

NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council or the Attorney General. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

Editor's Note: The following Notice of Final Rulemaking was reviewed per the Governor's Regulatory Review Plan memorandum, January 22, 2009 and the continuation issued April 30, 2009. (See a copy of the memoranda in this issue on pages 1104 and 1105.) The Governor's Office authorized the notice to proceed through the rulemaking process on April 1, 2009.

[R09-58]

PREAMBLE

1. Sections Affected

Rulemaking Action

R12-1-101	Amend
R12-1-102	Amend
R12-1-103	Amend
R12-1-201	Amend
R12-1-203	Amend
R12-1-205	Amend
R12-1-206	Amend
R12-1-207	Amend
Appendix A	Amend
R12-1-302	Amend
R12-1-303	Amend
R12-1-306	Amend
R12-1-310	Amend
R12-1-311	Amend
R12-1-313	Amend
R12-1-323	Amend
R12-1-324	Amend
R12-1-403	Amend
R12-1-419	Amend
R12-1-422	Amend
R12-1-431	Amend
R12-1-432	Amend
R12-1-434	Amend
R12-1-435	Amend
R12-1-440	Amend
R12-1-443	Amend
R12-1-446	Amend
R12-1-447	Amend
R12-1-448	Amend
R12-1-449	Amend
R12-1-454	New Section
R12-1-602	Amend
R12-1-603	Amend
R12-1-604	Amend
R12-1-605	Amend
R12-1-606	Amend
R12-1-607	Amend
R12-1-608	Amend
R12-1-610	Amend

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R12-1-611	Amend
R12-1-612	Amend
R12-1-614	Amend
R12-1-902	Amend
R12-1-904	Amend
R12-1-905	Amend
R12-1-907	Amend
R12-1-910	Amend
R12-1-911	Amend
R12-1-913	Amend
Appendix A	Amend
R12-1-1142	Amend
R12-1-1215	Amend
R12-1-1401	Amend
R12-1-1502	Amend
R12-1-1503	New Section
R12-1-1504	Amend
R12-1-1505	Amend
R12-1-1506	Amend
R12-1-1507	Amend
R12-1-1508	Amend
R12-1-1509	Reserved
R12-1-1510	New Section
R12-1-1511	New Section
R12-1-1512	New Section
R12-1-1513	Reserved
R12-1-1514	Reserved
R12-1-1515	New Section
R12-1-1713	Amend

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 30-654(B)(5)

Implementing statutes: A.R.S. §§ 30-651, 30-654, 30-657, 30-671(B), 30-672, 30-673, 30-681, 30-687, 30-688, and 30-689

3. The effective date of the rules:

August 1, 2009

4. A list of all previous notices appearing in the Register addressing the final rules:

Notice of Rulemaking Docket Opening: 14 A.A.R. 1620, May 2, 2008

Notice of Proposed Rulemaking: 14 A.A.R. 2652, June 27, 2008

5. The name and address of Agency personnel with whom persons may communicate regarding the rulemaking:

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6. An explanation of the rules, including the Agency's reasons for initiating the rules:

There are four main areas of change included in this rulemaking. The first area contains changes resulting from Five-year Reviews conducted on Articles 1, 3, 4, 6, 9, 12, 15, and 17. The purpose of the changes resulting from these reviews is to ensure that the affected rules stay compatible with current national radiation safety standards.

The second area contains changes made at the request of Agency staff. These changes arise from discrepancies resulting from a rulemaking oversight that were discovered while performing day-to-day licensing operations, or due to earlier rulemaking that resulted in incorrect language or an incorrect reference.

The third area contains changes recommended by the staff to bring the x-ray rules in Article 6 up to current standards. These are minor changes to make the rules in Article 6 compatible with regulations suggested by Conference of Radiation Control Program Directors (CRCPD).

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The fourth area contains changes requested by the Nuclear Regulatory Commission (NRC). The Agency is required to make these changes as a result of the Agreement signed with the NRC in January 1967. This agreement requires the Agency to incorporate in Arizona rule certain NRC prescribed requirements. Included in this rule package are:

- A. NRC requirements for specific licensees, having quantities of specified radioactive material exceeding the quantities requiring increased controls, to communicate their activities involving the affected radioactive material to the NRC as part of the new National Source Tracking System.
- B. NRC requirements for licensees that transport radioactive material regulated under Article 15. The NRC in conjunction with Department of Transportation has revised the standards for safe transport of radioactive material. As stated earlier all Agreement states are required to incorporate these NRC changes in state programs.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

None

8. A showing of good cause why the rules are necessary to promote a statewide interest if the rules will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

For the rulemaking identified in item 6, there should be minimal increase in costs associated with the administrative changes presented in the affected rules. In all cases the regulated community is already familiar with the regulation of medical x-ray and radioactive material transportation. The regulated community is also very familiar with the need for a source tracking system, instituted as a result of the NRC Agreement. This new requirement is administrative in nature and should result in minimal cost to the affected licensees.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

Non-substantive changes were made as result of the comments received during the public hearing. The comments from the Nuclear Regulatory Commission included a clarification to where information could currently be found for the definition of A₁ in R12-1-102. Although this item was marked "No change," the rule R12-1-102 was open in the definition Section and the information was added for clarity. An additional comment received from G.R.R.C. pointed out that R12-1-306(B)(2) had a typo missing the clarification letter "(B)." As this was a non-substantive clarification, the letter "(B)" was added to this rule. One member of the public or regulated community attended the meeting. In R12-1-419(B)(12) an incorrect reference was made to R12-1-806(D). The corrected reference is R12-1-806(C) and (F). This correction was made for the final rulemaking package to include the appropriate reference.

Rules R12-1-310(B)(2) and R12-1-310(B)(3) were made into "No change" Sections as the new verbiage of "will be approved" was redundant to the stem of the rule. Rules R12-1-311(A), R12-1-311(B), and R12-1-311(C) were deleted as the removal of the rules had no effect on licensees as the mentioned Sections are currently regulated by the Nuclear Regulatory Commission at the federal level. Missing incorporated material was added to R12-1-323(E)(1), (5), and (6) that addressed federal equivalencies to the remaining two out of three areas. R12-1-614(A)(15)(b) was removed as the information in that rule was already included in the incorporated material in rule R12-1-614(A)(15)(a).

Members of the Radiation Regulatory Hearing Board requested the word "non-occupational" be added to R12-1-603(C)(5), a rule that was not adopted in the final rulemaking due to public comments. They also requested that the Agency replace the word "all" with the wording "at least 50% of the membership" in R12-1-904(B)(3). An additional clarification was made to R12-1-904(B)(1) from the word "three" to "four" to match the subsections below it.

The public hearing brought out a verbiage issue with the amended rules in Article 9. It was noted that the term "licensee" was used in several cases where the more appropriate term "registrant" should have been used. This is because those that possess a particle accelerator register the unit instead of license it. This verbiage was changed where appropriate to reflect this in Article 9.

In addition to comments discussed in item 11, the Agency made changes based upon comments from letters previously supplied by the Nuclear Regulatory Commission. The Nuclear Regulatory Commission provided a comment which was received on October 12, 2006 to correct R12-1-1511(A)(3) in which an incorrect reference was made to R12-1-1504(A)(2). This correction was made. An additional comment provided by the Nuclear Regulatory Commission was received March 21, 2007. This comment requested the word "disassembles" be added in R12-1-454(A). This word was added to the rule. A further comment was made by the Nuclear Regulatory Commission on November 15, 2005. This comment noted that a provision from incorporated material from 10 CFR 31.5(d) was missing from rule R12-1-306(B)(1). This correction was made to the rule to include this provision.

Finally, additional editorial comments that are still valid were made by the Nuclear Regulatory Commission in a letter dated November 10, 2004. The first of these edits corrects a reference in R12-1-324 which had referenced R12-1-451 and R12-1-452. The correct reference is R12-1-452(C) and (D). This correction was made to the rule in this rulemaking package. The second comment was that R12-1-324(1)(b) should reference R-12-1-452(D). This correction was

made in this rule package. The third and fourth comments were specific to typos in the text of rule R12-1-320(D) and R12-1-320(F). These typos had previously been corrected by the Secretary of State in the published rules currently available. No change was made based upon these comments. The fifth comment addressed a concern that a reference in R12-1-1507 of 10 CFR 71 needed to be more specific and include only 10 CFR 71, Subpart H. This clarification was made in this rule package.

A definition for Radiologic Physicist was added for clarification of existing rules in Article 6.

11. A summary of the comments made regarding the rules and the agency response to them:

No written comments were received from the public by the time-frame indicated in the published notice.

Written comments were provided by the Nuclear Regulatory Commission in a letter dated September 22, 2008. Fourteen of the comments requested changes or deletions of rules that were not open in the original Notice of Proposed Rulemaking; therefore these comments were not implemented in this rulemaking package. These comments will be addressed in future rulemaking where appropriate. The Agency made changes to the rules based upon its determination of whether the final rule would be substantially different from the proposed rule. Where there was not a substantial difference, the Agency made the change.

In the letter, a comment was provided requesting a change to incorporated material for the definition of A₁. The incorporated material was changed to reflect the appropriate location for additional information. A comment was provided requesting a change to incorporated material for the definition of A₂. The incorporated material was changed to reflect the appropriate location for additional information. A comment was made requesting a Section be added to the rules to meet the objectives of 10 CFR 71.8 on Deliberate Misconduct. This Section already exists in Agency rules under R12-1-107. No additional Sections repeating this information were created in this rulemaking. A comment was made requesting a correction to the citation of incorporated material for rule R12-1-1515. This correction was made in this rule package. A comment was made requesting additional clarification language for R12-1-403 in the definition of Nationally Tracked Source. The Agency added the following sentence to rule 403, "In this context sealed source does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet." A comment was made requesting additional verbiage be added to R12-1-303(B) for clarification. This verbiage, "or persons who initially transfer for sale or distribution the following products," was added. In the same comment, deletion of rules and additional verbiage was requested for neighboring Sections. However, these changes were not made because they were not noticed in the Notice of Proposed Rulemaking and the public did not have the opportunity to be aware of intended changes. The remainder of the comment will be addressed in future rulemaking. Two comments were made to remove rules R12-1-311(A), R12-1-311(B), and R12-1-311(C) as they are items that are currently category NRC and are regulated on the federal level. As there was no impact to current registrants or licensees, these three Sections were deleted. A comment was received on deleting the reference to 10 CFR 32.17 in R12-1-303(B)(2) because it is no longer used. This material was removed from the rule. Two additional comments were received requesting the deletion of R12-1-303(B)(2); however, there remains a jurisdiction dispute between the state and the federal government on this rule so it will remain in its current form for the time being.

During the public hearing, eight comments were received. A comment was made on the definition of "TODE" in R12-1-102, and whether the determination in R12-1-411 was correct. It was pointed out in the hearing that it was correct. No additional changes to the definition were made in reference to the comment. Two additional comments referred to rules that were not open in the original notice of rulemaking, R12-1-412, R12-1-419(B)(1). In this case the Agency elected not to include any comments for rules that were not listed as open as the public was not aware that those rules would be discussed or modified. A comment was received on R12-1-419(B)(12) listing a concern that an inaccurate reference to subsection (D) was made when subsection (C) was more correct. The final rulemaking includes a corrected reference to subsection (C) as well as a clarifying reference to subsection (F). An additional comment was received on R12-1-603(C)(5) expressing a concern that the rule proposed would take a controlled area and re-categorize it as an uncontrolled area. This in turn would increase the shielding levels that would be used in these areas and result in a need for retro-fitting of some existing facilities. The comments eventually led to the removal of the proposed rule in the final rulemaking package. The next comment was on a clarification of R12-1-604(A)(5)(b). The concern addressed was whether the rule allowed an apron that was repaired to be brought back into service, and it was pointed out that the second sentence of the rule allowed for this. No change to the rule resulted from the comment. The next comment was on R12-1-904(B) and why it was not in Article 7. It was pointed out that similar conditions are already in the rules for Article 7 for those using nuclear medicine and that Article 9 applies to particle accelerators. A further clarification pointed out that if a facility had both nuclear medicine and a particle accelerator that members of a radiation safety committee that satisfied the requirements of Article 9 would also satisfy the requirements in Article 7 eliminating the need for two committees. No change to the rule resulted from the comment. A second comment was made by the Director of the Agency during the public hearing where it was noted that the term "licensee" was used in Article 9 when the correct term "registrant" should have been used as accelerator units are registered not licensed. The verbiage was corrected to accurately reflect the registrant in Article 9 in the appropriate rules. An additional comment on R12-1-904(B)(6) questions the need for creating a table that addresses the need to set ALARA levels when using a particle accelerator when the vault shielding design already factors into it protection from the public dose limits. It was pointed out that changes to the facility usable space may cause changes to the received dose and an ALARA system allows for investigation and correction of issues before an annual dose level is exceeded. No change to the rule resulted from the comment.

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The Radiation Regulatory Hearing Board and G.R.R.C. staff have offered a number of suggestions concerning punctuation, format, and grammatical corrections, which have been appropriately incorporated.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None

13. Incorporations by reference and their location in the rules:

<u>Rule</u>	<u>Incorporated Material</u>
R12-1-101	NRC Agreement
R12-1-102	
“A ₁ ”	10 CFR 71, Appendix A
“A ₂ ”	10 CFR 71, Appendix A
“Certifiable cabinet x-ray system”	21 CFR 1020.40
“Certified cabinet x-ray system”	21 CFR 1010.2 and 21 CFR 1020.40
“Generally applicable environmental radiation standards”	40 CFR 190 and 191
“Major processor”	10 CFR 71.4
“Nuclear waste”	49 CFR 173.403
“Regulations of the U.S. Department of Transportation”	49 CFR 107, and 171 through 180
“Special form radioactive material”	10 CFR 71.75
R12-1-103(A)	49 CFR 107.109, 107.111, 107.113, 171.2, 171.3, 172.200, 173.1, 173.3, 173.4, 173.401, 175.3, 175.10, 176.3, 176.5, 176.11, 176.24, 176.27, and 177.801
	39 CFR 111.1
R12-1-206(C)	21 CFR 1020.30(d)
R12-1-306(B)(1)	10 CFR 31.5(b), (c), and (d)
R12-1-306(E)(3)	10 CFR 32.21
R12-1-311(A)(1)(f)	10 CFR 31.5(c)(13)(i)
R12-1-311(A)(4)(b)(i)	10 CFR 32.52
R12-1-311(B)(2)	10 CFR 32.53 through 32.56 and 32.101
R12-1-311(C)(2)	10 CFR 32.57, 32.58, 32.59, 32.102, and 70.39
R12-1-311(F)(2)	10 CFR 32.61, 32.62, and 32.103
R12-1-311(G)	10 CFR 32.72
R12-1-311(I)	10 CFR 32.74
R12-1-311(K)(1)	10 CFR 32.201
R12-1-323(C)	10 CFR 30.35, 40.36, and 70.25
R12-1-323(E)(1)	10 CFR 30.36(g)(1), 40.42 (g)(1), and 70.38(g)(1)
R12-1-323(E)(5)	10 CFR 30.36(i), 40.42(i), and 70.38(i)
R12-1-323(E)(6)	10 CFR 30.36(j), 40.42 (j), and 70.38(j)
R12-1-403	
“Nationally tracked source”	10 CFR 20, Appendix E
R12-1-432(4)	49 CFR 173.403, 173.421 through 173.424
	49 CFR 172.436 through 172.440
R12-1-454(A)	10 CFR 20.2207(a) through (e)
	10 CFR 20.2207(f)
R12-1-454(B)	10 CFR 20.2207(f) and (h)(1) through (6)
R12-1-454(C)	10 CFR 20.2207(g)
R12-1-603(C)(2)	NCRP Report No. 147, Structural Shielding Design for Medical X-ray Imaging Facilities

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R12-1-614(A)(5)	Equipment Requirements and Quality Control for Mammography, August 1990
R12-1-614(A)(15)(a)	Mammography Quality Control Manual, 1999 edition
R12-1-614(B)(2)	21 CFR 900.12(d)(1), and (e)(1) through (e)(10)
R12-1-614(C)(1)(a)	21 CFR 900.12(a)(1)
R12-1-614(C)(1)(b)	21 CFR 900.12(a)(2)
R12-1-614(C)(1)(c)	21 CFR 900.12(a)(3)
R12-1-904(G)	Radiation Oncology in Integrated Cancer Management
R12-1-1503	10 CFR 71.5
R12-1-1504(A)(1)	49 CFR 171 through 180
R12-1-1504(A)(2)	49 CFR 171 through 180
R12-1-1505(B)	49 CFR 177.848
R12-1-1506(1)	49 CFR 171 through 180, and 39 CFR 111.1
R12-1-1507(A)	10 CFR 71, Subpart H
R12-1-1508(B)(2)	49 CFR 172.202 and 172.203(d)
R12-1-1510(B)(1)(a)	10 CFR 71.85(c)
R12-1-1510(B)(1)(b)	49 CFR 173.403
R12-1-1510(B)(2)(a)	10 CFR 71.85(c)
R12-1-1510(B)(2)(b)	49 CFR 173.403
R12-1-1510(B)(3)(a)	10 CFR 71.71 and 71.73
R12-1-1510(B)(3)(b)	10 CFR 71.71 and 71.73
R12-1-1510(B)(5)	10 CFR 71.4
R12-1-1510(C)	49 CFR 173 and 178
R12-1-1510(C)(2)(b)	10 CFR 71, Subparts A, G, and H
R12-1-1510(C)(3)	49 CFR 173.403
R12-1-1510(D)(1)	49 CFR 171.12
R12-1-1510(D)(3)(b)(ii)	10 CFR 71, Subparts A, G, and H
R12-1-1511(A)	49 CFR 107, and 171 through 180
R12-1-1511(A)(2)	10 CFR 71, Appendix A, Table A-2
R12-1-1511(A)(3)	10 CFR 71.5
R12-1-1511(B)	10 CFR 73.24
R12-1-1511(C)	49 CFR 175.704
R12-1-1512	10 CFR 71.97
R12-1-1515	10 CFR 71.14(a)

