State of Utah
GARY R. HERBERT
*Governor*

SPENCER J. COX
*Lieutenant Governor*

Department of
Environmental Quality

Amanda Smith
*Executive Director*

DIVISION OF RADIATION CONTROL
Rusty Lundberg
*Director*

October 27, 2014

Susan Abraham, Acting Deputy Director
Division Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
T8-E24
Washington D.C. 20555-0001

Dear Ms. Abraham:

In response to RATS ID 2012-1, enclosed are two copies of letters sent to the Utah Division of Radiation Control (DRC) by the Nuclear Regulatory Commission stating that the DRC has equivalent rules in R313-21 to those found in 10 CFR Parts 31.5 and 31.6, as required by RATS ID 2001-1. A copy of R313-21 is also enclosed for your convenience.

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-200.

If you have any questions, please feel free to contact me at (801) 536-4257 or Spencer Wickham of my staff at (801) 536-0082 or swickham@utah.gov.

Sincerely,

Rusty Lundberg

Rusty Lundberg, Director
Radiation Control Program

Enclosures:
As stated

195 North 1950 West • Salt Lake City, UT
Mailing Address: P.O. Box 144850 • Salt Lake City, UT 84114-4850
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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001



March 8, 2004

Dane Finerfrock, Director
Division of Radiation Control
Department of Environmental Quality
168 North 1950 West, P.O. Box 144850
Salt Lake City, Utah 84114-4850

Dear Mr. Finerfrock:

We have reviewed the final revisions to the Utah Administrative Code Title R313, *"Environmental Quality, Radiation Control"*, received by our office on February 26, 2004. In addition, we reviewed your responses to our letter, dated October 15, 2003, which contained our comments on your proposed version of these rules. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) regulations in 10 CFR Parts 30, 31 and 32 and the requirements of the one amendment identified in the enclosed States Regulation Status Data Sheet (SRS). We discussed our review of the regulations with Philip Griffin on February 26, 2004.

As a result of our review, we have no comments. Please note that we have limited our review to regulations required for compatibility and/or health and safety. We have determined that the regulations, as adopted, meet the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200.

The SRS Data Sheet summarizes our knowledge of the status of other Utah Regulations, as indicated. Please let us know if you note any inaccuracies, or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet, is posted on the STP website: http://www.hrsd.ornl.gov/nrc/rulemaking.htm.

If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact me, or John Zabko of my staff at (301)415-2308 or JGZ@NRC.GOV.

Sincerely,

Kathleen A. Schneider for

Josephine Piccone, Deputy Director
Office of State and Tribal Programs

Enclosures:
As stated

## STATE REGULATION STATUS

**State: Utah**
**One amendment reviewed is identified by a ★**
**at the beginning of each equivalent NRC regulation**

**Tracking Ticket Number:4-44**
**Date: March 8, 2004**

| NRC Chronology Identification | FR Notice (Due Date for State Implementation) | RATS ID | Proposed (P) / Final (F)[1] Rule / ML #[4] | NRC Review / Y, N[2] / Date / ML #[4] | Final State Regulation[1] (Effective Date) |
|---|---|---|---|---|---|
| Safety Requirements for Radiographic Equipment-Part 34 | 55 FR 843; (1/10/94) | 1991-1 | F ML032180130 | N 8/28/03 ML032400630 | 1/10/94 |
| ASNT Certification of Radiographers-Part 34 | 56 FR 11504; (none) | 1991-2 | | | Not required[3] |
| Standards for Protection Against Radiation-Part 20 | 56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877; 58 FR 67657; 59 FR 41641; 60 FR 20183; (1/1/94) | 1991-3 | F | N 2/10/98 | 1/23/98 |
| Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70 | 56 FR 64980; (10/15/94) | 1991-4 | F ML032180130 | Y 8/28/03 ML032400630 | 10/26/94 |
| Quality Management Program and Misadministrations-Part 35 | 56 FR 34104; (1/27/95) | 1992-1 | P | N 1/26/98 | 3/10/95 |
| Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30, 35 | 57 FR 45566; (none) | 1992-2 | | | Not required[3] |
| Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40 | 58 FR 39628; (10/25/96) | 1993-1 | F | N 1/8/97 | 11/15/96 |
| Licensing and Radiation Safety Requirements for Irradiators-Part 36 | 58 FR 7715; (7/1/96) | 1993-2 | F | N 6/14/00 | 3/10/00 |
| Definition of Land Disposal and Waste Site QA Program-Part 61 | 58 FR 33886; (7/22/96) | 1993-3 | P | N 9/23/96 | 5/31/96 |
| Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70 | 58 FR 68726; 59 FR 1618; | 1994-1 | | | Not required[3] |
| Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40 | 59 FR 28220; (7/1/97) | 1994-2 | F ML023100574 | N 11/22/02 ML023290240 | 10/7/02[5] |
| Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70 | 59 FR 36026; (8/15/97) | 1994-3 | F | N 2/10/98 | 7/18/97 |
| Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use-Parts 30, 32, 35 | 59 FR 61767; 59 FR 65243; 60 FR 322; (1/1/98) | 1995-1 | F | N 2/10/98 | 7/18/97 |
| Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20 | 60 FR 7900; (3/13/98) | 1995-2 | P | N 1/26/98 | 3/20/98 |
| Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61 | 60 FR 15649; 60 FR 25983; (3/1/98) | 1995-3 | P | N 1/26/98 | 1/23/98 |
| Performance Requirements for Radiography Equipment-Part 34 | 60 FR 28323; (6/30/98) | 1995-4 | F ML032180130 | N 8/28/03 ML032400630 | 7/18/97 |
| Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20 | 60 FR 36038; (8/14/98) | 1995-5 | P | N 1/26/98 | 3/20/98 |
| Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70 | 60 FR 38235; (11/24/98) | 1995-6 | F | N 2/10/98 | 7/18/97 |
| Medical Administration of Radiation and Radioactive Materials-Parts 20, 35 | 60 FR 48623; (10/20/98) | 1995-7 | P | N 1/26/98 | 8/11/98 |

