

NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* 1st as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Arizona Administrative Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 10. BOARD OF COSMETOLOGY

PREAMBLE

1. Sections Affected

R4-10-101
R4-10-104
R4-10-104
R4-10-105
R4-10-105
R4-10-106
R4-10-106
Table 1
R4-10-107
R4-10-107
R4-10-108
R4-10-109
R4-10-110
R4-10-111
R4-10-112
R4-10-113
R4-10-114
R4-10-115
R4-10-201
R4-10-201
R4-10-401
R4-10-401
R4-10-402
R4-10-402
R4-10-403
R4-10-404
R4-10-405

Rulemaking Action

Amend
Re-number
New Section
Re-number
New Section
Repeal
New Section
New Table
Re-number
New Section
Re-number
Re-number
Re-number
Re-number
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Repeal
New Section
Repeal
New Section
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New Section
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2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 32-504(A)(1)

Implementing statutes: A.R.S. §§ 32-504(A)(5), 32-510, 32-511, 32-512, 32-517, 32-513, 32-531, 32-532, 32-535, 32-541, 32-544, 32-551, 32-564, 41-1072 through 41-1078

3. The effective date of the rules:

May 18, 1999

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

Notice of Rulemaking Docket Opening: 4 A.A.R. 3046, October 16, 1998.

Notice of Proposed Rulemaking: 4 A.A.R. 2996, October 16, 1998.

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

Name: Sue Sansom, Executive Director
Address: State Board of Cosmetology
1721 East Broadway
Tempe, Arizona 85282
Telephone: (602) 784-4539
Fax: (602) 255-3680

6. **An explanation of the rule, including the agency's reasons for initiating the rule:**

A.R.S. §§ 41-1072 through 41-1078 require all state agencies, boards, and commissions that are subject to the Administrative Procedure Act to establish by rule, time-frames for granting or denying licenses issued by the Board. The proposed rules establish time-frames for granting or denying an aesthetician, a cosmetologist, a nail technician, an instructor, a school, or a salon license or renewal. The Board has added or amended definitions to clarify terms used within the proposed rules. The proposed rules have been reorganized in a logical format and clarify the time periods for providing the Board with written notification of changes in a salon's location, ownership, name, or corporate officer or statutory agent. The Board did not rely on any study to evaluate or justify the proposed rule.

7. **A reference to any study the agency proposes to rely on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study, and other supporting material.**

None.

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

Not applicable.

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

The principal economic impact of the proposed rules will be borne by the Board. The costs are moderate and include costs for drafting the rules, distributing and providing education on the revised rules, mailing notices of incompleteness, and implementing a system to track applications for administrative and substantive time-frames. Because the Board already notifies an applicant by examination of the date of an examination, the Board should not incur additional costs for notification of completeness of an application. Applicants and the Board should benefit because of the increased consistency and efficiency in the application process. There are no other expected costs on other government entities, cosmetologists, aestheticians, nail technologists, instructors, salons, schools, consumers, or small businesses.

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

R4-10-104(E)(3)

The Board changed the introductory sentence from: "...signed by an owner or manager of a licensed salon, an individual with personal knowledge of the applicant's practice for at least 1 of the 5 years immediately preceding the date of the application, or a supplier of cosmetology products that includes the:" to: "...that is completed and signed by an owner or manager of a licensed salon or an individual or supplier of cosmetology products with personal knowledge of the applicant's practice for 1 year that includes the:"

R4-10-104(E)(1)(d)

The Board deleted "or a bachelor's degree".

R4-10-106(B)(1)(a)

The Board changed:

a. For approval to take an examination or approval or denial of a school or salon license, when the Board receives an application packet; or

to:

a. For approval to take an examination, approval or denial of school or salon license, or approval or denial of a license by reciprocity, when the Board receives an application packet; or

R4-10-106(B)(1)(b)

The Board deleted "or reciprocity".

Arizona Administrative Register
Notices of Final Rulemaking

R4-10-106(C)(2)

The Board inserted R4-10-106(C)(2) as follows and renumbered subsequent subsections:

2. During the substantive review time-frame, the Board may make 1 comprehensive written request for additional information or documentation. The time-frame for the Board to complete the substantive review is suspended from the postmark date of the comprehensive written request for additional information or documentation until the Board receives the additional information or documentation.

R4-10-106(D)

The Board inserted R4-10-106(D) as follows:

D. The Board shall consider an application withdrawn if within 180 days from the application submission date the applicant fails to:

1. Supply the missing information under subsection (B)(2) or (C)(2); or
2. Take an examination.

R4-10-106(E)

The Board inserted R4-10-106(E) as follows and renumbered subsequent subsections:

E. An applicant who does not wish an application withdrawn may request a denial in writing within 180 days from the application submission date.

Table 1

The Board added citations to statutory authority.

The Board added time-frames for license reactivation.

R4-10-401(3)

The Board added the following and conformed subsequent numbering:

3. If a partnership, a copy of the partnership agreement;

11. The summary of the principal comments and the agency response to them:

The Board did not receive any comments.

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

None.

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

None.

14. Was this rule previously adopted as an emergency rule?

No.

15. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 10. STATE BOARD OF COSMETOLOGY

ARTICLE 1. GENERAL PROVISIONS

Section

R4-10-101. Definitions

~~R4-10-104.~~ R4-10-108. Licensing Examinations

R4-10-104. Application for License by Examination

~~R4-10-105.~~ R4-10-109. Instructor Examinations

R4-10-105. Application for License by Reciprocity

R4-10-106. License Application and Renewal Repealed

R4-10-106. Licensing Time-frames

Table 1 Time-frames (in days)

R4-10-107. License Renewal

Notices of Final Rulemaking

R4-10-107 <u>R4-10-110.</u>	Reactivating an Inactive License
R4-10-108 <u>R4-10-111.</u>	Display of Licenses and Signs
R4-10-109 <u>R4-10-112.</u>	Infection Control and Safety Standards
R4-10-110 <u>R4-10-113.</u>	Establishment Management
R4-10-111 <u>R4-10-114.</u>	Disciplinary Action
R4-10-112 <u>R4-10-115.</u>	Rehearing or Review of Decision