14. Were these rules previously made as emergency rules?

No

15. The full text of the rules follows:

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

ARTICLE 1. GENERAL PROVISIONS

Section

R12-1-101. Scope and Incorporated Materials

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- R12-1-102. Definitions
- R12-1-103. Exemptions

ARTICLE 2. REGISTRATION, INSTALLATION, AND SERVICE OF IONIZING RADIATION-PRODUCING MACHINES; AND CERTIFICATION OF MAMMOGRAPHY FACILITIES

Section

- R12-1-201. Exemptions
- R12-1-203. Application for Registration of Servicing and Installation
- R12-1-205. Expiration of Notice of Registration or Certification
- R12-1-206. Assembly, Installation, Removal from Service, and Transfer
- R12-1-207. Reciprocal Recognition of Out-of-state Radiation Machines
- Appendix A. Application Information

ARTICLE 3. RADIOACTIVE MATERIAL LICENSING

Section

- R12-1-302. Source Material; Exemptions
- R12-1-303. Radioactive Material Other ~~than~~ Than Source Material; Exemptions
- R12-1-306. General License – Radioactive Material Other Than Source Material
- R12-1-310. Special Requirements for Issuance of Specific Broad Scope Licenses
- R12-1-311. Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices that Contain Radioactive Material
- R12-1-313. Specific Terms and Conditions
- R12-1-323. Financial Assurance and Recordkeeping for Decommissioning
- R12-1-324. Public Notification and Public Participation

ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

Section

- R12-1-403. Definitions
- R12-1-419. Conditions Requiring Individual Monitoring of External and Internal Occupational Dose
- R12-1-422. Control of Access to Irradiators (Very-high Radiation Areas)
- R12-1-431. Labeling Containers and Radiation Machines
- R12-1-432. Labeling Exemptions
- R12-1-434. General Requirements for Waste Disposal
- R12-1-435. Method for Obtaining Approval of Proposed Disposal Procedures
- R12-1-440. Compliance with Environmental and Health Protection Regulations
- R12-1-443. Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation
- R12-1-446. Notifications and Reports to Individuals
- R12-1-447. Vacating Premises
- R12-1-448. Additional Reporting
- R12-1-449. Survey Instruments and Pocket Dosimeters
- R12-1-454. ~~Reserved~~ Nationally Tracked Sources

ARTICLE 6. USE OF X-RAYS IN THE HEALING ARTS

Section

- R12-1-602. Definitions
- R12-1-603. Operational Standards, Shielding, and Darkroom Requirements
- R12-1-604. General Procedures
- R12-1-605. X-ray Machine Standards
- R12-1-606. Fluoroscopic and Fluoroscopic Treatment Simulator Systems
- R12-1-607. Additional X-ray Machine Standards, Shielding Requirements, and Procedures, Except Fluoroscopic and Dental Intraoral Radiographic Systems
- R12-1-608. Mobile Diagnostic Radiographic and Fluoroscopic Systems, Except Dental Intraoral Radiographic Systems
- R12-1-610. Dental Intraoral Radiographic Systems
- R12-1-611. Therapeutic X-ray Systems of Less Than 1 MeV
- R12-1-612. Computerized Tomographic Systems
- R12-1-614. Mammography

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ARTICLE 9. PARTICLE ACCELERATORS

Section

- R12-1-902. Definitions
- R12-1-904. Registration of Particle Accelerators Used in the Practice of Medicine
- R12-1-905. Medical Particle Accelerator Equipment, Facility and Shielding, and Spot Checks
- R12-1-907. Shielding and Safety Design
- R12-1-910. Operating Procedures
- R12-1-911. Radiation Surveys
- R12-1-913. Misadministration
- Appendix A. Quality Control Program

ARTICLE 11. INDUSTRIAL USES OF X-RAYS, NOT INCLUDING ANALYTICAL X-RAY SYSTEMS

Section

- R12-1-1142. Baggage and Package Inspection Systems

ARTICLE 12. ADMINISTRATIVE PROVISIONS

Section

- R12-1-1215. License and Registration Divisions

ARTICLE 14. REGISTRATION OF NONIONIZING RADIATION SOURCES AND STANDARDS FOR PROTECTION AGAINST NONIONIZING RADIATION

Section

- R12-1-1401. Registration of Nonionizing Radiation Sources and Service Providers

ARTICLE 15. TRANSPORTATION

Section

- R12-1-1502. Definitions
- R12-1-1503. ~~Repealed~~ Transportation of Licensed Material
- R12-1-1504. Intrastate Transportation and Storage of Radioactive Materials
- R12-1-1505. Storage of Radioactive Material in Transport
- R12-1-1506. Preparation of Radioactive Material for Transport
- R12-1-1507. Packaging Quality Assurance
- R12-1-1508. Advance Notification of Nuclear Waste Transportation
- R12-1-1509. Reserved
- R12-1-1510. Packaging
- R12-1-1511. Air Transport of Plutonium
- R12-1-1512. Advance Notification of Shipment of Irradiated Reactor Fuel and Nuclear Waste
- R12-1-1513. Reserved
- R12-1-1514. Reserved
- R12-1-1515. Exemption for Low-level Radioactive Materials

ARTICLE 17. WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

Section

- R12-1-1713. Transportation ~~precautions~~ Precautions

ARTICLE 1. GENERAL PROVISIONS

R12-1-101. Scope and Incorporated Materials

- A. Except as otherwise specifically provided, this Chapter applies to all persons who receive, possess, use, transfer, own, or acquire any source of radiation.
- B. This Chapter does not apply to any person that is subject to regulation by the Nuclear Regulatory Commission.
- C. State control of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the state and the U.S. Nuclear Regulatory Commission, signed March 30, 1967; ~~incorporated by reference in this rule and on file with the Office of the Secretary of State and incorporated by reference.~~ This incorporated material contains no later editions or amendments, and together with all other incorporated materials in this Chapter, is available for inspection or copying at the Arizona Radiation Regulatory Agency, 4814 S. 40th St., Phoenix, AZ 85040.
- D. Federal regulations incorporated by reference in this Chapter are available from the U.S. Government Printing Office, P.O. Box 979050, St. Louis, MO 63197-9000 and <http://www.gpoaccess.gov/cfr/>.

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R12-1-102. Definitions

Terms defined in A.R.S. § 30-651 have the same meanings when used in this Chapter, unless the context otherwise requires. Additional subject-specific definitions are used in other Articles.

“A₁” means the maximum activity of special form radioactive material permitted in a type A package. These values are either listed in 10 CFR 71, Appendix A, Table A-1, or may be derived in accordance with the procedures prescribed in 10 CFR 71, Appendix A, revised January 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.

“A₂” means the maximum activity of radioactive material, other than special form radioactive material, low specific activity (LSA) material, and surface contaminated object (SCO) material, permitted in a Type A package. These values are either listed in 10 CFR ~~71-137~~ 71, Appendix A, Table A-1, or may be derived in accordance with the procedure prescribed in 10 CFR ~~71-137~~ 71, Appendix A, ~~2001 Edition, published~~ revised January 1, 2008, incorporated by reference, and on file with the Agency and the Office of the Secretary of State available under R12-1-101. This incorporation by reference incorporated material contains no future editions or amendments.

“Absorbed dose”	No change
“Accelerator”	No change
“Accelerator produced material”	No change
“Act”	No change
“Activity”	No change
“Adult”	No change
“Agency” or “ARRA”	No change
“Agreement State”	No change
“Airborne radioactive material”	No change
“Airborne radioactivity area”	No change
“ALARA”	No change
“Analytical x-ray equipment”	No change
“Analytical x-ray system”	No change
“Annual”	No change
“Background radiation”	No change
“Becquerel”	No change
“Bioassay”	No change
“Brachytherapy”	No change
“By-product material”	No change
“Calendar quarter”	No change
“Calibration”	No change
“Certifiable cabinet x-ray system”	means an existing uncertified x-ray system that meets or has been modified to meet the certification requirements specified in 21 CFR 1020.40, 2001 Edition, published <u>revised April 1, 2008</u> , incorporated by reference, <u>and on file with the Agency and the Office of Secretary of State available under R12-1-101. This incorporation by reference incorporated material contains no future editions or amendments.</u>
“Certified cabinet x-ray system”	means an x-ray system that has been certified in accordance with 21 CFR 1010.2, as being manufactured and assembled on or after April 10, 1975, in accordance with the provisions of 21 CFR 1020.40, both <u>sections references</u> 2001 Edition, published <u>revised April 1, 2008</u> , incorporated by reference, <u>and on file with the Agency and the Office of Secretary of State available under R12-1-101. These This incorporations by reference incorporated material contain contains</u> no future editions or amendments.
“CFR”	No change
“Chelating agent”	No change
“Civil penalty”	No change
“Collective dose”	No change
“Committed dose equivalent”	No change
“Committed effective dose equivalent”	No change
“Curie”	No change
“Current license or registration”	No change

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“Deep-dose equivalent”	No change
“Depleted uranium”	No change
“Dose”	No change
“Dose equivalent”	No change
“Dose limits”	No change
“Dosimeter”	No change
“Effective dose equivalent”	No change
“Effluent release”	No change
“Embryo/fetus”	No change
“Enclosed beam x-ray system”	No change
“Enclosed radiography”	No change
“Cabinet radiography”	No change
“Shielded room radiography”	No change
“Entrance or access point”	No change
“Exhibit”	No change
“Explosive material”	No change
“Exposure”	No change
“Exposure rate”	No change
“External dose”	No change
“Extremity”	No change
“Fail-safe characteristics”	No change
“Field radiography”	No change
“Field station”	No change
“Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities”	No change
“Generally applicable environmental radiation standards” means standards issued by the U.S. Environmental Protection Agency (EPA), 40 CFR 190 and 191, 2001 Edition, published <u>revised July 1, 2004</u> , incorporated by reference, and on file with the Agency and the Office of the Secretary of State <u>available under R12-1-101</u> , under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material. This incorporation by reference <u>incorporated material</u> contains no future editions or amendments.	
“Gray”	No change
“Hazardous waste”	No change
“Healing arts”	No change
“Health care institution”	No change
“High radiation area”	No change
“Human use”	No change
“Impound”	No change
“Individual”	No change
“Individual monitoring”	No change
“Individual monitoring device”	No change
“Individual monitoring equipment”	No change
“Industrial radiography”	No change
“Injection tool”	No change
“Inspection”	No change
“Interlock”	No change

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“Internal dose”	No change
“Irradiate”	No change
“Laser”	No change
“Lens dose equivalent”	No change
“License”	No change
“Licensed material”	No change
“Licensed practitioner”	No change
“Licensee”	No change
“Licensing State”	No change
“Limits”	No change
“Local components”	No change
“Logging supervisor”	No change
“Logging tool”	No change
“Lost or missing licensed or registered source of radiation”	No change
“Low-level waste”	No change
“Major processor” means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material or exceeding four times Type B quantities as sealed sources but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in 10 CFR 71.4, 2001 Edition, published <u>revised</u> January 1, 2001 <u>2008</u> , incorporated by reference, and on file with the Agency and the Office of the Secretary of State available under R12-1-101. <u>This incorporation by reference incorporated material contains no future editions or amendments.</u>	
“Medical dose”	No change
“Member of the public”	No change
“MeV”	No change
“Mineral logging”	No change
“Minor”	No change
“Monitoring”	No change
“Multiplier”	No change
“NARM”	No change
“Normal operating procedures”	No change
“Natural radioactivity”	No change
“NRC”	No change
“Nuclear waste” means any highway route controlled quantity (defined in 49 CFR 173.403, 2001 Edition, published <u>revised</u> October 1, 2001 <u>2007</u> , incorporated by reference, and on file with the Agency and the Secretary of State available under R12-1-101; <u>this incorporated material containing contains no future editions or amendments</u>) of source, byproduct, or special nuclear material required to be in NRC-approved packaging while transported to, through, or across state boundaries to a disposal site, or to a collection point for transport to a disposal site. Additional requirements associated with transportation of radioactive material can be found in Article 15.	
“Occupational dose” means the dose received by an individual in the course of employment in which the individual’s assigned duties involve exposure to sources of radiation, whether in the possession of a licensee, registrant, or other person. Occupational dose does not include a dose received from background radiation, medical administration of radiation to the individual, exposure to an individual who has been administered radioactive material and released in accordance with R12-1-719 <u>R12-1-717</u> , voluntary participation in a medical research program, or as a member of the public.	
“Open beam system”	No change
“Package”	No change
“Particle accelerator”	No change
“Permanent radiographic installation”	No change
“Personnel dosimeter”	No change

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“Personnel monitoring equipment”	No change
“Personal supervision”	No change
“Pharmacist”	No change
“Physician”	No change
“Primary beam”	No change
“Public dose” means the dose received by a member of the public from radiation from radioactive material released by a licensee or registrant, or exposure to a source of radiation used in a licensed or registered operation. It does not include an occupational dose or a dose received from background radiation, medical administration of radiation to the individual, exposure to an individual who has been administered radioactive material and released in accordance with R12-1-719 <u>R12-1-717</u> , or voluntary participation in a medical research program.	
“Pyrophoric liquid”	No change
“Pyrophoric solid”	No change
“Qualified expert”	No change
“Quality Factor”	No change
“Quarter”	No change
“Rad”	No change
“Radiation”	No change
“Radiation area”	No change
“Radiation dose”	No change
“Radiation machine”	No change
“Radiation safety officer”	No change
“Radioactive marker”	No change
“Radioactive material”	No change
“Radioactivity”	No change
“Radiographer”	No change
“Radiographer’s assistant”	No change
“Registrant”	No change
“Registration”	No change
“Regulations of the U.S. Department of Transportation” means the federal regulations in 49 CFR 100 through 199 107, 171 through 180, 1995 Edition, published revised October 1, 1995 <u>2007</u> , incorporated by reference, and on file with the Agency and the Office of the Secretary of State available under R12-1-101 . This incorporation by reference <u>incorporated material</u> contains no future editions or amendments.	
“Rem”	No change
“Research and Development”	No change
“Restricted area”	No change
“Roentgen”	No change
“Safety system”	No change
“Sealed source”	No change
“Sealed Source and Device Registry”	No change
“Shallow-dose equivalent”	No change
“Shielded position”	No change
“Sievert”	No change
“Site boundary”	No change
“Source changer”	No change
“Source holder”	No change
“Source material”	No change
“Source material milling”	No change
“Source of radiation” or “source”	No change

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“Special form radioactive material” means radioactive material that satisfies all of the following conditions:

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

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

It satisfies the test requirements specified in 10 CFR ~~71.75, 2000 Edition, published~~ revised January 1, ~~2000~~ 2008, incorporated by reference, ~~in this rule and on file with the Agency and the Office of the Secretary of State available under R12-1-101.~~ This ~~incorporation by reference~~ incorporated material contains no future editions or amendments. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation constructed after June 30, 1985, shall meet requirements of this definition applicable at the time of its construction.

“Special nuclear material in quantities not sufficient to form a critical mass”

No change

“Storage area”

No change

“Storage container”

No change

“Subsurface tracer study”

No change

“Survey”

No change

“TEDE” means ~~Total Effective Dose Equivalent, the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures. (See “Total Effective Dose Equivalent”)~~

“Teletherapy”

No change

“Temporary job site”

No change

“Test”

No change

“These rules”

No change

“Total Effective Dose Equivalent” (TEDE)

No change

“Total Organ Dose Equivalent” (TODE) means ~~total organ dose equivalent, the sum of the deep-dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in R12-1-419(D)(1)(d) of these rules. Determination of TODE is described in R12-1-411.~~

“Unrefined and unprocessed ore”

No change

“Unrestricted area”

No change

“U.S. Department of Energy”

No change

“Very high radiation area”

No change

“Waste”

No change

“Waste handling licensees”

No change

“Week”

No change

“Well-bore”

No change

“Well-logging”

No change

“Whole body”

No change

“Wireline”

No change

“Wireline service operation”

No change

“Worker”

No change

“WL”

No change

“WLM”

No change

“Workload”

No change

“Year”

No change

R12-1-103. Exemptions

A. Common and contract carriers, freight forwarders, and warehousemen who are subject to 49 CFR 107.109, 107.111, 107.113, 171.2, 171.3, 172.200, 173.1, 173.3, 173.4, 173.401, 175.3, 175.10, 176.3, 176.5, 176.11, 176.24, 176.27, and 177.801, ~~2000 Edition, published~~ revised October 1, ~~2000~~ 2007, of the U.S. Department of Transportation, or 39 CFR 111.1 of the U.S. Postal Service, ~~2001 Edition, published~~ revised July ~~January~~ 1, ~~2001~~ 2007, incorporated by reference, and ~~on file with the Agency and the Office of the Secretary of State~~ available under R12-1-101, and who if need be, store

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radioactive material, for periods of less than 72 hours, in the regular course of their carriage for another, are exempt from this Chapter. The incorporated materials above ~~incorporation by reference contains~~ contain no future editions or amendments.