| NRC Chronology Identification | FR Notice (Due Date for State Implementation) | RATS ID | Proposed (P) / Final (F)[1] Rule / ML #[4] | NRC Review / Y, N[2] / Date / ML #[4] | Final State Regulation[1] (Effective Date) |
|---|---|---|---|---|---|
| 10 CFR Part 71: Compatibility with the International Atomic Energy Agency - Part 71 | 60 FR 50248; 61 FR 28724; (4/1/99) | 1996-1 | F | N 4/16/99 | 3/12/99 |
| One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses-Parts 30, 40, 70 | 61 FR 1109; (none) | 1996-2 | F | N 2/10/98 | Not required[3] |
| Termination or Transfer of Licensed Activities:Recordkeeping Requirements-Parts 20, 30, 40, 61, 70 | 61 FR 24669; (6/17/99) | 1996-3 | F Part 30 | N 2/10/98 | 3/20/98 |
| Resolution of Dual Regs.of Airborne Effluents of Radioactive Mats.; Clean Air Act-Part 20 | 61 FR 65120; (1/9/00) | 1997-1 | P | N 1/26/98 | 3/20/98 |
| Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State-Part 150 | 62 FR 1662; (2/27/00) | 1997-2 | F ML032180130 | N 8/28/03 ML032400630 | 6/11/99 |
| Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35 | 62 FR 4120; (5/29/00) | 1997-3 | P | N 1/26/98 | 3/20/98 |
| Fissile Material Shipments and Exemptions-Part 71 | 62 FR 5907; (none) | 1997-4 | | | Not required[3] |
| Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150 | 62 FR 28947; (6/27/00) | 1997-5 | F | N 4/1/98 | 5/15/97 |
| Radiological Criteria for License Termination-Parts 20, 30, 40, 70 | 62 FR 39057; (8/20/00) | 1997-6 | F | N 6/14/00 | 3/10/00 |
| Exempt Distrib. of Radioactive Drug Containing One Microcurie of Carbon-14 Urea-Part 30 | 62 FR 63634; (1/02/01) | 1997-7 | F | N 4/16/99 | 3/12/99 |
| Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150 | 63 FR 1890; 63 FR 13773; (2/12/01) | 1998-1 | F ML011100015 | N 7/31/01 ML012150220 | 1/26/01 |
| Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70 | 63 FR 29535; (none) | 1998-2 | | | Not required[3] |
| License Term for Medical Use Licenses-Part 35 | 63 FR 31604; (none) | 1998-3 | | | Not required[3] |
| Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34 | 63 FR 37059; (7/9/01) | 1998-4 | P ML010870073 | N 4/27/01 ML011170330 | 5/11/01 |
| Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36 | 63 FR 39477; 63 FR 45393; (10/26/01) | 1998-5 | F ML013530478 | Y 2/7/02 ML020390486 | 9/14/01 |
| Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20 | 63 FR 50127; (11/20/01) | 1998-6 | F ML013530478 | N 2/7/02 ML020390486 | 9/14/01 |
| Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40 | 64 FR 17506; (6/11/02) | 1999-1 | F ML023100574 | N 11/22/02 ML023290240 | 10/7/02[5] |
| Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information-Part 31 | 64 FR 42269; (none) | 1999-2 | | | Not required[3] |
| Respiratory Protection and Controls to Restrict Internal Exposure-Part 20 | 64 FR 54543; 64 FR 55524; (2/2/03) | 1999-3 | F ML013530478 | N 2/7/02 ML020390486 | 9/14/01 |
| Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39 | 65 FR 20337; (5/17/03) | 2000-1 | F ML012850044 | N 12/27/01 ML020020182 | 9/14/01 |
| New Dosimetry Technology-Parts 34, 36, 39 | 65 FR 63750; (1/8/04) | 2000-2 | P Part 34 ML010870073 | N 4/27/01 ML011170330 | |

| NRC Chronology Identification | FR Notice (Due Date for State Implementation) | RATS ID | Proposed (P) / Final (F)[1] Rule / ML #[4] | NRC Review / Y, N[2] / Date / ML #[4] | Final State Regulation[1] (Effective Date) |
|---|---|---|---|---|---|
| ★ Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material-Parts 30, 31, and 32 | 65 FR 79162; (2/16/04) | 2001-1 | F ML04058276 | N 3/08/04 ML040690493 | |
| Revision of the Skin Dose Limit-Part 20 that became effective April 5, 2002. | 67 FR 16298; (4/5/05) | 2002-1 | | | |
| Medical Use of Byproduct Material-Parts 20, 32, and 35 | 67 FR 20249; (4/24/05) | 2002-2 | | | |
| Financial Assurance for Materials Licensees – Parts 30, 40, 70 | 68 FR 57327 12/3/06 | 2003-1 | | | |

1. Or other generic Legally Binding Requirements.

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

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

4. ADAMS ML Number

5. The regulation package contained several regulations with earlier effective dates. The uranium milling regulations are not to be implemented until the amended Agreement is signed and effective.