ARTICLE 2. SCHOOLS

Section

- ~~R4-10-201. School License Procedure Repealed~~
~~R4-10-201. Application for a School License; Renewal~~

ARTICLE 4. SALONS

Section

- ~~R4-10-401. Salon License Application, Modifications, Transfers Repealed~~
~~R4-10-401. Application for a Salon License~~
~~R4-10-402~~R4-10-403. Salon Requirements and Minimum Equipment
~~R4-10-402. Changes Affecting a Salon License~~
~~R4-10-403~~R4-10-404. Mobile Services
~~R4-10-404~~R4-10-405. Shampoo Assistants

ARTICLE 1. GENERAL PROVISIONS

R4-10-101. Definitions

In this Chapter unless otherwise specified:

1. "Accredited" means approved by the:
 - a. New England Association of Schools and Colleges.
 - b. Middle states Association of colleges and Secondary Schools.
 - c. North Central Association of Colleges and Schools.
 - d. Northwest Association of Schools and Colleges.
 - e. Southern Association of Colleges and Schools, or
 - f. Western Association of Schools and Colleges.
2. "Administrative completeness review" means the Board's process for determining that an individual has:
 - a. Provided all of the information and documents required by Board statute or rule for an application; and
 - b. If applicable, taken an examination given by the Board.
3. "Applicant" means an individual or any of the following seeking licensure by the Board:
 - a. If a corporation, any 2 officers of the corporation;
 - b. If a partnership, any 2 of the partners; or
 - c. If a limited liability company, the designated manager, or if no manager is designated, any 2 members of the limited liability company.
4. "Application packet" means the forms and documents the Board requires an applicant to submit or have submitted on the applicant's behalf.
- ~~A5.~~ "Certification of hours" means a document that states the total number of hours completed at a school, including:
 - ~~1.~~a. No Change.
 - ~~2.~~b. No Change.
- ~~B6.~~ No Change.
- ~~C7.~~ "Course" means the whole program of school instruction in 1 of the following categories:
 - ~~1.~~ Aesthetics or aesthetics instructor,
 - ~~2.~~ Cosmetology or cosmetology instructor, or
 - ~~3.~~ Nail technology or nail technology instructor.an organized subject matter in which instruction is offered within a given period of time and for which credit toward graduation or certification is given.
8. "Credit" means 1 earned academic unit of study based on completing a high school's required number of class sessions per calendar week in a course or an earned academic unit of study based on attending a 1-hour class session per calendar week at a community college, an accredited college or university, or a school.
9. "Days" means calendar days.
- ~~D10.~~ "Delinquent" ~~regarding a license renewal application~~ means ~~1~~ a license renewal that is not completed and filed with the Board or postmarked on or before the license renewal date required by A.R.S. § 32-501 through 32-564 or this Chapter.

~~E11.~~ "Double bracing" means using a stable base of support and 2 points of contact for the hand while performing the a procedure.

~~F12.~~ "Establishment" means a business ~~which that~~ operates as a school or salon in a structure that has a physical street address and functions as a salon or school at least an average of 20 hours a week for the majority of the year.

~~13.~~ "Family member" means:

- a. The applicant's spouse;
- b. The natural or adopted children, father, mother, grandparents, brothers, sisters, aunts, uncles, 1st cousins, and 2nd cousins of the applicant; or
- c. The natural or adopted children, father, mother, grandparents, brothers, sisters, aunts, uncles, 1st cousins, and 2nd cousins of the applicant's spouse.

~~G14.~~ "Graduation" or "graduated from a ~~cosmetology~~ school" means the completion of the criteria established by ~~the a~~ cosmetology, an aesthetics, or a nail technology school for the course in which the applicant was enrolled, including completion of the curriculum hours specified in R4-10-302, R4-10-303, R4-10-304, or R4-10-305.

~~H15.~~ No Change.

~~I16.~~ No Change.

~~17.~~ "Instructor training" means the courses required by R4-10-302.

~~18.~~ "Manager" means an individual licensed by the Board who is responsible for ensuring a salon's compliance with A.R.S. §§ 32-501 through 32-575 and this Chapter.

~~J19.~~ No Change.

~~20.~~ "Owner" means an individual or entity that has controlling legal or equitable interest and authority in an establish-ment.

~~21.~~ "Personal knowledge" means actual observation of an individual, other than a family member, who is currently prac-ticing aesthetics, cosmetology, or nail technology in any state or country.

~~22.~~ "Practice" means engaging in the occupation of aesthetics, cosmetology, or nail technology.

~~K23.~~ No Change.

~~L24.~~ "Reciprocity" means the manner in which the Board may grant a license based on an applicant's license or quali-fications received in another jurisdiction, procedure for granting an Arizona license to an applicant who is licensed in another state of the United States or a foreign country.

~~M.~~ "Sanitation", as used in A.R.S. § 32-501 *et seq.*, means infection control.

~~N.~~ "Sanitize" means to disinfect.

~~25.~~ "Substantive review" means the Board's process for determining that an applicant for licensure meets the require-ments of A.R.S. §§ 32-501 through 32-575 and this Chapter.

~~O26.~~ No Change.

~~P27.~~ No Change.

~~R4-10-104.~~ **R4-10-108.** Licensing Examinations

No Change.

R4-10-104. Application for License by Examination

A. An applicant for an aesthetics, a cosmetology, a nail technician, or an instructor license by examination shall submit to the Board the applicable fee required in R4-10-102 and an application provided by the Board, signed by the applicant, and notarized that contains:

1. The applicant's name, address, telephone number, social security number, and birth date;
2. The name and address of each school attended by the applicant;
3. The name of each aesthetics, cosmetology, or nail technician course completed by the applicant, and school name and address where completed;
4. If applicable, the starting date and date of graduation from a school, type of degree received, and the name and address of the school where received;
5. If previously licensed by the Board, type of license, license number, license expiration date, and the name used on the license;
6. If previously licensed in a state other than Arizona or a foreign country, the name of the state or foreign country and type of license;
7. A statement of whether the applicant has ever had an aesthetician, a cosmetologist, a nail technician, or an instructor license suspended or revoked in any state or foreign country; and
8. A sworn statement by the applicant verifying the truthfulness of the information provided by the applicant.