- B. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - a. No change
 - b. No change
- C. No change

ARTICLE 2. REGISTRATION, INSTALLATION, AND SERVICE OF IONIZING RADIATION-PRODUCING MACHINES; AND CERTIFICATION OF MAMMOGRAPHY FACILITIES

R12-1-201. Exemptions

- A. Electronic equipment that produces X-radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this Article, provided that an exposure rate, from any accessible surface, averaged over an area of 10 ~~square~~ centimeters squared (1.55 ~~in. 2~~ inches squared) does not exceed ~~129~~ 5 ~~microsieverts (0.5 milliroentgen per hour) per hour at 5 cm centimeters (2.0 in. inches).~~ microsieverts (0.5 milliroentgen per hour) per hour at 5 cm centimeters (2.0 in. inches). ~~The production, testing, or factory servicing of electronic equipment that produces X-radiation incidental to its operation is not exempt.~~
- ~~B.~~ The production, testing, or factory servicing of the electronic equipment in subsection (A) is not exempt from the requirements of this Article.
- ~~B-C.~~ Radiation machines in storage or in transit to or from storage are exempt from the requirements of this Article.
- ~~C-D.~~ Radiation machines rendered incapable of producing radiation are exempt from ~~this~~ the requirements of this Article.

R12-1-203. Application for Registration of Servicing and Installation

- A. Each person who is engaged in the business of installing or offering to install radiation machines ~~or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this state~~ shall apply for registration. ~~If registration is required, any subsequent application shall be submitted before furnishing or offering to furnish any radiation machine service or installation.~~ For purposes of this Chapter, install includes selling and servicing, or offering to sell or service, x-ray machines in Arizona.
- B. ~~Application~~ The applicant shall complete the application for registration shall be completed on forms furnished on forms that request information required by A.R.S. § 30-672.01, provided by the Agency and shall contain all information required by A.R.S. § 30-672.01.

R12-1-205. Expiration of Notice of Registration or Certification

A Notice of Registration, or certificate issued according to R12-1-208, expires at the end of the day on the date stated in the Notice of Registration or certificate unless the registrant or certificate holder, not less than 30 days prior to the expiration of the Notice of Registration or certificate, files a complete application for renewal. If a timely application for renewal is filed, the Notice of Registration or certificate does not expire until the application status is finally determined by the Agency.

- ~~A.~~ Except as provided in subsection (B), a Notice of Registration, issued according to R12-1-204, or a certificate issued according to R12-1-208, expires at the end of the day on the expiration date stated in the Notice of Registration or certificate.
- ~~B.~~ If an application for renewal is filed by the registrant or certificate holder not less than 30 days prior to the expiration of the Notice of Registration or certificate, the Notice of Registration or certificate does not expire until a final determination is made by the Agency on the renewal application.

R12-1-206. Assembly, Installation, Removal from Service, and Transfer

- A. No change
 - 1. No change
 - 2. No change
 - 3. No change
- B. No change
- C. In the case of diagnostic x-ray systems that contain certified components, an assembler shall ~~submit to the Agency a copy of the assembler's report (FDA Report No. 2579) prepared in compliance with requirements in 21 CFR 1020.30(d)(1), April 1, 2004, published by the Office of the Federal Register, National Archives and Records Administration, incorporated by reference and on file with the Agency, containing no future editions or amendments, within 15 days following completion of the assembly;~~ submit to the Agency a copy of the assembler's report (FDA Report No. 2579) prepared in compliance with requirements in 21 CFR 1020.30(d), revised April 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments. The report shall suffice in lieu of any other report by the assembler, if it contains the information required in subsection (A).

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D. No change

R12-1-207. Reciprocal Recognition of Out-of-state Radiation Machines

A. No change

B. No change

1. No change

2. Upon request, supply the Agency with a copy of the machine's registration and other information regarding the safe operation of a the machine while it is in the state; and

3. No change

C. No change

Appendix A. Application Information

An application shall contain the following information as required in R12-1-202(B), before a registration will be issued. The Agency shall provide an application form to an applicant with a guide, if available, or shall assist the applicant to ensure that only correct information is provided on the application.

Name and mailing address of applicant	Use location
Person responsible for radiation safety program	Telephone number
Type of facility	Facility subtype
Legal structure and ownership	Signature of certifying agent
Radiation machine information	Equipment identifiers
Shielding information	Scale drawing, if applicable
Equipment operator instructions and restrictions	Physicist name and training, if applicable
Classification of professional in charge	
Record of calibration for therapy units	Type of request: amendment, new, or renewal
Protection survey results, if applicable	
Type of industrial radiography program, if applicable	
Radiation Safety Officer name, if applicable	Contact person
Other registration requirements listed in Articles 2, 6, 8, and 9, <u>and 11</u>	Appropriate fee listed in Article 13 schedule

ARTICLE 3. RADIOACTIVE MATERIAL LICENSING

R12-1-302. Source Material; Exemptions

A. Any person is exempt from this Article to the extent the person receives, possesses, uses, delivers or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20th of 1 percent (~~0.05 percent~~ 0.0005) of the mixture, compound, solution, or alloy.

B. No change

C. No change

1. No change

a. No change

b. No change

c. No change

d. No change

e. No change

f. No change

g. No change

2. No change

a. No change

b. No change

c. No change

3. No change

4. No change

5. No change

a. No change

b. No change

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

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- d. No change
- e. No change
- 6. No change
 - a. No change
 - b. No change
- 7. No change
 - a. No change
 - b. No change
- 8. No change
- 9. No change
 - a. No change
 - b. No change

D. No change

R12-1-303. Radioactive Material Other than Than Source Material; Exemptions

A. No change

- 1. Except as provided in subsection (A)(2), ~~a~~ any person is exempt from this Article if the person receives, possesses, uses, transfers, owns, or acquires products or materials containing radioactive material in concentrations not in excess of those listed in Exhibit A.
- 2. A person shall not introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under subsection (A)(1) or equivalent Regulations of the U.S. Nuclear Regulatory Commission or any Agreement State or Licensing State, except in accordance with ~~a specific license issued under R12-1-311(A) or~~ a general license prescribed in R12-1-320.

B. No change

- 1. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, or persons who initially transfer for sale or distribution the following products, a person is exempt from this Chapter to the extent that the person receives, possesses, uses, transfers, owns, or acquires the following products:
 - a. Timepieces, hands, or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - v. No change
 - vi. No change
 - vii. No change
 - (1) No change
 - (2) No change
 - (3) No change
 - viii. No change
 - b. No change
 - c. Balances of precision containing not more than 37 ~~Mbq~~ megabecquerels (1 millicurie) of tritium per balance or not more than 18.5 ~~Mbq~~ megabecquerels (0.5 millicurie) of tritium per balance part manufactured before December 17, 2007;
 - d. No change
 - e. Marine compasses containing not more than 27.75 ~~GBq~~ gigabecquerels (750 millicuries) of tritium gas and other marine navigational instruments containing not more than 9.25 ~~GBq~~ gigabecquerels (250 millicuries) of tritium gas manufactured before December 17, 2007;
 - f. No change
 - g. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - v. No change
 - vi. No change
 - h. No change
 - i. No change
 - ii. No change

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- iii. No change
- iv. No change
- 2. Resins containing scandium-46 and designed for sand consolidation in oil wells. A person is exempt from this Chapter if the person receives, possesses, uses, transfers, owns, or acquires synthetic plastic resins containing ~~scandium-46~~ scandium-46 which are designed for sand consolidation in oil wells. The described resins shall be manufactured, initially transferred for sale or distribution, or imported according to a specific license issued by the U.S. Nuclear Regulatory Commission, or shall be manufactured according to the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer of the described resins according to licensing requirements equivalent to those in 10 CFR 32.16 ~~and 10 CFR 32.17~~ of the U.S. Nuclear Regulatory Commission. This exemption does not authorize the manufacture, or initial transfer for sale or distribution, of any resins containing scandium-46.
- 3. No change
 - a. Except for persons who manufacture, process, initially transfer for sale or distribution, or produce self-luminous products containing tritium, krypton-85, or promethium-147, a person is exempt from this Chapter if the person receives, possesses, uses, owns, transfers or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, initially transferred for sale or distribution, or transferred under a specific license issued by the U.S. Nuclear Regulatory Commission and described in 10 CFR 32.22, and the license authorizes the transfer of the products to persons who are exempt from regulatory requirements. This exemption does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.
 - b. No change
- 4. No change
 - a. Except for persons who manufacture, process, initially transfer for sale or distribution, or produce gas and aerosol detectors containing radioactive material, a person is exempt from this Chapter if the person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, provided that detectors containing radioactive material shall be manufactured, imported, or transferred according to a specific license issued by the U.S. Nuclear Regulatory Commission and described in 10 CFR 32.26, or equivalent regulations of an Agreement or Licensing State, and the license authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.
 - b. Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State are exempt under subsection (B)(4)(a), provided that the device is labeled in accordance with the specific license authorizing distribution of the general licensed device, and that the detectors meet the requirements of ~~R12-1-311(C)~~ the regulations of the U.S. Nuclear Regulatory Commission.
- C. No change
 - 1. Except as provided in subsections (C)(2) and (3), a person is exempt from ~~these rules~~ this Chapter if the person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Exhibit B of this Article.
 - 2. This subsection does not authorize the production, packaging, or repackaging or transfer of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.
 - 3. Except as specified in this subsection, a person shall not, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Exhibit B of this Article, knowing or having reason to believe the described quantities of radioactive material will be transferred to persons exempt under subsection (C) or equivalent Regulations of the U.S. Nuclear Regulatory Commission or any Agreement State or Licensing State. A person may transfer radioactive material for commercial distribution under a specific license issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.18, ~~or by the Agency according to R12-1-311(B)~~ which license states that the radioactive material may be transferred by the licensee to persons exempt under this subsection or the equivalent ~~Regulations~~ regulations of the U.S. Nuclear Regulatory Commission or any Agreement State or Licensing State.
 - 4. No change
 - 5. No change

R12-1-306. General License – Radioactive Material Other Than Source Material

- A. No change
 - 1. No change
 - 2. No change
- B. Certain measuring, gauging or controlling devices,
 - 1. This subsection grants a general license that authorizes a person such as a commercial or industrial firm; a research, educational or medical institution; an individual conducting business; or a state or local government agency to receive, acquire, possess, use, or transfer radioactive material according to the provisions of 10 CFR 31.5(b), ~~and (e)~~ (c), and (d), revised January 1, 2005 2008, which are incorporated by reference, ~~published by the Office of the Fed-~~

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eral Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency, available under R12-1-101. The incorporated material ~~incorporated by reference~~ contains no future editions or amendments.

2. A general licensee shall receive a device from one of the specific licensees described in this Section or through a transfer made under subsection ~~(4)(k)~~ (B)(4)(k).
3. No change
 - a. A specific license issued under ~~R12-1-311(D)~~ R12-1-311(A); or
 - b. No change
4. No change
 - a. No change
 - b. No change
 - i. No change
 - ii. No change
 - c. No change
 - i. No change
 - ii. By a person holding a specific license under ~~R12-1-311(D)~~ R12-1-311(A) or in accordance with the provisions of a specific license issued by the NRC or an Agreement State which authorizes distribution of devices to persons generally licensed by the NRC or an Agreement State.
 - d. No change
 - e. No change
 - i. A general licensee shall not operate the device until it has been repaired by the manufacturer or another person holding a specific license to repair this type of device that was issued by the Agency under ~~R12-1-311(D)~~ R12-1-311(A), the NRC, or an Agreement State which authorizes distribution of devices to persons generally licensed by the NRC or an Agreement State.
 - ii. No change
 - iii. No change
 - f. No change
 - g. No change
 - h. No change
 - i. No change
 - i. No change
 - ii. No change
 - iii. No change
 - j. No change
 - k. No change
 - i. No change
 - ii. No change
 - l. No change
 - m. No change
 - n. No change
 - o. Register, in accordance with subsections (B)(4)(p) and (q), any device that contains at least 370 ~~millibecquerel~~ megabecquerels (10 millicuries) of cesium-137, 3.7 ~~millibecquerel~~ megabecquerels (0.1 millicuries) of strontium-90, 37 ~~millibecquerel~~ megabecquerels (1 millicurie) of cobalt-60, or 37 ~~millibecquerel~~ megabecquerels (1 millicurie) of americium-241 or any other transuranic (i.e., element 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 subsection (B)(4)(q)(iv), represents a separate general licensee and requires a separate registration and fee.
 - p. Register each device annually with the Agency and pay the fee required by R12-1-1306, Category D4, if in possession of a device that meets the criteria in subsection (B)(4)(o). The general licensee shall register by verifying, correcting, and adding to the information provided in a request for registration received from the Agency. The registration information shall be submitted to the Agency within 30 days from the date on the request for registration. In addition, a general licensee holding devices meeting the criteria of subsection (B)(4)(o) is subject to the bankruptcy notification requirements in R12-1-313(D).
 - q. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - v. No change
 - vi. No change

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- r. No change
- s. No change
- 5. No change
- 6. No change
- C. No change
 - 1. This subsection grants a general license that authorizes a person to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided that each device contains not more than 370 ~~GBq~~ gigabecquerels (10 curies) of tritium or 11.1 ~~GBq~~ gigabecquerels (300 millicuries) of promethium-147; and each device has been manufactured, assembled, initially transferred, or imported according to a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled according to the specifications contained in a specific license issued to the manufacturer or assembler of the device by the Agency or any Agreement State or Licensing State in accordance with licensing requirements equivalent to those in 10 CFR 32.53.
 - 2. A person who owns, receives, acquires, possesses, or uses a luminous safety device according to the general license granted in subsection (C)(1) is:
 - a. No change
 - b. Not authorized to manufacture, assemble, ~~or~~ repair, or import a luminous safety device that contains tritium or promethium-147;
 - c. Not authorized to export luminous safety devices containing tritium or promethium-147;
 - ~~e-d~~. Not authorized to own, receive, acquire, possess, or use radioactive material contained in instrument dials; and
 - ~~d-e~~. No change
- D. This subsection grants a general license that authorizes a person who holds a specific license to own, receive, possess, use, and transfer radioactive material if the Agency issues the license; or special nuclear material if the NRC issues the license. For americium-241, radium-226, and plutonium contained in calibration or reference sources, this subsection grants a general license in accordance with the provisions of subsections (D)(1), (2), and (3). For plutonium, ownership is included in the licensed activities.
 - 1. No change
 - 2. No change
 - a. No change
 - b. No change
 - i. No change
 - ii. No change
 - c. No change
 - d. No change
 - e. No change
 - 3. The general license granted under ~~subsections~~ subsection (D) or (D)(1) does not authorize the manufacture or import of calibration or reference sources that contain americium-241, plutonium, or radium-226.
 - 4. The general license granted under subsections (D) or (D)(1) does not authorize the manufacture or export of calibration or reference sources that contain americium-241, plutonium, or radium-226.
- E. No change
 - 1. No change
 - 2. No change
 - 3. A physician who desires to manufacture, prepare, process, produce, package, repackage, or transfer carbon-14 urea capsules for commercial distribution shall obtain a specific license from the Agency, issued according to the requirements in 10 CFR ~~32~~ 32.21, revised January 1, ~~2005~~ 2008, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency and available under R12-1-101. The ~~This incorporated material incorporated by reference~~ contains no future editions or amendments.
 - 4. No change
- F. No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. Cobalt-57 or selenium-75, in units not exceeding 370 ~~kBq~~ kilobecquerels (10 microcuries) each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation from such material, to human beings or animals.

