ARIZONA
RADIATION REGULATORY AGENCY

Janet Napolitano
Governor

Aubrey V. Godwin
Director

4814 South 40th Street **Phoenix, Arizona 85040-2940** **(602) 255-4845**
Fax (602) 437-0705

February 14, 2007

William Rautzen, Regulation Project Mgr.
Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike, 3rd Floor
Rockville, MD 20852

Dear Mr. Rautzen:

Enclosed is a copy of the ARRA rules contained in RMP-0061. A public hearing is scheduled for May 29, 2007. Any nonsubstantive changes that your office feels should be made must be received by that date to be included in the package. Any substantive changes may have to be made at a later date.

The Agency believes that adoption of the rules in this package satisfies all of the compatibility and health/safety issues addressed in your office's previous letter. If you have any questions, please feel free to contact me.

The following is a listing of the compatibility changes in RMP-0061.

AZ Rule	RATS ID	NRC Section
R12-11504	1996-1	71.5
R12-1-1510(D)	1996-1	71.21
R12-1-1511	1996-1	71.88
R12-1-1512	1996-1	71.97
R12-1-1513	1996-1	71.12
R12-1-1514	1996-1	71.13
R12-1-1515	1996-1	71.14
The definition of "person" is in Arizona law.		150.3 (g)

The new source tracking rules are located in the following Sections
R12-1-311(N), Definitions in R12-1-403, and R12-1-454

Sincerely,

Daniel H. Kuhl
State Health Physicist
Rule Writer
dkuhl@azarra.gov

Enclosures

NOTICE OF PROPOSED RULE MAKING

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

PREAMBLE

1. Sections Affected — Rule making Action

Sections Affected	Rule making 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
R12-1-306	Amend
R12-1-311	Amend
R12-1-324	Amend
R12-1-403	Amend
R12-1-419	Amend
R12-1-422	Amend
R12-1-431	Amend

1	R12-1-432	Amend
2	R12-1-434	Amend
3	R12-1-435	Amend
4	R12-1-438	Amend
5	R12-1-440	Amend
6	R12-1-443	Amend
7	R12-1-446	Amend
8	R12-1-447	Amend
9	R12-1-448	Amend
10	R12-1-449	Amend
11	R12-1-454	New Section
12	R12-1-602	Amend
13	R12-1-603	Amend
14	R12-1-604	Amend
15	R12-1-605	Amend
16	R12-1-606	Amend
17	R12-1-607	Amend
18	R12-1-608	Amend
19	R12-1-610	Amend
20	R12-1-611	Amend
21	R12-1-612	Amend
22	R12-1-614	Amend

1	R12-1-902	Amend
2	R12-1-904	Amend
3	R12-1-905	Amend
4	R12-1-907	Amend
5	R12-1-910	Amend
6	R12-1-911	Amend
7	R12-1-913	Amend
8	Appendix A	Amend
9	R12-1-1142	Amend
10	R12-1-1215	Amend
11	R12-1-1401	Amend
12	R12-1-1502	Amend
13	R12-1-1503	New Section
14	R12-1-1504	Amend
15	R12-1-1505	Amend
16	R12-1-1506	Amend
17	R12-1-1507	Amend
18	R12-1-1508	Amend
19	R12-1-1510	New Section
20	R12-1-1511	New Section
21	R12-1-1512	New Section
22		

R12-1-1513	New Section
R12-1-1514	New Section
R12-1-1515	New Section
R12-1-1713	Amend

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

General:

A.R.S. § 30-654(B)

Specific:

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

3. A list of all previous notices appearing in the *Register* addressing the proposed rules:

Notice of Docket Opening, 11 A.A.R. ____, _____ (Published in this issue)

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

Name: Daniel H. Kuhl

Address: Arizona Radiation Regulatory Agency
4814 South 40th Street
Phoenix, Arizona 85040

Telephone: (602) 255-4845 ext. 233

Fax: (602) 437-0705

E-mail: dkuhl@azrra.gov

5. <u>An explanation of the rules, including the Agency's reasons for initiating the rule:</u>

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

The second group of changes include those made at the request of Agency staff. These changes arise from reviews that discover discrepancies or changes needed as a result of a rulemaking oversight, or because earlier rulemaking has resulted in incorrect language or an incorrect reference in the rule under going the five-year review.

The third group consists of changes recommended by the staff that will bring the x-ray rules in Article 6 up to current standards. Included are minor changes that are needed after comparing the rules in Article 6 to similar rules published by the Conference of Radiation Control Program Directors (CRCPD).

The fourth group of changes are requested revisions placed on the Agency 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 is the NRC requirement 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.

A second group of NRC required-changes effects those 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.

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

None

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

Not applicable

8. **The preliminary summary of the economic, small business, and consumer impact:**

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 potential for change resulting from the very unstable world political environment resulting in the 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.

