PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Pursuant to the authority of Iowa Code section 136C.3, the Department of Public health hereby gives Notice of Intended Action to amend Chapter 38, "General Provisions"; Chapter 39, "Registration of Radiation Machine Facilities, Licensure of Radioactive Materials and Transportation of Radioactive Materials"; Chapter 40, "Standards for Protection Against Radiation"; Chapter 41, "Safety Requirements for the Use of Radiation Machines and Certain Uses of Radioactive Materials"; Chapter 42, "Minimum Certification Standards for Diagnostic Radiographers, Nuclear Medicine Technologists, and Radiation Therapists"; Chapter 45, "Radiation Safety Requirements for Industrial Radiographic Operations"; and Chapter 46, "Minimum Requirements for Tanning Facilities," Iowa Administrative Code.

The following amendments incorporate changes in references for clarification and/or to correct errors in the rules: items 11, 18, 24, 44, 48, 52, 55, 76, 90, and 96. The following amendments incorporate changes at the federal level which establish national radiation protection standards and/or are compatibility issues with the Nuclear Regulatory Commission and FDA agreements: items 1, 2, 7, 11, 13, 14, 15, 16, 17, 18, 20, 21, 35, 36, 38, 39, 40, 46, 48, 50, 51, 52, 55, 57, 58, 59, 60, 61, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 92, 93, 94, 95, 96, 98, 100, 101, and 102. The following amendments update the rules to incorporate changes in current technology: items 10, 40, 41, 42, 43, 44, 47, and 75. The following amendments tie together the chapters governed by the Bureau: items 3, 6, 37, 54, 62, 74, and 99. Item 4 adds a fees for food sterilization and bone densitometry which are new categories. Item 5 increases examination fees to allow the Bureau to recover the cost of administering the examination. Item 9 adds processors to the service categories because this is a critical area in providing readable x-ray films. Item 76 adds an important area for discipline to the operator certification rules. Item 103 adds words that were omitted when the rules were changed in 1998 – it is important that the warnings are read by the customer annually in order to remind them about the possible hazards of tanning.

These rules are subject to waiver pursuant to the Department's variance and waiver provision contained at 641—38.3(136C) "Exemptions from the regulatory requirements." For this reason, the Department has not provided a specific provision for waiver of this particular rule.

Any interested person may make written suggestions or comments on these proposed amendments prior to the close of business on March 1, 2000. Such written materials should be directed to Donald A. Flater, Chief, Bureau of Radiological Health, Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319; fax 515/242-6284 or E-mail at: dflater@idph.state.ia.us.

A public hearing will be held on February 29, 2000, at 8:30am, 5th Floor South Side conference room, Lucas State Office Building, Des Moines, Iowa 50319, at which time persons may present their views orally or in writing. At the hearing, persons will be asked to give their name and address for the record and to confine remarks to the subject of the rules.

Any person who intends to attend a public hearing and has special requirements such as hearing or mobility impairments should contact the Department of Public Health to advise of specific needs.

The proposed amendments are intended to implement Iowa Code chapter 136C.

The following amendments are proposed:

ITEM 1. Amend subrule **38.1(2)** as follows:

38.1(2) All references to Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~July 1, 1999~~ May 10, 2000.

ITEM 2. Amend and add definitions in **641—38.2(136C)** as follows:

"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 or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include sources of radiation from radioactive materials regulated by the agency.

"Barrier" (see "Protective barrier").

"Beam axis" means the axis of rotation of the beam–limiting device.

"Beam–limiting device" means a field defining collimator, integral to the system, which provides a means to restrict the dimensions of the X–ray field or useful beam

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

"Bone densitometry unit" means a medical device which uses electronically-produced ionizing radiation to determine the density of bone structures of human patients.

"Critical Group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

"*Decommission*" means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:

(1) Release of the property for unrestricted use and termination of the license; or

(2) Release of the property under restricted conditions and termination of the license.

"*Detector*" (see "Radiation detector").

"*Distinguishable from background*" means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

~~*"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).~~

"High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body 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 30 centimeters from any surface that the radiation penetrates.

"*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~~

preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

"*Irradiation*" means the exposure of a living being or matter to ionizing radiation.

"*Kilovolt (kV)(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.

"*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.

"Lens dose equivalent (LDE)" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

"*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.

"Mammogram" means an image produced through radiography of the breast.

"Mammography" means radiography of the breast.

"Mammography unit" means an assemblage of components for the production of X-rays for use during mammography, including, at a minimum: an X-ray generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the supporting structures for these components.

"*mA*" means milliampere.

"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~~ and 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.

"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 any medical administration the individual has received, from exposure to individuals administered sources of radiation and released in accordance with 41.2(27), from voluntary participation in medical research programs, or as a member of the public.

"*Primary protective barrier*" (see "Protective barrier").

"*Protective barrier*" means a barrier 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.

"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~~ from any medical administration the individual has received, from exposure to individuals administered sources of radiation and released in accordance with 41.2(27) or from voluntary participation in medical research programs.

"*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.

"*Radiographic imaging system*" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

"*Residual radioactivity*" means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of 641—Chapter 40 or any previous state or federal licenses, rules or regulations.

"*Secondary dose monitoring system*" means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

"*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.

"*Simulator (radiation therapy simulation system)*" means any X-ray system intended for localizing the volume to be exposed during radiation therapy and reproducing the position and size of the therapeutic irradiation field.

"*SSD*" means the distance between the source and the skin entrance plane of the patient. (See "Target-to-skin distance (TSD)")

"*Stray radiation*" means the sum of leakage and scattered radiation.

"*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.

"*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.

"*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.

"*Very high radiation area*" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body 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 1 meter from any surface that the radiation penetrates.

ITEM 3. Amend subrule **38.3(1)** as follows:

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~~ the rules in 641—Chapters 38, 39, 40, 41, 42, 43, 44, 45, and 46 as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

ITEM 4. Amend subrule **38.8(1)** paragraph "*a*", as follows:

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.	Food Sterilization	~~$80~~$1000	—
9.	Accelerators	$100	—
10.	Electron Microscope	$20	—
11.	Bone densitometry	$25	

ITEM 5. Amend subrule **38.8(3)** paragraph "*a*" as follows:

a. A nonrefundable fee of ~~$100~~ $125 shall be submitted with each application for taking an industrial radiography examination to become certified by the agency.

ITEM 6. Amend subrule **38.8(6)** as follows:

38.8(6) *Certification fees.* Diagnostic radiographers, radiation therapists, and nuclear medicine technologists (as defined in 641—Chapter 42), 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:

ITEM 7. Add subrule **641—38.10(136C)** as follows:

641—38.10(136C) Deliberate misconduct.

a. Any licensee, registrant, applicant for a license or certificate of registration, employee of a licensee, registrant or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or registrant or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, registrant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, registrant's or applicant's activities in this part, may not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, registrant, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license or registration issued by the agency; or

(2) Deliberately submit to the agency, a licensee, registrant, an applicant, or a licensee's, registrant's, or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the agency.

b. A person who violates paragraph "*a*"(1) or *"a"*(2) of this subrule may be subject to enforcement action in accordance with the procedures in 641—38.9(136C).

c. For the purposes of paragraph "*a*"(1) of this subrule, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee, registrant, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the agency; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, registrant, applicant, contractor, or subcontractor.

ITEM 8. Amend subrule **39.1(3)** as follows:

39.1(3) All references to any Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~July 1, 1999~~ May 10, 2000.

ITEM 9. Amend paragraph **39.3(3)***"d"* as follows:

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.~~ Processor and/or processor servicing.

ITEM 10. Amend paragraph **39.3(2)***"a"* as follows:

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 non-wireless 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).

ITEM 11. Amend subrule **39.3(10)** paragraph "*a*", as follows:

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~~ 3 working days before such machine is to be used in the state. The notice shall include:

ITEM 12. Amend subrule **39.4(24)** as follows:

"*a*" to "*d*" no change.