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- g. No change
- 2. No change
 - a. No change
 - b. No change
- 3. No change
 - a. Not possess at any one time, in storage or use, a combined total of not more than 7.4 ~~Mbq megabecquerels~~ (200 microcuries) of iodine-125, iodine-131, iron-59, ~~or cobalt-57,~~ or selenium-75 in excess of 7.4 ~~Mbq megabecquerels~~ (200 microcuries), or acquire or use in any one calendar month more than 18.5 ~~Mbq megabecquerels~~ (500 microcuries) of these radionuclides.
 - b. No change
 - c. No change
 - d. No change
 - e. No change
- 4. No change
 - a. Except as prepackaged units that are labeled according to the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, or any Agreement State that authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, cobalt-57, selenium-75, or mock iodine-125 for distribution to persons generally licensed under subsection (F) or its equivalent federal law; and
 - b. No change
 - i. No change
 - ii. No change
- 5. No change
 - a. No change
 - b. No change
- 6. No change
- G.** This subsection grants a general license that authorizes a person to own, receive, acquire, possess, use, and transfer strontium-90, contained in ice detection devices, provided each device contains not more than 1.85 ~~Mbq megabecquerels~~ (50 microcuries) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured according to the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer of the device under licensing requirements equivalent to those in 10 CFR 32.61. A person who receives, owns, acquires, possesses, uses, or transfers strontium-90 contained in ice detection devices under a general license in accordance with subsection (G):
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. Shall not manufacture, assemble, disassemble, ~~or repair,~~ or import an ice detection device that contains strontium-90.
 - 5. No change

R12-1-310. Special Requirements for Issuance of Specific Broad Scope Licenses

- A.** No change
 - 1. No change
 - a. No change
 - b. No change
 - 2. A broad scope class B license is any specific license which authorizes the acquisition, possession, ~~and use,~~ and transfer of the radioactive materials specified in Exhibit C of 12 A.A.C. 1, Article 3 in any chemical or physical form and in quantities determined as follows:
 - a. No change
 - b. No change
 - 3. No change
 - a. No change
 - b. No change
- B.** No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - i. No change
 - ii. No change
 - iii. No change
 - (1) No change

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- (2) No change
 - (3) No change
 - 2. No change
 - a. No change
 - b. No change
 - i. No change
 - ii. No change
 - (1) No change
 - (2) No change
 - (3) No change
 - 3. No change
 - a. The applicant satisfies the general requirements specified in R12-1-309; and
 - b. No change
 - i. No change
 - ii. No change
 - c. No change
- C. No change
 - 1. No change
 - 2. Acquire, receive, possess, use, own, import, or transfer devices containing 3.7 ~~petabecquerel~~ petabecquerels (100,000 curies) or more of radioactive material in sealed sources used for irradiation of materials;
 - 3. No change
 - 4. No change
- D. No change
- E. No change
- F. No change

R12-1-311. Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices that Contain Radioactive Material

- A.** ~~Licensing the introduction of radioactive material into products in exempt concentrations.~~
 - 1. ~~The Agency shall grant a specific license to introduce radioactive material into a product or material, owned by or in the possession of the specific licensee or another that will be transferred to persons exempt under R12-1-303(A)(1), if the applicant satisfies the requirements of R12-1-309 and:~~
 - a. ~~The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and~~
 - b. ~~The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Exhibit A; reconcentration of the radioactive material in concentrations exceeding those in Exhibit A is not likely; use of lower concentrations is not feasible; and product or material is not likely to be incorporated in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.~~
 - 2. ~~Each person licensed under subsection (A)(1) to initially transfer devices to generally licensed persons shall comply with the requirements of this subsection.~~
 - a. ~~The specific licensee shall report to the Agency in writing any transfer of a device to a person for use under the general license in R12-1-306(B) and any receipt of a device from a person licensed under R12-1-306(B). The specific licensee shall submit the report on a quarterly basis and ensure that the report contains the following information:~~
 - i. ~~The identity of each general licensee by name and mailing address for the location of use. If there is no mailing address for the location of use, the specific licensee shall submit an alternate address for the general licensee, along with information on the actual location of use;~~
 - ii. ~~The name, title, and telephone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with applicable radiation safety laws;~~
 - iii. ~~The date of transfer;~~
 - iv. ~~The type, model number, and serial number of the device transferred; and~~
 - v. ~~The quantity and type of radioactive material contained in the device.~~
 - b. ~~If any person other than the intended user will temporarily possess the device at the place of use before its possession by the user, the specific licensee shall provide the same type of information provided under subsection (A)(2)(a) for the user and each person who will temporarily possess the device, clearly identifying each person.~~

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- e. For a device received from a R12-1-306(B) general licensee, the specific licensee shall provide the identity of the general licensee by name and address, type of device, model number, and serial number of the device received, the date of receipt, and, in the case of a device not initially transferred by the specific licensee, the name of the manufacturer or initial transferor.
 - d. If the specific licensee makes changes to a device possessed by a R12-1-306(B) general licensee that necessitate a label change, the specific licensee shall ensure that the report identifies the general licensee, the device, and the changes to information on the device label.
 - e. The specific licensee shall prepare a report that covers each calendar quarter. The report shall be filed within 30 days of the end of the calendar quarter, and clearly indicate the period covered by the report.
 - f. The report shall clearly identify the specific licensee submitting the report and include the license number of the specific licensee.
 - g. If no transfers have been made to or from a person generally licensed under R12-1-306(B) during the reporting period, the specific licensee shall include this information in the report.
 - h. The specific licensee shall report any transfer of a device to a person for use under a general license in an Agreement State's regulations that is equivalent to R12-1-306(B) and any receipt of a device from any general licensee in the Agreement State's jurisdiction. The specific licensee shall submit a clear and legible report that contains all of the following information:
 - i. The identity of each general licensee by name and mailing address for the location of use. If there is no mailing address for the location of use, the specific licensee shall submit an alternate address for the general licensee, along with information on the actual location of use.
 - ii. The name, title, and telephone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with applicable radiation safety laws;
 - iii. The date of transfer;
 - iv. The type, model number, and serial number of the device transferred; and
 - v. The quantity and type of radioactive material contained in the device.
 - i. If any person other than the intended user will temporarily possess the device at the place of use before its possession by the user, the specific licensee shall record the same type of information provided for the user and for each person who will temporarily possess the device, clearly identifying each person.
 - j. For a device received from a general licensee, the specific licensee shall provide the identity of the general licensee by name and address, type of device, model number, and serial number of the device received, the date of receipt, and, in the case of a device not initially transferred by the specific licensee, the name of the manufacturer or initial transferor.
 - k. If the specific licensee makes changes to a device possessed by a general licensee that necessitate a label change to update required information, the specific licensee shall ensure that the report identifies the general licensee, the device, and the changes to information on the device label.
 - l. The specific licensee shall prepare a report that covers each calendar quarter, is filed within 30 days from the end of the calendar quarter, and clearly indicates the period covered by the report.
 - m. The report shall clearly identify the specific licensee submitting the report and include the license number of the specific licensee.
 - n. If no transfers have been made to or from a general licensee in a particular Agreement State during the reporting period, the specific licensee shall report this information to the Agency, NRC, or responsible Agreement State agency at the request of the agency.
3. The specific licensee shall maintain all information concerning transfer and receipt of each device that supports the reports required by subsection (A). Records maintained in accordance with this subsection shall be maintained for a period of 3 years following the date of the recorded event.
- B.** Licensing the distribution of naturally occurring and accelerator-produced radioactive material (NARM) in exempt quantities:
- 1. The Agency shall grant a specific license to distribute naturally occurring and accelerator-produced radioactive material (NARM) to a person exempted from these rules according to R12-1-303(C) if the applicant satisfies the requirements of R12-1-309 and:
 - a. The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;
 - b. The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but it is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and
 - e. The applicant submits copies of prototype labels and brochures and the Agency approves the labels and brochures.
 - 2. The specific license issued under subsection (B)(1) is subject to the following conditions:

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- a. ~~The licensee may sell or transfer 10 exempt quantities in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantities provided the sum of the fractions does not exceed unity.~~
 - b. ~~The licensee shall individually package each exempt quantity. No more than 10 packaged exempt quantities shall be contained in any outer package for transfer to a person exempt according to R12-1-303(C). The licensee shall ensure that the dose rate at the external surface of the outer package does not exceed 5 microsieverts (0.5 millirem) per hour.~~
 - e. ~~The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label that:
 - i. ~~Identifies the radionuclide and the quantity of radioactivity, and~~
 - ii. ~~Bears the words "Radioactive Material."~~~~
 - d. ~~In addition to the labeling information required by subsection (B)(2)(e), the label affixed to the immediate container, or an accompanying brochure, shall:
 - i. ~~State that the contents are exempt from Licensing State requirements;~~
 - ii. ~~Bear the words "Radioactive Material — Not for Human Use — Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited — Exempt Quantities Should Not Be Combined"; and~~
 - iii. ~~Provide additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.~~~~
3. ~~Each person licensed under subsection (B) shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under R12-1-303(C) or an equivalent rule of a Licensing State, and state the type and quantity of radioactive material transferred. The licensee shall file an annual report with the Agency stating the total quantity of each radionuclide transferred under the specific license. The annual report shall be provided to the Agency even if no transfers of radioactive material have been made according to this subsection during the reporting period. The report shall cover the year ending June 30 and be filed within 30 days after June 30.~~
- C.** ~~The Agency shall grant a specific license to incorporate radioactive material, other than source or by-product material, into gas or aerosol detectors to be distributed to persons exempt under R12-1-303(B) if the applicant satisfies requirements contained in 10 CFR 32.26, January 1, 2006, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency, and contains no future editions or amendments, and provided:~~
- 1. ~~The applicant satisfies the requirements of R12-1-309.~~
 - 2. ~~The licensee files annual reports required by 10 CFR 32.29, January 1, 2006, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408 and on file with the Agency. The material incorporated by reference contains no future editions or amendments.~~
- D.A.** No change
- 1. No change
 - a. No change
 - b. No change
 - i. No change
 - ii. No change
 - iii. No change
 - c. No change
 - i. No change
 - ii. No change
 - iii. No change
 - d. No change
 - e. No change
 - f. ~~Each device meets the criteria in 10 CFR 31.5(c)(13)(i); (revised January 1, 2005-2008, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency; and available under R12-1-101. This incorporated material contains no future editions or amendments;) and bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing, if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in R12-1-428.~~
 - 2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change

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- f. No change
- g. No change
- h. No change
- i. No change
- j. No change
- 3. No change
- 4. A licensee authorized under subsection ~~(D)~~ (A) to distribute a device to a generally licensed person shall provide, if a device that contains radioactive material is to be transferred for use under the general license granted in R12-1-306(B), the name of each person that is licensed under ~~R12-1-311(D)~~ R12-1-311(A) and the information specified in this subsection for each person to whom a device will be transferred. The licensee shall provide this information before the device may be transferred. In the case of transfer through another person, the licensee shall provide the listed information to the intended user before initial transfer to the other person.
 - a. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - v. No change
 - b. No change
 - i. Report on a quarterly basis to the responsible Agreement State or NRC all transfers of devices to persons for use under a general license in accordance with 10 CFR 32.52, revised January 1, 2006 2008, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration Washington, DC 20408, and on file with the Agency available under R12-1-101. This ~~incorporated reference~~ incorporated material contains no future editions or amendments.
 - ii. Maintain all information concerning transfers and receipts of devices that supports the reports required by subsection ~~(D)(4)(b)~~ (A)(4)(b).
 - iii. Maintain records required by subsection ~~(D)(4)(b)~~ (A)(4)(b) for a period of three years following the date of the recorded event.
- 5. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
- 6. No change
- 7. No change
- 8. No change
 - a. The person licensed under subsection ~~(D)~~ (A) shall report all transfers of devices to persons for use under a general license obtained under R12-1-306(B), and all receipts of devices from persons licensed under R12-1-306(B) to the Agency, NRC, or other affected Agreement State. The report shall be submitted on a quarterly basis, in a clear and legible form, and contain the following information:
 - i. The identity of each general licensee by name and mailing address for the location of use. If there is no mailing address for the location of use, the person licensed under subsection ~~(D)~~ (A) shall submit an alternate address for the general licensee, along with information on the actual location of use;
 - ii. No change
 - iii. No change
 - iv. No change
 - v. The quantity and type of ~~byproduct~~ radioactive material contained in the device.
 - b. If one or more intermediaries will temporarily possess the device at the intended place of use before its possession by the intended user, the report shall include the information required of the general licensee in subsection ~~(D)(4)~~ (A)(4) for both the intended user and each intermediary, clearly identifying the intended user and each intermediary.
 - c. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - d. If the person licensed under subsection ~~(D)~~ (A) makes a change to a device possessed by a general licensee so that the label must be changed to update required information, the report shall identify the general licensee, the device, and the changes to information on the device label.

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- e. No change
 - f. The report shall clearly identify the person licensed under subsection ~~(D)~~ (A) submitting the report and include the license number of the license.
 - g. If no transfers are made to or from persons generally licensed under R12-1-306(B) during a reporting period, the person licensed under subsection ~~(D)~~ (A) shall submit a report indicating the lack of activity.
9. No change

~~F.B.~~ The Agency shall grant a specific license to manufacture, assemble, ~~or repair, or initially transfer~~ luminous safety devices that contain tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under R12-1-306(C), if the applicant satisfies:

- 1. No change
- 2. The requirements of 10 CFR 32.53 through 32.56 and 32.101, revised January 1, ~~2005~~ 2008, which are incorporated by reference, ~~published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency available under R12-1-101. The~~ This incorporated material ~~incorporated by reference~~ contains no future editions or amendments.

~~F.C.~~ No change

- 1. No change
- 2. The requirements of 10 CFR 32.57, 32.58, 32.59, 32.102, and 70.39, revised January 1, ~~2006~~ 2008, which are incorporated by reference, ~~published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency available under R12-1-101. The~~ This incorporated material ~~incorporated by reference~~ contains no future editions or amendments.

~~G.D.~~ No change

- 1. No change
- 2. No change
 - a. No change
 - b. No change

~~H.E.~~ No change

- 1. No change
- 2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. Cobalt-57 or selenium-75 in units not exceeding 370 ~~kBq~~ kilobecquerels (10 microcuries) each;
 - g. No change
- 3. No change
 - a. Identifying the radioactive contents as to chemical form and radionuclide and indicating that the amount of radioactivity does not exceed 370 ~~kBq~~ kilobecquerels (10 microcuries) of iodine-125, iodine-131, cobalt-57, selenium-75, or carbon-14; 1.85 ~~Mbq~~ megabecquerels (50 microcuries) of hydrogen-3 (tritium); 740 ~~kBq~~ kilobecquerels (20 microcuries) of iron-59; or mock iodine-125 in units not exceeding 1.85 ~~kBq~~ kilobecquerels (~~50 nanocurie~~ 0.05 microcurie) of iodine-129 and 185 ~~Bq~~ becquerels (~~5 nanocuries~~ 0.005 microcurie) of americium-241 each; and
 - b. No change
- 4. No change
 - a. No change
 - b. No change
- 5. No change

~~I.F.~~ No change

- 1. No change
- 2. The criteria of 10 CFR 32.61, 32.62, and 32.103, revised January 1, ~~2006~~ 2008, which are incorporated by reference, ~~published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency available under R12-1-101. The~~ This incorporated material ~~incorporated by reference~~ contains no future editions or amendments.

~~J.G.~~ The Agency shall grant a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs that contain radioactive material for use by a person authorized in accordance with Article 7 of this Chapter, if the applicant meets all of the requirements in 10 CFR 32.72, revised January 1, ~~2006~~ 2008, which is incorporated by reference, ~~published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency available under R12-1-101. The~~ This incorporated material ~~incorporated by reference~~ contains no future editions or amendments.

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~~K.H.~~ No change

1. No change
2. No change
 - a. No change
 - b. No change
3. No change
4. No change
5. No change
 - a. No change
 - b. No change

~~L.I.~~ The Agency shall grant a specific license to manufacture and distribute sources and devices that contain radioactive material to a person licensed in accordance with Article 7 of this Chapter for use as a calibration, transmission, or reference source or for medical purposes, if the applicant meets all of the requirements in 10 CFR 32.74, revised January 1, 2006 2008, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency available under R12-1-101. The This incorporated material incorporated by reference contains no future editions or amendments.

~~M.J.~~ No change

1. No change
 - a. No change
 - b. No change
 - c. No change
2. No change
3. No change
4. Each person licensed under subsection ~~(M)(1)~~ (J)(1) shall:
 - a. No change
 - b. No change
 - i. Identify the manufacturer of the product or device, the number of the license under which the product or device was manufactured or initially transferred, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and
 - ii. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - i. No change
 - ii. Report to the responsible state agency all transfers of devices manufactured and distributed under subsection ~~(M)(4)(f)~~ (J)(4)(f) for use under a general license in that state's regulations equivalent to R12-1-305(C);
 - iii. The report required in subsection ~~(M)(4)(f)(i)~~ (J)(4)(f)(i) or (ii) shall identify each general licensee by name and address, an individual by name or position who serves as the contact person for the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which a product or device is transferred to the generally licensed person;
 - iv. No change
 - v. No change
 - vi. No change

~~K.~~ A licensee who manufactures nationally tracked sources, as defined in Article 4, shall:

1. Serialize the sources in accordance with 10 CFR 32.201, revised January 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments; and
2. Report manufacturing activities in accordance with R12-1-454.