9. **The name and address of Agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:**

Name: Daniel H. Kuhl, State Health Physicist II

Address: Arizona Radiation Regulatory Agency

4814 South 40th Street

Phoenix, Arizona 85040

Telephone: (602) 255-4845 ext. 233

Fax: (602) 437-0705

E-mail: dkuhl@azrra.gov

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rules or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rules:

An oral proceeding at the Agency is scheduled for Tuesday, May 28, 2007, at 10:00 A.M. The directions to the Agency may be obtained by calling (602)255-4845. A person may submit written comments concerning the proposed rules by submitting them to the Agency no later than 5 P.M., on May 28, 2007, to the following person:

Name:	Aubrey V. Godwin, Director
Location:	Arizona Radiation Regulatory Agency
Address:	4814 South 40 the Street
	Phoenix, Arizona 85040
Telephone:	(602) 255-4845
Fax:	(602) 437-0705

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

None

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

Rule	Incorporation
R12-1-101	NRC Agreement

R12-1-102	
"A_2"	10CFR 71.137
"Certifiable cabinet x-ray system"	21CFR 1020.40
"Certified cabinet x-ray system"	21CFR 1010.2
"Generally applicable environmental radiation Standard"	40CFR 190 and 191
"Major processor"	10CFR 71.4
"Nuclear waste"	49CFR 173.403
"Regulations of the U.S. Department of Transportation"	49 CFR 100 through 199
"Special form radioactive material"	10CFR 71
R12-1-103	49CFR 107.109, 107.111, 107.113, 171.2, 171.3, 172.200, 173.1, 173.3, 173.4, 173.401, 175.3, 175.5, 175.10, 176.3, 176.5, 176.11, 176.24, 176.27, and 177.801
	39CFR 111.1
R12-1-206(C)	21CFR 1020.30(d)
R12-1-306(B)(1)	10CFR 31(b), (c), and (d)
R12-1-311(N)(1)	10CFR 32.201
R12-1-403	
"Nationally tracked source"	10CFR 20, Appendix E
R12-1-432(4)	49CFR 173.403, 173,421 through 173-424

	49CFR 172.436 through 172.440
R12-1-454(A)	10CFR 20.2207(a) through (e)
	10CFR 20.2207(f)
R12-1-454(B)	10CFR 20.2207(g)
R12-1-454(C)	10CFR 20.2207(f) and (h)(1) through (2)
R12-1-603(C)(2)	NCRP Report 147 "Structural Shielding Design for Medical X-ray Imaging Facilities"
R12-1-614(A)(5)	AAPM Report 29, Table 3-3
R12-1-614(A)(5)	"Mammography Quality Control" by the American College of Radiology
R12-1-614(B)(2)	21CFR 900..12(d)(1); (e)(2)(i), (ii), and (iii); (e)(3); (e)(4); (e)(5)(i), (ii), (iii)(A), (iv), (v), (vi), and (vii)(B) and (C), (viii), (ix), (x); (e)(8)(ii); (e)(9)(ii); and (e)(10)
R12-1-614(C)(1)(a)	21CFR 900.12(a)(1)(i) and (ii)(A) and (B)
R12-1-614(C)(1)(b)	21CFR 900.12(a)(2)(i)(B),(ii), and (iii)
R12-1-614(C)(1)(c)	21CFR 900.12(a)(3)(i) and (iii)
	21 CFR 900.12(a)(4)
R12-1-904(G)	ISCRT Report "Radiation Oncology in Integrated Cancer Management"
R12-1-1503	10CFR 71.5

1	R12-1-1504(A)(2)	49CFR 171 through 180
2	R12-1-1505(B)	49CFR 177.848
3	R12-1-1506(1)	49CFR 171 through 180
4	R12-1-1507(A)	10CFR 71, subpart H
5	R12-1-1508(B)	49CFR 172.202 and 172.203(d)
6	R12-1-1510(B)(1)(a)	10CFR 71.85(c)
7	R12-1-1510(B)(1)(b)	49CFR 173.403
8	R12-1-1510(B)(2)(a)	10CFR 71.85(c)
9	R12-1-1510(B)(2)(b)	49CFR 173.403
10	R12-1-1510(B)(3)(a)	10CFR 71.71 and 71.73
11	R12-1-1510(B)(3)(b)	10CFR 71.71 and 71.73
12	R12-1-1510(B)(5)	10CFR 71
13	R12-1-1510(C)	49CFR 173 and 178
14	R12-1-1510(C)(2)(b)	10CFR 71 subparts A, G, and H
15	R12-1-1510 (C)(3)	49CFR 173.403
16	R12-1-1510(D)(1)	49CFR 171.12
17	R12-1-1510(D)(3)(b)(ii)	10CFR 71 subparts A, G, and H
18	R12-1-1511(B)	10CFR 73.24
19	R12-1-1511(C)	49CFR 175.714
20	R12-11512	10CFR 71.97
21	R12-1-1515	10CFR 71.14
22		

13. The full text of the rules follows:

ARTICLE 1. GENERAL PROVISIONS

Section

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

Section

ARTICLE 3. RADIOACTIVE MATERIAL LICENSING

Section

ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

Section

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

Section

ARTICLE 9. PARTICLE ACCELERATORS

Section

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

Section

ARTICLE 12. ADMINISTRATIVE PROVISIONS

Section

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

R12-1-1510. 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. Reserve

R12-1-1514. Reserve

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

ARTICLE 17. WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

Section

R12-1-1713. Transportation precautions

ARTICLE 1. GENERAL PROVISIONS

R12-1-101. Scope

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~~ which is incorporated by reference and on file with the Agency. This incorporation by reference contains no future editions or references:

R12-1-102 Definitions

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

"A_1" No change

"A_2 " means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are either listed in 10 CFR 71.137, Appendix A, Table A-1, or may be derived in accordance with the procedure prescribed in 10 CFR 71.137, Appendix A, ~~2001 Edition, published~~ January 1, ~~2001~~ 2007, incorporated by reference and on file with the Agency ~~and the Office of the Secretary of State~~. This incorporation by reference 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

1	"Bioassay"	No change
2	"Brachytherapy"	No change
3	"By-product material"	No change
4	"Calendar quarter"	No change
5	"Calibration"	No change

6 "Certifiable cabinet x-ray system" means an existing uncertified x-ray system that meets or has
7 been modified to meet the certification requirements specified in 21 CFR 1020.40, ~~2001 Edition,~~
8 ~~published~~ April 1, ~~2001~~ 2007, incorporated by reference and on file with the Agency ~~and the~~
9 ~~Office of Secretary of State~~. This incorporation by reference contains no future editions or
10 amendments.
11 "Certified cabinet x-ray system" means an x-ray system that has been certified in accordance with
12 21 CFR 1010.2, as being manufactured and assembled on or after April 10, 1975, in accordance
13 with the provisions of 21 CFR 1020.40, both references ~~2001 Edition, published~~ April 1, ~~2001~~
14 2007, incorporated by reference and on file with the Agency ~~and the Office of Secretary of State~~.
15 These incorporations by reference contain no future editions or amendments.

16	"CFR"	No change
17	"Chelating agent"	No change
18	"Civil penalty"	No change
19	"Collective dose"	No change
20	"Committed dose equivalent"	No change
21	"Committed effective dose equivalent"	No change
22	"Curie"	No change

1	"Current license or registration"	No change
2	"Deep-dose equivalent"	No change
3	"Depleted uranium"	No change
4	"Dose"	No change
5	"Dose equivalent "	No change
6	"Dose limits"	No change
7	"Dosimeter"	No change
8	"Effective dose equivalent"	No change
9	"Effluent release"	No change
10	"Embryo/fetus"	No change
11	"Enclosed beam x-ray system"	No change
12	"Enclosed radiography"	No change
13	"Cabinet radiography"	No change
14	"Shielded room radiography"	No change
15	"Entrance or access point"	No change
16	"Exhibit"	No change
17	"Explosive material"	No change
18	"Exposure"	No change
19	"Exposure rate"	No change
20	"External dose"	No change
21	"Extremity"	No change
22	"Fail-safe characteristics"	No change

1	"Field radiography"	No change
2	"Field station"	No change
3	"Former U.S. Atomic Energy Commission (AEC)	
4	or U.S. Nuclear Regulatory Commission (NRC)	
5	licensed facilities"	No change

6 "Generally applicable environmental radiation standards" means standards issued by the U.S.
7 Environmental Protection Agency (EPA), 40 CFR 190 and 191, ~~2001 Edition, published~~ July 1,
8 ~~2001~~ 2006, incorporated by reference and on file with the Agency ~~and the Office of the Secretary~~
9 ~~of State~~, under the authority of the Atomic Energy Act of 1954, as amended, that impose limits
10 on radiation exposures or levels, or concentrations or quantities of radioactive material, in the
11 general environment outside the boundaries of locations under the control of persons possessing
12 or using radioactive material. This incorporation by reference contains no future editions or
13 amendments.

14	"Gray"	No change
15	"Hazardous waste"	No change
16	"Healing arts"	No change
17	"Health care institution"	No change
18	"High radiation area"	No change
19	"Human use"	No change
20	"Impound"	No change
21	"Individual"	No change
22	"Individual monitoring"	No change

1	"Individual monitoring device" or	
2	"individual monitoring equipment"	No change
3	"Industrial radiography"	No change
4	"Injection tool"	No change
5	"Inspection"	No change
6	"Interlock"	No change
7	"Internal dose"	No change
8	"Irradiate"	No change
9	"Laser"	No change
10	"Lens dose equivalent"	No change
11	"License"	No change
12	"Licensed material"	No change
13	"Licensed practitioner"	No change
14	"Licensee"	No change
15	"Licensing State"	No change
16	"Limits"	No change
17	"Local components"	No change
18	"Logging supervisor"	No change
19	"Logging tool"	No change
20	"Lost or missing licensed or registered source of	
21	radiation"	No change
22	"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~~ January 1, ~~2001~~ 2007, incorporated by reference and on file with the Agency ~~and the Office of the Secretary of State~~. This incorporation by reference contains no future editions or amendments.

"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~~ October 1, ~~2001~~ 2006, incorporated by reference and on file with the Agency ~~and the Secretary of State~~, containing no future editions or amendments) 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~~ R12-1-717, 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
"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~~ R12-1-717, 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

1	"Registration"	No change

2 "Regulations of the U.S. Department of Transportation" means the federal regulations in 49 CFR
3 100 through 199, ~~1995 Edition, published~~ October 1, ~~1995~~ 2006, incorporated by reference and
4 on file with the Agency ~~and the Office of the Secretary of State~~. This incorporation by reference
5 contains no future editions or amendments.