~~*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.~~e. 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.~~f. (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"~~ 39.4(24)"*f*"(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"~~ 39.4(24)"*f*"(1)"2" must include the following information:

ITEM 13. Amend subrule **39.4(26)** paragraph "*e*" to read:

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. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate and a signed original of the financial instrument obtained to satisfy the requirements of 39.4(26)"*f*".

ITEM 14. Amend subparagraph **39.4(26)**"*f*"(2) to read:

(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. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test

may be used if the guarantee and test are as contained in Appendix H to this suburule. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in Appendix I to this subrule. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in Appendix J to this part. A guarantee by the applicant or licensee may not be used in combination with any other financial methods used to satisfy the requirements of this paragraph or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

ITEM 15. Amend subrule **39.4(26)** paragraph "*f*" by adding new subparagraph:

(5) When a governmental entity assumes custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity

ITEM 16. Rescind subrule **39.4(27)** paragraph "*e*" and replace with new paragraph "*e*":

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 the application contains:

(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 of Chapter 45;

(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. Non-wireless 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 to 641—Chapter 45); 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.

ITEM 17. Amend paragraph **39.4(33)***"j"* subparagraph (2) to read:

(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~~ in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 641—40.28(136C) through 641—40.31(136C). The licensee shall, as appropriate:

ITEM 18. Amend paragraph **39.4(33)***"k"* subparagraph (3) to read:

(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 to demonstrate that the premises are suitable for release in accordance with ~~state of Iowa requirements~~ the criteria for decommissioning in 641—40.28(136C) through 641—40.31(136C).

ITEM 19. Amend paragraph **39.4(90)***"a"* subparagraph (3) as follows:

(3) The out–of–state licensee shall notify the agency in writing at least ~~three~~ 3 working 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~~ 3–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."*

ITEM 20. Rescind **641—39.5(136C)** in its entirety and replace with:

641-39.5(136C) *Transportation of Radioactive Material.* All persons who transport radioactive material or deliver radioactive material to a carrier for transport must comply with the provision contained in 10 CFR Part 71 as it applies to the State of Iowa.

ITEM 21. Rescind Chapter 39 Appendix E in its entirety and replace with:

CHAPTER 39—APPENDIX E (RESERVED)

ITEM 22. Add new appendices H, I and J to 641—Chapter 39:

Appendix H

Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. To pass the financial test, a company must meet all of the following criteria:

(1) Tangible net worth at least 10 times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used).

(2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used.

(3) A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moodys.

B. To pass the financial test, a company must meet all of the following additional requirements:

(1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

(2) The company's independent certified public accountant must have compared the data used by the company in the financial test which is derived from the independently audited, yearend financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(3) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

C. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send immediate notice to the agency of its intent to establish alternate financial assurance as specified in these rules within 120 days of such notice.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the agency, as evidenced by the return receipt.

B. The licensee shall provide alternative financial assurance as specified in these rules within 90 days following receipt by the agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the agency has terminated the license or until another financial assurance method acceptable to the agency has been put in effect by the licensee.

D. The licensee will promptly forward to the agency and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poors and Moodys, the licensee no longer meets the requirements of Section II.A. of this appendix.

F. The applicant or licensee must provide to the agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

Appendix I

Criteria Relating To Use of Financial Tests and Self-Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That Have No Outstanding Rated Bonds

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. To pass the financial test a company must meet the following criteria:

(1) Tangible net worth greater than $10 million, or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(3) A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by net worth less than 1.5.

B. In addition, to pass the financial test, a company must meet all of the following requirements:

(1) The company's independent certified public accountant must have compared the data used by the company in the financial test, which is required to be derived from the independently audited year end financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the agency within 90 days of any matters that may cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(2) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of paragraph II.A of this appendix, the licensee must send notice to the agency of intent to establish alternative financial assurance as specified in these rules. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data shows that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the agency. Cancellation may not occur until an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in the regulations within 90 days following receipt by the agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

D. The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

Appendix J

Criteria Relating to Use of Financial Tests and Self-Guarantee For Providing Reasonable Assurance of Funds For Decommissioning by Nonprofit Colleges, Universities, and Hospitals

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the applicant or licensee passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. For colleges and universities to pass the financial test, a college or university must meet either the criteria in Paragraph II.A.(1) or the criteria in Paragraph II.A.(2) of this appendix.

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P) or Aaa, Aa, or A as issued by Moodys.

(2) For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least $50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

B. For hospitals to pass the financial test, a hospital must meet either the criteria in Paragraph II.B.(1) or the criteria in Paragraph II.B.(2) of this appendix:

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P) or Aaa, Aa, or A as issued by Moodys.

(2) For applicants or licensees that do not issue bonds, all the following tests must be met:

(a) (Total revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.

(b) Long term debt divided by net fixed assets must be less than or equal to 0.67.

(c) (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.

(d) Operating revenues must be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing license.

C. In addition, to pass the financial test, a licensee must meet all the following requirements:

(1) The licensee's independent certified public accountant must have compared the data used by the licensee in the financial test, which is required to be derived from the

independently audited year end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform this agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test.

(2) After the initial financial test, the licensee must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of Section I of this appendix, the licensee must send notice to this agency of its intent to establish alternative financial assurance as specified in these regulations. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, and/or return receipt requested, to the Agency. Cancellation may not occur unless an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in these rules within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

D. The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer or officer of the institution) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee shall provide notice in writing of such fact to the agency within 20 days after publication of the change by the rating service.

ITEM 23. Amend subrule **40.1(5)** as follows:

40.1(5) All references to Code of Federal Regulations (CFR) in this chapter are those in effect on or before ~~July 1, 1999~~ May 10, 2000.

ITEM 24. Amend subrule **40.2(2)** as follows:

"Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

~~*"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.~~

ITEM 25. Amend subrule **40.10(2)** as follows:

40.10(2) The licensee or registrant shall use, to the extent ~~practicable~~ practical, 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).

ITEM 26. Amend paragraph **40.15(1)***"b"* subparagraph (1) to read:

(1) An ~~eye~~ lens dose equivalent of 15 rem (0.15 Sv), and

ITEM 27. Amend subrule **40.15(3)** to read:

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~~ lens 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.

ITEM 28. Amend subrule **40.20(1)** as follows:

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~~ dose estimated to result from the planned special exposure are unavailable or impractical.

ITEM 29. Amend **641—40.22(136C)** as follows:

641—40.22(136C) Dose equivalent to an embryo/fetus.

40.22(1) The licensee or registrant shall ensure that the dose equivalent 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 equivalent 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 equivalent 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 equivalent 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 equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder

of the pregnancy.

ITEM 30. Amend paragraph **40.36(1)***"b"* subparagraph (1) to read:

(1) ~~Radiation~~ The magnitude and extent of radiation levels; and

ITEM 31. Amend subrule **40.62(2)** to read:

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~~ licensee control pursuant to ~~641—41.27(136C)~~ 41.2(27).

ITEM 32. Amend **641—40.62(136C)** by adding new subrule:

40.62(5) Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under 641—40.61(136C) if:

a. Access to the room is controlled pursuant to 41.2(53); and

b. Personnel in attendance take necessary precautions to prevent an inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this chapter.

ITEM 33. Rescind **641—40.75(136C)** in its entirety and replace with:

641—40.75(136C) Transfer for disposal and manifests.

40.75(1) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix D to this chapter.

40.75(2) Each shipment manifest must include a certification by the waste generator as specified in section II of Appendix D to this chapter.

40.75(3) Each person involved in the transfer for disposal and 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 to this chapter.

ITEM 34. Amend **641—40.80(136C)** to read as follows:

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~~ lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

40.80(3) In the records required by this chapter the licensee may record quantities in SI units in parentheses following each of the units specified in 40.80(1). However, all quantities must be recorded as stated in 40.80(1).

40.80(4) Not withstanding the requirements of 40.80(1), when recording information on shipment manifests, as required in 641—40.75(136C), information must be recorded in the International System of Units (SI) or in SI and units as specified in 40.80(1).