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

October 15, 2003

Craig Jones, Director
Division of Radiation Control
Department of Environmental Quality
168 North 1950 West, P.O. Box 144850
Salt Lake City, Utah 84114-4850



Dear Mr. Jones:

We have reviewed the proposed changes to the Utah Administrative Code Title R313, *"Environmental Quality, Radiation Control"*, received by our office on October 2, 2003. In addition, we reviewed your responses to our letter, dated August 28, 2003, which contained our comments on a previous version of these rules. In this submission, we did not receive Utah's proposed changes to regulations equivalent to 10 CFR Parts 30.31 and 30.34, as required by amendment RATS ID # 2001-1. We were able to review Utah's current equivalent rules (available at http://www.rules.utah.gov/publicat/code/r313/r313.htm ) and found them to be compatible to the NRC for these missing sections. Our review and comments are in response to the State's request for Nuclear Regulatory Commission (NRC) evaluation of the changes to Utah's radiation control rules that incorporated the amendments identified on the States Regulation Status Data Sheet (SRS). These regulations were reviewed by comparison to the equivalent NRC rules in 10 CFR Parts 30, 31 and 32 and the requirements of the amendment identified in the enclosed SRS. We discussed our review of the regulations with Philip Griffin on October 15, 2003.

As a result of our review, we have no comments and two editorial suggestions. Please note that we have limited our review to regulations required for compatibility and/or health and safety. Under our current procedure, a finding that a State regulation meets the compatibility and health and safety categories of the equivalent NRC regulation may only be made based on a review of the final State regulation. However, we have determined that if these regulations are adopted without significant change, they would meet the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200. We request that when the proposed regulations are adopted and published as final regulations, a copy of the "as published" regulations be provided to the NRC for review.

The SRS Data Sheet summarizes our knowledge of the status of other Utah regulations, as indicated. Please let us know if you note any inaccuracies, or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet, is posted on the STP website: http://www.hrsd.ornl.gov/nrc/rulemaking.htm.

If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact me, or John Zabko of my staff at (301)415-2308 or JGZ@NRC.GOV.

Sincerely,

Kathleen M. Schneider for

Josephine Piccone, Deputy Director
Office of State and Tribal Programs

Enclosures:
As stated

## EDITORIAL SUGGESTIONS

1. In R313-21-22 (4)(c)(xiii.)(B.), the State omitted the first "e" in Executive Secretary.

2. In R313-22-75 (4)(d)(ii)(A.), the State has referenced 10 CFR 20.2002 instead of 10 CFR 20.2202 as found in the NRC's equivalent regulation.

## STATE REGULATION STATUS

**State: Utah One amendment reviewed is identified by a ★ at the beginning of each equivalent NRC regulation**

**Tracking Ticket Number: 3-226**
**Date:10/15/03**

| NRC Chronology Identification | FR Notice (Due Date for State Implementation) | RATS ID | Proposed (P) / Final (F)[1] Rule / ML #[4] | NRC Review / Y, N[2] / Date / ML #[4] | Final State Regulation[1] (Effective Date) |
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| Safety Requirements for Radiographic Equipment-Part 34 | 55 FR 843; (1/10/94) | 1991-1 | F ML032180130 | N 8/28/03 ML032400630 | 1/10/94 |
| ASNT Certification of Radiographers-Part 34 | 56 FR 11504; (none) | 1991-2 | | | Not required[3] |
| Standards for Protection Against Radiation-Part 20 | 56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877; 58 FR 67657; 59 FR 41641; 60 FR 20183; (1/1/94) | 1991-3 | F | N 2/10/98 | 1/23/98 |
| Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70 | 56 FR 64980; (10/15/94) | 1991-4 | F ML032180130 | Y 8/28/03 ML032400630 | 10/26/94 |
| Quality Management Program and Misadministrations-Part 35 | 56 FR 34104; (1/27/95) | 1992-1 | P | N 1/26/98 | 3/10/95 |
| Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30, 35 | 57 FR 45566; (none) | 1992-2 | | | Not required[3] |
| Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40 | 58 FR 39628; (10/25/96) | 1993-1 | F | N 1/8/97 | 11/15/96 |
| Licensing and Radiation Safety Requirements for Irradiators-Part 36 | 58 FR 7715; (7/1/96) | 1993-2 | F | N 6/14/00 | 3/10/00 |
| Definition of Land Disposal and Waste Site QA Program-Part 61 | 58 FR 33886; (7/22/96) | 1993-3 | P | N 9/23/96 | 5/31/96 |
| Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70 | 58 FR 68726; 59 FR 1618; | 1994-1 | | | Not required[3] |
| Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards-Part 40 | 59 FR 28220; (7/1/97) | 1994-2 | F ML023100574 | N 11/22/02 ML023290240 | 10/7/02[5] |
| Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70 | 59 FR 36026; (8/15/97) | 1994-3 | F | N 2/10/98 | 7/18/97 |
| Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use-Parts 30, 32, 35 | 59 FR 61767; 59 FR 65243; 60 FR 322; (1/1/98) | 1995-1 | F | N 2/10/98 | 7/18/97 |
| Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20 | 60 FR 7900; (3/13/98) | 1995-2 | P | N 1/26/98 | 3/20/98 |
| Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61 | 60 FR 15649; 60 FR 25983; (3/1/98) | 1995-3 | P | N 1/26/98 | 1/23/98 |
| Performance Requirements for Radiography Equipment-Part 34 | 60 FR 28323; (6/30/98) | 1995-4 | F ML032180130 | N 8/28/03 ML032400630 | 7/18/97 |
| Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20 | 60 FR 36038; (8/14/98) | 1995-5 | P | N 1/26/98 | 3/20/98 |
| Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70 | 60 FR 38235; (11/24/98) | 1995-6 | F | N 2/10/98 | 7/18/97 |
| Medical Administration of Radiation and Radioactive Materials-Parts 20, 35 | 60 FR 48623; (10/20/98) | 1995-7 | P | N 1/26/98 | 8/11/98 |