B. In addition to submitting the fee and documents in subsection (A), an applicant for an aesthetics license shall:

1. Comply with A.R.S. § 32-510(A)(2) by submitting a copy of 1 of the following:
 - a. Documentation of 23 years of age as demonstrated by a government-issued driver's license, identification card, birth certificate, or passport;
 - b. A high school transcript demonstrating a 10th grade equivalency;

Arizona Administrative Register
Notices of Final Rulemaking

- c. A high school diploma;
 - d. A high school equivalency diploma;
 - e. Documentation of an associate degree or an official transcript from an accredited college that only offers courses to be completed in 2 years that shows completion of 15 credits; or
 - f. A bachelor's degree from an accredited college or university.
2. Comply with A.R.S. § 32-510(A)(3) by submitting a copy of 1 of the following:
- a. If the applicant graduated from an aesthetician course presented by a school licensed by the Board, a written statement signed by the administrator of the school that documents proof of graduation and completion of 600 hours in the course;
 - b. If the applicant attended more than 1 school in Arizona, a copy of a transfer application or certification of hours from each school attended, including the starting and ending dates, the total number of hours completed at the school, and the signature of the administrator of the school; or
 - c. If the applicant graduated from or completed hours at a school licensed by a state other than Arizona or a foreign country, a graduation certificate and documentation of:
 - i. Completing the theory of aesthetic as required in R4-10-303(A)(1), and
 - ii. Meeting the requirements in R4-10-303(A)(2) and R4-10-303(A)(3).
- C.** In addition to submitting the fee and documents in subsection (A), an applicant for a cosmetology license shall:
- 1. Comply with A.R.S. § 32-511(A)(2) by submitting a copy of 1 of the documents in subsection (B)(1).
 - 2. Comply with A.R.S. § 32-511(A)(3) by submitting a copy of 1 of the following:
 - a. If the applicant graduated from a cosmetology course presented by a school licensed by the Board, a written statement signed by the administrator of the school that documents proof of graduation and completion of 1600 hours in the course;
 - b. If the applicant attended more than 1 school in Arizona, a copy of a transfer application or certification of hours from each school attended, including the initial and ending dates, the total number of hours completed at the school, and the signature of the administrator of the school; or
 - c. If the applicant graduated from or completed hours at a school licensed by a state other than Arizona or a foreign country, a graduation certificate and documentation of:
 - i. Completing the theory of cosmetology as required in R4-10-304(A)(1), and
 - ii. Meeting the requirements in R4-10-304(A)(2) and R4-10-304(A)(3).
- D.** In addition to submitting the fee and documents in subsection (A), an applicant for a nail technician license shall:
- 1. Comply with A.R.S. § 32-512(A)(2) by submitting a copy of 1 of the documents in subsection (B)(1).
 - 2. Comply with A.R.S. § 32-512(A)(3) by submitting a copy of 1 of the following:
 - a. If the applicant graduated from a nail technician's course presented by a school licensed by the Board, a written statement signed by the administrator of the school who documents proof of graduation and completion of 300 hours in the course; or
 - b. For each school attended by the applicant, a copy of a transfer application or certification of hours from each school attended, including the starting and ending dates, the total number of hours completed at the school, and the signature of the administrator of the school;
- E.** In addition to submitting the fee and documents in subsection (A), an applicant for an instructor license by examination shall:
- 1. Comply with A.R.S. § 32-531(A)(2) by submitting a written copy of 1 of the following:
 - a. A high school diploma;
 - b. A high school equivalency diploma;
 - c. Documentation of an associate degree or an official transcript from an accredited college that only offers courses to be completed in 2 years that shows completion of 15 credits; or
 - d. Documentation of completion of 15 credits from an accredited college or university.
 - 2. Submit a copy of 1 of the following:
 - a. If the applicant graduated from a school licensed by the Board, documentation of graduation that includes in its course of study:
 - i. If applying for a cosmetology instructor license, completion of a minimum of 650 hours of instructor training;
 - ii. If applying for a nail technician instructor license, completion of a minimum of 350 hours of instructor training; or
 - iii. If applying for an aesthetics instructor license, completion of a minimum of 500 hours of instructor training;
 - b. If the applicant graduated from or completed hours at a school licensed by a state other than Arizona or a foreign country, a graduation certificate and documentation of meeting the requirements in R4-10-302, except for R4-10-302(A)(6); or

Arizona Administrative Register
Notices of Final Rulemaking

- c. If the applicant attended more than 1 school in Arizona, a copy of a transfer application or certification of hours from each school attended, including the initial and ending dates, total number of hours completed, and signature of the administrator of the school.
3. Comply with A.R.S. § 32-531(A)(3) by submitting documentation of practical experience in the profession applied for on a notarized form, supplied by the Board, that is completed and signed by an owner or manager of a licensed salon or an individual or supplier of cosmetology products with personal knowledge of the applicant's practice for 1 year that includes the:
 - a. Name of the applicant;
 - b. Occupation in which applicant gained the experience;
 - c. Initial and final dates of applicant's experience in the occupation;
 - d. Name and address where applicant gained the experience in the occupation;
 - e. If licensed by the Board, license number; and
 - f. Name, address, and telephone number of the individual completing the information.

~~R4-10-105.~~R4-10-109. Instructor examinations

No Change.