ITEM 35. Rescind Appendix D to 641—Chapter 40 in its entirety and replace with new Appendix D:

Appendix D

Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests

I. Manifest

A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a Manifest reflecting information requested on applicable forms 540 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an applicable form 542 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)). forms 540 and 540A must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between shipper and consignee, forms 541 and 541A and 542 and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. Licensees are not required by this agency to comply with the manifesting requirements of this part when they ship:

(a) LLW for processing and expect its return (i.e., for storage under their license) prior to disposal at a licensed land disposal facility;

(b) LLW that is being returned to the licensee who is the "waste generator" or "generator," as defined in this part; or

(c) Radioactively contaminated material to a "waste processor" that becomes the processor's "residual waste."

For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

Forms 540, 540A, 541, 541A, 542 and 542A, and the accompanying instructions, in hard copy, may be obtained from the Information and Records Management Branch, Office of Information Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415 - 7232.

This appendix includes information requirements of the Department of Transportation, as codified in 49 CFR part 172. Information on hazardous, medical, or other waste required to meet Environmental Protection Agency regulations, as codified in 40 CFR parts 259, 261 or elsewhere, is not addressed in this section, and must be provided on the required EPA forms. However, the required EPA forms must accompany the Uniform Low-Level Radioactive Waste Manifest required by this chapter.

As used in this appendix, the following definitions apply:

Chelating agent means amine polycarboxylic acids (e.g., EDTA, DTPA), hydroxy-carboxylic acids, and polycarboxylic acids (e.g., citric acid, carbolic acid, and glucinic acid).

Chemical description means a description of the principal chemical characteristics of a low-level radioactive waste.

Computer-readable medium means that the regulatory agency's computer can transfer the information from the medium into its memory.

Consignee means the designated receiver of the shipment of low-level radioactive waste.

Decontamination facility means a facility operating under an Agreement State or Nuclear Regulatory Commission license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this rule, is not considered to be a consignee for LLW shipments.

Disposal container means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"). Note that for some shipments, the disposal container may be the transport package.

EPA identification number means the number received by a transporter following application to the Administrator of EPA as required by 40 CFR part 263.

Generator means a licensee operating under an Agreement State or Nuclear Regulatory Commission license who (1) is a waste generator as defined in this rule, or (2) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

High integrity container (HIC) means a container commonly designed to meet the structural stability requirements of 10 CFR 61.56, and to meet Department of Transportation requirements for a Type A package.

Land disposal facility means the land, buildings and structures, and equipment which are intended to be used for the disposal of radioactive wastes. For purposes of this rule, a "geologic repository" as defined in 10 CFR 60 is not considered a land disposal facility.

Forms 540, 540A, 541, 541A, 542, and 542A are official forms referenced in this appendix. Licensees need not use originals of these forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, forms 541 (and 541A) and forms 542 (and 542A) may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

Package means the assembly of components necessary to ensure compliance with the packaging requirements of DOT regulations, together with its radioactive contents, as presented for transport.

Physical description means the items called for on form 541 to describe a low-level radioactive waste.

Residual waste means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches

attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

Shipper means the licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

Shipping paper means form 540 and, if required, form 540A which includes the information required by DOT in 49 CFR part 172.

Uniform Low-Level Radioactive Waste Manifest or *uniform manifest* means the combination of forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

Waste collector means an entity, operating under an Agreement State or Nuclear Regulatory Commission license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

Waste description means the physical, chemical and radiological description of a low-level radioactive waste as called for on form 541.

Waste generator means an entity, operating under an Agreement State or Nuclear Regulatory Commission license, who (1) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (2) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a "waste generator" if the transfer of low-level radioactive waste from its facility is defined as "residual waste."

Waste processor means an entity, operating under an Agreement State or Nuclear Regulatory Commission license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

Waste type means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically defined media).

Information Requirements

A. General Information

The shipper of the radioactive waste, shall provide the following information on the uniform manifest:

1. The name, facility's address, and telephone number of the licensee shipping the waste;

2. An explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and

3. The name, address, and telephone number, or the name and EPA identification number for the carrier transporting the waste.

B. Shipment Information

The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

1. The date of the waste shipment;

2. The total number of packages/disposal containers;

3. The total disposal volume and disposal weight in the shipment;

4. The total radionuclide activity in the shipment;

5. The activity of each of the radionuclides, H - 3, C - 14, Tc-99, and I - 129 contained in the shipment; and

6. The total masses of U - 233, U - 235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

C. Disposal Container and Waste Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

1. An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

2. A physical description of the disposal container, including the manufacturer and model of any high integrity container;

3. The volume displaced by the disposal container;

4. The gross weight of the disposal container, including the waste;

5. For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

6. A physical and chemical description of the waste;

7. The total weight percentage of chelating agent for any waste containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

8. The approximate volume of waste within a container;

9. The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

10. The identities and activities of individual radionuclides contained in each container, the masses of U - 233, U - 235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained in these waste types within a disposal container shall be reported;

11. The total radioactivity within each container; and

12. For wastes consigned to a disposal facility, the classification of the waste pursuant to 10 CFR 61.55. Waste not meeting the structural stability requirements of 10 CFR 61.56(b) must be identified.

D. Uncontainerized Waste Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

1. The approximate volume and weight of the waste;

2. A physical and chemical description of the waste;

3. The total weight percentage of chelating agent if the chelating agent exceeds 0.1% by weight, plus the identity of the principal chelating agent;

4. For waste consigned to a disposal facility, the classification of the waste pursuant to 10 CFR 61.55. Waste not meeting the structural stability requirements of 10 CFR 61.56(b) must be identified;

5. The identities and activities of individual radionuclides contained in the waste, the masses of U - 233, U - 235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

6. For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

E. Multi-Generator Disposal Container Information

This section applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the LLW resulting from a processor's activities may be attributable to one or more "generators" (including "waste generators") as defined in this rule. It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

1. For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

2. For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained on these waste types within the disposal container. For each generator, provide the following:

(a) The volume of waste within the disposal container;

(b) A physical and chemical description of the waste, including the solidification agent, if any;

(c) The total weight percentage of chelating agents for any disposal container containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

(d) The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in 10 CFR 61.56(b); and

(e) Radionuclide identities and activities contained in the waste, the masses of U - 233, U - 235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

II. Certification

An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the Department of Transportation and this agency. A collector in signing the certification is certifying that nothing has been done to the collected waste that would invalidate the waste generator's certification.

III. Control and Tracking

A. Any licensee who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in paragraphs A.1 through A.9 of this appendix. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of paragraphs A.4 through A.9 of this appendix. A licensee shall:

1. Prepare all wastes so that the waste is classified according to 10 CFR 61.55 and meets the waste characteristics requirements in 10 CFR 61.56,

2. Label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater then Class C waste, in accordance with 10 CFR 61.55,

3. Conduct a quality assurance program to assure compliance with 10 CFR 61.55 and 61.56 (the program must include management evaluation of audits);

4. Prepare the Uniform Low-Level Radioactive Waste Manifest as required by this appendix;

5. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either (i) receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

6. Include form 540 (and form 540A, if required) with the shipment regardless of the option chosen in paragraph A.5 of this section;

7. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of form 540;

8. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by 39.4(41); and

9. For any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix.

B. Any waste collector licensee who handles only prepackaged waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of form 540;

2. Prepare a new manifest to reflect consolidated shipments that meet the requirements of this appendix. The waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;

3. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: (i) Receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

4. Include form 540 (and form 540A, if required) with the shipment regardless of the option chosen in paragraph B.3 of this section;

5. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of form 540;

6. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by 39.4(41);

7. For any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

8. Notify the shipper and this agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

C. Any licensed waste processor who treats or repackages waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of form 540;

2. Prepare a new manifest that meets the requirements of this appendix. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information as required in paragraph I.E. of this appendix;

3. Prepare all wastes so that the waste is classified according to 10 CFR 61.55 and meets the waste characteristics requirements in 10 CFR 61.56;

4. Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with 10 CFR 61.55 and 61.57;

5. Conduct a quality assurance program to assure compliance with 10 CFR 61.55 and 61.56 (the program shall include management evaluation of audits);

6. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: (i) Receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

7. Include form 540 (and form 540A, if required) with the shipment regardless of the option chosen in paragraph C.6 of this section;

8. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of form 540;

9. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by 39.4(41);

10. For any shipment or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

11. Notify the shipper and the this agency of any shipment, or part of a shipment, that has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

D. The land disposal facility operator shall:

1. Acknowledge receipt of the waste within one week of receipt by returning, as a minimum, a signed copy of form 540 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the Uniform Low-Level Radioactive Waste Manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;

2. Maintain copies of all completed manifests and electronically store the information required by 10 CFR 61.80(l) until the license is terminated; and

3. Notify the shipper and the this agency when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

E. Any shipment or part of a shipment for which acknowledgement is not received within the times set forth in this section must:

1. Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

2. Be traced and reported. The investigation shall include tracing the shipment and filing a report with this agency. Each licensee who conducts a trace investigation shall file a written report with this agency within 2 weeks of completion of the investigation.