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| 10 CFR Part 71: Compatibility with the International Atomic Energy Agency - Part 71 | 60 FR 50248; 61 FR 28724; (4/1/99) | 1996-1 | F | N 4/16/99 | 3/12/99 |
| One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses-Parts 30, 40, 70 | 61 FR 1109; (none) | 1996-2 | F | N 2/10/98 | Not required[3] |
| Termination or Transfer of Licensed Activities:Recordkeeping Requirements-Parts 20, 30, 40, 61, 70 | 61 FR 24669; (6/17/99) | 1996-3 | F Part 30 | N 2/10/98 | 3/20/98 |
| Resolution of Dual Regs.of Airborne Effluents of Radioactive Mats.; Clean Air Act-Part 20 | 61 FR 65120; (1/9/00) | 1997-1 | P | N 1/26/98 | 3/20/98 |
| Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State-Part 150 | 62 FR 1662; (2/27/00) | 1997-2 | F ML032180130 | N 8/28/03 ML032400630 | 6/11/99 |
| Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35 | 62 FR 4120; (5/29/00) | 1997-3 | P | N 1/26/98 | 3/20/98 |
| Fissile Material Shipments and Exemptions-Part 71 | 62 FR 5907; (none) | 1997-4 | | | Not required[3] |
| Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150 | 62 FR 28947; (6/27/00) | 1997-5 | F | N 4/1/98 | 5/15/97 |
| Radiological Criteria for License Termination-Parts 20, 30, 40, 70 | 62 FR 39057; (8/20/00) | 1997-6 | F | N 6/14/00 | 3/10/00 |
| Exempt Distrib. of Radioactive Drug Containing One Microcurie of Carbon-14 Urea-Part 30 | 62 FR 63634; (1/02/01) | 1997-7 | F | N 4/16/99 | 3/12/99 |
| Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150 | 63 FR 1890; 63 FR 13773; (2/12/01) | 1998-1 | F ML011100015 | N 7/31/01 ML012150220 | 1/26/01 |
| Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees- Parts 30, 40, 70 | 63 FR 29535; (none) | 1998-2 | | | Not required[3] |
| License Term for Medical Use Licenses-Part 35 | 63 FR 31604; (none) | 1998-3 | | | Not required[3] |
| Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34 | 63 FR 37059; (7/9/01) | 1998-4 | P ML010870073 | N 4/27/01 ML011170330 | 5/11/01 |
| Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 35, 36 | 63 FR 39477; 63 FR 45393; (10/26/01) | 1998-5 | F ML013530478 | Y 2/7/02 ML020390486 | 9/14/01 |
| Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20 | 63 FR 50127; (11/20/01) | 1998-6 | F ML013530478 | N 2/7/02 ML020390486 | 9/14/01 |
| Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40 | 64 FR 17506; (6/11/02) | 1999-1 | F ML023100574 | N 11/22/02 ML023290240 | 10/7/02[5] |
| Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information-Part 31 | 64 FR 42269; (none) | 1999-2 | | | Not required[3] |
| Respiratory Protection and Controls to Restrict Internal Exposure-Part 20 | 64 FR 54543; 64 FR 55524; (2/2/03) | 1999-3 | F ML013530478 | N 2/7/02 ML020390486 | 9/14/01 |
| Energy Compensation Sources for Well Logging and Other Regulatory | 65 FR 20337; (5/17/03) | 2000-1 | F | N 12/27/01 | 9/14/01 |

| NRC Chronology Identification | FR Notice (Due Date for State Implementation) | RATS ID | Proposed (P) / Final (F)[1] Rule / ML #[4] | NRC Review / Y, N[2] / Date / ML #[4] | Final State Regulation[1] (Effective Date) |
|---|---|---|---|---|---|
| Clarifications-Part 39 | | | ML012850044 | ML020020182 | |
| New Dosimetry Technology-Parts 34, 36, 39 | 65 FR 63750; (1/8/04) | 2000-2 | P Part 34 ML010870073 | N 4/27/01 ML011170330 | |
| ★ Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material-Parts 30, 31, and 32 | 65 FR 79162; (2/16/04) | 2001-1 | P ML032751628 | N 10/15/03 ML032930349 | |
| Revision of the Skin Dose Limit-Part 20 that became effective April 5, 2002. | 67 FR 16298; (4/5/05) | 2002-1 | | | |
| Medical Use of Byproduct Material-Parts 20, 32, and 35 | 67 FR 20249; (4/24/05) | 2002-2 | | | |

1. Or other generic Legally Binding Requirements.

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

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

4. ADAMS ML Number

5. The regulation package contained several regulations with earlier effective dates. The uranium milling regulations are not to be implemented until the amended Agreement is signed and effective.

**R313. Environmental Quality, Radiation Control.**
**R313-21. General Licenses.**
**R313-21-1. Purpose and Scope.**

(1) R313-21 establishes general licenses for the possession and use of radioactive material contained in certain items and a general license for ownership of radioactive material.