R4-10-105. Application for License by Reciprocity

An applicant for an aesthetics, cosmetology, nail technician, or instructor license by reciprocity shall submit the applicable fee required in R4-10-102 and all of the following to the Board:

1. An application provided by the Board, signed by the applicant, and notarized that contains:
 - a. The applicant's name, address, telephone number, social security number, and birth date;
 - b. If previously licensed by the Board, the type of license, license number, license expiration date, and the name used on the license;
 - c. A statement of whether the applicant has ever had an aesthetics, a cosmetology, a nail technician, or an instructor license suspended or revoked in any state or foreign country; and
 - d. A statement under oath by the applicant verifying the truthfulness of the information provided by the applicant;
2. A certification of licensure that shows the initial and final dates of licensure; and
3. To demonstrate compliance with the practice requirements in A.R.S. § 32-513 (A)(2) or A.R.S. § 32-532(3), a notarized form, supplied by the Board, that is completed by an owner or manager of a licensed salon, a licensee with personal knowledge of the applicant's practice for at least 1 of the 5 years immediately preceding the date of the application, or a supplier of aesthetics, cosmetology, or nail technology products to the applicant that contains:
 - a. The name of the applicant;
 - b. The type of practice engaged in by the applicant;
 - c. The initial and final dates of applicant's practice;
 - d. The name, address, and telephone number of the salon where the applicant is or was practicing;
 - e. If completed by a licensee with personal knowledge, the initial and final dates of the practice;
 - f. If completed by an individual who is a supplier, the initial and final dates the aesthetics, cosmetology, or nail technology products were provided;
 - g. If completed by an owner or manager of a salon, the name, current address, and current telephone number of the owner and license number of the salon where the applicant is or was practicing or the name, current address, and current telephone number of the manager of the salon where the applicant is or was practicing and the manager's license number; and
 - h. A statement under oath, signed by the owner or manager, licensed individual, or supplier, verifying the truthfulness of the information.

R4-10-106. License Application and Renewal Repealed

- ~~**A.** An aesthetician, cosmetology, nail technician, or instructor license expires on the birthday of the individual to whom it was issued. Upon request by an applicant, the Board may delay the effective date of an applicant's 1st license until after the applicant's next birthday. The applicant shall not practice until the effective date of the license.~~
- ~~1. An aesthetician, cosmetology, nail technician, or instructor license renewal application and the fee specified by R4-10-102 shall be completed and filed with the Board or postmarked on or before the individual's birthday. If that date is a Saturday, Sunday, or legal holiday, the renewal application and fee shall be filed on the next ensuing business day.~~
 - ~~2. An aesthetician, cosmetology, nail technician, or instructor shall notify the Board, in writing, within 10 calendar days of an address change.~~
- ~~**B.** A salon which has a permanent location where cosmetology services are performed shall apply for licensure pursuant to A.R.S. § 32-541.~~
- ~~**C.** A school which has a permanent location shall apply for licensure pursuant to A.R.S. § 32-551.~~
- ~~**D.** An establishment license expires on June 30 of every year.~~
- ~~1. An establishment license renewal application and the fee specified by R4-10-102 shall be filed with the Board or postmarked on or before June 30 to be timely.~~

Arizona Administrative Register
Notices of Final Rulemaking

- 2. ~~An establishment license which has been delinquent for more than 1 year shall not be renewed.~~
- E.** If a renewal application is complete and filed with the Board or postmarked before the expiration of the license, along with the correct fee, the licensee may continue to practice pending issuance of the renewal license. If the expiration is a Saturday, Sunday, or legal holiday, the application shall be filed on the next ensuing business day.
- F.** ~~A delinquent renewal application shall be accompanied by the delinquent license renewal penalty specified in R4-10-102.~~

R4-10-106. Licensing Time-frames

- A.** The overall time-frame described in A.R.S. § 41-1072 for each type of approval granted by the Board is set forth in Table 1. The applicant and the Executive Director of the Board may agree in writing to extend the overall time-frame. The substantive review time-frame may not be extended by more than 25% of the overall time-frame
- B.** The administrative completeness time-frame described in A.R.S. § 41-1072(1) for each type of approval granted by the Board is set forth in Table 1.
 - 1. The administrative completeness review time-frame begins:
 - a. For approval to take an examination, approval or denial of school or salon license, or approval or denial of a license by reciprocity, when the Board receives an application packet; or
 - b. For approval or denial of a license by examination, when the applicant takes an examination;
 - 2. If an application packet is incomplete, the Board shall send to the applicant a written notice specifying the missing document or incomplete information. The administrative completeness review time-frame and the overall time-frame are suspended from the postmark date of the notice until the date the Board receives a complete application packet from the applicant.
 - 3. If an application packet is complete, the Board shall send a written notice of administrative completeness to the applicant.
 - 4. If the Board grants a license or approval during the time provided to assess administrative completeness, the Board shall not issue a separate written notice of administrative completeness.
- C.** The substantive review time-frame described in A.R.S. § 41-1072(3) is set forth in Table 1 and begins on the postmark date of notice of administrative completeness.
 - 1. As part of the substantive review for a school license, the Board shall conduct an inspection that may require more than 1 visit to the school.
 - 2. During the substantive review time-frame, the Board may make 1 comprehensive written request for additional information or documentation. The time-frame for the Board to complete the substantive review is suspended from the postmark date of the comprehensive written request for additional information or documentation until the Board receives the additional information or documentation.
 - 3. If an applicant meets the requirements of A.R.S. § 32-501 through § 32-575 and this Chapter, the Board shall send written notice of approval to the applicant. If an applicant is applying for approval to take an examination, the notice shall include the date, time, and place the applicant is scheduled to take an examination.
 - 4. If an applicant does not meet the requirements of A.R.S. § 32-501 through § 32-575 and this Chapter, the Board shall send a written notice of denial to the applicant including a basis for the denial and an explanation of the applicant's right to appeal as prescribed in A.R.S. § 41-1076.
- D.** The Board shall consider an application withdrawn if within 180 days from the application submission date the applicant fails to:
 - 1. Supply the missing information under subsection (B)(2) or (C)(2); or
 - 2. Take an examination.
- E.** An applicant who does not wish an application withdrawn may request a denial in writing within 180 days from the application submission date.
- F.** An individual shall not practice as an aesthetician, cosmetologist, instructor, or nail technician until the individual receives and posts the license at the individual's place of employment.
- G.** If a time-frame's last day falls on a Saturday, Sunday, or a legal holiday, the Board shall consider the next business day the time-frame's last day.