6	"Rem"	No change
7	"Research and Development"	No change
8	"Restricted area"	No change
9	"Roentgen"	No change
10	"Safety system"	No change
11	"Sealed source"	No change
12	"Sealed Source and Device Registry"	No change
13	"Shallow-dose equivalent"	No change
14	"Shielded position"	No change
15	"Sievert"	No change
16	"Site boundary"	No change
17	"Source changer"	No change
18	"Source holder"	No change
19	"Source material"	No change
20	"Source material milling"	No change
21	"Source of radiation" or "source"	No change

22 "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, ~~2000 Edition, published~~ January 1, ~~2000~~ 2007, incorporated by reference in this rule and on file with the Agency ~~and the Office of the Secretary of State~~. This incorporation by reference 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, 175.5, 175.10, 176.3, 176.5, 176.11, 176.24, 176.27, and 177.801, ~~2000 Edition, published~~ October 1, ~~2000~~2006, of the U.S. Department of Transportation, or 39 CFR 111.1 of the U.S. Postal Service, ~~2001 Edition, published~~ January 1, ~~2001~~2007, incorporated by reference and on file with the Agency ~~and the Office of the Secretary of State~~, and if need be, store radioactive material, for periods of less than 72 hours, in the regular course of their carriage for another, are exempt from this Chapter. The above incorporation by ~~reference~~ references contains 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 (1.55 in.~~2~~ ²) does not exceed ~~129μC/kg per hour~~ 5 μSv (0.5 milliroentgen ~~per hour~~) per hour at 5 cm (2.0 in.). ~~The production, testing, or factory servicing of electronic equipment that produces X-radiation incident 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 these rules, install includes selling and servicing, or offering to sell or service, x-ray machines in Arizona.

B. No change

~~B~~C. ~~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. A Notice of Registration, or certificate issued according to R12-1-204 and 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.

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), 2000 Edition, published April 1, 2000 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.~~ , 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), April 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. This

incorporation by reference 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)(2).

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~~ ,9 and 11	Appropriate fee listed in Article 13 schedule

ARTICLE 3. RADIOACTIVE MATERIAL LICENSING

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 firms; a research, educational or medical; 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 (c)~~ (b), (c), and (d), January 1, ~~2005~~ 2007, 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. The 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)(i)~~ (4)(k).

3. No change

a. No change

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. No change

d. No change

e. No change

i. No change

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. No change

p. No change

q. No change

i No change

ii. No change

iii. No change

iv. No change

v. No change

vi. No change

r. No change

s. No change

5. No change

6. No change

C. No change

1. No change

2. No change

a. No change

b. No change

c. No change

d. No change

D. No change

1.

2.

a. No change

b. No change

i. No change

ii. No change

c. No change

d. No change

e. No change

3. No change

E. No change

1. No change

2. No change

3. No change

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. No change

g. No change

2. No change

a. No change

b. No change

3. No change

a. ~~No change~~

b. No change

c. No change

d. No change

e. No change

4. No change

a. No change

b. No change

i. No change

ii. No change

5. No change

a. No change

b. No change

6. No change

G. No change

1. No change

2. No change

3. No change

4. No change

5. No change

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

A. No change

1. No change

a. No change

b. No change

2. No change

a. No change

i. No change

ii. No change

iii. No change

iv. No change

v. No change

b. No change

c. No change

d. No change

e. No change

f. No change

g. No change

h. No change

i. No change

ii. No change

iii. No change

iv. No change

v. No change

vi. No change

i. No change

j. No change

k. No change

l. No change

m. No change

3. 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

c. No change

i. No change

ii. No change

d. No change

i. No change

ii. No change

iii. No change

3. No change

C. No change

1. No change

2. No change

D. No change

1. No change

a. No change

b. No change

i. No change

ii. No change

iii. No change

c. No change

d. No change

i. No change

ii. No change

iii.

e. No change

f. No change

2. 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

i. No change

j. No change

3. No change

4. 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

iii. No change

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. No change

i. No change

ii. No change

iii. No change

iv. No change

v. No change

b. No change

c. No change

i. No change

ii. No change

iii. No change

iv. No change

d. No change

e. No change

f. No change

g. No change

9. No change

E. No change

1. No change

2. No change

F. No change

1. No change

2. No change

G. No change

1. No change

2. No change

a. No change

b. No change

H. No change

1. No change

2. No change

a. No change

b. No change

c. No change

d. No change

e. No change

f. No change

g. No change

3. No change

a. No change

b. No change

4. No change

a. No change

b. No change

5. No change

I. No change

1. No change

2. No change

J. No change

1. No change

a. No change

b. No change

i. No change

ii. No change

c. No change

d. No change

e. No change

2. No change

K. 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. No change

1. No change

2. 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

i. No change

j. No change

M. No change

1. No change

a. No change

b. No change

c. No change

2. No change

3. No change

4. No change

a. No change

b. No change

i. No change

ii. No change

c. No change

d. No change

e. No change

f. No change

i. No change

ii. No change

iii. No change

iv. No change

v. No change

vi. No change

N. A licensee who manufacturers nationally tracked sources, as defined in Article 4, shall:

1. Serialize the sources in accordance with 10CFR 32.201, January 1, 2007, which is incorporated by reference, published by the Office of Federal Register, National

Archives and Records Administration, Washington D.C., and on file with the Agency (This incorporation by reference contain no future editions or amendments); and