R12-1-313. Specific Terms and Conditions

- A. Each license issued under this Article is subject to all provisions of A.R.S. Title 30, Chapter 4 and to all rules, regulations, and orders of the Agency.
- B. No change
- C. No change
- D. No change
 1. No change
 - a. No change
 - b. No change
 - c. No change

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2. No change
 - a. The bankruptcy court in which the petition for bankruptcy was filed; and
 - b. No change
 - c. No change

R12-1-323. Financial Assurance and Recordkeeping for Decommissioning

- A. No change
 1. No change
 2. No change
 3. No change
 4. No change
 5. No change
- B. When applying, each ~~nongovernment~~ non-government applicant for a specific license that authorizes the possession and use of radioactive material, and each ~~nongovernment~~ non-government holder of a license to possess and use radioactive material issued before the effective date of this Section, shall submit to the Agency a decommissioning funding plan or certification of financial security, as required in A.R.S. § 30-672(H). A licensee required to meet the ~~requirement~~ requirements in subsection (C) is exempt from the requirements in this subsection.
- C. When applying, each applicant for a specific license that authorizes the possession and use of radioactive material, and each holder of a license to possess and use radioactive material issued before the effective date of this Section, shall submit to the Agency a decommissioning funding plan or certification of financial assurance that meets the requirements in 10 CFR 30.35, 40.36, and 70.25, revised January 1, 2005 2008, ~~which are~~ incorporated by reference, ~~published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency available under R12-1-101. The~~ This incorporated material ~~incorporated by reference~~ contains no future editions or amendments.
- D. Each licensee required to provide financial assurance for decommissioning a radioactive material facility under this Section shall maintain records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the Agency. The licensee shall maintain the following records during the decommissioning process:
 1. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, and site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. The licensee shall keep records identifying the involved radionuclides and associated quantities, forms, and concentrations.
 2. No change
 3. No change
- E. No change
 1. Upon expiration or termination of principal activities a licensee shall notify the Agency in writing whether the licensee is discontinuing licensed activities. The licensee shall begin decommissioning its facility within 60 days after the Agency receives notice of the decision to permanently terminate principal activities, or within 12 months after receipt of notice, submit to the Agency a decommissioning plan, as prescribed in 10 CFR 30.36(g)(1), 40.42(g)(1), and 70.38(g)(1), revised January 1, 2005 2008, ~~which is~~ incorporated by reference, and ~~published by the Office of the Federal Register, National Archives and Records Administration, Washington D.C. 20408, and on file with the Agency available under R12-1-101. The~~ This incorporated material ~~incorporated by reference~~ contains no future editions or amendments. The licensee shall begin decommissioning upon approval of the plan if the license has expired or no licensed activities have been conducted at the licensee's facility for a period of 24 months.
 2. No change
 3. No change
 - a. No change
 - b. No change
 4. No change
 5. The Agency shall approve a request for an alternate schedule for completion of decommissioning and license termination if the Agency determines that the alternative is warranted by consideration of the conditions specified in 10 CFR 30.36(i), 40.42(i), and 70.38(i), revised January 1, 2005 2008, ~~which are~~ incorporated by reference, ~~published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency and available under R12-1-101. The~~ This incorporated material ~~incorporated by reference~~ contains no future editions or amendments.
 6. As a final step in decommissioning, the licensee shall meet the requirements specified in 10 CFR 30.36(j), 40.42(j), and 70.38(j), revised January 1, 2005 2008, ~~which are~~ incorporated by reference, ~~published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency and available under R12-1-101. The~~ This incorporated material ~~incorporated by reference~~ contains no future editions

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or amendments.

R12-1-324. Public Notification and Public Participation

Upon the receipt of a license termination plan (LTP) or decommissioning plan from a licensee, or a proposal by a licensee for decommissioning of a site in accordance with ~~R12-1-451~~ and ~~R12-1-452~~, R12-1-452(C) and (D) or for other events when the Agency deems a notice to be in the public interest, the Agency shall:

1. No change
 - a. No change
 - b. The Arizona Department of Environmental Quality for cases in which the licensee proposes to decommission a site in accordance with ~~R12-1-452~~ R12-1-452(D).
2. No change

ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

R12-1-403. Definitions

The following definitions apply in this Article, unless the context otherwise requires:

“Air-purifying respirator”	No change
“ALI”	No change
“Assigned protection factor” <u>or (“APF”)</u>	No change
“Atmosphere-supplying respirator”	No change
“Class”	No change
“Constraint” or “dose constraint”	No change
“Critical group”	No change
“DAC”	No change
“DAC-hour”	No change
“Declared pregnant woman”	No change
“Decommission”	No change
“Demand respirator”	No change
“Deterministic effect” {see (See “Nonstochastic effect”)-}	
“Disposable respirator”	No change
“Distinguishable from background”	No change
“Dosimetry processor”	No change
“Filtering face piece (dust mask)”	No change
“Fit factor”	No change
“Fit test”	No change
“Helmet”	No change
“Hood”	No change
“Inhalation class” {see (See “Class”)-}	
“Loose-fitting face piece”	No change
“Lung class” {see (See “Class”)-}	
<u>“Nationally tracked source” means a sealed source that contains a quantity equal to or greater than Category 1 or Category 2 levels of radioactive material listed in 10 CFR 20, Appendix E, revised January 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments. In this context sealed source does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.</u>	
“Negative pressure respirator (tight fitting)”	No change
“Nonstochastic effect”	No change
“Planned special exposure”	No change
“Positive pressure respirator”	No change
“Powered air-purifying respirator” <u>or (“PAPR”)</u>	No change
“Pressure demand respirator”	No change
“Probabilistic effect” {see (See “Stochastic effect”)-}	

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“Qualitative fit test” or (“QLFT”)	No change
“Quantitative fit test” or (“QNFT”)	No change
“Reference Man”	No change
“Residual radioactivity”	No change
“Respiratory protective equipment”	No change
“Sanitary sewerage”	No change
“Self-contained breathing apparatus” or (“SCBA”)	No change
“Stochastic effect”	No change
“Supplied-air respirator” or (“SAR”) or “airline respirator”	No change
“Tight-fitting face piece”	No change
“User seal check” or (“fit check”)	No change
“Very-high radiation area”	No change
“Weighting factor”	No change

R12-1-419. Conditions Requiring Individual Monitoring of External and Internal Occupational Dose

- A. No change
- B. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
 - 6. No change
 - 7. No change
 - 8. No change
 - 9. No change
 - 10. Individuals operating open beam fluoroscopic systems and ancillary personnel working in the room when the fluoroscopic system is in use, except when relieved of this requirement by registration condition; ~~and~~
 - 11. Individuals performing well logging, as described in Article 17-; ~~and~~
 - 12. Individuals, wearing a finger or wrist individual monitoring device, during the operation of an open-beam or hand held analytical x-ray system or equipment with no safety devices as described in R12-1-806(C) and (F).
 - 13. Individuals, wearing a finger or wrist individual monitoring device, performing repairs that require the presence of a primary beam of the analytical x-ray system or equipment, as described in R12-1-806(C) and (F).
- C. No change
 - 1. No change
 - 2. No change
 - 3. No change
- D. Each licensee or registrant shall require that all individual monitoring devices be located on individuals according to the following requirements:
 - 1. An individual monitoring device, used to obtain the dose equivalent to an embryo or fetus of a declared pregnant woman according to R12-1-415, shall be located under the protective apron at the waist. A qualified expert shall be consulted to determine the dose equivalent to the embryo or fetus if this individual monitoring device has a monthly reported dose equivalent value that exceeds 0.5 millisieverts (50 millirem). For purposes of this subsection, the value for determining the dose equivalent to an embryo or fetus under R12-1-415(C), for occupational exposure to radiation from medical fluoroscopic equipment, is the value reported by the individual monitoring device worn at the waist underneath the protective apron, which has been corrected for the particular individual and the work environment by a qualified expert.
 - 2. An individual monitoring device used for lens dose equivalent shall be located at the neck or an unshielded location closer to the eye, outside the protective apron.
 - 3. If only one individual monitoring device is used to determine the effective dose equivalent for external radiation, according to R12-1-408(C)(2)(a), the device shall be located at the neck outside the protective apron. If a second individual monitoring device is used for the same purpose, it shall be located under the protective apron at the waist. A second individual monitoring device is required for a declared pregnant woman.
 - 4. An individual, wearing an extremity personnel monitoring device, during the operation of an open-beam or hand-held analytical x-ray system with no safety devices or an individual performing repairs in the presence of a primary beam of the analytical x-ray system or equipment, as described in R12-1-806(C) and (F), shall wear the device on the indi-

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vidual's finger or wrist.

- ~~D-E.~~ No change
1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 2. No change
 3. No change
 4. No change
 5. No change

R12-1-422. Control of Access to Irradiators (Very-high Radiation Areas)

- A. No change
- B. No change
1. No change
 - a. No change
 - b. No change
 - c. No change
 2. No change
 - a. No change
 - b. No change
 3. No change
 - a. No change
 - b. No change
 4. No change
 5. No change
 6. No change
 7. No change
 8. The licensee or registrant shall check each area by radiation measurement to ensure that, before the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area ~~is below that at which it would be possible for an individual to receive~~ will not expose an individual to a deep-dose equivalent in excess of 1 mSv millisievert (0.1 rem) in one hour.
 9. No change
 - a. No change
 - b. Testing shall be conducted before resumption of operation of the source of radiation after any unintentional interruption: ~~and;~~
 - c. The licensee or registrant shall submit to the Agency ~~and adhere to a schedule for periodic tests of the entry control and warning systems: a schedule of testing; and~~
 - d. The licensee or registrant shall include in the schedule a listing of the periodic testing that will be followed.
 10. No change
 11. The licensee or registrant shall control entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by ~~individuals personnel,~~ with devices and administrative procedures necessary to physically protect and warn against inadvertent entry by ~~any an~~ individual through ~~these one of the~~ portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any uncontained radioactive material that is carried toward an exit and automatically prevent contained radioactive material from being carried out of the area.
- C. No change
- D. No change
- E. No change
1. No change
 2. No change

R12-1-431. Labeling Containers and Radiation Machines

- A. No change
- B. ~~Each licensee shall, before~~ Before removal or disposal of an empty, uncontaminated container to an unrestricted area, each licensee shall remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

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C. No change

D. ~~A licensee shall label each syringe and each vial that contains a radiopharmaceutical, used in the practice of medicine, to identify its radiopharmaceutical content~~ licensee shall label each syringe and vial that contains a radiopharmaceutical used in the practice of medicine with the radiopharmaceutical content. Each syringe shield and vial shield shall also be labeled, unless the label on the syringe or vial is visible when shielded. The label shall ~~indicate~~ contain the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the name of the person being administered the radiopharmaceutical. Color-coding syringe shields and vial shields does not meet the labeling requirement.

R12-1-432. Labeling Exemptions

A licensee is not required to label:

1. No change
2. No change
3. No change
4. Containers holding radioactive material that ~~does do~~ not exceed the limits for excepted quantity or article as defined and limited in 49 CFR 173.403, and 173.421 through 173.424, and are transported, packaged, and labeled in accordance with 49 CFR 172.436 through 172.440, ~~1999 Edition, published (Revised October 1, 1999 2007, by the Office of Federal Register National Archives and Records Administration, incorporated by reference, and on file with the Agency and Office of Secretary of State. This incorporation by reference contains no future editions or amendments; available under R12-1-101. This incorporated material contains no future editions or amendments.)~~
5. Containers that are accessible only to individuals authorized to handle, use, or work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record, retained as long as the container is in use for the purpose indicated on the record. (Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells.) ~~A licensee shall retain the record as long as the containers are in use for the purpose indicated on the record; or~~
6. No change

R12-1-434. General Requirements for Waste Disposal

A. No change

1. No change
2. No change
3. No change
4. No change

B. ~~A person shall be specifically licensed to receive waste containing licensed material from other persons~~ To receive waste that contains licensed material from other persons, a person shall be specifically licensed for:

1. No change
2. No change
3. No change
4. No change
5. No change

R12-1-435. Method for Obtaining Approval of Proposed Disposal Procedures

~~A licensee or applicant for a license may apply to the Agency for approval of proposed procedures, not otherwise authorized in this Chapter for disposal of licensed material generated in the licensee's operations. For disposal of licensed material generated in the licensee's operations, a licensee or applicant for a license may apply to the Agency for approval of proposed disposal procedures, not otherwise authorized in this Chapter.~~ Each application shall include:

1. No change
2. No change
3. No change
4. No change
5. No change

R12-1-440. Compliance with Environmental and Health Protection Regulations

Nothing in R12-1-434, R12-1-435, R12-1-436, R12-1-437, R12-1-438, or R12-1-439 relieves the licensee from complying with other applicable federal, state, and local rules or regulations governing any other toxic or hazardous properties of materials that may be disposed of according to ~~R12-1-434, R12-1-435, R12-1-436, R12-1-437, R12-1-438, or R12-1-439~~ Article 4 of this Chapter.

R12-1-443. Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation

A. No change

1. No change
2. No change
3. No change

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- B. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
 - 6. No change
- C. No change
- D. The licensee or registrant shall provide the Agency with the names of individuals who may have received an exposure to radiation as a result of an incident ~~as required in~~ reported to the Agency under subsection (B).

R12-1-446. Notifications and Reports to Individuals

- A. No change
- B. ~~Each~~ In addition to the reporting requirements in R12-1-445, each licensee or registrant shall notify the individual exposed to radiation or radioactive material ~~in the report to the Agency required in R12-1-445. A separate~~ The notice to the exposed individual shall be provided no later than the date the report is submitted to the Agency and shall comply with R12-1-1004(A).

R12-1-447. Vacating Premises

- A. If a facility has been used for activities involving radioactive material ~~each~~ a licensee shall notify the Agency in writing of the intent to vacate the facility no less than 45 days before relinquishing possession or control of the facility.
- B. If a facility is contaminated with radioactive material, ~~the~~ a licensee vacating the facility shall decontaminate it using Agency-approved procedures.
- C. No change

R12-1-448. Additional Reporting

- A. No change
- B. Each licensee shall notify the Agency within 24 hours after ~~the discovery of~~ discovering any of the following events involving licensed material:
 - 1. A contamination event that:
 - a. Requires that anyone having access to the contaminated area, ~~by workers or the public, being~~ be restricted for more than 24 hours by the imposition of additional radiological controls to prohibit entry into the area; and
 - b. No change
 - c. No change
 - 2. No change
 - a. No change
 - b. No change
 - c. No change
 - 3. No change
 - 4. No change
 - a. No change
 - b. No change
- C. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
- D. Each licensee who makes a report required by subsection (A) or (B) shall submit to the Agency a written follow-up report within 30 days of the initial report. Written reports prepared as required by other rules may be submitted to fulfill this requirement if the reports contain all of the required information in this ~~Section~~ subsection. ~~The licensee shall send the written report to the Agency.~~ The report shall include the following:
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
 - 6. The extent of personnel exposure of individuals to radiation or to radioactive materials without identification of ~~individuals~~ each exposed individual by name.

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R12-1-449. Survey Instruments and Pocket Dosimeters

- A. No change
- B. No change
 - 1. No change
 - 2. No change
- C. No change
- D. No change
 - 1. No change
 - 2. No change
- E. No change
- F. No change
 - 1. Have been evaluated for proper operation annually and following repair, using a procedure acceptable to the Agency, unless a more frequent evaluation is required by license condition ~~using a procedure acceptable to the Agency, for proper operation annually, and following repair, unless a more frequent evaluation is required by license condition.~~ With the exception of electronic pocket dosimeters, which are exempted from the drift test, the evaluation shall include a check for drift over a 24-hour period; (Unless the dosimeter is electronic, the evaluation of the dosimeter shall include a drift test over a 24-hour period.); and
 - 2. Meet the performance criteria listed in ~~R12-1-523(B)~~ R12-1-523(C) and R12-1-1130(C).
- G. No change

R12-1-454. ~~Reserved~~ Nationally Tracked Sources

- A. A licensee who manufactures, receives, transfers, disassembles, or disposes of a nationally tracked source shall complete and submit to the Nuclear Regulatory Commission's National Source Tracking System and the Agency, a National Source Tracking Transaction Report that contains the information required in 10 CFR 20.2207(a) through (e), revised January 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments. The report shall be submitted by the close of the next business day after the transaction using a reporting method specified in 10 CFR 20.2207(f), revised January 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.
- B. The initial National Source Tracking Transaction Report shall contain the information required in subsection (A), be submitted using a method specified in 10 CFR 20.2207(f) and include the additional information required by 10 CFR 20.2207(h)(1) through (6), revised January 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.
- C. A licensee shall correct any error in previously filed National Source Tracking Transaction Reports or file a new report for any missed transaction within five business days of the discovery of the error or missed transaction in accordance with 10 CFR 20.2207(g), revised January 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.
- D. A licensee who receives a nationally tracked sealed source shall not disassemble the source unless specifically authorized to do so by the Agency.