(2) The rules set forth herein are adopted pursuant to the provisions of Sections 19-3-104(3)and 19-3-104(6).

**R313-21-21. General Licenses--Source Material.**

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

(2) Persons who receive, possess, use, or transfer source material pursuant to the general license issued in R313-21-21(1) are exempt from the provisions of R313-15 and R313-18, to the extent that such receipt, possession, use or transfer is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to a person who is also in possession of source material under a specific license issued pursuant to R313-22.

(3) Persons who receive, possess, use, or transfer source material pursuant to the general license in R313-21-21(1) are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Director in a specific license.

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

(5) Depleted uranium in industrial products and devices.

(a) A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of R313-21-21(5)(b), (c), (d), and (e), depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

(b) The general license in R313-21-21(5)(a) applies only to industrial products or devices which have been manufactured or initially transferred, either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to R313-22-75(11) or in accordance with a specific license issued to the manufacturer by the Nuclear Regulatory Commission, an Agreement State, or a Licensing State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

(c)(i) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by R313-21-21(5)(a) shall file form DRC-12 "Registration Form-Use of Depleted Uranium Under General License," with the Director. The form

shall be submitted within 30 days after the first receipt or acquisition of depleted uranium. The registrant shall furnish on form DRC-12 the following information and other information as may be required by that form:

(A) name and address of the registrant;

(B) a statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in R313-21-21(5)(a) and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

(C) name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in R313-21-21(5)(c)(i)(B).

(ii) The registrant possessing or using depleted uranium under the general license established by R313-21-21(5)(a) shall report in writing to the Director any changes in information previously furnished on form DRC-12 "Registration Form - Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of the change.

(d) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by R313-21-21(5)(a):

(i) shall not introduce depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

(ii) shall not abandon depleted uranium;

(iii) shall transfer or dispose of depleted uranium only by transfer in accordance with the provisions of R313-19-41. In the case where the transferee receives the depleted uranium pursuant to the general license established by R313-21-21(5)(a), the transferor shall furnish the transferee a copy of R313-21 and a copy of form DRC-12. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the Nuclear Regulatory Commission's or Agreement State's regulation equivalent to R313-21-21(5)(a), the transferor shall furnish the transferee a copy of this rule and a copy of form DRC-12 accompanied by a note explaining that use of the product or device is regulated by the Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in R313-21;

(iv) within 30 days of any transfer, shall report in writing to the Director the name and address of the person receiving the depleted uranium pursuant to the transfer;

(v) shall not export depleted uranium except in accordance with a license issued by the Nuclear Regulatory Commission pursuant to 10 CFR Part 110; and

(vi) shall pay annual fees pursuant to R313-70.

(e) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by R313-21-21(5)(a) is exempt from the requirements of R313-15 and R313-18 of these rules with respect to the depleted uranium covered by that general license.

**R313-21-22. General Licenses*--Radioactive Material Other Than**

**Source Material.**

NOTE: *Different general licenses are issued in this section, each of which has its own specific conditions and requirements.

(1) Certain devices and equipment. A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the Director, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State for use pursuant to 10 CFR 31.3. This general license is subject to the provisions of R313-12-51 through R313-12-70, R313-14, R313-15, R313-18 and R313-19 as applicable.

(a) Static Elimination Devices. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 megabecquerel (500 uCi) of polonium-210 per device.

(b) Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 megabecquerel (500 uCi) of polonium-210 per device or a total of not more than 1.85 gigabecquerel (50 mCi) of hydrogen-3 (tritium) per device.

(2) Certain items and self-luminous products containing radium-226.

(a) A general license is hereby issued to a person to acquire, receive, possess, use, or transfer, in accordance with the provisions of Subsections R313-21-22(2)(b), R313-21-22(2)(c), and R313-21-22(2)(d), radium-226 contained in the following products manufactured prior to November 30, 2007.

(i) Antiquities originally intended for use by the general public. For the purposes of Subsection R313-21-22(2)(a), antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

(ii) Intact timepieces containing greater than 37 kilobecquerels (1 uCi), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

(iii) Luminous items installed in air, marine, or land vehicles.

(iv) All other luminous products provided that no more than 100 items are used or stored at the same location at one time.

(v) Small radium sources containing no more than 37 kilobecquerels (1 uCi) of radium-226. For the purposes of Subsection R313-21-22(2)(a), "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations such as cloud chambers and spinthariscopes, electron tubes, static eliminators, or as designated by the Director.

(b) Persons who acquire, receive, possess, use, or transfer radioactive material under the general license issued in Subsection R313-21-22(2)(a) are exempt from the provisions of Rules R313-15, R313-18, and Sections R313-12-51 and R313-19-50, to the extent that the receipt, possession, use, or transfers of radioactive material is within the terms of the general license; provided, however, that

this exemption shall not be deemed to apply to a person specifically licensed under Rule R313-22.

(c) A person who acquires, receives, possesses, uses, or transfers radioactive material in accordance with the general license in Subsection R313-21-22(2)(a):

(i) Shall notify the Director should there be an indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Director within 30 days.

(ii) Shall not abandon products containing radium-226. The product, and radioactive material from the product, may only be disposed of according to Section R313-15-1008 or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the Director.

(iii) Shall not export products containing radium-226 except in accordance with 10 CFR Part 110.

(iv) Shall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with Federal or State solid or hazardous waste laws, inluding the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 under Rule R313-22 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State or as otherwise approved by the Director.