2. Report manufacturing activities in accordance with R12-1-454.

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(D).
2. No change

ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

R12-1-403. Definitions

"Air-purifying respirator" No change

"ALI" No change

Assigned protection factor (APF)" No change

"Atmosphere-supplying respirator" No change

"Class" No change

"Critical group" No change

"DAC" No change

"DAC-hour" No change

"Declared pregnant woman" No change

"Demand respirator" No change

"Deterministic effect" [see " nonstochastic effect"] No change

"Disposable respirator" No change

"Dosimetry processor" No change

"Filtering face piece (dust mask)" No change

"Fit test" No change

"Helmet" No change

"Hood" No change

"Inhalation class" [see "Class"] No change

"Loose-fitting face piece" No change

"Lung class" [see "Class"] No change

"Nationally tracked source" means a sealed source containing a quantity equal to or greater than Category 1 or category 2 levels of radioactive material listed in Appendix E in 10CFR20. January 1, 2007, which is incorporated by reference, published by the Office of Federal Register, National

Archives and Records Administration, Washington D.C., and on file with the Agency. This incorporation by reference contain no future editions or amendments.

"Negative pressure respirator (tight fitting)" No change

"Positive pressure respirator" No change

"Powered air-purifying respirator (PAPR)" No change

"Pressure demand respirator" No change

"Probabilistic effect" [see "Stochastic effect"] No change

"Qualitative fit test (QLFT)" No change

"Quantitative fit test (QNFT)" No change

"Reference Man" No change

"Respiratory protective equipment" No change

"Sanitary sewerage" No change

"Self-contained breathing apparatus (SCBA)" No change

"Stochastic effect" No change

"Supplied-air respirator (SAR) or airline respirator" No change

"Tight-fitting face piece" No change

"User seal check (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 on their extremities during the operation of an open-beam or hand-held analytical x-ray machine with no safety devices or if service is performed in the primary beam of the analytical x-ray machine, as described in R12-1-806(D).

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 for the dose to an embryo or fetus of a declared pregnant woman, according to R12-1-415(A), shall be located under the protective apron at the waist. A qualified expert shall be consulted to determine the dose to the embryo or fetus for the rare occasion in which this individual monitoring device has a monthly reported dose equivalent value in excess of 0.5 mSv (50 mrem). For purposes of these rules, the value to be used for determining the dose to an embryo or fetus according to R12-1-415(C)(1), 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), it 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. (Note: The second individual monitoring device is required for a declared pregnant woman.)

~~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 (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.

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 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

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~~ October 1, ~~1999~~ 2006, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and ~~;~~ , 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;

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. 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~~ container is 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 containing licensed material from other persons, a persons 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 disposal proposed 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

R12-1-438. Disposal of Specific Wastes

A. No change

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

B. No change

C. No change

1. No change

2. No change

D. 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 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~~ to the rules listed above in this Section.

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

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 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~~ 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. ~~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.

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. Nationally Tracked Sources

A. A licensee who manufactures, receives, transfers, or disposes of a nationally tracked sealed source shall complete and submit to the Nuclear Regulatory Commission's (NRC) National Source Tracking System and the Agency, a National Source Tracking

Transaction Report that contains the information required in 10CFR 20.2207(a) through (e). January 1, 2007,which is incorporated by reference, published by the Office of Federal Register, National Archives and Records Administration, Washington D.C., and on file with the Agency. This incorporation by reference contain no future editions or amendments. The report shall be submitted before the close of the next business day after the transaction in a reporting form specified in 10CFR 20.207(f), January 1, 2007,which is incorporated by reference, published by the Office of Federal Register, National Archives and Records Administration, Washington D.C., and on file with the Agency. This incorporation by reference contain no future editions or amendments.

B. 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 10CFR 20.207(g), January 1, 2007, which is incorporated by reference, published by the Office of Federal Register, National Archives and Records Administration, Washington D.C., and on file with the Agency. This incorporation by reference contain no future editions or amendments.

C. Initial National Source Tracking Transaction Report shall contain the information required in Part (A), shall be submitted in a form specified in 10CFR 20.2207(f) and include the additional information in 10CFR 20.2207(h)(1) through (6), January 1, 2007, both references are incorporated by reference, published by the Office of Federal Register, National Archives and Records Administration, Washington D.C., and on file with the Agency. The incorporation by references contain 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:

"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")	No change
"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

1	"Collimator"	No change
2	"Compression device"	No change
3	"Computed tomography"	No change
4	"Contact therapy system"	No change
5	"Control panel"	No change
6	"Cooling curve"	No change
7	"CT gantry"	No change
8	"Dead-man switch"	No change
9	"Diagnostic source assembly"	No change
10	"Diagnostic x-ray system"	No change
11	"Direct scattered radiation"	No change
12	"Entrance exposure rate"	No change
13	"Equipment" (See "X-ray equipment")	No change
14	"Filter"	No change
15	"Fluoroscopic imaging assembly"	No change
16	"Fluoroscopic system"	No change
17	"Focal spot"	No change
18	"General purpose radiographic x-ray system"	No change
19	"Gonadal shield"	No change