ARTICLE 6. USE OF X-RAYS IN THE HEALING ARTS

R12-1-602. Definitions

The following definitions apply in this Article, unless the context otherwise requires:

“Accessible surface”	No change
“Added filter”	No change
“Aluminum equivalent”	No change
“Assembler”	No change
“Attenuation block”	No change
“Automatic exposure control”	No change
“Barrier” (See “Protective barrier”)	
“Beam axis”	No change
“Beam-limiting device”	No change
“C-arm x-ray system”	No change
“Changeable filter”	No change
“Cinefluorography”	No change
“Coefficient of variation”	No change
“Collimator”	No change

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“Compression device”	No change
“Computed tomography”	No change
“Contact therapy system”	No change
“Control panel”	No change
“Cooling curve”	No change
“CT gantry”	No change
“Dead-man switch”	No change
“Diagnostic source assembly”	No change
“Diagnostic x-ray system”	No change
“Direct scattered radiation”	No change
“Entrance exposure rate”	No change
“Equipment” (See “X-ray equipment”)	
“Filter”	No change
“Fluoroscopic imaging assembly”	No change
“Fluoroscopic system”	No change
“Focal spot”	No change
“General purpose radiographic x-ray system”	No change
“Gonadal shield”	No change
“Grid”	No change
“Half-value layer or (“HVL)”	No change
<p>“Healing arts radiography” means the practice of applying <u>application of</u> x-radiation to human patients <u>for diagnostic or therapeutic purposes by a licensed practitioner or a person certified in accordance with R12-1-603(B)(1), for diagnostic or therapeutic purposes</u> at the direction of a licensed practitioner. Healing arts radiography includes:</p> <ul style="list-style-type: none"> Positioning the x-ray beam with respect to the patient; Anatomical positioning of the patient; Selecting exposure factors; or Initiating the exposure. 	
“Healing arts screening”	No change
“Image intensifier”	No change
“Image receptor”	No change
“Inherent filtration”	No change
“Kilovolts peak” or (“kVp”) (See “Peak tube potential”)	
“Lead equivalent”	No change
“Leakage radiation”	No change
“Leakage technique factors”	No change
“mA”	No change
“Mammographic x-ray system”	No change
“mAs”	No change
“Mobile equipment” (See “X-ray equipment”)	
“Peak tube potential”	No change
“Phantom”	No change
“Phototimer” (See “automatic <u>Automatic</u> exposure control?)	
“Portable equipment” (See “X-ray equipment”)	
“Primary protective barrier” (See “Protective barrier”)	
“Protective apron”	No change
“Protective barrier”	No change

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“Primary protective barrier”	No change
“Secondary protective barrier”	No change
“Protective glove”	No change
<u>“Radiologic physicist” means an individual who:</u>	
<u>Is certified by the American Board of Radiology, American Board of Medical Physics, or the American Board of Health Physics;</u>	
<u>Possesses documentation of state approval;</u>	
<u>Holds a master’s degree or higher in a physical science; and</u>	
<u>Meets the training and certification requirements in R12-1-614(C)(1)(c).</u>	
“Scattered radiation”	No change
“Screen” or “intensifying screen”	No change
“Secondary protective barrier” (See “Protective barrier”)	
“Shutter” (See collimator <u>“Collimator”</u>)-	
“Source”	No change
“Source-to-image receptor distance” or (“SID”)	No change
“Spot check”	No change
“Stationary equipment” (See “X-ray equipment”)	
“Stray radiation”	No change
“System” (See x-ray <u>“X-ray system”</u>)	
“Technique chart”	No change
“Technique factors”	No change
“Treatment simulator”	No change
“Tube”	No change
“Tube housing assembly”	No change
“Tube rating chart”	No change
“Useful beam”	No change
“Visible area”	No change
“X-ray equipment”	No change
<u>“_Mobile_” means x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.</u>	
<u>“_Portable_” means x-ray equipment designed to be hand-carried.</u>	
<u>“_Stationary_” means x-ray equipment installed in a fixed location.</u>	
<u>“_Transportable mobile_” means x-ray equipment installed in a vehicle or trailer.</u>	
“X-ray system”	No change
“X-ray tube”	No change

R12-1-603. Operational Standards, Shielding, and Darkroom Requirements

- A. No change
- B. No change
 - 1. No change
 - 2. No change
 - 3. No change
- C. No change
 - 1. No change
 - 2. A registrant shall ensure that attenuation provided by a protective barrier meets or exceeds the level of protection established in ~~the National Council on Radiation Protection Report No. 49, “Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies Up To 10 MeV,” September 15, 1976 Edition edition, published 147 Structural Shielding Design for Medical X-ray Imaging Facilities, November 19, 2004, by the National Council on Radiation Protection and Measurement Measurements, Inc., (NCRP), NCRP Publications, 7910 Woodmount Ave., Suite 400, Bethesda, MD 20814-3095, which This report is incorporated by reference and on file with the Agency available under R12-1-101. This incorporation by reference~~ The incorporated material contains no future

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editions or amendments. Copies of the report are available from NCRP Publications: online at <http://www.ncrppublications.org>; toll free at (800) 229-2652 (Ext. 25); or e-mail at NCRPpubs@NCRPonline.org. Each registrant shall use this incorporated ~~reference~~ material to provide sufficient shielding to prevent a public exposure ~~in excess of that exceeds~~ the limits in R12-1-416.

3. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
4. No change

D. Film Processing and Darkroom Requirements. A registrant shall:

- ~~1. Use darkroom conditions to prevent film fog of greater than or equal to 0.05 optical density. The registrant shall use following procedure to test for film fog:~~
 - a. ~~The registrant shall expose the film radiographically so the processed film has an optical density of at least 1.0 over Base density, but less than an optical density of 1.0 under Dmax;~~
 - b. ~~The registrant shall then expose half of the radiographically exposed film in the darkroom for two minutes; and~~
 - e. ~~The registrant shall then compare the difference in optical densities between the darkroom exposed half and non-darkroom exposed half to determine whether film fog is less than 0.05 optical density. Note: Base is the optical density of unexposed film as used at the facility; (Base + Fog) is the optical density of Base unexposed film exposed in the darkroom for two minutes.~~
- ~~2. Use a thermometer and timer operable and appropriate to the type of film processing in the darkroom; and~~
- ~~3. Develop film according to the manufacturer's instructions.~~
1. Ensure that the darkroom is light-tight and use proper safe-lighting, so that any film type in use is exposed in a cassette to x-ray radiation sufficient to produce an optical density from 1 to 2 when processed, the film is exposed in the darkroom for two minutes, and exposure will not produce an increase in optical density greater than 0.1 (0.05 for mammography). (A processor with a daylight loader satisfies this requirement.);
2. Ensure that film is stored in a cool, dry place and is protected from radiation exposure; and that film located in open packages is stored in a light-tight container;
3. Ensure that film cassettes and intensifying screens are inspected annually, cleaned, and replaced as necessary;
4. Ensure that film cassettes contain film and intensifying screens that have the same sensitivity;
5. Ensure that automatic film processors develop film in accordance with time-temperature relationships recommended by the film manufacturer;
6. Ensure that manually developed film is developed in accordance with the time-temperature relationships recommended by the manufacturer, and that a timer, thermometer, and a time-temperature chart are available and used in the darkroom;
7. Ensure that film processing solutions are prepared and maintained in accordance with the directions of the manufacturer; and
8. Ensure that outdated film is not used for diagnostic radiographs.

R12-1-604. General Procedures

A. ~~The Each~~ registrant shall ensure the following procedural requirements are met in the operation of x-ray equipment:

1. No change
2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
3. No change
 - a. No change
 - b. No change
 - c. Exposure of an individual for the purpose of healing arts screening, except as authorized by the Agency after submitting to the Agency the information listed in Appendix A of this Article. (If any information submitted to the Agency changes, the registrant shall immediately notify the Agency of the changes.);
 - d. Routinely holding film or a patient during an exposure to x-ray radiation; or
 - e. Exposure of an individual to fluoroscopy as a positioning method for general purpose radiological procedures.
4. No change
5. The registrant shall check radiation protective equipment for reliability and integrity defects on an annual basis, as follows:
 - a. Aprons, gloves, and shields shall be checked for holes, tears, and breaks.

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- b. If defects are found in the equipment, the registrant shall replace or remove it from service. Equipment removed from service shall not be put back into service until it is repaired.
- c. A record of the annual reliability and integrity check and any equipment replacement shall be maintained for three years.

B. No change

- 1. ~~Maximum rating of technique factors.~~
- 2. ~~Aluminum equivalent filtration of the useful beam, including any routine variation.~~
- 3. ~~Tube rating charts and cooling curves.~~
- 4. 1. Record of surveys ~~Survey~~, ~~calibrations~~ calibration, maintenance, and ~~modifications~~ modification records (from the original schematics and drawings) performed on regarding the x-ray machine or room after the effective date of these rules, along with the names of persons, which include the name of the person who performed the service; and
- 5. 2. A copy of all correspondence ~~Correspondence~~ with the Agency regarding the x-ray machine facility.

R12-1-605. X-ray Machine Standards

A. No change

B. No change

C. No change

- 1. No change
- 2. No change
- 3. No change
- 4. No change
- 5. When determining the minimum aluminum equivalent filtration, ~~The~~ the registrant shall include the filtration contributed by all materials that are always present between the focal spot of the tube and the patient (for example, a tabletop when the tube is mounted “under the table” and inherent filtration of the tube).

D. No change

E. No change

F. No change

- G. Accuracy deviation. A registrant shall not use an x-ray machine if the measured technique factors for kVp and time duration are not within the limits specified by the manufacturer. In the absence of the manufacturer’s specifications, a registrant shall not use an x-ray machine if the measured kVp is not within 10% of the indicated kVp value and the measured time duration is not within 20% of the indicated time.

R12-1-606. Fluoroscopic and Fluoroscopic Treatment Simulator Systems

A. No change

- 1. No change
- 2. Ensure that the x-ray field size produced by fluoroscopic systems without image intensification † does not extend beyond the visible area of the image receptor at any SID;
- 3. No change
- 4. No change
- 5. No change

B. Fluoroscopic primary protective barrier. A registrant shall:

- 1. No change
- 2. No change
- 3. No change
- 4. No change
 - a. For equipment installed before November 15, 1967, the required lead equivalent of the barrier † is not less than 1.5 millimeters for fluoroscopes that produce less than 100 kVp, 1.8 millimeters for fluoroscopes that produce ~~from at least 100 kVp up to~~ but less than 125 kVp, and 2.0 millimeters for fluoroscopes that produce 125 or more kVp. (For conventional fluoroscopes, these requirements may be assumed to have been met if the exposure rate measured at the viewing surface of the fluorescent screen does not exceed 12.9 ~~μC/kg~~ microcoulombs per kilogram (50 milliroentgens) per hour with the screen in the primary beam of the fluoroscope without a patient, under normal operating conditions.) For equipment installed or reinstalled, the required lead equivalent of the barrier is 2.0 millimeters for fluoroscopes that produce less than ~~up to~~ 125 kVp or 2.7 millimeters for fluoroscopes that produce 125 or more kVp.
 - b. No change
 - c. No change

C. No change

- 1. No change
- 2. No change
 - a. No change

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- b. No change
- 3. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
- D.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
- E.** No change
 - 1. No change
 - 2. No change
 - 3. No change
- F.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
- G.** No change
- H.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change

R12-1-607. Additional X-ray Machine Standards, Shielding Requirements, and Procedures, Except Fluoroscopic and Dental Intraoral Radiographic Systems

- A.** No change
 - 1. No change
 - 2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - 3. No change
- B.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - a. No change
 - b. No change
- C.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
- D.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - a. No change
 - b. No change

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- c. No change
- d. No change
- e. No change
- 5. ~~Provide documentation of the patient's identity, the x-ray examination performed, the date it is performed, number of projections (if applicable), and a method of identifying the individual who performed the examination, for Agency review. The registrant shall maintain the documentation for three years from the date the examination is performed.~~
- 5. Provide documentation in the order specified:
 - a. The patient's identity;
 - b. The x-ray examination, as recorded in a radiographic log;
 - c. The date the examination is performed;
 - d. The number of projections (if applicable); and
 - e. A method of identifying the individual who performed the examination.
- 6. The registrant shall maintain in chronological order, the documentation required in subsection (D)(5) in written or readily available electronic form. The documentation shall be maintained for three years from the date the examination is performed.

R12-1-608. Mobile Diagnostic Radiographic and Fluoroscopic Systems, Except Dental Intraoral Radiographic Systems

- A. No change
 - 1. No change
 - 2. ~~A For mobile radiographic units the registrant shall provide a "dead-man" switch, together with an electrical cord of sufficient length so that the operator can stand out of the useful beam and at least 1.82 meters (6 feet) from the patient during all x-ray exposures.~~
 - 3. No change
- B. No change
- C. No change
 - 1. No change
 - 2. No change

R12-1-610. Dental Intraoral Radiographic Systems

- A. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
 - 6. No change
 - 7. No change
 - 8. Use a control panel that includes:
 - a. ~~A device that will give positive indication during radiation production; and~~
 - a. A means to provide visual or audible indication, detectable at or from the operator's position, during x-ray production or exposure termination; and
 - b. ~~Indicators, labeled control settings, or meters, indicating the appropriate technical factors: kVp, mA, or exposure time, and any special mode selected for the exposure.~~
 - b. Indication of technique factors for kVp, mA, exposure time, and any special mode that may be selected for the exposure.
 - 9. Use technique factors, where deviation of measured or indicated values for kVp and exposure time do not exceed the limits specified by the manufacturer. In the absence of the manufacturer's specifications, the deviation shall not exceed plus or minus 10% of the indicated value for kVp and plus or minus 20% for exposure time duration.
 - 10. For a digital system, use digital radiography techniques that permit reducing x-ray beam on-time to 25% of the exposure time required for "D" speed film, reducing radiation to the patient by the same rate.
- B. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
- C. No change
 - 1. No change
 - 2. No change
 - 3. No change

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- 4. No change
- 5. No change

R12-1-611. Therapeutic X-ray Systems of Less Than 1 MeV

A. No change

- 1. No change
 - a. Contact therapy systems. Leakage radiation † does not exceed ~~258 $\mu\text{C/kg}$ microcoulombs per kilogram~~ 25.8 $\mu\text{C/kg}$ microcoulombs per kilogram (100 milliroentgens) per hour at 5 centimeters (2 inches) from the surface of the tube housing assembly.
 - b. 0-150 kVp systems. Systems that are manufactured or installed before January 2, 1996, † have a leakage radiation that does not exceed ~~258 $\mu\text{C/kg}$ microcoulombs per kilogram~~ (1 roentgen) in 1 hour at 1 meter (3.3 feet) from the source.
 - c. 0-150 kVp systems. Systems that are manufactured on or after January 2, 1996, † have a leakage radiation that does not exceed ~~258 $\mu\text{C/kg}$ microcoulombs per kilogram~~ (100 milliroentgens) in 1 hour at 1 meter from the source.
 - d. No change
- 2. No change
- 3. No change
 - a. Removable and adjustable beam-limiting devices †, for the portion of the useful beam to be blocked by these devices, transmit not more than 1 percent of the original x-ray beam at the maximum kilovoltage and maximum treatment filter; and
 - b. No change
- 4. No change
 - a. No change
 - b. No change
 - c. No change
- 5. No change
- 6. No change
- 7. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
- 8. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
- 9. No change
 - a. No change
 - b. No change
 - c. No change
- 10. No change
- 11. No change
 - a. No change
 - b. No change
- 12. No change

B. No change

- 1. No change
- 2. No change
- 3. No change
- 4. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change

C. No change

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1. No change
2. No change
3. No change
- D.** No change
 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 2. No change
 3. No change
 4. No change
 5. No change
 6. No change
- E.** No change
 1. No change
 2. No change
 3. No change
 4. No change
 5. No change
- F.** No change
 1. No change
 2. No change
 3. No change
 4. No change

R12-1-612. Computerized Tomographic Systems

- A.** No change
 1. No change
 2. No change
 3. No change
 4. No change
 5. No change
 6. No change
 7. No change
 8. No change
 9. No change
 10. No change
- B.** No change
 1. No change
 2. No change
- C.** No change
 1. No change
 - a. No change
 - b. No change
 2. No change
 - a. No change
 - b. No change
 3. No change
 - a. No change
 - b. No change
 - c. No change
 4. No change
 5. No change
 6. No change
 7. No change
 8. No change
- D.** No change
 1. No change
 2. No change

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- a. No change
- b. No change
- c. No change
- d. No change
- 3. No change
- E. No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
- F. No change
 - 1. No change
 - 2. No change
 - a. No change
 - b. No change
 - 3. No change
 - a. No change
 - b. No change
 - 4. No change
 - a. No change
 - b. No change
 - 5. No change
- G. CT units designated for simulator use, veterinary use, and non-diagnostic conjunctive use in a positron emission tomography (PET) unit are exempt from the requirements in subsection (F).

