidents and sources lost in other than downhole logging operations shall be made in accordance with appropriate provisions of 641—Chapter 40.

b. Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall:

(1) Monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations; and

(2) Notify the agency immediately by telephone and subsequently, within 30 days, by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. This letter shall identify the well or other location, describe the magnitude and extent of the escape of radioactive material, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.

c. When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall:

(1) Advise the well operator of the regulations of the appropriate state agency regarding abandonment and an appropriate method of abandonment, which shall include:

1. The immobilization and sealing in place of the radioactive source with a cement plug;

2. The setting of a whipstock or other deflection device; and

3. The mounting of a permanent identification plaque at the surface of the well, containing the appropriate information required by 45.6(25)*"d."*

(2) Notify the agency by telephone, giving the circumstances of the loss, and request approval of the proposed abandonment procedures; and

(3) File a written report with the agency within 30 days of the abandonment. The licensee shall send a copy of the report to the appropriate state agency that issued permits or otherwise approved of the drilling operation. The report shall contain the following information:

1. Date of occurrence;

2. A description of the well–logging source involved, including the radionuclide and its quantity, chemical, and physical form;

3. Surface location and identification of the well;

4. Results of efforts to immobilize and seal the source in place;

5. A brief description of the attempted recovery effort;

6. Depth of the source;

7. Depth of the top of the cement plug;

8. Depth of the well;

9. Any other information, such as a warning statement, contained on the permanent identification plaque; and

10. The names of state agencies receiving a copy of this report.

d. Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque [2] for posting the well or well–bore. This plaque shall:

(1) Be constructed of long–lasting material, such as stainless steel or monel; and

(2) Contain the following information engraved on its face:

1. The word "CAUTION";

2. The radiation symbol without the conventional color requirement;

3. The date of abandonment;

4. The name of the well operator or well owner;

5. The well name and well identification number(s) or other designation;

6. The sealed source(s) by radionuclide and activity;

7. The source depth and the depth to the top of the plug; and

8. An appropriate warning, depending on the specific circumstances of each abandonment. [3]

e. The licensee shall immediately notify the agency by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable aquifer. Such notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss, and explain efforts planned or being taken to mitigate these consequences.

[2]An example of a suggested plaque is shown in Appendix F of this chapter.

[3] Appropriate warnings may include: (a) "Do not drill below plug–back depth"; (b) "Do not enlarge casing"; or (c) "Do not re–enter the hole", followed by the words, "before contacting the Iowa Department of Public Health."

CHAPTER 45—APPENDIX A

SUBJECTS FOR INSTRUCTION OF

RADIOGRAPHER TRAINEES

Training provided to qualify individuals as radiographer trainees in compliance with 45.1(10) shall be presented on a formal basis. The training shall include the following subjects:

I. Fundamentals of radiation safety

A. Characteristics of radiation

B. Units of radiation dose and quantity of radioactivity

C. Significance of radiation dose

1. Radiation protection standards

2. Biological effects of radiation

3. Case histories of radiography accidents

D. Levels of radiation from sources of radiation

E. Methods of controlling radiation dose

1. Working time

2. Working distances

3. Shielding

II. Radiation detection instrumentation to be used

A. Use of radiation survey instruments

1. Operation

2. Calibration

3. Limitations

B. Survey techniques

C. Use of personnel monitoring equipment

1. Film badges

2. Thermoluminescent dosimeters (TLDs)

3. Pocket dosimeters

III. The requirements of pertinent federal and state regulations

IV. The licensee's or registrant's written operating and emergency procedures

V. Radiographic equipment to be used

A. Remote handling equipment

B. Operation and control of radiographic exposure devices and sealed sources, including pictures or models of source assemblies (pigtails)

C. Storage and transport containers, source changers

D. Operation and control of X–ray equipment

E. Collimators

CHAPTER 45—APPENDIX B

GENERAL REQUIREMENTS FOR INSPECTION OF INDUSTRIAL RADIOGRAPHIC EQUIPMENT

I. Panoramic devices (devices in which the sealed source is physically removed from the shielded container during exposure) shall be inspected for:

A. Radiographic exposure unit

1. Abnormal surface radiation levels anywhere on camera, collimator, or guide tube;

2. Condition of safety plugs;

3. Proper operation of locking mechanism;

4. Condition of pigtail connector;

5. Condition of carrying device (straps, handle, etc.);

6. Proper labeling.

B. Source tube

1. Rust, dirt, or sludge buildup inside the source tube;

2. Condition of source tube connector;

3. Condition of source stop;

4. Kinks or damage that could prevent proper operation;

5. Presence of radioactive contamination.

C. Control cables and drive mechanism

1. Proper drive mechanism with camera, as appropriate;

2. Changes in general operating characteristics;

3. Condition of connector on drive cable;

4. Drive cable flexibility, wear, and rust;

5. Excessive wear or damage to crank assembly parts;

6. Damage to drive cable conduit that could prevent the cable from moving easily;

7. Connection of the control cable connector with the pigtail connector for proper mating;

8. Proper operation of source position indicator, if applicable;

9. Presence of radioactive contamination.

II. Directional beam devices shall be inspected for:

A. Abnormal surface radiation;

B. Changes in the general operating characteristics of the unit;

C. Proper operation of shutter mechanism;

D. Chafing or binding of shutter mechanism;

E. Damage to the device that might impair its operation;

F. Proper operation of locking mechanism;

G. Proper drive mechanism with camera, as appropriate;

H. Condition of carrying device (strap, handle, etc.);

I. Proper labeling.

III. X–ray equipment shall be inspected for:

A. Change in the general operating characteristics of the unit;

B. Wear of electrical cables and connectors;

C. Proper labeling of console;

D. Proper console with machine, as appropriate;

E. Proper operation of locking mechanism;

F. Timer run–down cutoff;

G. Damage to tube head housing that might result in excessive radiation levels.

CHAPTER 45—APPENDIX C

TIME REQUIREMENTS FOR RECORD KEEPING

Specific Section	Name of Record	Time Interval Required for Record Keeping
45.1(4)	Receipt, transfer	Until disposal is