"Grid" No change

"Half-value layer (HVL)" No change

"Healing arts radiography" means the ~~practice of applying~~ application of x-radiation to human patients by a person certified in accordance with R12-1-603(B)(1), or a licensed practitioner, for diagnostic or therapeutic purposes at the direction of a licensed practitioner. Healing arts radiography includes:

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 (kVp)" (See "Peak tube potential") No change

"Lead equivalent"

"Leakage radiation" No change

"Leakage technique factors" No change

1	"mA"	No change
2	"Mammographic x-ray system"	No change
3	"mAs"	No change
4	"Mobile equipment" (See "X-ray equipment")	No change
5	"Peak tube potential"	No change
6	"Phantom"	No change
7	"Phototimer" (See automatic exposure control)	No change
8	"Portable equipment" (See X-ray equipment")	No change
9	"Primary protective barrier" (See "Protective barrier")	No change
10	"Protective apron"	No change
11	"Protective barrier"	No change
12	"Primary protective barrier"	No change
13	"Secondary protective barrier"	No change
14	"Protective glove"	No change
15	"Scattered radiation"	No change
16	"Screen" or "intensifying screen"	No change
17	"Secondary protective barrier" (See "Protective barrier")	No change
18	"Shutter" (See collimator).	No change
19	"Source"	No change

1	"Source-image receptor distance (SID)"	No change
2	"Spot check"	No change
3	"Stationary equipment" (See "X-ray equipment")	No change
4	"Stray radiation"	No change
5	"System"- (See x-ray system)	No change
6	"Technique chart"	No change
7	"Technique factors"	No change
8	"Treatment simulator"	No change
9	"Tube"	No change
10	"Tube housing assembly"	No change
11	"Tube rating chart"	No change
12	"Useful beam"	No change
13	"Visible area"	No change
14	"X-ray equipment"	No change
15	"X-ray system"	No change
16	"X-ray tube"	No change
17		

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

19 **A.** No change

B. No change

1. No change

2. No change

3. No change

C. No change

1. No change

2. Each 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, published~~ 147, "Structural Shielding Design For Medical X-ray Imaging Facilities," November 19, 2004, which is incorporated by reference, published by the National Council on Radiation Protection and Measurement, Inc., and on file with the Agency. The material incorporated by reference contains no future editions or amendments. ~~which is incorporated by reference and on file with the Agency. This incorporation by reference contains no future editions or amendments.~~ Each registrant shall use this incorporated reference to provide sufficient shielding to prevent public exposure in excess of 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

5. The registrant shall install shielding that limits radiation exposure to 2 mRem in a week for personnel in the x-ray machine control booth.

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~~

~~c. 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 the darkroom is light-tight and utilize proper safe-lighting, such that any film type in use exposed in a cassette to x-ray radiation sufficient to produce an optical density between 1 and 2 when processed, exposing the film in the darkroom for two minutes will not produce an increase in density greater than 0.1 (0.05 for mammography). A processor with a daylight loader shall meet this same 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. Outdated film shall not be used for diagnostic radiographs;

3. Ensure film cassettes and intensifying screens are inspected annually, cleaned, and replaced as necessary;

4. Ensure that cassettes contain film and screens of 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 utilized in the darkroom; and

7. Ensure that film processing solutions are prepared and maintained in accordance with the directions of the manufacturer.

R12-1-604. General Procedures

A. No change

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 patients being exposed to x-ray radiation; or

   e. Exposure of an individual to fluoroscopy as a positioning tool for general purpose radiological procedures.

4. No change

5. Each registrant shall check radiation protective equipment for reliability and integrity defects on an annual basis.

a. Aprons, gloves, and shields shall be checked for holes, tears, and breaks.

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 reliability and integrity checks, and 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~~ Surveys, calibrations, maintenance, modifications (from the original schematics and drawings) performed on the x-ray machine or room after the effective date of these rules, along with the names of persons who performed the service.

~~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 ~~I~~ 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 ł is not less than 1.5 millimeters for fluoroscopes that produce less than 100 kVp, 1.8 millimeters for fluoroscopes that produce from 100 kVp up to 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 (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 up to 125 kVp or 2.7 millimeters for 125 or more kVp.

b. No change

c. No change

C. No change

1. No change

2. No change

a. No change

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 Chang

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

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.~~

Provide documentation in chronological order of:

a. The patient's identity,

b. The x-ray examination performed in a radiographic log,

c. The date ~~it~~ 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 the documentation required in subsection (D)(5) in written or immediately 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 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 means to provide visual or audible indication, detectable at or from

the operator's position, indicating 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.~~ Indication of the appropriate technical factors for kVp, mA, exposure time, and any special mode selected for the exposure.

9. Use technique factors, where deviation of measured or indicated values for kVp and 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 minus10% of the indicated value for the kVp and plus or minus 20% for time duration.

10. Utilize digital radiography techniques that permit reducing x-ray beam on-time to 25 % of the time required for "D" speed film, thereby reducing radiation to the patient by the same rate. (Exposure times shall be reduced accordingly with digital systems.)

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

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 ~~,~~ that does not exceed 25.8 μC/kg (100 milliroentgens) per hour at 5 centimeters (2 inches) from the surface of the tube housing assembly.

b. No change

c. 0-150 kVp systems. Systems that are manufactured on or after January 2, 1996, ~~,~~ that have a leakage radiation that does not exceed 25.8 μC/kg (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 one

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. Surveys. A registrant shall ensure that:

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

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 PET unit are exempt from the requirements in subsection (F).