(v) Shall respond to written requests from the Director to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Director a written justification using the method stated in Section R313-12-110.

(d) The general license in R313-21-22(2)(a) does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

(3) RESERVED.

(4) Certain detecting, measuring, gauging or controlling devices and certain devices for producing light or an ionized atmosphere.*

NOTE: *Persons possessing radioactive material in devices under a general license in R313-21-22(4) before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of R313-21-22(4) in effect on January 14, 1975.

(a) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, acquire, receive, possess, use or transfer, in accordance with the provisions of R313-21-22(4)(b), (c) and (d), radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density,

level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(b)(i) The general license in R313-21-22(4)(a) applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in:

(A) a specific license issued by the Director pursuant to R313-22-75(4); or

(B) an equivalent specific license issued by the Nuclear Regulatory Commission or an Agreement State; or

(C) An equivalent specific license issued by a State with provisions comparable to R313-22-75.*

NOTE: *Regulations under the Federal Food, Drug, and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in 21 CFR 179.21.

(ii) The devices must have been received from one of the specific licensees described in R313-21-22(4)(b)(i) or through a transfer made under R313-21-22(4)(c)(ix).

(c) Any person who owns, acquires, receives, possesses, uses or transfers radioactive material in a device pursuant to the general license in R313-21-22(4)(a):

(i) shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by the labels;

(ii) shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at other intervals as are specified in the label; however:

(A) Devices containing only krypton need not be tested for leakage of radioactive material, and

(B) Devices containing only tritium or not more than 3.7 megabecquerel (100 uCi) of other beta, gamma, or both, emitting material or 0.37 megabecquerel (10 uCi) of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(iii) shall assure that other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

(A) in accordance with the instructions provided by the labels; or

(B) by a person holding a specific license pursuant to R313-22 or from the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform such activities;

(iv) shall maintain records showing compliance with the requirements of R313-21-22(4)(c)(ii) and (iii). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from the installation the radioactive material and its shielding or containment. The licensee shall retain these records as follows:

(A) Each record of a test for leakage of radioactive material

required by R313-21-22(4)(c)(ii) shall be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of;

(B) Each record of a test of the on-off mechanism and indicator required by R313-21-22(4)(c)(ii) shall be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of;

(C) Each record that is required by R313-21-22(4)(c)(iii) shall be retained for three years from the date of the recorded event or until the device is transferred or disposed of;

(v) shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 185 becquerel (0.005 uCi) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair the device that was issued by the Director, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the Director, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 185 becquerel (0.005 uCi) or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the Director within 30 days. Under these circumstances, the criteria set out in R313-15-402 may be applicable, as determined by the Director on a case-by-case basis;

(vi) shall not abandon the device containing radioactive material;

(vii) shall not export the device containing radioactive materials except in accordance with 10 CFR 110;

(viii)(A) shall transfer or dispose of the device containing radioactive material only by export as provided by R313-21-22(4)(c)(vii), by transfer to another general licensee as authorized in R313-21-22(4)(c)(ix), to a person authorized to receive the device by a specific license issued under R313-22, to an authorized waste collector under R313-25, or equivalent regulations of the Nuclear Regulatory Commission, an Agreement State, or a Licensing State , or as otherwise approved under R313-21-22(4)(c)(viii)(C);

(B) shall furnish a report to the Director within 30 days after transfer of a device to a specific licensee or export. The report must contain:

(I) the identification of the device by manufacturer's or initial transferor's name, model number, and serial number;

(II) the name, address, and license number of the person receiving the device, the license number is not applicable if exported; and

(III) the date of the transfer;

(C) shall obtain written approval from the Director before

transferring the device to any other specific licensee not specifically identified in R313-21-22(4)(c)(viii)(A); however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if the holder:

(I) verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(II) removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by R313-21-22(4)(c)(i)) so that the device is labeled in compliance with R313-15-904; however, the manufacturer, model number, and serial number must be retained;

(III) obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

(IV) reports the transfer under R313-21-22(4)(c)(viii)(B);

(ix) shall transfer the device to another general licensee only if:

(A) the device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of R313-21-22(4), R313-12-51, R313-15-1201, and R313-15-1202, and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the Director:

(I) the manufacturer's or initial transferor's name;

(II) the model number and serial number of the device transferred;

(III) the transferee's name and mailing address for the location of use; and

(IV) the name, title, and phone number of the responsible individual identified by the transferee in accordance with R313-21-22(4)(c)(xii) to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(B) the device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee;

(x) shall comply with the provisions of R313-15-1201 and R313-15-1202 for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of R313-15 and R313-18;

(xi) shall respond to written requests from the Director to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by submitting a letter to the Director and provide written justification as to why it cannot comply;

(xii) shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate

regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard;

(xiii)(A) shall register, in accordance with R313-21-22(4)(c)(xiii)(B) and (C), devices containing at least 370 megabecquerel (ten mCi) of cesium-137, 3.7 megabecquerel (0.1 mCi) of strontium-90, 37 megabecquerel (one mCi) of cobalt-60, 3.7 megabecquerel (0.1 mCi) of radium-226, or 37 megabecquerel (one mCi) of americium-241 or any other transuranic, (elements with atomic number greater than uranium-92), based on the activity indicated on the label. Each address for a location of use, as described under R313-21-22(4)(c)(xiii)(C)(IV) represents a separate general licensee and requires a separate registration and fee;