	and disposal.	authorized by the agency.
45.1(5)	Survey instrument calibrations.	2 years.
45.3(4)	Leak tests.	2 years.
45.1(6)	Quarterly inventory.	2 years.
45.1(7)	Utilization logs.	Until disposal is authorized by the agency.
45.1(8)	Quarterly inspection and maintenance.	2 years.
45.1(9)	High radiation area control devices or alarm systems.	Until disposal is authorized by the agency.
45.1(10)	Training and testing records.	Until disposal is authorized by the agency.
45.1(12)	Pocket dosimeter readings.	2 years or until disposal is authorized by the agency if dosimeters were used to determine external radiation dose.
	Pocket dosimeter calibrations.	2 years.
	Alarming ratemeter calibrations.	2 years.
	Alarming ratemeter functions.	2 years.
45.3(6)	Internal audit program.	3 years
	Radiographer audits.	2 years
45.2(5) and 45.3(7)	Radiation surveys.	2 years or until disposal is authorized by the agency if a survey was used to determine

		an individual's exposure.
45.1(16)	Records at temporary job sites.	During temporary job site operations.
45.2(6) and	Annual evaluation of enclosed X–ray systems.	2 years.
45.3(8)	Film badge or TLD records.	Until disposal is authorized by the agency.
45.1(9)	Tests of Chapter 45 high radiation control devices and alarm systems.	Until disposal is authorized by the agency.
45.2(6)	Evaluation of certified cabinet X–ray systems.	2 years.

CHAPTER 45—APPENDIX D

OPERATING AND EMERGENCY PROCEDURES

The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

A. Handling and use of sources of radiation for industrial radiography such that no individual is likely to be exposed to radiation doses that exceed the limits established in 641—Chapter 40;

B. Methods and occasions for conducting radiation surveys, including lock–out survey requirements;

C. Methods for controlling access to industrial radiography areas;

D. Methods and occasions for locking and securing sources or radiation;

E. Personnel monitoring and the use of personnel monitoring equipment, including steps to be taken immediately by industrial radiographic personnel in the event a pocket dosimeter is found to be off–scale;

F. Methods of transporting equipment to field locations, including packing of sources of radiation in the vehicles, placarding of vehicles, and controlling of sources of radiation during transportation (including applicable U.S. Department of Transportation requirements);

G. Methods or procedures for minimizing exposure of individuals in the event of an accident, including procedures for a disconnect accident, a transportation accident, and loss of a sealed source;

H. Procedures for notifying proper personnel in the event of an accident;

I. Specific posting requirements;

J. Maintenance of records (Appendix C); and

K. Inspection and maintenance of radiographic exposure devices, source changers, storage containers, transport containers, source guide tubes, crank–out devices, and radiation machines.

CHAPTER 45—APPENDIX E

SUBJECTS TO BE INCLUDED IN TRAINING COURSES FOR LOGGING SUPERVISORS

I. Fundamentals of radiation safety.

A. Characteristics of radiation.

B. Units of radiation dose and quantity of radioactivity.

C. Significance of radiation dose.

1. Radiation protection standards.

2. Biological effects of radiation dose.

D. Levels of radiation from sources of radiation.

E. Methods of minimizing radiation dose.

1. Working time.

2. Working distances.

3. Shielding.

F. Radiation safety practices including prevention of contamination and methods of decontamination.

II. Radiation detection instrumentation to be used.

A. Use of radiation survey instruments.

1. Operation.

2. Calibration.

3. Limitations.

B. Survey techniques.

C. Use of personnel monitoring equipment.

III. Equipment to be used.

A. Handling equipment.

B. Sources of radiation.

C. Storage and control of equipment.

D. Operation and control of equipment.

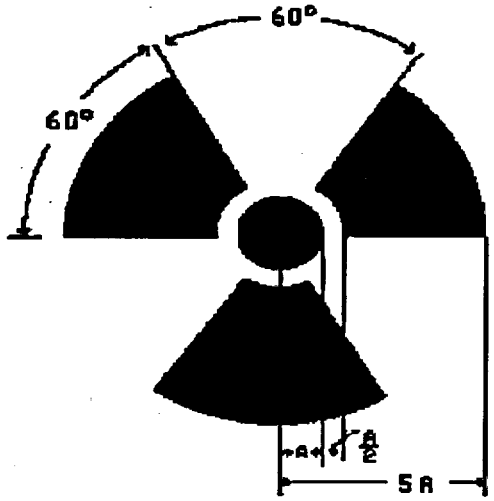
IV. The requirements of pertinent federal and state regulations.

V. The licensee's or registrant's written operating and emergency procedures.

VI. The licensee's or registrant's record–keeping procedures.

CHAPTER 45—APPENDIX F

EXAMPLE OF PLAQUE FOR IDENTIFYING WELLS CONTAINING SEALED SOURCES CONTAINING RADIOACTIVE MATERIAL ABANDONED DOWNHOLE



The size of the plaque should be convenient for use on active or inactive wells, e.g., a 7–inch square. Letter size of the word "CAUTION" should be approximately twice the letter size of the rest of the information, e.g., ½–inch and ¼–inch letter size, respectively.

These rules are intended to implement Iowa Code chapters 136B and 136C.

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effective 8/15/99

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