R12-1-614. Mammography

A. No change:

1. No change
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 of Physicists in Medicine, Report No. 29, August 1990 edition, which is incorporated by reference, published by the American Institute of Physics, Inc., which is incorporated by reference, and on file with the Agency~~, and~~ . The material incorporated by reference contains no future editions or amendments;
6. No change
7. No change
   a.
   b. No change
   c. No change
8. No change
   a. No change
   b.

9. No change

10. No change

11. No change

12. No change

13. No change

14. ~~Cassettes~~ Screens are not used for mammography if one or more areas of greater than 1 cm ~~2~~ ^{2} of poor screen-film contact are seen when tested, using a 40 mesh screen test;

15. No change

a. Meets the minimum mammography film standards for phantom performance in "Mammography Quality Control," ~~1992~~ 1999 edition, which is incorporated by reference, published by the American College of Radiology, ~~which is incorporated by reference,~~ and on file with the Agency~~, and~~ . This material incorporated by reference 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 and results with a background density of at least 1.40 optical density;

16. No change

17. No change

a. No change

b. No change

c. No change

B. No change

1. Each mammography 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 results that fall within the specified limits or corrective action taken ~~if results fall outside of the specified limits~~ with documentation of results prior to 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 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), ~~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~~ April 1, 2006, 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. The material incorporated by reference contains no future editions or amendments:

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~~ 1.40 optical density ~~of operating level~~, not varying by ~~+/-~~ more than 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. 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 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. ;

j. For systems with image receptor modalities other than screen film, the quality assurance and quality control program shall meet or exceed the recommendations by the manufacturer; and

k. Each registrant shall maintain records documenting the requirements in this subsection for three years from the date the requirement is met. The records shall be available for Agency inspection.

C. No change

1. No change

a. An interpreting physician shall meet the requirements of 21 CFR 900.12(a)(1)(i) and (ii)(A) and (B), ~~2001 edition, published April 1, 2001, which is incorporated by reference, on file with the Agency, and contains no future editions or amendments~~ April 1, 2006, 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. The material incorporated by reference contains no future editions or amendments; or:

i. No change

ii. No change

iii. No change

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 mammography modality prior to independent interpretation.

b. A mammography technologist shall meet the requirements of 21 CFR 900.12(a)(2)(i)(B), (ii), and (iii), ~~2001 edition, published April 1, 2001, which is incorporated by reference, on file with the Agency, and contains no future editions or amendments~~ April 1, 2006, 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. The material incorporated by reference 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 certificate, ~~and~~

ii. Have performed at least 200 mammographic examinations in the preceding two years;

~~ii.~~ 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 requirements in 21 CFR 900.12(a)(3)(i) and (iii), and 21 CFR 900.12(a)(4), ~~2001 edition, published April 1, 2001, which is incorporated by reference and on file with the Agency, and contains no future editions or amendments~~ April 1, 2006, 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. The material incorporated by reference contains no future editions or amendments; or

i. No change

ii. No change

iii. No change

iv. No change

v. Have, after completing the experience requirements in subsection (C)(1)(c)(iv), continuing experience surveying two mammography

facilities and evaluating six mammography 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. No change

1. No change

2. No change

ARTICLE 9. PARTICLE ACCELERATORS

R12-1-902. Definitions

"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 qualifies as 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. A committee membership shall consist of at least three individuals and shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate;

2. A Committee shall meet at least once in each 12 month period, unless otherwise specified by license condition;

3. To establish a quorum and to conduct business, half of the committee's membership 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 to the review required in R12-1-407;

5. Review the radiation safety program for all sources of radiation as required in R12-1-407;

6. Establish a table of investigational levels for occupational 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).

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 if 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 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 a minimum the tests and checks listed in Appendix A.

F. Each registrant shall ensure that a particle accelerator ~~shal be~~ is calibrated by ~~a qualified expert~~ an authorized medical physicist meeting 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, ~~1986 edition, published in~~ November 1986,which is incorporated by reference, published by the Inter-Society Council for Radiation Therapy, and on file with the Agency, ~~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 incorporation contains no future additions or amendments.

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
    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. Mo 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 shall provide the survey results in 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 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. No change

ii. No change

iii. No change

C. No change

1. No change

2. No change

3. No change

4. No change

5. Records of spot checks shall be maintained available for inspection by the Agency for two 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 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 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 and before treatment of the first patient, the registrant shall provide to the Agency a copy of the installation report signed by the contractor who installed the shielding material recommended by the authorized medical physicist who performed the shielding calculations for the particle accelerator facility.