ITEM 36. Amend subrule **41.1(1)** as follows:

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~~ May 10, 2000.

ITEM 37. Amend subrule **41.1(2)** as follows:

41.1(2) *Definitions.* For the purpose of this chapter, the definitions of 641—Chapter 38 and 40 may also apply. The following are specific to ~~rule 41.1~~641—Chapter 41(136C).

ITEM 38. Amend and add definitions to subrule **41.1(2)** as follows:

"*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 2 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.

"*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.

"*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.

"*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 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, chemical, or heat exposure during storage, handling, and processing.

"*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.

"*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.

"*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.

"*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.

"*Sensitometer*" means a device used to reproducibility 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.

"*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.

"*X–ray exposure 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.

ITEM 39. Delete definitions from subrule **41.1(2)** as follows:

~~"Barrier" (see "Protective barrier").~~

~~"Beam–limiting device" means a device which provides a means to restrict the dimensions of the X–ray field.~~

~~"Detector" (see "Radiation detector").~~

~~"kV" means kilovolts.~~

~~"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.~~

~~"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.~~

~~"mA" means milliampere.~~

~~"Primary protective barrier" (see "Protective barrier").~~

~~"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.~~

~~"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.~~

~~"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.~~

~~"SSD" means the distance between the source and the skin entrance plane of the patient.~~

~~"Stray radiation" means the sum of leakage and scattered radiation.~~

~~"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.~~

~~"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.~~

ITEM 40. Amend paragraph **41.1(3)**"*a*" subparagraph (6) as follows:

(6) Gonad shielding of not less than ~~0.25~~ 0.50 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.

ITEM 41. Amend subparagraph **41.1(3)**"*f*" (1)"2" as follows:

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~~.

ITEM 42. Amend subparagraph **41.1(3)**"*f*"(2)"1" as follows:

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~~.

ITEM 43. Amend paragraph **41.1(3)**"*f*" by adding subparagraph (4) as follows:

(4) Records shall be maintained to verify that the items in 41.1(3)"*f*" are performed according to the requirements. Records may be discarded only after an agency inspection has been completed and the facility determined to be in compliance.

ITEM 44. Amend subrule **41.1(4)**"*i*" as follows:

i. ~~Locks.~~ All position locking, holding, and centering devices on X–ray system components and systems shall function as intended. All X-ray systems shall be maintained in good mechanical repair and comply with all state and local electrical code requirements.

ITEM 45. Add the following to subrule **41.1(6)**:

41.1(6) *Radiographic systems other than fluoroscopic, dental intraoral, or computed tomography X–ray systems but including veterinary.*

ITEM 46. Rescind subparagraph **41.1(6)**"*h*"(1)3.:

~~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.~~

ITEM 47. Amend paragraph **41.1(7)**"*c*" subparagraph (5) as follows:

(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~~ Stationary X-ray systems shall be required to have the X-ray exposure switch located in a protected area or have an exposure switch cord of sufficient length to permit the operator to activate the unit while in a protected area, e.g., corridor outside the operatory. The procedures required under 41.1(3)"*a*"(4) must instruct the operator to remain in the protected area during the entire exposure.

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.

ITEM 48. Add the following paragraphs to subrule **41.1(9)** :

e. Bone densitometry on human patients shall be conducted only under a prescription of a licensed physician, a licensed physician assistant as defined in Iowa Code section 148C.1, subsection 6, or a licensed registered nurse who is registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152.

f. During the operation of the bone densitometry system:

(1) The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during the examination.

(2) The operator shall advise the patient that the bone densitometry examination is a type of X-ray procedure.

g. Equipment shall be maintained and operated in accordance with the manufacturer's specifications. Records shall be kept of the maintenance for inspection by the agency.

ITEM 49. Amend paragraph **41.1(11)** paragraph "a" as follows:

a. Definitions. In addition to the definitions provided in 641—38.2(136C), 641—40.2(136C), and 41.1(2), the following definitions shall be applicable to 41.1(11):

ITEM 50. Amend subrule **41.2(14)** paragraph "*c*" as follows:

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 or equivalent 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)~~ a dose exceeding 5 rem (0.05 Sv) effective dose equivalent or 50 rem (0.5 Sv) dose equivalent to any individual organ. Licensees may use dosimetry tables in package inserts, corrected only for amount of radioactivity administered, to determine whether a report is required.

ITEM 51. Amend paragraph **41.2(60)***"a"* subparagraphs (2)"1" and (2)"2" to read:

1. Radiation ~~levels~~ dose rates in restricted areas are not likely to cause ~~personnel~~ any occupationally exposed individual to receive a dose ~~exposures~~ in excess of the limits specified in 641—40.15(136C); and

2. Radiation ~~levels~~ dose rates in controlled or unrestricted areas ~~do not exceed~~ are not likely to cause any individual member of the public to receive a dose in excess of the limits specified in 641—40.26(136C).

ITEM 52. Amend subrule **41.2(62)** to read:

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~~ any individual member of the public is likely to receive a dose greater than those permitted by 641—40.26(136C) before beginning the treatment program the licensee shall:

ITEM 53. Amend paragraph **41.3(1)**"*b*" as follows:

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."~~ 41.3(5)

ITEM 54. Amend subrule **41.3(2)** as follows:

41.3(2) *Definitions.* In addition to the definitions provided in 641—38.2(136C) and 641—40.2(136C), ~~T~~the following definitions are specific to 641—41.3(136C).

ITEM 55. Delete the following definitions from subrule **41.3(2)**:

~~*"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.~~

~~"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.~~

~~"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.~~

~~"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.~~

ITEM 56. Amend definition in subrule **41.3(2)** as follows:

"Filter" means material placed in the useful beam to change beam quality in therapeutic radiation machines. ~~subject to subrule 41.3(6).~~

ITEM 57. Amend subrule **41.3(12)** as follows:

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). All required records shall be retained in an active file from at least the time of generation until the next agency inspection. Any required record generated before the last agency inspection may be microfilmed or otherwise archived as long as a complete copy can be retrieved until such time the agency authorizes final disposal.

ITEM 58. Rescind subrule **41.3(13)** and place in reserve:

~~**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.~~

ITEM 59. Add the following to paragraph **41.3(17)**"*a*" subparagraph (1):

3. For each therapeutic machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at positions specified in 41.3(17)"*a*"(1)"1" and 41.3(17)"*a*"(1)"2" for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the facility for inspection by the agency.

ITEM 60. Amend subparagraph **41.3(18)**"*a*" (15) as follows:

(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~~ until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;

ITEM 61. Amend subrule **41.3(18)** paragraph "*e*" and "*f*" as follows:

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~~

2. Full calibration shall include measurement of all parameters listed in Appendix D of 641—Chapter 41. Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not to exceed 12 calendar months, unless a more frequent interval is required by this agency.

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. 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."

~~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)~~ (2) 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)~~(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 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;~~ as specified in Appendix D of 641—Chapter 41;

(3) 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~~ inter-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);

ITEM 62. Amend subrule **41.6(1)** as follows:

41.6(1) *Definitions.* In addition to the definitions provided in 641—38.2(136C), 641—40.2(136C), and 641—41.1(136C), the following definitions shall be applicable to this rule.