Arizona Administrative Register
Notices of Final Rulemaking

Table 1. Time-frames (in days)

<u>Type of Approval</u>	<u>Statutory Authority</u>	<u>Overall Time-frame</u>	<u>Administrative Completeness Time-frame</u>	<u>Substantive Review Time-frame</u>
<u>Approval to Take an Examination</u>	<u>A.R.S. §§ 32-514, 32-515, 32-533</u>	<u>90</u>	<u>60</u>	<u>30</u>
<u>License by Examination</u>	<u>A.R.S. §§ 32-510, 32-511, 32-512, 32-531</u>	<u>60</u>	<u>30</u>	<u>30</u>
<u>License by Reciprocity</u>	<u>A.R.S. §§ 32-513, 32-532</u>	<u>60</u>	<u>30</u>	<u>30</u>
<u>School License</u>	<u>A.R.S. § 32-551</u>	<u>90</u>	<u>30</u>	<u>60</u>
<u>License Renewal</u>	<u>A.R.S. §§ 32-517, 32-535, 544, 32-564</u>	<u>75</u>	<u>45</u>	<u>30</u>
<u>Salon License</u>	<u>A.R.S. §§ 32-541, 32-542</u>	<u>90</u>	<u>30</u>	<u>60</u>
<u>License Reactivation</u>	<u>A.R.S. § 32-518</u>	<u>30</u>	<u>15</u>	<u>15</u>

R4-10-107. License Renewal

- A.** An aesthetician, cosmetologist, nail technician, or instructor licensee shall submit an application packet for renewal to the Board no later than the licensee's birthday.
1. If the applicant mails the application packet, the application packet shall be postmarked on or before the applicant's birthday.
 2. If the applicant's birthday falls on Saturday, Sunday or legal holiday, an applicant may file the application packet on the next business day following the applicant's birthday.
 3. An application packet consists of:
 - a. An application on a form provided by the Board that contains:
 - i. The applicant's name, address, and social security number;
 - ii. A statement of whether the applicant has changed their name since the previous initial or renewal application;
 - iii. The fee required in R4-10-102; and
 - iv. The signature of the applicant; and
 - b. A copy of a legal document showing the applicant's name change, such as a marriage license or divorce decree.
- B.** An establishment licensee shall submit an application for renewal and fee required in R4-10-102 to the Board no later than June 30 of every year.
1. If the applicant mails the application, the application shall be postmarked on or before June 30.
 2. If June 30th falls on Saturday, Sunday or a legal holiday, an applicant may file the application on the next business day following June 30th.
 3. An application consists of a form provided by the Board that contains:
 - a. The establishment's name, manager's license number, and type of license;
 - b. If the establishment is a salon that is no longer in business, the date of closure; and
 - c. The date and notarized signature of the owner.
 4. If the establishment is a school, the licensee shall submit the information and documents required in R4-10-201 in addition to the application form.

~~**R4-10-107.**~~ **R4-10-110.** **Reactivating an Inactive License**
 No Change.

~~**R4-10-108.**~~ **R4-10-111.** **Display of Licenses and Signs**
 No Change.

Arizona Administrative Register
Notices of Final Rulemaking

~~R4-10-109~~**R4-10-112.** **Infection Control and Safety Standards**
No Change.

~~R4-10-110~~**R4-10-113.** **Establishment Management**
No Change.

~~R4-10-111~~**R4-10-114.** **Disciplinary Action**
No Change.

~~R4-10-112~~**R4-10-115.** **Rehearing or Review of Decision**
No Change.

ARTICLE 2. SCHOOLS

R4-10-201. School Licensing Procedures Repealed

- A.** An application for a school license shall be submitted at least 20 days before the planned date of opening. In addition to the requirements of A.R.S. § 32-551, the application packet shall include:
1. A floor plan of the school which is between 8 1/2" x 11" and 14" x 14";
 2. A copy of all contract forms to be used for enrollment of students;
 3. The fee specified by R4-10-102;
 4. A schedule of operations specifying the days of the week and hours of the day the school shall be open for instruction and the proposed class schedule; and
 5. The name and license number of the manager of the school.
- B.** The school owner shall submit the following at the time of renewing the school license:
1. An updated floor plan not exceeding 14" x 14" for all structural improvements;
 2. The most recent school catalog showing any modifications, additions, or deletions and an index reflecting where the information required by A.R.S. § 32-559 is located in the catalog;
 3. A subject description of new courses and their schedules;
 4. A new operating schedule if changes occur;
 5. The name or address of any new statutory agent;
 6. A letter requesting approval of the new school name with the fee specified in R4-10-102; or
 7. The name and license number of a new manager.
- C.** Whenever the terms "accredited" "approved", or similar terms are used in school catalogs or advertising, the name of the accrediting or approving organization shall also be shown.
- D.** A school license renewal application submitted to the Board office shall be postmarked by June 30.

R4-10-201. Application for a School License; Renewal

- A.** An applicant for a school license shall submit the documents required in A.R.S. § 32-551 and:
1. Submit an application on a form provided by the Board, signed by the applicant, and notarized that contains:
 - a. The applicant's name, address, social security number, and telephone number;
 - b. If a partnership, each partner's name and address and an identification of whether a limited or general partner;
 - c. If a corporation, the state of incorporation and the name, title, and address of each officer of the corporation;
 - d. The name under which the school will be operated;
 - e. The name and address of the Board licensed instructor who is in charge of the school;
 - f. If an existing school, the date the applicant will be assuming ownership;
 - g. If a new school, the date of scheduled opening of the school;
 2. If a corporation, submit the articles of incorporation;
 3. Submit an 8 1/2" by 11" floor plan of the school;
 4. Submit an uncompleted contract form required by A.R.S. § 32-558;
 5. Submit a schedule that includes the hours of each day and each day of a calendar week during which the school will be open for instruction;
 6. Submit a proposed schedule of classes to be taught at the school;
 7. Submit a school catalog containing the information required by A.R.S. § 32-559;
 8. Demonstrate compliance with A.R.S. § 32-551 through § 32-575 and these rules through a school inspection conducted by the Board; and
 9. Submit the fee required in R4-10-102.
- B.** In addition to the requirements in R4-10-107, a licensee shall submit the following when renewing a license:
1. An updated floor plan not exceeding 8 1/2" by 11" for all structural improvements;
 2. The most recent school catalog showing:
 - a. Any modifications, additions, or deletions;
 - b. An index reflecting where the information required by A.R.S. § 32-559 is located in the catalog; and
 - c. The names of each accrediting or approving organization.