D. As part of the annual ALARA review required in R12-1-407, the registrant shall document a review of the patient workload and associated change, if any, in public exposure resulting from the installed facility shielding and other public 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 by-pass 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

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(D), 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).~~ 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 the physician, allied health personnel, the patient, and the patient's referring physician; the patient's identification number if one has been assigned; a brief description of the event; the effect on the patient; and 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 1. No change

2 2. No change

3 3. No change

4 4. No change

5 5. No change

6 6. No change

7 7. No change

8 8. No change

9 B. No change

10 1. No change

11 2. No change

12 3. No change

13 4. No change

14 5. No change

15 6. No change

16 7. No change

17 8. No change

18 9. No change

19 C. 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

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 at airlines, railroads, bus terminals, package inspection systems 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 a means to insure operator presence at the control area in a position which 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. No change

E. No change

F. No change

ARTICLE 12. ADMINISTRATIVE PROVISIONS

R12-1-1215. License and Registration Divisions

A. No change

1. No change

2. No change

3. Division III licenses and registrations:

Class A Laser Facility

Class A Industrial Radio-frequency Facility

~~Depleted Uranium~~ General industrial

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. No change

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 who transports licensed material outside the site of usage, as specified in an Agency license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the USDOT regulations listed in 10 CFR 71.5, January 1, 2007, 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. This incorporation by reference contains no future editions or amendments.

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

A. No change

1. No change

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, October 1, ~~2003~~ 2006, which are incorporated by reference ~~and on file with the Agency~~ , published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency.. This incorporation by reference 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~~ October 1, ~~2000~~2006, incorporated by reference and on file with the Agency ~~and the Office of the Secretary of State~~, containing 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 packaging, monitoring, manifesting, marking, and labeling requirements, applicable to the mode of transport, of the U.S. Department of Transportation, 49 CFR 171 through 180, October 1, ~~2003~~2006, or 39 CFR 111.1, July 1, ~~2003~~2006, both of which are incorporated by reference and on file with the Agency. This incorporation 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, January 1, 2007, 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. The material incorporated by reference contains no future editions or amendments. A licensee shall have, 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 Edition, published~~ October 1, ~~2001~~2006, incorporated by reference and on file with the Agency ~~and the Office of the Secretary of State~~. This incorporation by reference contains no future editions or amendments.

3. No change

4. No change

5. No change

6. No change

C. No change

D. No change

R12-1-1510. Packaging

A. A general license is hereby 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 who has a quality assurance program approved by the Agency as satisfying R12-1-1507;

2. This general license applies only to a licensee who:

a. Has a copy of the 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 was satisfactorily completed by August 31, 1986, as demonstrated by application of its model number in accordance

with 10CFR71.85(c), January 1, 2007, 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. This incorporation by reference contains no future editions or amendments;

b. A package that is used for a shipment to a location outside the United States is multilaterally approved, as defined in 49 CFR 173.403; October 1, 2006, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, on file with the Agency, and containing no future editions or amendments; and

c. A serial number that uniquely identifies each packaging which conforms to the approved design is assigned to, and legibly and durably marked on, the outside of each packaging.

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 designation "-85" 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 package is satisfactorily completed by April 1, 1999 as demonstrated by application of its model number in accordance with 10CFR71.85(c); January 1, 2007, 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. This incorporation by reference contains no future editions or amendments;

b. A package used for a shipment to a location outside the United States is subject to multilateral approval as defined in 49CFR 173.403; October 1, 2006, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, on file with the Agency, and containing no future editions or amendments; and

c.. A serial number which uniquely identifies each packaging which conforms to the approved design is assigned to and legibly and durably marked on the outside of each packaging.

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 10CFR 71.71 and 71.73; January 1, 2007, which are incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, on file with the Agency, and containing 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 10CFR 71.71 and 71.73; January 1, 2007, which are incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, on file with the Agency, and 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 appropriate, 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 rule the different types of packages are defined in 10CFR 71, January 1, 2007, 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. This incorporation by reference contains no future editions or amendments.

C. A general license is issued to any licensee of the Agency to transport, or to deliver to a carrier for transport, licensed material in a specification container for fissile material or for a Type B quantity of radioactive material as specified in 49CFR 173 and 178 October 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. This incorporation by reference contains no future editions or amendments.

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

2. The licensee operating under this general license:

a. Maintains a copy of the specification; and

b. Complies with the terms and conditions of the specification and the applicable requirements of subparts A, G, and H of 10CFR 71, January 1, 2007, 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. This incorporation by reference contains no future editions or amendments.

3. The licensee operating under a general license authorized under this subsection may not use the specification container for a shipment to a location outside the United States, except by multilateral approval, as defined in 49CFR 173.403, October 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. This incorporation by reference 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 Federal Department of Transportation as meeting the applicable requirements of 49CFR 171.12., October 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. This incorporation by reference 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 who:

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 of subparts A, G, and H of 10CFR 71, January 1, 2007, 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. This incorporation by reference contains no future editions or amendments. With respect to the quality assurance provisions of subpart H of this incorporation, the licensee is exempt from design, construction, and fabrication considerations.

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, 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 not greater than 70 Bq/g (0.002 μCi/g) of material 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 R12-1-1504(A)(2) 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 10CFR 73.24, January 1, 2007, 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. This incorporation by reference contains no future editions or amendments.

C. For a shipment of plutonium by air which is subject to subsection (A)(4), the licensee shall, through special arrangement with the carrier, require compliance with 49CFR 175.704, October 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, applicable to the air transport of plutonium. This incorporation by reference 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 10CFR 71.97, January 1, 2007, 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,. This incorporation by reference 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, January 1, 2007, 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. This incorporation by reference contains no future editions or amendments.

ARTICLE 17. WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

R12-1-1713. Transportation 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.