R12-1-614. Mammography

- A. No change
 - 1. Only radiation machines specifically designed for ~~mammography~~ mammographic examinations are used;
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. The combination of focal spot size, source-to-image distance and magnification produces a radiograph with a resolution of at least 12 line pairs per millimeter at an object-to-image receptor distance of 4.5 centimeters; or the standards in Table 3-3 of the American ~~Associates~~ Association of Physicists in Medicine (AAPM), Report No. 29, Equipment Requirements and Quality Control for Mammography, August 1990 ~~edition~~, published by the American Institute of Physics, ~~Inc.~~ Suite 1N01, 2 Huntington Quadrangle, Melville, NY 11747 (This report is incorporated by reference and available under R12-1-101. The incorporated material contains no future editions or amendments. The report is available online at: <http://www.aapm.org/pubs/reports>; print copies may be purchased from Medical Physics Publishing, 4513 Vernon Blvd., Madison, WI 53705; toll free at (800) 442-5778.); ~~which is incorporated by reference, on file with the Agency, and contains no future editions or amendments;~~
 - 6. No change
 - 7. The ~~mammography~~ mammographic x-ray system with initial power drive:
 - a. No change
 - b. No change
 - c. No change
 - 8. A ~~mammography~~ mammographic x-ray system using screen-film image receptors has:
 - a. No change
 - b. No change
 - 9. All ~~mammography~~ mammographic x-ray systems ~~±~~ indicate, or provide a means of determining, the mAs resulting from each exposure made with automatic exposure control;
 - 10. No change
 - 11. No change
 - 12. ~~Mammography~~ Mammographic x-ray systems operating with automatic exposure control are capable of maintaining a film density within ~~±~~ plus or minus 0.15 optical density units over the clinical range of kVp used, for a breast having an equivalent phantom thickness from 2 to 6 centimeters. ~~If the film density cannot be maintained to within ± 0.15~~

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of the average kVp used and phantom thickness from 2 to 6 centimeters cannot be maintained by the automatic exposure control, a technique chart is used that alters kVp and density control settings as a function of breast thickness and density. If a technique chart is used, the operator shall maintain the film density ~~at ±~~ within plus or minus 0.15 optical density units of the mean optical density.

13. At a kVp of 28, the ~~mammography~~ mammographic x-ray system is capable of generating at least 2.0 μC/kg/mAs (8mR/mAs) and at least 200 μC/kg/second (800 mR/second), measured at a point 4.5 centimeters above the surface of the patient support device when the Source-image receptor distance is at its maximum;
14. ~~Cassettes~~ Screens are not used for mammography if one or more areas of greater than 1 ~~cm~~ 2 centimeter squared of poor screen-film contact are seen when tested, using a 40 mesh screen test;
15. ~~Mammography~~ Mammographic image quality:
 - a. ~~Meets~~ meets the minimum mammography film standards for phantom performance in “Mammography Quality Control Manual,” ~~1992~~ 1999 edition, published by the American College of Radiology (ACR). ~~or (This manual is incorporated by reference and available under R12-1-101. The incorporated material contains no future editions or amendments. The manual is available from ACR Publication Sales, P.O. Box 533, Annapolis Junction, MD 20701; toll free at (800) 227-7762; e-mail at: acr@brightkey.net), which is incorporated by reference, on file with the Agency, and contains no future editions or amendments; or~~
 - b. ~~Is sufficient to demonstrate in the image produced the presence of at least 4 fibers, 3 speck groups, and 3 masses that include a 0.75 millimeter fiber, a 0.32 millimeter speck group, and a 0.75 millimeter mass, using a Radiation Measurements Inc. (RMI), Model 156 phantom or its equivalent;~~
16. No change
17. A radiologic physicist who meets the requirements in R12-1-614(C)(1)(c) evaluates the operation of a ~~mammography~~ mammographic x-ray system:
 - a. No change
 - b. No change
 - c. No change

B. No change

1. Each ~~mammography~~ mammographic facility has a quality assurance program, and that the quality assurance program includes performance and documentation of the quality control tests in subsection (B)(2), conducted at the required time intervals; ~~with test~~ Test results that shall fall within the specified limits in subsection (B)(2) or the registrant shall take corrective action ~~taken if results fall outside of the specified limits and maintain documentation that the results are within specified limits before performing or processing any further examinations using the system that failed.~~ A radiologic physicist, as defined in R12-1-614(C)(1)(c), shall review the program and make any recommendations necessary for the facility to comply with this Section;
2. The quality assurance program meets ~~the federal~~ requirements ~~contained in 21 CFR 900.12(d)(1); (e)(1); (e)(2)(i),(ii), and (iii); (e)(3); (e)(4); (e)(5)(i), (ii), (iii)(A), (iv), (v), (vi), (vii)(B) and (C), (viii), (ix), (x), and (xi); (e)(8)(ii); (e)(9)(ii); and (e)(10), (Contained in 21 CFR 900.12(d)(1), and (e)(1) through (e)(10), 2001 edition, published April 1, 2001, which is incorporated by reference, on file with the Agency, and contains no future editions or amendments; or meets the following requirements revised April 1, 2008, incorporated by reference and available under R12-1-101. This incorporated material contains no future editions or amendments.); or the following requirements:~~
 - a. No change
 - b. Weekly phantom image quality evaluations demonstrate the visualization of at least four fibers, three speck groups, and three masses with a background of ~~≥1.20~~ greater than 1.40 optical density ~~of operating level, not varying by ±0.20 optical density of operating level;~~
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - g. Semiannual screen film contact evaluations meet the limit of ~~< 1.0 centimeter squared area of poor contact of less than one area of poor contact of 1 centimeter squared,~~ using a 40 mesh screen on all clinically-used screens;
 - h. Semiannual automatic compression force evaluations meet the limit of ~~≥~~ greater than or equal to 25 pounds (111 Newtons) and ~~< 47 less than 45 pounds (209 200 Newtons); and~~
 - i. A survey shall be conducted annually ~~Annually~~ and whenever indicated for installation, major repairs, parts replacement, or as deemed necessary by a qualified expert when quality control test results indicate a survey is necessary; the survey shall include all of the following tests: automatic exposure control performance and thickness response; kVp accuracy and reproducibility; system resolution; breast entrance air kerma and automatic exposure control reproducibility; average glandular dose; x-ray field, light field and image receptor alignment; compression paddle alignment; uniformity of screen speed; system artifacts; radiation output; decompression; and beam quality and half value layer.
 - i. Automatic exposure control performance and thickness response;

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- ii. Accuracy and reproducibility of kVp;
- iii. System resolution;
- iv. Breast entrance air kerma and automatic exposure control reproducibility;
- v. Average glandular dose;
- vi. X-ray field, light field, and image receptor alignment;
- vii. Compression paddle alignment;
- viii. Uniformity of screen speed;
- ix. System artifacts;
- x. Radiation output;
- xi. Decompression;
- xii. Beam quality and half value layer;
- j. For systems with image receptor modalities other than screen film, the quality assurance and quality control program meets or exceeds the recommendations by the manufacturer; and
- k. The registrant maintains records documenting compliance with the provisions in this subsection for three years from the date each requirement is met. The records shall be made available for Agency inspection.

C. No change

- 1. Each registrant shall require personnel who perform mammography, which includes the production, processing, and interpretation of mammograms and related quality assurance activities, to meet the following requirements:
 - a. An interpreting physician shall meet ~~the federal requirements of 21 CFR 900.12(a)(1)(i) and (ii)(A) and (B), (Contained in 21 CFR 900.12(a)(1), 2001 edition, published April 1, 2001, which is incorporated by reference, on file with the Agency, and contains no future editions or amendments revised April 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.);~~ or:
 - i. No change
 - ii. No change
 - iii. Be certified by the American Board of Radiology or the American Osteopathic Board of Radiology or be approved by the Arizona ~~Board of Medical Examiners~~ Medical Board or the Arizona Board of Osteopathic Examiners as qualified to read and interpret mammogram images;
 - iv. Have interpreted or reviewed an average of 300 mammograms per year during the preceding two years or have completed a radiology residency that included mammogram image interpretation; ~~and~~
 - v. Have completed 15 hours of continuing medical education credits in mammography during the preceding three years; ~~and~~
 - vi. Have received at least eight hours of training specific to each mammographic modality before engaging in independent interpretation.
 - b. A ~~mammography~~ mammographic technologist shall meet ~~the federal requirements of 21 CFR 900.12(a)(2)(i)(B), (ii), and (iii) (Contained in 21 CFR 900.12(a)(2), 2001 edition, published April 1, 2001, which is incorporated by reference, on file with the Agency, and contains no future editions or amendments revised April 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.);~~ or:
 - i. Possess a valid mammographic technologist certificate issued by the Medical Radiologic Technology Board of Examiners, as required in A.R.S. § 32-2841, or be pursuing mammography certification by training under the direct supervision of a technologist who possesses a valid mammographic technologist certificate; ~~and;~~
 - ii. Have performed at least 200 mammographic examinations in the preceding two years;
 - ~~iii.~~ Have completed 15 hours of continuing medical education credits in mammography during the preceding three years; ~~and~~
 - iv. Have received at least eight hours of training specific to each mammographic modality to be used by the technologist in performing mammographic examinations.
 - c. A radiologic physicist shall meet ~~the federal requirements in 21 CFR 900.12(a)(3)(i) and (iii), and 21 CFR 900.12(a)(4) (Contained in 21 CFR 900.12(a)(3), 2001 edition, published April 1, 2001, which is incorporated by reference and on file with the Agency, and contains no future editions or amendments revised April 1, 2008, incorporated by reference and available under R12-1-101. This incorporated material contains no future editions or amendments.);~~ or
 - i. No change
 - ii. No change
 - iii. No change
 - iv. Have, upon initial employment as a radiologic physicist, experience conducting, at least one ~~mammography~~ mammographic facility survey and evaluating at least 10 ~~mammography~~ mammographic units;
 - v. Have, after completing the experience requirements in subsection (C)(1)(c)(iv), continuing experience surveying two ~~mammography~~ mammographic facilities and evaluating six ~~mammography~~ mammographic

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- units during the preceding two years; ~~and~~
- vi. Have completed 15 hours of continuing medical education credits in mammography during the three preceding years;
- vii. Have received at least eight hours of training specific to any modality surveyed; and

2. No change

D. Mammography ~~Mammographic~~ films and reports. ~~A registrant shall:~~

- 1. ~~Maintain~~ A registrant shall maintain films and reports for a minimum of five years. In those cases where no subsequent ~~mammography~~ mammographic procedures are performed, the registrant shall maintain films and associated reports for 10 years. If the ~~mammography~~ mammographic facility is closed, the registrant shall make arrangements for storage of the films and associated reports for five years after the closure; and
- 2. ~~Make~~ A registrant shall make films and reports available for comparison upon request for temporary or permanent transfer to other ~~mammography~~ mammographic facilities.

ARTICLE 9. PARTICLE ACCELERATORS

R12-1-902. Definitions

The following definitions apply in this Article, unless the context otherwise requires:

“Added filter” No change

“Arc therapy” No change

“Authorized medical physicist” means an individual who meets the requirements in R12-1-711. For purposes of ensuring that personnel are adequately trained, an authorized medical physicist is a “qualified expert” as defined in Article 1.

“Beam-limiting device” No change

“Beam-monitoring system” No change

“Control panel” No change

“Full beam detector” No change

“Gantry” No change

“Interlock” No change

“Isocenter” No change

“Monitor unit” No change

“Moving beam therapy” No change

“Rotational beam therapy” No change

“Skip therapy” No change

“Spot check” No change

“Stationary beam therapy” No change

“Virtual source” No change

R12-1-904. Registration of Particle Accelerators Used in the Practice of Medicine

A. No change

B. An applicant that is a “medical institution,” as defined in 12 A.A.C. 1, Article 7, and performing human research shall appoint a radiation safety committee, ~~meeting the requirements in R12-1-706.~~ that meets the following requirements:

- 1. The committee shall consist of at least four individuals and shall include:
 - a. An authorized user of each type of use permitted by the registration.
 - b. The Radiation Safety Officer.
 - c. A representative of the nursing service, and
 - d. A representative of management who is neither an authorized user nor a Radiation Safety Officer, and
 - e. Any other members the registrant selects.
- 2. The committee shall meet at least once in each 12-month period, unless otherwise specified by registration condition;
- 3. To conduct business at least 50 percent of the membership of the committee shall be present including the Radiation Safety Officer and the management representative;
- 4. The minutes of each radiation safety committee meeting shall include a reference of any discussion or documents related to the review required in R12-1-407(C);
- 5. Review the radiation safety program for all sources of radiation as required in R12-1-407(C);
- 6. Establish a table that contains investigational levels for occupational and public dose that, when exceeded, will initiate an investigation and consideration of actions by the Radiation Safety Officer; and
- 7. Establish the safety objectives of the quality management program required by subsection (E).

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- C. The applicant shall ensure that an individual designated as an authorized user ~~on the application~~ is an Arizona licensed physician; approved by the radiation safety committee, if applicable; and is:
1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 2. No change
 - a. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - b. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - v. No change
 - c. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
- D. With the application the applicant shall provide the name of each authorized user to the Agency so the names can be listed on the registration form, and so that the Agency can determine whether the authorized user's ~~the~~ training and experience ~~that~~ satisfies the requirements in subsection (C).
- E. Each registrant shall establish and maintain a written quality management program to provide high confidence that the radiation produced by the particle accelerator will be administered as directed by an authorized user. The quality management program shall include, ~~written policies and procedures to meet the specific patient safety objectives established by the Radiation Safety Officer or Radiation Safety Committee if applicable, and at minimum, contain a quality control program that addresses at minimum,~~ the tests and checks listed in Appendix A.
- F. Each registrant shall ensure that a particle accelerator ~~shall be~~ is calibrated by ~~a qualified expert~~ an authorized medical physicist meeting who meets the training and experience qualifications in ~~R12-1-716(G)~~ R12-1-711.
- G. At the time of application for registration or when a therapy program is expanded to multiple sites, each applicant or registrant shall provide the Agency with a description of the quality management program, a listing of the professional staff assigned to the facility, and the expected ratio of patient workload to staff member for programs involving multiple therapy sites. If the staffing ratio exceeds the recommended levels in Radiation Oncology in Integrated Cancer Management, Report of the Inter-Society Council for Radiation Oncology, 1986 edition, published in November 1986 December 1991, by the Inter-Society Council for Radiation Therapy, which is incorporated by reference and on file with the Agency, the applicant shall provide to the Agency for approval the justification for the larger ratio and the safety considerations that have been addressed in establishing the program. This report is incorporated by reference and available under R12-1-101. This incorporation ~~The incorporated material~~ contains no future ~~additions~~ editions or amendments. The report is available from the American Association of Physicists in Medicine: online at <http://www.aapm.org/pubs/reports>; print copies may be purchased from Medical Physics Publishing, 4513 Vernon Blvd., Madison, WI 53705; toll free at (800) 442-5778.

R12-1-905. Medical Particle Accelerator Equipment, Facility and Shielding, and Spot Checks

- A. No change
1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 2. No change
 3. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change

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- f. No change
- 4. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - i. Maintains a reading until intentionally reset to θ zero;
 - ii. No change
 - iii. No change
 - f. No change
 - g. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - v. No change
- 5. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - i. No change
 - ii. No change
- 6. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
- 7. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
- 8. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
- 9. No change
 - a. No change
 - b. No change
 - c. No change
- 10. No change
- B.** No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - 2. ~~A qualified expert~~ An authorized medical physicist, trained and experienced in the principles of radiation protection, shall perform a radiation protection survey on all installations before human use and after any change in an installation that might produce a radiation hazard. The ~~person~~ authorized medical physicist shall provide the survey results in

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writing to the individual in charge of the installation and transmit a copy of the survey results to the Agency.

3. No change
 - a. No change
 - b. No change
 - c. Calibration of a particle accelerator shall be performed by, or under the supervision of ~~a person~~ an authorized medical physicist who meets the qualification requirements specified in ~~R12-1-716(G)~~ R12-1-711, and a copy of the calibration report shall be maintained by the registrant for inspection by the Agency.
 - d. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - v. No change
 - e. Records of calibrations shall be maintained for ~~two~~ three years following the date the calibration was performed.
 - f. No change
 - i. The action taken by the ~~person~~ authorized medical physicist performing the calibration if it indicates a change has occurred since the last calibration.
 - ii. No change
 - iii. No change
- C. No change
 1. The spot check procedures shall be in writing and shall have been developed by ~~a person~~ an authorized medical physicist trained and experienced in performing calibrations.
 2. No change
 3. No change
 4. No change
 5. Records of spot checks shall be maintained and available for inspection by the Agency for three years following the spot check measurements. Records of spot checks not performed by ~~a qualified expert~~ an authorized medical physicist shall be signed by ~~a qualified expert~~ an authorized medical physicist within 15 days of the spot check.
- D. No change
 1. No change
 2. No change

R12-1-907. Shielding and Safety Design

- A. ~~A person~~ An authorized medical physicist experienced in the principles of radiation protection and installation design shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation. The registrant shall provide a copy of the installation radiation survey to the Agency before an Agency inspection conducted according to ~~R12-1-904(G)~~ R12-1-914.
- B. No change
- C. At the time of application for registration and before treatment of the first patient, the applicant shall provide to the Agency a copy of an installation report, signed by the contractor who installed required shielding material recommended by the authorized medical physicist who performed the shielding calculations for the particle accelerator facility.
- D. As part of the annual radiation protection program review required in R12-1-407(C), the registrant shall document installed facility shielding and other radiation exposure controls, review patient workload, and note associated changes, if any, in public exposure that are the result of installed facility shielding, increased workload, and other radiation exposure controls in use at the time of the review.