ITEM 63. Delete the following definitions from subrule **41.6(1)**:

~~"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.~~

~~"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.~~

~~"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.~~

~~"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.~~

~~"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).~~

~~"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.~~

~~"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.~~

~~"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.~~

~~"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.~~

ITEM 64. Add the following definition to subrule **41.6(1)** as follows:

"Positive mammogram" means a mammogram that has an overall assessment of findings that are either "suspicious" or "highly suggestive" of malignancy.

ITEM 65. Add subparagraph (8) to subrule **41.6(2)** paragraph "*a*" as follows:

(8) Provisional authorization. A new facility beginning operation after September 30, 1994, is eligible to apply for a provisional authorization. This will enable the facility to perform mammography and to obtain the clinical images needed to complete the authorization process. To apply for and receive a provisional certificate, a facility must meet the requirements of 641—41.6(136C). A provisional authorization shall be effective for up to 6 months from the date of issuance and cannot be renewed. The facility may apply for a 60-day extension.

ITEM 66. Amend subrule **41.6(2)** paragraph "*c*" as follows:

c. Withdrawal or denial of mammography authorization.

(1) Mammography authorization may be withdrawn with cause if any facility or machine does not meet one or more of the standards of these rules, will not permit inspections or provide access to records or information in a timely fashion, or has been guilty of misrepresentation in obtaining the authorization.

(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.

(5) If a facility's authorization is revoked, no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility within 2 years of the date of revocation.

ITEM 67. Amend subrule **41.6(3)** as follows:

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.~~

a Rescinded May 10, 2000, and place in reserve.

b. Interpreting physician. ~~All mammograms must be interpreted by a radiologist who meets~~ All radiologists qualifying before October 1, 1994, must meet the requirements in effect as of October 1, 1994. All radiologists qualifying after April 28, 1999, must mett MQSA rules effective on that date or meet 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~~ 3 months of documented full–time mammographic training from a person recognized by this agency. The training must include interpretation of mammograms and topics in mammography, including instructions in radiation physics specific to mammography, radiation effects and radiation protection.

(2) Has interpreted or multi-read an average of ~~ten or more mammograms per workweek in the prior six months~~ 960 mammograms in the prior 24 months or has completed a radiology residency within the past ~~two~~ 2 years. The multi-reading shall be under the direct supervision of an interpreting physician who meets the qualifications of these rules.

(3) Has successfully completed or taught a minimum of ~~40~~ 60 hours (includes radiology residency) of postgraduate instruction in mammography interpretation, basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be category I and at least 16 of the category I hours shall have been acquired within the last 36 months immediately prior to the date that the physician qualifies as an interpreting physician. Before beginning to independently interpret mammograms produced by a new mammographic modality in which the interpreting physician has not previously been

trained, the interpreting physician shall have at least 8 hours of training in the new mammographic modality.

(4) Has successfully completed or taught a minimum of 15 Category I hours ~~of postgraduate instruction~~ in mammography ~~interpretation~~ every 36 months thereafter. This training shall include at least 6 category I continuing medical education credits in each mammographic modality used by the interpreting physician in practice. Credits earned through teaching a specific course can be counted only once towards the 15 required even if the course is taught multiple times during the previous 36 months.

(5) Continues to interpret or multi-read ~~an average of ten or more mammograms per workweek~~ 960 mammograms in 24 months.

(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~~ facility, for inclusion in the patient's medical record.

(9) Reestablishing qualifications.

1. Interpreting physicians who fail to maintain the required continuing interpreting experience or continuing education requirements of 41.6(3)"*b*"(5) shall reestablish their qualifications before resuming the independent interpretation of mammograms by:

- Interpreting or multi-reading at least 240 mammographic examinations under the direct supervision of an interpreting physician who meets the qualifications of these rules, or
- Interpreting or multi-reading a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician who meets the qualifications of these rules, to bring the physician's total up to 960 examinations for the prior 24 months, whichever is less.

2. The interpretations required shall be done within the 6 months immediately prior to resuming independent interpretation.

3. Interpreting physicians who fail to meet the continuing education requirements of 41.6(3)"*b*"(4) shall obtain a sufficient number of additional category I continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming independent interpretation.

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~~ and 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 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 30 semester hours or equivalent of college level physics or radiation science, ~~have two years of experience in conducting performance evaluations of mammography facilities~~ ,have experience of conducting surveys of at least 1 mammography facility and a total of at least 10 mammography units (no more than 1 survey of a specific unit within a period of 60 days can be counted towards this requirement), 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 a mammography 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, h~~ 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.

3. Before a medical physicist may begin independently performing mammographic surveys of a new mammographic modality other than one for which the physicist received initial training, the physicist must receive at least 8 hours of training in surveying units of the new mammographic modality.

(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~~ previous 36 months. 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. Units earned through teaching a specific course can be counted

only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36-month period.

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~~ 3 Iowa mammography units within the last 12 months. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. 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).~~

(5) Reestablishing qualifications. Medical physicists who fail to maintain the required continuing qualifications of this subrule shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous 36 months. Those failing to meet the continuing experience requirements of this subrule must complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualifications of this subrule to bring the total surveys up to the required 3 Iowa units in the previous 12 months. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

d. Equipment operators. Any individual operating mammography equipment must be ~~a physician as defined in 641 Chapter 38 or must~~ 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~~ Joint Review Committee on Education on Radiologic Technology; 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~~ compression, quality assurance/control, technique factor settings, imaging of patients with breast implants, and other areas pertinent to mammography prior to the time the individual begins performing mammography. Training shall include the performance of a minimum of 25 examinations under the direct supervision of an individual already qualified under this subrule and at least 8 hours of training in each mammography modality to be used by the technologist in performing mammography exams. ~~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.

(3) Continuing education. Each general radiographer shall have completed or taught an average of 5 hours of specialized mammographic training every 12 months thereafter to be averaged over no more than a 36–month period. Units earned through teaching a specific course can be counted only once towards the 15 required hours even if the course is taught multiple times during the previous 36 months to a maximum of 7.5 hours. Beginning April 28, 1999, at least 6 of the continuing education hours shall be related to each mammographic modality used by the radiographer.

(4) Beginning April 28, 1999, each general radiographer shall have performed a minimum of 200 mammography examinations during each 24 month period thereafter.

(5) Requalification.

1. General radiographers who fail to meet the continuing education requirements of this subrule shall obtain a sufficient number of continuing education hours in mammography to bring their total up to at least 15 in the previous 36 months, at least 6 of which shall be related to each modality used by the radiographer. The general radiographer may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

2. General radiographers who fail to meet the continuing experience requirements of this subrule shall perform a minimum of 25 mammography examinations under the direct supervision of a qualified radiologic technologist before resuming the performance of unsupervised mammography examinations.

(6) Before a general radiographer may begin independently performing mammographic examinations using a mammographic modality other than the one for which the radiographer received training under this subrule, the radiographer shall have at least 8 hours of continuing education hours in the new modality.

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. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed and it has been determined that the facility is in compliance.

ITEM 68. Amend subrule **41.6(4)** as follows:

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, and the name of the interpreting physician.

(2) The name of the patient and an additional patient identifier.

(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.

(7) The overall final assessment of findings, classified in one of the following categories:

1. "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained).

2. "Benign:" Also a negative assessment.

3. "Probably Benign:" Finding(s) has a high probability of being benign.

4. "Suspicious:" Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant.

5. "Highly suggestive of malignancy:" Finding(s) has a high probability of being malignant.

(8) In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician.

(9) Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

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 or other mammographic facility.

(4) The supplier shall upon request by or on behalf of, the patient, permanently or temporarily, transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly.

(5) Any fee charged to the patients for providing the services in (4) above shall not exceed the documented costs associated with this service.

d. Communication of results to the patient. Each facility shall maintain a system to ensure that the results of each mammographic examination are communicated to the patient in a timely manner. If assessments are "Suspicious" or "Highly suggestive of malignancy" and the patient has not named a health care provider, the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

(1) As soon as possible, but no later than 30 days from the date of the mammography examination, patients who do not name a health care provider to receive the mammography report shall be sent the report described in 41.6(4)"*e*"(1) in addition to a written notification of results in lay terms.