Arizona Administrative Register
Notices of Final Rulemaking

3. A subject description of each new course and its schedule;
4. A new operating schedule if changes occur;
5. The name and address of any new statutory agent;
6. If the school changes its name, a request for approval of the name and the fee required in R4-10-102; and
7. The name and license number of the current manager of the school.

ARTICLE 4. SALONS

R4-10-401. Salon License Application; Modifications; Transfers Repealed

- A.** An application shall be filed with the Board to license a new salon, for a salon location change, if a salon has a new owner, if there is a change in the controlling interest of a corporate entity, or if the salon name changes. Applicants shall submit a complete application for a salon license to the Board at least 10 calendar days prior to the planned date of opening. The application shall include a floor plan at least 8 1/2" x 11". An incomplete application shall be returned to the applicant.
- B.** A complete application, for applicants who will open after an inspection, shall be submitted at least 45 calendar days before the planned date of opening, during which period the Board shall inspect the salon.
- C.** The salon shall have and designate on the floor plan specified in subsection(A) the location of the following:
1. Wet disinfectant as specified by R4-10-109;
 2. Dry, closed, disinfected container to store disinfected tools and implements as specified by R4-10-109;
 3. Sink or shampoo bowl with hot or cold running water that is not also used as a dispensary or rest room sink;
 4. Stations;
 5. Rest rooms;
 6. Electrical outlets; and
 7. Activities performed by people that are not licensed by the Board, which are related to cosmetology, but not regulated by A.R.S. § Title 32, Chapter 5.
- D.** The application shall include:
1. The fee specified by R4-10-102;
 2. The name and license number of the manager designated by pursuant to A.R.S. § 32-541(C);
 3. A schedule of operations specifying the days and hours the salon is open for business;
 4. The request for mobile services if applicable as specified by R4-10-403;
 5. A statement that the salon requirements and minimum equipment requirements as specified by R4-10-402 are met; and
 6. The documents identifying the owner of the salon and the statutory agent, if any.
- E.** For location changes, a new application shall be submitted as specified in subsections (A), (C), and (D) with the fee as required by R4-10-102. The license of the former location shall be forwarded to the Board after the licensee has received the new location license from the Board.
- F.** For a transfer of ownership or corporation reorganization that changes the controlling interest, a new owner shall file a salon application pursuant to subsections (A), (C), and (D), identifying the date of transfer, the new owner's name, and the original owner's name. The application shall also indicate whether the original owner relinquishes the right to the license, salon name, and location. The application shall also include the prescribed fee for a transfer of ownership as required in R4-10-102.
- G.** For name changes, a request in writing shall be submitted with the fee specified by R4-10-102.
- H.** Within 10 calendar days of closing, the salon shall submit written notice and forward its license to the Board. If an original salon owner has not relinquished the use of the salon name when an application is filed pursuant to subsection (F), the Board may reserve the use of the salon's name for 1 year from the date of last closing, upon request by the original owner.

R4-10-401. Application for a Salon License

An applicant for a salon license shall submit:

1. An application on a form provided by the Board, signed by the applicant, and notarized that contains:
 - a. The applicant's name, address, social security number, and telephone number;
 - b. If applicant is a partnership, each partner's name, address, and an identification of whether a limited or general partner;
 - c. If a corporation, the state of incorporation and the name, title, and address of each officer of the corporation and statutory agent;
 - d. The name of the salon;
 - e. The name and license number of the manager licensed by the Board;
 - f. If a location change, the previous address;
 - g. A history of the salon including:
 - i. If previously licensed by the Board, the last name of the salon or school;
 - ii. The name of each business operating at the salon address;
 - iii. A statement of whether the applicant, any partner of the applicant, or any corporate officer has ever owned a salon in any state or foreign country;

Notices of Final Rulemaking

- iv. A statement of whether the applicant, any partner of the applicant, or any corporate officer has ever had a salon license suspended or revoked in any state or foreign country; and
- v. A statement of whether the salon provides mobil services as stated in R4-10-403.
- 2. If a corporation, the articles of incorporation;
- 3. If a partnership, a copy of the partnership agreement;
- 4. An 8 ½" by 11" floor plan of the salon. The floor plan shall designate the location of each:
 - a. Wet disinfectant as specified by R4-10-109;
 - b. Dry, closed, disinfected container to store disinfected tools and implements as specified by R4-10-109;
 - c. Sink or shampoo bowl with hot and cold running water that is not also used as a dispensary or rest room sink;
 - d. Station;
 - e. Restroom;
 - f. Electrical outlet; and
 - g. Activity performed by individuals who are not licensed by the Board, which are related to cosmetology, but not regulated by A.R.S. § 32-501 through § 32-575; and
- 5. The fee required in R4-10-102.

R4-10-402. Changes Affecting a Salon License

- A.** A licensee changing a salon's location shall submit the fee required in R4-10-102 and an application packet as prescribed in R4-10-401.
- B.** A licensee shall notify the Board in writing at least 30 days before making a change in the ownership of a salon. A new owner shall obtain a license from the Board before beginning operation of a salon.
- C.** When the controlling ownership in a corporation is transferred or a corporation is reorganized, the new owner shall submit the fee required in R4-10-102, an application packet as prescribed in R4-10-401 and the following:
 - 1. Former owner's name;
 - 2. Date of transfer; and
 - 3. A statement of whether the former owner relinquishes the license, salon name, and salon location.
- D.** A licensee shall notify the Board in writing at least 30 days before the date of a change in a salon's name and submit the fee required in R4-10-401.
- E.** A licensee that is a corporation or a limited liability company shall notify the Board in writing at least 3 days before a change in any corporate officer or statutory agent.