R12-1-910. Operating Procedures

- A. No change
- B. No change
- C. A registrant shall ensure that all safety and warning systems, including interlocks, are tested for proper operation at intervals not to exceed three months, and maintain ~~results~~ a record of each test for Agency inspection for at least three years from the date of the test.
- D. No change
- E. ~~By-pass of~~ A registrant shall not bypass an interlock is prohibited unless the by-pass is:
 1. No change
 2. No change
 3. No change
- F. No change

R12-1-911. Radiation Surveys

- A. No change

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- B. ~~A person experienced in the principles of radiation protection and installation design~~ An authorized medical physicist shall:
1. No change
 2. No change
 3. No change
 4. No change
- C. No change
1. Radiation protection surveys required in subsection (B)(2), and the associated facility description, required in ~~R12-1-202(E)~~ R12-1-202, until the registration is terminated; and
 2. No change

R12-1-913. Misadministration

- A. No change
1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 2. No change
- B. No change
1. No change
 2. No change
 - ~~3. Records of misadministration shall be maintained according to R12-1-708(C).~~
 3. Each registrant shall maintain records of all misadministrations for Agency inspection. The records shall:
 - a. Contain the names of all individuals involved in the event, including:
 - i. The physician.
 - ii. The allied health personnel.
 - iii. The patient.
 - iv. The patient's referring physician.
 - v. The patient's identification number if one has been assigned.
 - vi. A brief description of the event.
 - vii. The effect on the patient, and
 - viii. The action taken to prevent recurrence.
 - b. Be maintained for three years beyond the termination date of the affected registration.

Appendix A. Quality Control Program

- A. No change
1. No change
 2. No change
 3. No change
 4. No change
 5. No change
 6. No change
 7. No change
 8. No change
- B. No change
1. No change
 2. No change
 3. No change
 4. No change
 5. No change
 6. No change
 7. No change
 8. No change
 9. No change
- C. No change
1. No change
 2. No change
 3. No change
 4. No change

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- 5. No change
- 6. No change
- 7. No change
- 8. No change
- D. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
- E. No change
 - 1. Each registrant shall use the services of a third party ~~qualified expert~~ authorized medical physicist or third party TLD system to verify the accelerator's radiation output every two years.
 - 2. No change
 - 3. No change
- F. No change
 - 1. No change
 - 2. No change

ARTICLE 11. INDUSTRIAL USES OF X-RAYS, NOT INCLUDING ANALYTICAL X-RAY SYSTEMS

R12-1-1142. Baggage and Package Inspection Systems

- A. For x-ray systems designed to screen carry-on baggage or packages at airlines, railroads, bus terminals, package inspection facilities, or similar facilities, a registrant shall ~~station the operator at the control area in a position that permits surveillance of the ports and doors during generation of x-radiation~~ ensure the x-ray system has an operator present at the control area in a position that permits surveillance of the ports and doors during generation of x-radiation to prevent exposure to passengers and other members of the public.
- B. No change
- C. No change
- D. A registrant shall operate a baggage or package inspection system according to the manufacturer's instructions.
- E. A registrant shall not disconnect or otherwise tamper with the safety systems of a baggage or package inspection system, except for maintenance purposes.
- F. In addition to the requirements in this Section, a registrant using a baggage or package inspection system shall meet the requirements in R12-1-1140(A), (B), and (D).

ARTICLE 12. ADMINISTRATIVE PROVISIONS

R12-1-1215. License and Registration Divisions

- A. No change
 - 1. No change
 - 2. Division II licenses and registrations:
 - Broad Industrial Class B
 - Broad Industrial Class C
 - Class B Industrial Radiofrequency Facility
 - Class B Laser Facility
 - Class C Industrial Radiofrequency Facility
 - Fixed Gauge Class B
 - Health Physics Class A
 - Industrial Radiation Machine
 - Industrial Radiography Class B
 - Laser Light Show
 - Limited Academic
 - ~~Medical Laser~~ Medical Imaging Facility
 - ~~Medical Materials Class B~~ Medical Laser
 - ~~Medical Radiofrequency Device Facility~~ Medical Materials Class B
 - ~~NORM Commercial Disposal Site~~ Medical Radiofrequency Device Facility
 - ~~Medical Imaging Facility~~ NORM Commercial Disposal Site
 - Research and Development
 - Self Shielded Irradiator
 - Tanning Facility
 - Waste Processor Class B
 - X-Ray Machine Class B

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3. Division III licenses and registrations:
~~Class A Laser Facility~~ Class A Industrial Radiofrequency Facility
~~Class A Industrial Radiofrequency Facility~~ Class A Laser Facility
~~Depleted Uranium~~
Gas Chromatograph
General Depleted Uranium
General Industrial
General Medical
General Veterinary Medicine
Health Physics Class B
Laboratory
Leak Detector
Limited Industrial
Medical Materials Class C
Other Ionizing Radiation Machine
Other Nonionizing Radiation Machine
Portable Gauge
Possession Only
Radioactive waste transfer-for-disposal
Unclassified
Veterinary Medicine
X-ray Machine Class C

- B. No change
C. No change
D. No change
1. No change
2. No change
3. Any person not required to register a source of radiation who violates the Act or 12 A.A.C. 1; and
4. No change

ARTICLE 14. REGISTRATION OF NONIONIZING RADIATION SOURCES AND STANDARDS FOR PROTECTION AGAINST NONIONIZING RADIATION

R12-1-1401. Registration of Nonionizing Radiation Sources and Service Providers

- A. No change
B. A person who possesses a nonexempt nonionizing source shall submit to the Agency an application for registration ~~at least 30 days before~~ within 30 days of its first use.
1. No change
2. No change
3. No change
C. No change
D. No change
E. No change
F. No change

ARTICLE 15. TRANSPORTATION

R12-1-1502. Definitions

Terms defined in Article 1 have the same meaning when used in this Article. ~~Federal regulations incorporated by reference in this Article are on file at the Agency and the Office of the Secretary of State.~~

R12-1-1503. ~~Repealed~~ Transportation of Licensed Material

Each licensee that transports licensed material outside the site of usage, as specified in an Agency license, or where transport is on public highways, or that delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the U.S. Department of Transportation regulations listed in 10 CFR 71.5, revised January 1, 2008, incorporated by reference and available under R12-1-101. This incorporated material contains no future editions or amendments.

R12-1-1504. Intrastate Transportation and Storage of Radioactive Materials

- A. No change
1. Any common or contract carrier not exempt under R12-1-103 to receive, possess, transport, and store radioactive material in the regular course of carriage for others or to store radioactive material incident to the transport activities, provided the transportation or storage is in accordance with applicable requirements for the mode of transport of the

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U.S. Department of Transportation, 49 CFR 171 through 180, revised October 1, 2003 ~~2007~~, ~~which are~~ incorporated by reference, and available under R12-1-101 on file with the Agency. This ~~incorporation~~ incorporated material by reference contains no future editions or amendments.

2. Any private carrier or licensee who transports and stores radioactive material, provided the transportation and storage are in accordance with the requirements applicable to the mode of transport, of the U.S. Department of Transportation, 49 CFR 171 through 180, revised October 1, 2003 ~~2007~~, ~~which are~~ incorporated by reference, ~~and on file with the Agency~~ and available under R12-1-101. This ~~incorporation by reference~~ incorporated material contains no future editions or amendments.

B. No change

C. No change

R12-1-1505. Storage of Radioactive Material in Transport

A. No change

B. A carrier shall not store a package that contains radioactive material with other hazardous materials, except as authorized by U.S. Department of Transportation regulations in 49 CFR 177.848, ~~2000 Edition, published~~ revised October 1, 2000 ~~2007~~, incorporated by reference, ~~and available under R12-1-101, and on file with the Agency and the Office of the Secretary of State~~, This incorporated material containing contains no future editions or amendments.

C. No change

D. No change

1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - g. No change
 - h. No change
2. No change
3. No change

R12-1-1506. Preparation of Radioactive Material for Transport

A licensee shall not deliver any package that contains radioactive material to a carrier for transport or transport radioactive material, unless the licensee:

1. Complies with the U.S. Department of Transportation packaging, monitoring, manifesting, marking, and labeling requirements regulations applicable to the mode of transport, ~~of the U.S. Department of Transportation, (Contained in 49 CFR 171 through 180, revised October 1, 2003 2007, or 39 CFR 111.1, revised July 1, 2003 2007, both of which are incorporated by reference, and on file with the Agency available under R12-1-101. This incorporation incorporated material~~ contains no future editions or amendments.); and
2. No change
3. No change
 - a. No change
 - b. No change

R12-1-1507. Packaging Quality Assurance

A. A licensee that transports radioactive material in the course of business or delivers radioactive material to a carrier for transport in a package for which a license, certificate of compliance, or other approval has been issued by the Nuclear Regulatory Commission, or meets the applicable criteria ~~specified in (10 CFR 71, 2001 Edition, published January 1, 2001, incorporated by reference and on file with the Agency and the Office of Secretary of State, shall have, maintain, Subpart H, revised January 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.)~~, shall establish, maintain, and execute the quality assurance program specified in 10 CFR 71, Subpart H. ~~This incorporation by reference contains no future editions or amendments.~~

B. No change

C. No change

D. No change

R12-1-1508. Advance Notification of Nuclear Waste Transportation

A. No change

B. No change

1. No change
2. A description of the nuclear waste contained in the shipment as required by 49 CFR 172.202 and 172.203(d), ~~2001~~

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~~Edition, published (Revised October 1, 2004, 2007, incorporated by reference, and on file with the Agency available under R12-1-101 and the Office of the Secretary of State. This incorporation by reference incorporated material contains no future editions or amendments.);~~

3. No change
 4. No change
 5. No change
 6. No change
- C. No change
D. No change

R12-1-1509. Reserved

R12-1-1510. Packaging

- A.** A general license is issued to any licensee to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance, or other approval has been issued by the NRC.
1. This general license applies only to a licensee that has a quality assurance program approved by the Agency as satisfying R12-1-1507;
 2. This general license applies only to a licensee that:
 - a. Has a copy of the license, certificate of compliance, or other approval of the package, and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment;
 - b. Complies with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of this Article; and
 - c. Before the licensee's first use of the package, submits in writing to the Agency the licensee's name, license number, and the package identification number specified in the package approval.
 3. This general license applies only when the package approval authorizes use of the package under this general license.
 4. For a Type B or fissile material package, the design of which was approved by NRC before April 1, 1996, the general license is subject to the additional restrictions of subsection (B).
- B.** Type B packages.
1. A Type B package previously approved by NRC but not designated as B(U) or B(M) in the identification number of the NRC Certificate of Compliance, may be used under the general license of subsection (A) with the following additional conditions:
 - a. Fabrication of the packaging is satisfactorily completed by August 31, 1986, as demonstrated by application of its model number in accordance with 10 CFR 71.85(c) (Revised January 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.);
 - b. A package that is used for a shipment to a location outside the United States is subject to multilateral approval, as defined in 49 CFR 173.403 (Revised October 1, 2007, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.); and
 - c. A serial number that uniquely identifies each package which conforms to the approved design and is assigned to, and legibly and durably marked on, the outside of each package.
 2. A Type B(U) package, a Type B(M) package, a low specific activity (LSA) material package or a fissile material package, previously approved by the NRC but without the "-85" designation in the identification number of the NRC certificate of compliance, may be used under the general license of subsection (A) with the following additional conditions:
 - a. Fabrication of the packaging is satisfactorily completed by April 1, 1999 as demonstrated by application of its model number in accordance with 10 CFR 71.85(c) (Revised January 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.);
 - b. A package that is used for a shipment to a location outside the United States is subject to multilateral approval as defined in 49 CFR 173.403 (Revised October 1, 2007, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.); and
 - c. A serial number which uniquely identifies each package which conforms to the approved design and is assigned to, and legibly and durably marked on, the outside of each package.
 3. A licensee may modify the design and authorized contents of a Type B package, or a fissile material package, previously approved by NRC, provided:
 - a. The modifications of a Type B package are not significant with respect to the design, operating characteristics, or safe performance of the containment system, when the package is subjected to the tests specified in 10 CFR 71.71 and 71.73 (Revised January 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.);
 - b. The modifications of a fissile material package are not significant, with respect to the prevention of criticality, when the package is subjected to the tests specified in 10 CFR 71.71 and 71.73 (Revised January 1, 2008, incor-

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porated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.); and

c. The modifications to the package satisfy the requirements of this Section.

4. The NRC will revise the package identification number to designate previously approved package designs as B(U), B(M), AF, BF, or A as applicable, and with the identification number suffix “-85” after receipt of an application demonstrating that the design meets the requirements of this Section.

5. For purposes of this Section, package types are defined in 10 CFR 71.4, revised January 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.

C. A general license is issued to any licensee of the Agency to transport fissile material, or to deliver to a carrier for transport, licensed material in a specification container for fissile material or for a Type B quantity of radioactive material as specified in 49 CFR 173 and 178 (Revised October 1, 2007, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.), if the following requirements are met:

1. The licensee shall maintain a quality assurance program approved by the Agency as satisfying R12-1-1507.

2. The licensee shall:

a. Maintain a copy of the specification; and

b. Comply with the terms and conditions of the specification and the applicable requirements in 10 CFR 71, Subparts A, G, and H, revised January 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.

3. The licensee may not use the specification container for a shipment to a location outside the United States, except by multilateral approval, as defined in 49 CFR 173.403, revised October 1, 2007, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.

D. Foreign packaging.

1. A general license is issued to any licensee of the Agency to transport, or to deliver to a carrier for transport, licensed material in a package the design of which has been approved in a foreign national competent authority certificate that has been revalidated by the Federal Department of Transportation as meeting the applicable requirements of 49 CFR 171.12, revised October 1, 2007, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.

2. Except as otherwise provided in this Section, the general license applies only to a licensee who has a quality assurance program approved by the Agency as satisfying the applicable provisions of R12-1-1507.

3. This general license applies only to:

a. Shipments made to or from locations outside the United States.

b. A licensee that:

i. Has a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate, relating to the use and maintenance of the packaging and to the actions to be taken before shipment; and

ii. Complies with the terms and conditions of the certificate and revalidation, and with the applicable requirements in 10 CFR 71, Subparts A, G, and H, revised January 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments. With respect to the quality assurance provisions of Subpart H of the regulations, the licensee is exempt from design, construction, and fabrication requirements.

R12-1-1511. Air Transport of Plutonium

A. Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this Section or included indirectly by citation of 49 CFR 107, and 171 through 180, previously incorporated in this Article, as may be applicable, the licensee shall ensure that plutonium in any form, whether for import, export, or domestic shipment, is not transported by air or delivered to a carrier for air transport unless:

1. The plutonium is contained in a medical device designed for individual human application; or

2. The plutonium is contained in a material in which the specific activity is less than or equal to the activity concentration values for Plutonium specified in 10 CFR 71, Appendix A, Table A-2 (Revised January 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.), and in which the radioactivity is essentially uniformly distributed; or

3. The plutonium is shipped in a single package containing no more than an A2 quantity of plutonium in any isotope or form, and is shipped in accordance with R12-1-1503 and 10 CFR 71.5 (Revised January 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.); or

4. The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the NRC.

B. Nothing in subsection (A) is to be interpreted as removing or diminishing the requirements of 10 CFR 73.24, January 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.

C. For a shipment of plutonium by air that is subject to subsection (A)(4), the licensee shall, through special arrangement

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with the carrier, require compliance with 49 CFR 175.704, revised October 1, 2007, incorporated by reference, and available under R12-1-101. This U.S. Department of Transportation regulation is applicable to the air transport of plutonium. This incorporated material contains no future editions or amendments.

R12-1-1512. Advance Notification of Shipment of Irradiated Reactor Fuel and Nuclear Waste

A licensee shall provide advance notification to the Governor, or the Director of the Agency, of the shipment of licensed material as specified in 10 CFR 71.97, revised January 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.

R12-1-1513. Reserved

R12-1-1514. Reserved

R12-1-1515. Exemption for Low-level Radioactive Materials

A licensee is exempt from all the requirements of 10 CFR 71 with respect to shipment or carriage of the low-level materials listed in 10 CFR 71.14(a), revised January 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.

ARTICLE 17. WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

R12-1-1713. Transportation ~~precautions~~ Precautions

Each licensee shall ensure that ~~Transport~~ transport containers shall be ~~are~~ physically secured ~~to~~ in the transporting vehicle to prevent accidental movement, loss, tampering, or unauthorized removal.