(2) Each facility that accepts patients who do not have a primary care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

e. Communication of results to health care providers. When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

(1) Provide a written report of the mammography examination, including the items listed in 41.6(4)"*b*"(7) to the health care provider as soon as possible, but no later than 30 days from the date of the examination, and

(2) If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider as soon as possible, or if the health care provider is unavailable, to a responsible designee of the health care provider.

f. Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(1) Name of patient and an additional patient identifier.

(2) Date of examination.

(3) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by FDA shall be used to identify view and laterality.

(4) Facility name and location. At a minimum, the location shall include the city, state, and zip code of the facility.

(5) Technologist identification.

(6) Cassette/screen identification.

(7) Mammography unit identification, if there is more than one unit in the facility.

ITEM 69. Amend subrule **41.6(5)** paragraphs "*a*", "*b*", and "*c*" as follows:

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. Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

(1) Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of these rules. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

(2) Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall:

1. Follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality, and

2. Participate in the facility's medical outcomes audit program.

(3) Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality

assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys and mammography equipment evaluations and providing the facility with the applicable reports.

(4) Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of 41.6(5)"*e*" through "*k*".

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 lead interpreting 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.

ITEM 70. Amend subrule **41.6(5)** paragraph "*h*" as follows:

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.

(3) If the total repeat or reject rate changes from the previously determined rate by more than 2.0 % of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

ITEM 71. Amend subrule **41.6(5)** paragraph *"i"*, rescind paragraph "*j*", and add paragraphs "*j*", "*k*", "*l*", "*m*", "*n*", and "*o*".

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.~~ the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

(1) Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among

women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy. Responsibility for each requirement for monitoring shall be assigned to qualified personnel and documented in the supplier's records.

(2)Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than 12 months after the date the facility becomes certified, or 12 months after April 28, 1999, whichever date is the latest. This audit analysis shall be completed within an additional 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months.

(3) Reviewing interpreting physician. Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results, notifying other interpreting physicians of their results and the facility aggregate results. If follow-up actions are taken, the reviewing interpreting physician shall also be responsible for documenting the nature of the follow-up.

j. Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, and protection are properly maintained and updated. These quality control records shall be kept for each test specified in these rules until the next annual inspection has been completed and the facility is in compliance with the quality assurance requirements or until the test has been performed 2 additional times at the required frequency, whichever is longer.

k. Quality assurance – equipment.

(1). Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that examinations are performed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.

1. The base plus fog density shall be within plus or minus 0.03 of the established operating level.

2. The mid-density shall be within plus or minus 0.15 of the established operating level.

3. The density difference shall be within plus or minus 0.15 of the established operating level.

(1) Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.

1. The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.

2. The optical density of the film at the center of the phantom image shall not change by more than plus or minus 0.20 from the established operating level.

3. The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by FDA .

4. The density difference between the background of the phantom and an added test object used to assess image contrast, shall be measured and shall not vary by more than plus or minus 0.05 from the established operating level.

(2) Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square centimeters.

(3) Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

1. Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for 2 minutes while such film is placed on the counter top emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

2. Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.

3. Compression device performance. A compression force of at least 25 pounds (111 newtons) shall be provided. Effective October 28, 2002, the maximum compression force for the initial power drive shall be between 25 pounds (111 newtons) and 47 pounds (209 newtons).

(4) Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

1. Automatic exposure control (AEC) performance.

- The AEC shall be capable of maintaining film optical density within plus or minus 0.30 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 centimeters and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that must be used so that optical densities within plus or minus 0.30 of the average under phototimed conditions can be produced.

- After October 28, 2002 , the AEC shall be capable of maintaining film optical density (OD) within plus or minus 0.15 of the mean optical density when thickness of a homogenous material is varied over a range of 2 to 6 centimeters and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.

- The optical density of the film in the center of the phantom image shall not be less than 1.20.

2. kVp accuracy and reproducibility.

- The kVp shall be accurate within plus or minus 5 percent of the indicated or selected kVp at the lowest clinical kVp that can be measured by a kVp test device, the most commonly used clinical kVp, and the highest available clinical kVp.
- At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.

3. Focal spot condition. Until October 28, 2002, focal spot condition shall be evaluated either by determining system resolution or by measuring focal spot dimensions. After October 28, 2002, facilities shall evaluate focal spot condition only by determining the system resolution.

- Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 cycles/millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.
- The bar pattern shall be placed 4.5 centimeters above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 centimeter of the chest wall edge of the image receptor.
- When more than one target material is provided, the measurement above shall be made using the appropriate focal spot for each target material.
- When more than one SID is provided, the test shall be performed at SID most commonly used clinically.
- Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within tolerance limits specified in Table 1.

Table 1

Focal spot tolerance Limit Nominal Focal Spot Size (mm)	Maximum Measured Dimensions Width (mm)	Length (mm)
0.10	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

4. Beam quality and half-value layer (HVL). The HVL shall meet the specification of 41.1(4) and 41.1(6) for the minimum HVL. These values, extrapolated to the mammographic range, are shown in Table 2. Values not shown in Table 2 may be determined by linear interpolation or extrapolation.

Table 2

X-ray Tube Voltage (kilovolt peak) and Minimum HVL Designed Operating Range (kV) Below 50

Measured Operating Voltage (kV0	Minimum HVL (millimeters of aluminum)
20	0.20
25	0.25
30	0.30

5. Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

6. Dosimetry. The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 0.3 rad (3.0 milligray (mGy)) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

7. X-ray field/light field/image receptor/compression paddle alignment.

- All systems shall have beam-limiting devices that allow the useful X-ray beam to extend to or beyond the edges of the image receptor but by no more than 2 percent of the SID at the chest wall side.
- If a light field that passes through the X-ray beam limitation device is provided, it shall be aligned with the light field and the X-ray field along either the length or the width of the visually defined field at the plane of the breast support surface and shall not exceed 2 percent of the SID.
- The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than one percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall be not be visible on the image.

8. Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

9. System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

10. Radiation output.

- The system shall be capable of producing a minimum output of 513 milliRoentgen (mR) per second (4.5 mGy air kerma per second) when operating at 28 kVp in the standard mammography (moly/moly) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 centimeters above the breast support surface with the compression paddle in place between the source and the detector. After October 28, 2002, the system, under the same measuring conditions

shall be capable of producing a minimum output of 800 mR per second (7.0 mGy air kerma per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate.

- The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

11. Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

- An override capability to allow maintenance of compression;
- A continuous display of the override status; and
- A manual emergency compression release that can be activated in the event of power or automatic release failure.

(5) Quality control tests-other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in 41.6(5)"*k*"(6).

(6) Mobile units. The facility shall verify that mammography units used to produce mammograms at more than one location meet the requirements in 41.6(5)"*k*". In addition, at each examination location, before any examinations are conducted, the facility shall verify satisfactory performance of such units using a test method that establishes the adequacy of the image quality produced by the unit.

(7) Use of test results.

1. After completion of the tests specified in 41.6(5)"*k*" of this section, the facility shall compare the test results to the corresponding specified action limits; or, for non-screen-film modalities, to the manufacturer's recommended action limits; or, for post-move, pre-examination testing of mobile units, to the limits established in the test method used by the facility.

2. If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

- Before any further examinations are performed or any films are processed using the component of the mammography system that failed the test, if the failed test was that described in 41.6(5)"*k*"(1), (2), (4)1., (4)2., (4)3., (5)6., (6), or (7);
- Within 30 days of the test date for all other tests described in 41.6(5)"*k*".

(8) Surveys.

1. At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in 41.6(5)"*k*"(5) and (6) and the weekly phantom image quality test described in 41.6(5)"*k*"(2).

2. The results of all tests conducted by the facility in accordance with 41.6(5)"*k*"(1) through (7), as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.

3. The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.

4. The survey report shall be sent to the facility within 30 days of the date of the survey.

5. The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

(9) Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in 41.6(5). All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of an Iowa approved medical physicist.

(10) Facility cleanliness.

1. The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and view box cleanliness.

2. The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

(11) Calibration of air kerma measuring instruments. Instruments used by medical physicist in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every 2 years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of plus or minus 6 percent (95 percent confidence level) in the mammography energy range.