~~R4-10-402.~~ ~~R4-10-403.~~ Salon Requirements and Minimum Equipment Requirements

No Change.

~~R4-10-403.~~~~R4-10-404.~~ Mobile Services

No Change.

~~R4-10-404.~~~~R4-10-405.~~ Shampoo Assistants

No Change.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 19. BOARD OF NURSING

PREAMBLE

- 1. **Sections affected**
R4-19-303
- Rulemaking action:**
Amend
- 2. **The specific authority for the rulemaking, including both the authorizing statute general and the statutes the rules are implementing (specific):**
Authorizing statute: A.R.S. § 32-1606(A)
Implementing statutes: A.R.S. §§ 32-1635 and 32-1640
- 3. **The effective date of the rules:**
May 18, 1999
- 4. **A list of all previous notices appearing in the Register addressing the final rule:**
Notice of Rulemaking Docket Opening: 5 A.A.R.461, February 5, 1999.
Notice of Proposed Rulemaking: 5 A.A.R. 416, February 5, 1999.

Arizona Administrative Register
Notices of Final Rulemaking

5. Name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Janet M. Walsh, Associate Director
Address: Arizona State Board of Nursing
1651 E. Morten, Suite 150
Phoenix, Arizona 85020
Telephone: (602) 331-8111, Ext. 145
Fax: (602) 906-9365

6. An explanation of the rule, including the agency's reasons for initiating the rule:

Pursuant to A.R.S. § 32-1606(B), all applicants for initial licensure or certification are required to submit fingerprints to the Board for the purpose of obtaining a state and federal criminal history. The state criminal history is available within a short period of time. However, receipt of the federal criminal history takes 60 to 90 days from receipt of the applicant's fingerprint card at the Board. Applicants for licensure by examination who, while qualified for a temporary license under A.R.S. §§ 32-1635 and 32-1640, are ineligible to receive a temporary license under the current rule. In addition, the Board is concerned that these applicants will experience delays in the licensure process and be unable to work until the federal criminal history is received. The Board believes that amendment of this rule at the present time is urgently needed because the majority of professional and practical nurse applicants for licensure by examination submit applications to the Board in the months of May and June. To address these concerns, the Board proposes an amendment to R4-19-303 to allow applicants for licensure by examination to obtain a temporary license if they meet the qualifications for licensure, have passed the NCLEX examination, and lack a state criminal history.

7. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the proposed rule and where the public may obtain review the study, all data underlying each study, any analysis of the study and other supporting materials:

None.

8. A showing of good cause why the rule is 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.

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

The proposed amendment will have a minimal economic impact on professional and practical nurse applicants for licensure by examination who will be charged \$25 if they desire to receive a temporary license. The proposed amendment will have a positive economic impact because these applicants will be able to enter the work force sooner. The Board expects to receive a substantial economic impact as a result of the amendment to R4-19-303 because it anticipates that approximately 1,368 applicants for licensure by examination will apply for a temporary license, resulting in additional revenue in the amount of approximately \$34,200. The Board will also incur costs in the nature of time and resource allocation for the processing of applications and the issuance of temporary licenses. Additionally, the Secretary of State will incur costs for publication of the rule, and the Board will incur costs in promulgating the rule. The Board anticipates private and public employers will be indirectly benefited because they will be able to employ applicants for licensure by examination who currently are ineligible to receive a temporary license before they complete the application process.

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

The Board made stylistic changes to the rule to improve clarity. The changes do not affect the substance of the rule.

11. A summary of the principal comments and the agency response to them:

Two individuals representing 2 long-term care organizations in the state (Arizona Association of Homes and Housing for the Aging and Arizona Health Care Association) testified in support of the amendment to R4-19-303 at a public hearing held on March 11, 1999, although these individuals recommended that the Board make applicants for nursing assistant certification eligible for temporary certificates. The Board declined to make this change for 2 reasons: 1) the Board lacks statutory authority to issue temporary certificates to applicants for nursing assistant certification; and 2) federal law allows applicants for nursing assistant certification to work for 4 months pending certification by the Board. The Board received 1 written comment from a representative of the Arizona Association of Homes and Housing for the Aging before the close of record on March 31, 1999, expressing the same concern.

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

Not applicable.

Arizona Administrative Register
Notices of Final Rulemaking

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

Not applicable.

14. Was this rule previously adopted as an emergency rule:

Not applicable.

15. Full text of the rule follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 19. BOARD OF NURSING

ARTICLE 3. LICENSURE

Section

R4-19-303. Temporary License

ARTICLE 3. LICENSURE

R4-19-303. Temporary License

- A.** ~~Subject to subsection (B), the Board shall issue a temporary license to an applicant who is qualified pursuant to A.R.S. § 32-1635 or § 32-1640 and who desires~~ desiring to practice nursing pending licensure if the applicant lacks a state criminal history as verified by a report issued by the Arizona Department of Public Safety may submit a written request to the Board for a temporary permit, together with a completed application for licensure on a form provided by the Board in accordance with this Article, and other documents required to be submitted or an official statement from another state board of nursing verifying that the applicant has a current license in good standing. An applicant for licensure by endorsement may also submit a request to the Board for a temporary permit. The permit, if issued, shall be valid for a period of two months commencing from the date of the completed application and receipt of fees by the Board.
- B.** ~~An applicant who has filed an application for renewal of a license which has been inactive or expired for five or more years may also submit a written request to the Board for a temporary permit to practice to allow the applicant to complete a reentry update program. and the applicant:~~
1. Is qualified under:
 - a. A.R.S. § 32-1635 and § 32-1640; and
 - b. R4-19-301 and R4-19-302; and
 2. If seeking licensure by endorsement, has filed an application for licensure by endorsement and submitted documents or an official statement from another state board of nursing verifying that the applicant has a current license in good standing; or
 3. If seeking renewal of a license that has been inactive or expired for 5 or more years, has filed an application and enrolled in a reentry update program.
- B.** An applicant who discloses a pending disciplinary charge, criminal conviction, chemical dependency, pending investigation or disciplinary action by a regulatory agency, or malpractice claim is not eligible for a temporary license without prior Board approval.
- C.** Unless extended for good cause under subsection (D), a temporary license is valid for a maximum of 6 months.
- C.D.** A temporary permit shall expire on the date set forth on the permit. A temporary licensee may apply and the Board or the Executive Director shall grant an extension for good cause. Good cause means reasons beyond the control of the temporary licensee such as unanticipated delays in obtaining information required for licensure.