(B) if in possession of a device meeting the criteria of R313-21-22(4)(c)(xiii)(A), shall register these devices annually with the Director and shall pay the fee required by R313-70. Registration shall include verifying, correcting, or adding, as appropriate, to the information provided in a request for registration received from the Director. The registration information must be submitted to the Director within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of R313-21-22(4)(c)(xiii)(A) is subject to the bankruptcy notification requirement in R313-19-34(5) and (6);

(C) in registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Director:

(I) name and mailing address of the general licensee;

(II) information about each device: the manufacturer or initial transferor, model number, serial number, the radioisotope and activity as indicated on the label;

(III) name, title, and telephone number of the responsible person designated as a representative of the general licensee under R313-21-22(4)(c)(xii);

(IV) address or location at which the device(s) are used, stored, or both. For portable devices, the address of the primary place of storage;

(V) certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information; and

(VI) certification by the responsible representative of the general licensee that they are aware of the requirements of the general license; and

(D) persons generally licensed by the Nuclear Regulatory Commission, an Agreement State, or Licensing State with respect to devices meeting the criteria in R313-21-22(4)(c)(xiii)(A) are not subject to registration requirements if the devices are used in areas subject to Division jurisdiction for a period less than 180 days in any calendar year. The Director will not request registration information from such licensees;

(xiv) shall report changes to the mailing address for the location of use, including changes in the name of a general licensee, to the Director within 30 days of the effective date of the change. For a portable device, a report of address change is only required

for a change in the device's primary place of storage; and

(xv) may not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by R313-21-22(4)(c)(ii) need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

(d) The general license in R313-21-22(4)(a) does not authorize the manufacture or import of devices containing radioactive material.

(e) The general license provided in R313-21-22(4)(a) is subject to the provisions of R313-12-51 through R313-12-53, R313-12-70, R313-14, R313-19-34, R313-19-41, R313-19-61, and R313-19-100.

(5) Luminous safety devices for aircraft.

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

(i) each device contains not more than 370.0 gigabecquerel (10 Ci) of tritium or 11.1 gigabecquerel (300 mCi) of promethium-147; and

(ii) each device has been manufactured, assembled or initially transferred in accordance with a specific license issued by the Nuclear Regulatory Commission or an Agreement State, or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the Director or an Agreement State to the manufacturer or assembler of the device pursuant to licensing requirements equivalent to those in R313-22-75(5).

(b) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in R313-21-22(5) are exempt from the requirements of R313-15 and R313-18, except that they shall comply with the provisions of R313-15-1201 and R313-15-1202.

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

(d) This general license does not authorize the export of luminous safety devices containing tritium or promethium-147.

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

(f) This general license is subject to the provisions of R313-12-51 through R313-12-70, R313-14, R313-19-34, R313-19-41, R313-19-61, and R313-19-100.

(6) Ownership of radioactive material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of R313-21, this general license does not authorize the manufacture, production, transfer, receipt, possession, use, import, or export of radioactive material except as authorized in a specific license.

(7) Calibration and reference sources.

(a) A general license is hereby issued to own, receive, acquire,

possess, use and transfer, in the form of calibration or reference sources, americium-241, plutonium or radium-226 in accordance with the provisions of Subsections R313-21-22(7)(b) and (c), to a person who holds a specific license issued by the Director which authorizes that person to receive, possess, use and transfer radioactive material.

(b) The general license in Subsection R313-21-22(7)(a) applies only to calibration or reference sources which have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued by the Nuclear Regulatory Commission pursuant to 10 CFR 32.57 or 10 CFR 70.39 or which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer by the Director, or an Agreement State which authorizes manufacture of the sources for distribution to persons generally licensed, or in accordance with a specific license issued by a State with requirements equivalent to 10 CFR 32.57 or 10 CFR 70.39.

(c) The general license provided in Subsection R313-21-22(7)(a) is subject to the provisions of Sections R313-12-51 through R313-12-53, R313-12-70, and Rules R313-14, R313-19-34, R313-19-41, R313-19-61, R313-19-100, R313-15 and R313-18. In addition, persons who own, receive, acquire, possess, use or transfer one or more calibration or reference sources pursuant to the general license in Subsection R313-21-22(7)(a):

(i) shall not possess at any one time, at any one location of storage or use, more than 185.0 kilobecquerel (5 uCi) of americium-241, 185.0 kilobecquerel (5 uCi) of plutonium, or 185.0 kilobecquerel (5 uCi) of radium-226 in such sources;

(ii) shall not receive, possess, use or transfer a source unless the source, or the storage container, bears a label which includes one of the following statements or a substantially similar statement which contains the information called for in the following statement:

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

CAUTION - RADIOACTIVE MATERIAL
THIS SOURCE CONTAINS (AMERICIUM-241)(PLUTONIUM)(RADIUM-226)*
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.
.....
Typed or printed name of the manufacturer or initial transferor
NOTE: *Show the name of the appropriate material.

(iii) shall not transfer, abandon, or dispose of a source except by transfer to a person authorized by a license issued by the Director, the Nuclear Regulatory Commission, or an Agreement State to receive the source;

(iv) shall store a source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

(v) shall not use a source for any purpose other than the calibration of radiation detectors or the standardization of other

sources.

(d) A general license issued pursuant to Subsection R313-21-22(7)(a) does not authorize the manufacture, import, or export of calibration or reference sources containing americium-241, plutonium, or radium-226.

(8) RESERVED.