(12) Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

1. Comply with all applicable federal, state, and local regulations pertaining to infection control; and

2. Comply with the manufacturer's recommended procedures for the cleaning and disinfecting of the mammography equipment used in the facility; or

3. If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

l. Mammography procedures and techniques for mammography of patients with breast implants.

(1) Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic exam.

(2) Except where contraindicated, or unless modified by a physician's directions, patients with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue.

m. Consumer complaint mechanism. Each facility shall:

(1) Establish a written and documented system for collecting and resolving consumer complaints;

(2) Maintain a record of each serious complaint received by the facility for at least 3 years from the date the complaint was received;

(3) Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body if the facility is unable to resolve a serious complaint to the consumer's satisfaction.

(4) Report unresolved serious complaints to the accreditation body in a manner and time frame specified by the accreditation body.

n. Clinical image quality. Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.

o. Additional mammography review and patient notification.

(1) If the agency believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by the agency, for review by the accreditation body or other entity designated by the agency. This additional mammography review will help the agency to determine whether the facility is in compliance with this section and, if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.

(2) If the agency determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or their designees, their physicians, or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a time frame and a manner specified by the agency.

ITEM 72. Amend subrule **41.6(6)** as follows:

41.6(6) *Equipment standards.* The equipment used to perform mammography shall meet the following standards:

a. Be specifically designed for mammography. This prohibits systems that have been modified or equipped with special attachments 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.~~641—41.1(136C).

c. Have image receptor systems and individual components which are appropriate for mammography and used according to the manufacturer's recommendations.

(1) Systems using screen-film image receptors shall provide, at a minimum, for operation for image receptors of 18 x 24 centimeters and 24 x 30 centimeters.

(2) Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

(3) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

~~*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.~~

d. Have beam limiting devices that allow the useful beam to extend to or beyond the chest wall edge of the image receptor. For any system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 centimeters or the maximum source-image receptor distance (SID), whichever is less.

~~*e.* Check film/screen contact when cassettes are first placed into use and semiannually thereafter.~~

e. Magnification:

(1) Systems used to perform noninterventional problem solving procedures shall have radiographic magnification capability available for use by the operator.

(2) Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

e f. Shall ~~C~~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)"*e.*"~~

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

(1) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(2) When more than one target material is provided, the system shall indicate, prior to exposure, the pre-selected target material.

(3) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and/or focal spot actually used during the exposure.

h. Shall have compression devices.~~Devices~~ parallel to the imaging plane ~~shall be available~~ and able 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~~ 3 seconds. Effective October 28, 2002 each system shall provide:

(1) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

(2) Fine adjustment compression controls operable from both sides of the patient.

(3) Systems shall be equipped with different sized compression paddles that match the sizes of all full field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression") may be provided. Such compression paddles for special purposes are not subject to 41.6(6)"*h*"(6) and (7).

(4) Except as provided in 41.6(6)"*h*"(5), the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

(5) Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

(6) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

(7) The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

i. Shall have the capability for using antiscatter grids.

~~*j. Shall have the capability of automatic exposure control.*~~

j. Shall have automatic exposure control such that:

(1) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations.

(2) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

• The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.

• The selected position of the detector shall be clearly indicated.

(3) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

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.~~

(3) Has manual selection of milliampere seconds (mAs) or at least one of its component parts (milliampere (mA) and/or time).

(4) Has the technique factors (peak tube potential in kilovolts (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure indicated before the exposure begins, except

when AEC is used, in which case the technique factors that are set prior to the exposure shall be indicated.

(5) Has a system that, following AEC mode use, shall indicate the actual kilovoltage peak (kVp) and mAs used during the exposure. The mAs may be displayed as mA and time.

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~~ Shall have a viewbox that is 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. Equipment shall be recalibrated as necessary to maintain quality of phantom image.~~

n. Shall use X-ray film that has been designated by the film manufacturer as appropriate for mammography and that is matched to the screen's spectral output as specified by the manufacturer.

o. Shall use intensifying screens that have been designated by the screen manufacturer as appropriate for mammography.

p. Shall use chemical solutions for processing mammography films that are capable of developing the films in a manner equivalent to the minimum requirements specified by the film manufacturer.

q. Shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the viewbox, available to the interpreting physicians.

r. Shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.

s. For mobile units and vans.

(1) A phantom image shall be produced, processed, and evaluated after each relocation.

(2) If processing is not available, a check of the radiation output shall be made and compared to a preset standard for quality. Equipment shall be re-calibrated as necessary to maintain quality of phantom image.

ITEM 73. Amend 41.6(136C)—APPENDIX I as follows:

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 when bulbs or filter changed and semiannually	Minimum dust particles on film. Fog not greater than/ 0.05 OD with 2–minute test
Phantom image quality	At least ~~monthly~~ weekly	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.

ITEM 74. Amend subrule **41.7(1)** as follows:

41.7(1) *Definitions.* In addition to the definitions provided in rule 641—38.2(136C), 641—40.2(136C), and 641—41.1(136C), the following definitions are applicable to this rule.

ITEM 75. Amend 641—Chapter 41-Appendix B as follows:

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 or mirrors.

ITEM 76. Add paragraph "*f*" to subrule **42.2(2)**:

f. Performing procedures not allowed under the individual's current certification.

ITEM 77. Amend paragraph **42.3(1)**"*a*" subparagraph (7) as follows:

(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.~~ "Standards for an Accredited Education Program in Radiologic Sciences" as adopted by the Joint Review Committee on Education on Radiologic Technology.

ITEM 78. Amend subrule **45.1(2)** to include the following:

"Annual refresher safety training" means a review conducted or provided by the licensee for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions.

"Associated equipment" means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, e.g., guide tube, control tube, control (drive) cable, removable source stop, "J" tube and collimator when it is used as an exposure head.

"Certifying Entity" means an independent certifying organization meeting the requirements in Appendix E of this rule or Agreement State meeting the requirements of Appendix E or the requirements of Appendix A in 10 CFR Part 34.

"Control (drive) cable" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

"Control drive mechanism" means a device that enables the source assembly to be moved to and from the exposure device.

"Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

"Exposure head" means a device that locates the gamma radiography sealed source in the selected working position. (An exposure head is also known as a source stop.)

"Field station" means a facility where licensed material may be stored or used and from which equipment is dispatched.

"Guide tube (projection sheath)" means a flexible or rigid tube (i.e., "J" tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

"Hands on experience" means experience in all of those areas considered to be directly involved in the radiography process.

"Independent certifying organization" means an independent organization that meets all of the criteria of Appendix E to this rule.

"Permanent radiographic installation" means an enclosed shielded room, cell, or vault, not located at a temporary job site, in which radiography is performed.

"Practical examination" means a demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.

"Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

"Radiographic operations" means all activities associated with the presence of radioactive sources in a radiographic exposure device during use of the device or transport (except when being transported by a common or contract transport), to include surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

"S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

"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~~ source changer where the sealed source is secured and restricted from movement.

"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)~~ an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used to secure the source in the shielded position.

ITEM 79. Amend subrule **45.1(5)** paragraph "*c*" as follows:

c. Records of these calibrations shall be maintained for ~~two~~ 3 years after the calibration date for inspection by the agency.

ITEM 80. Amend subrule **45.1(7)** to read:

45.1(7) *Utilization logs.*

a. Each licensee ~~or registrant~~ shall maintain current logs of the use of each sealed source ~~of radiation~~. The logs shall include:

(1) A unique identification, which includes ~~such as~~ the make, model and ~~a~~ serial number ~~of each radiation machine,~~ of each radiographic exposure device containing a sealed source, and each sealed source;

(2) The identity of the radiographer using the sealed source ~~of radiation~~;

(3) Locations where each sealed source ~~of radiation~~ is used; and

(4) The date(s) each sealed 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. Each registrant shall maintain current logs of the use of each source of radiation. The logs shall include:

(1) A unique identification, which includes the make, model and serial number of each source of radiation;

(2) The identity of the radiographer using the source of radiation;

(3) The date(s) each source of radiation is energized or used and the number of exposures made.

~~*b*~~ *c*. 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~~ 3 years from the date of the recorded event. The records shall be kept at the location specified by the license or certificate of registration.

ITEM 81. Amend subrule **45.1(9)** paragraph "*b*" as follows:

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~~ 3 years from the date of the event.

ITEM 82. Rescind subrule **45.1(10)***"b"* subparagraph (1)"2" and replace with new subrule **45.1(10)***"b"* subparagraph (1)"2":

2. Has completed on-the-job training as a radiographic trainee supervised by one or more radiographic trainers. The on-the-job training shall be documented on the appropriate agency form or equivalent and shall include a minimum of 2 months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material and/or 1 month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on-the-job training (3 months or 480 hours). Active participation does not include safety meetings or classroom training;

ITEM 83. Amend subrule **45.1(10)** paragraph "*d*" to read:

d. Radiation Safety Officer 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 program.

ITEM 84. Amend paragraph **45.1(10)***"g"* subparagraph (1)"1" to read:

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 an equivalent exam. Certification by a certifying entity in accordance with 10 CFR 34.43(a)(1) meets the examination requirements of 45.1(10)*"f"*(2) but not the requirements of 45.1(10)"*b*"(1)..

ITEM 85. Rescind subrule **45.1(11)** and replace with new subrule **45.1(11)**:

45.1(11) *Internal Audits.* Except as provided in 45.1(11)"*c*", the RSO or designee shall conduct an inspection program of the job performance of each radiographer and radiographer trainee to ensure that these rules, license requirements, and the licensee's or registrant's operating and emergency procedures are followed. The inspection program must:

a. Include observation of the performance of each radiographer and radiographer trainee during an actual industrial radiographic operation, at intervals not to exceed 6 months; and

b. Provide that, if a radiographer or radiographer trainee has not participated in an industrial radiographic operation for more than 6 months since the last audit, the radiographer or radiographer trainee must demonstrate understanding of the subjects contained in Appendix A to this chapter by a practical examination before these individuals can next participate in a radiographic operation.

c. The agency may consider alternatives in those situations where the individual serves as both radiographer and RSO.

d. Records of audits shall be maintained by the licensee or registrant for agency inspection for 3 years from the date of the audit.

ITEM 86. Amend paragraph **45.1(12)**"*b*" to read:

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 at all times during radiographic operations ~~the~~ each individual wears, on the trunk of the body, a combination of ~~a~~ direct–reading pocket dosimeter, an operating alarm ratemeter, and either a film badge, an optically stimulated device (OSD) 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 or electronic personal dosimeters shall meet the criteria in ANSI N322–1977 and shall have a range of zero to at least 200 milliroentgens.

(3) Pocket dosimeters or electronic personal dosimeters shall be recharged at the start of each work shift.

(4) Pocket dosimeters or electronic personal 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"), or if the electronic personal dosimeter reads greater than 200millirem (2 millisievert), and the possibility of radiation exposure cannot be ruled out as the cause, 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. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in the exposure records maintained in accordance with 641—Chapter 40.

(6) Each film badge, OSD or TLD shall be assigned to and worn by only one individual.

(7) Film badges, OSD's and TLDs must be replaced at least monthly. After replacement, each film badge, OSD 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, OSD or TLD is lost or damaged, the worker shall cease work immediately until a replacement film badge, OSD or TLD is provided and the exposure is

calculated for the time period from issuance to loss or damage of the film badge, OSD or TLD.

ITEM 87. Amend subrule **45.1(13)** to read:

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. The personal supervision must include:

a. The radiographer's physical presence at the site where the source(s) of radiation are being used;

b. The availability of the radiographer to give immediate assistance if required; and

c. The radiographer's direct observation of the trainee's performance of the operations referred to in this sub-rule.

ITEM 88. Rescind subrule **45.3(1)** and insert new subrule **45.3(1)** as follows:

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 millirem (2 millisieverts) per hour at any exterior surface, and 10 millirem (0.1 millisievert) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

ITEM 89. Amend subrule **45.3(2)** paragraph "*a*" to read:

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, and, if applicable, the key removed, 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.

ITEM 90. Amend paragraph **45.3(4)**"*c*" subparagraph (5) to read:

(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~~ be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use;

ITEM 91. Amend paragraph **45.3(4)**"*c*" subparagraph (8) to read:

(8) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980;

ITEM 92. Amend subrule **45.3(4)** by adding new paragraph "*f*" and "*g*":

f. Notwithstanding the requirements of 45.3(4)"*a*" of this rule, equipment used in industrial radiographic operations need not comply with § 8.9.2© of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

g. Engineering analysis may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the Commission may find this an acceptable alternative to actual testing of the component pursuant to the above referenced standard.

ITEM 93. Rescind paragraph **45.3(5)**"*b*" and replace with new paragraph **45.3(5)**"*b*" as follows:

b. Leak testing

(1) Each sealed source shall be tested for leakage at intervals not to exceed 6 months. In the absence of a certificate from a transferor indicating that a test has been made within the 6–month period prior to the transfer, the sealed source shall not be put into use until tested.

(2) Each exposure device using depleted uranium (DU) shielding and an S-tube configuration must be tested for DU contamination at intervals not to exceed 12 months. Should the leak test reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while in storage and not in use. Before using or transferring such a device, however, the device must be tested for DU contamination if the interval of storage exceeded 12 months.

ITEM 94. Amend paragraph **45.3(6)**"*a*" subparagraphs (9) and (10) and add (11) and (12) as follows:

(9) Maintenance of records; ~~and~~

(10) The inspection and maintenance of radiographic exposure devices, source changers, storage containers, and radiation machines~~.~~;

(11) The procedure(s) for identifying and reporting defects and noncompliance in 10 CFR Part 21; and

(12) Source recovery procedure if the licensee will perform source recovery.

ITEM 95. Amend subrule 45.3(6) paragraph "*c*" to read:

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).~~Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or a radiographer trainee. If one of the personnel is a radiographer trainee, the other shall be a radiographer trainer authorized by the license. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Except for the situation of a radiographer trainer with a trainee, radiography may not be performed if only one qualified individual is present.

ITEM 96. Amend subrule **45.3(7)** paragraph "*b*" to read:

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. The survey required by this sub-rule must be done before exchanging films, repositioning the exposure head or dismantling the equipment.

ITEM 97. Amend subrule **45.3(9)** paragraph "*a*" to read:

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)~~ 39.4(27)"e".

ITEM 98. Rescind subrule **45.3(11)**.

ITEM 99. Amend subrule **45.4(2)** as follows:

45.4(2) *Definitions.* For purposes of this subrule, definitions in 641—Chapter 38, 40, and 45.1(2) may also apply. As used in this rule, the following definitions apply:

ITEM 100. Add the following definition to subrule **45.4(2)**:

"Cold Pasteurization" means the process of using radiation for destroying disease causing microorganisms in commercial products.

ITEM 101. Amend subrule **45.4(11)** paragraph "*c*" as follows:

c. Accelerator facilities registered pursuant to 45.4(3)*"a"* shall survey for removable contamination at intervals not to exceed ~~three~~ 6 months to determine the degree of contamination.

ITEM 102. Amend **641—46.1(136D)** paragraph two as follows:

641—46.1(136D) *Purpose and scope.* This chapter provides for the permitting and regulation of tanning facilities and devices used for the purpose of tanning human skin through the application of ultraviolet radiation. This includes, but is not limited to, public and private businesses, hotels, motels, apartments, condominiums, and health and country clubs.

All references to Code of Federal Regulations (CFR) in this chapter are those in effect as of ~~July 1, 1999~~ May 10, 2000.

ITEM 103. Amend subrule **46.5(1)** paragraph "*c*" as follows:

c. A tanning facility shall provide each consumer with a written warning statement prior to the consumer's initial exposure and annually thereafter which includes at least the following information:

Charlene R. Craig
Radiological Health

Iowa Department of Public Health
Lucas State Office Building
Des Moines, Iowa 50319-0075

(515) 281-4942
FAX: 515-242-6284
ccraig@idph.state.ia.us