(9) General license for use of radioactive material for certain in vitro clinical or laboratory testing.*

NOTE: *The New Drug provisions of the Federal Food, Drug and Cosmetic Act also govern the availability and use of any specific diagnostic drug in interstate commerce.

(a) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for the following stated tests, in accordance with the provisions of R313-21-22(9) (b), (c), (d), (e), and (f) the following radioactive materials in prepackaged units for use in in-vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

(i) iodine-125, in units not exceeding 370.0 kilobecquerel (10 uCi) each;

(ii) iodine-131, in units not exceeding 370.0 kilobecquerel (10 uCi) each;

(iii) carbon-14, in units not exceeding 370.0 kilobecquerel (10 uCi) each;

(iv) hydrogen-3 (tritium), in units not exceeding 1.85 megabecquerel (50 uCi) each;

(v) iron-59, in units not exceeding 740.0 kilobecquerel (20 uCi) each;

(vi) cobalt-57, in units not exceeding 370.0 kilobecquerel (10 uCi) each;

(vii) selenium-75, in units not to exceed 370.0 kilobecquerel (10 uCi) each; or

(viii) mock iodine-125, reference or calibration sources, in units not exceeding 1.85 kilobecquerel (0.05 uCi) of iodine-129 and 185.0 becquerel (0.005 uCi) of americium-241 each.

(b) A person shall not receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by R313-21-22(9)(a) until that person has filed form DRC-07, "Registration Form-In Vitro Testing with Radioactive Material Under General License," with the Director and received a Certificate of Registration signed by the Director, or until that person has been authorized pursuant to R313-32 to use radioactive material under the general license in R313-21-22(9). The physician, veterinarian, clinical laboratory or hospital shall furnish on form DRC-07 the following information and other information as may be required by that form:

(i) name and address of the physician, veterinarian, clinical laboratory or hospital;

(ii) the location of use; and

(iii) a statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with

radioactive material as authorized under the general license in Subsection R313-21-22(9)(a) and that the tests will be performed only by personnel competent in the use of radiation measuring instruments and in the handling of the radioactive material.

(c) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by Subsection R313-21-22(9)(a) shall comply with the following:

(i) The general licensee shall not possess at any one time, pursuant to the general license in Subsection R313-21-22(9)(a) at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, cobalt-57, or any combination, in excess of 7.4 megabecquerel (200 uCi).

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

(iii) The general licensee shall use the radioactive material only for the uses authorized by Subsection R313-21-22(9)(a).

(iv) The general licensee shall not transfer the radioactive material except to a person authorized to receive it pursuant to a license issued by the Director, the Nuclear Regulatory Commission, an Agreement State or Licensing State, nor transfer the radioactive material in a manner other than in the unopened, labeled shipping container as received from the supplier.

(v) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in Subsection R313-21-22(9)(a)(viii) as required by Section R313-15-1001.

(vi) The general licensee shall pay annual fees pursuant to Rule R313-70.

(d) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to Subsection R313-21-22(9)(a):

(i) Except as prepackaged units which are labeled in accordance with the provision of a specific license issued pursuant to R313-22-75(7) or in accordance with the provisions of a specific license issued by the Nuclear Regulatory Commission, or an Agreement State, or before November 30, 2007, in accordance with the provisions of a specific license issued by a State with comparable provisions to 10 CFR 32.71 (2010) which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3(tritium), iron-59, selenium-75, cobalt-57, or Mock Iodine-125 to persons generally licensed under Subsection R313-21-22(9) or its equivalent, and

(ii) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

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

of regulatory authority.

.....

Name of Manufacturer"

(e) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license in Subsection R313-21-22(9)(a) shall report in writing to the Director, changes in the information previously furnished in the "Registration Form-In Vitro Testing with Radioactive Material Under General License", form DRC -07. The report shall be furnished within 30 days after the effective date of the change.

(f) Any person using radioactive material pursuant to the general license of Subsection R313-21-22(9)(a) is exempt from the requirements of Rules R313-15 and R313-18 with respect to radioactive material covered by that general license, except that persons using the Mock Iodine-125 described in Subsection R313-21-22(9)(a)(viii) shall comply with the provisions of Sections R313-15-1001, R313-15-1201 and R313-15-1202.

(10) Ice Detection Devices.

(a) A general license is hereby issued to own, receive, acquire, possess, use and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 1.85 megabecquerel (50 uCi) of strontium-90 and each device has been manufactured or initially transferred in accordance with a specific license issued by the Nuclear Regulatory Commission, or each device has been manufactured in accordance with the specifications contained in a specific license issued by the Director, an Agreement State, or a Licensing State to the manufacturer of the device pursuant to licensing requirements equivalent to those in 10 CFR 32.61.

(b) Persons who own, receive, acquire, possess, use or transfer strontium-90 contained in ice detection devices pursuant to the general license in Subsection R313-21-22(10)(a):

(i) shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from over-heating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license from the Director, the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to manufacture or service the device; or shall dispose of the device pursuant to the provisions of Section R313-15-1001;

(ii) shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

(iii) are exempt from the requirements of Rules R313-15 and R313-18 except that the persons shall comply with the provisions of Sections R313-15-1001, R313-15-1201 and R313-15-1202.

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

(d) This general license is subject to the provision of Sections R313-12-51 through R313-12-53, R313-12-70, R313-14, R313-19-34, R313-19-41, R313-19-61, and R313-19-100 of these rules.

**KEY: radioactive materials, general licenses, source materials**
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