NOTICE OF FINAL RULEMAKING

TITLE 6. ECONOMIC SECURITY

CHAPTER 5. DEPARTMENT OF ECONOMIC SECURITY

SOCIAL SERVICES

PREAMBLE

1. Sections Affected:

Article 23
R6-5-2301
R6-5-2302
R6-5-2303
R6-5-2304

Rulemaking Action:

Repeal
Repeal
Repeal
Repeal
Repeal

Notices of Final Rulemaking

R6-5-2305	Repeal
R6-5-2306	Repeal
R6-5-2307	Repeal
R6-5-2308	Repeal
R6-5-2309	Repeal
R6-5-2310	Repeal
Article 56	New Article
R6-5-5601	New Section
R6-5-5602	New Section
R6-5-5603	New Section
R6-5-5604	New Section
R6-5-5605	New Section
R6-5-5606	New Section
R6-5-5607	New Section
R6-5-5608	New Section
R6-5-5609	New Section
R6-5-5610	New Section
R6-5-5611	New Section
R6-5-5612	New Section

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

Authorizing Statutes: A.R.S. §§ 41-1003, 41-1954(A)(3), and 46-134(A)(12)

Implementing Statutes: A.R.S. §§ 8-201, 8-531, 8-807, and 41-1959

3. The effective date of the rules:

May 18, 1999

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

Notice of Rulemaking Docket Opening: 1 A.A.R. 1157, July 21, 1995;

Notice of Proposed Rulemaking: 4 A.A.R. 1254, June 5, 1998;

Notice of Oral Proceedings: 4 A.A.R. 1255, June 5, 1998.

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

Name: Paulina Vazquez-Morris

Address: Department of Economic Security
1717 W. Jefferson
Phoenix, Arizona 85007

Telephone: (602) 542-1163

Fax: (602) 542-5339

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

The purpose of the rule is to set forth Departmental procedures for the protection and disclosure of confidential information in accordance with controlling state and federal statutes. The Department promulgated the current rules in May of 1976. These rules are outdated, inconsistent with controlling law, and ineffective. Legislation enacted since 1976 requires inclusion of new confidentiality and disclosure requirements and repeal of current rules. In this rule-making package, the Department is submitting a new set of rules to govern the protection and disclosure of Child Protective Services records and files. The rules describe the procedures for requesting confidential information, fees to be paid to the Department for processing requests, and information that will be redacted from records and files prior to release. The rules also include a set of definitions relevant to confidentiality and release of records and files. The new rules are consistent with federal and state authority and program policy and practice.

7. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the final rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

None.

8. A showing of good cause why the rule is 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.

Arizona Administrative Register
Notices of Final Rulemaking

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

There is an economic impact for some consumers attributable to the rules. The economic impact results from the legislative mandate to provide confidential records and files to authorized individuals. Specified consumers who request copies of Child Protective Services records and files, as permitted by Arizona Revised Statutes, will incur an expense for the Department to process the requested information. The authority to charge a fee for this service is permitted by A.R.S. § 8-807.

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

Technical Changes (Format, Style, Grammar, Consistency)

Based on public comments, the Department's review of the rules, review by the Attorney General's Office and the Office of the Secretary of State, the Department made nonsubstantive corrections and changes to punctuation and format to conform to the Secretary of State's requirements. The Department also corrected erroneous cross-references, changed statutory citations that became effective August 21, 1998.

R6-5-5601 Deleted statutory reference ~~8-546~~;

R6-5-5601 Changed statutory reference from ~~8-546.11~~ to 8-531, 8-201, and 8-807.

R6-5-5601(13)(A) Changed "A" to "a."

R6-5-5602 Changed statutory reference from ~~8-546.11~~ to 8-807.

R6-5-5603(A) Changed statutory reference from ~~8-546.11~~ to 8-807.

R6-5-5603(B)(3) and (4) Indented "a" through "d" to the 3rd level.

R6-5-5603(D) Changed statutory reference from ~~8-546.11(C)(10),(D),(F)~~ to 8-807 (C)(10), (D), or (F).

R6-5-5604(C)(3) Inserted a hyphen in "timeframe"; "time-frame."

R6-5-5605(A) Changed statutory reference from ~~8-546.11(C)~~ to 8-807(C).

R6-5-5605(A) Corrected cross reference from ~~R6-5-5604~~ to R6-5-5603.

R6-5-5605(B) Changed statutory reference from ~~8-546.11(C)~~ to 8-807(C).

R6-5-5605(C)(2) Changed statutory reference from ~~8-546.11(C)~~ to 8-807(C).

R6-5-5605(C)(2) indented "a" and "b" to the 3rd level.

R6-5-5606(A) Changed statutory reference from ~~8-546.11(C)~~ to 8-807(E).

R6-5-5606(B) Corrected cross-reference from ~~R6-5-5604~~ to R6-5-5603(B).

R6-5-5606(B)(1) Changed statutory reference from ~~8-546.11(E) and (G)~~, to 8-807(E) and (G).

R6-5-5607(A) Changed statutory reference from ~~8-546.11(H)~~ to 8-807(H).

R6-5-5607(C) Renumbered duplicate item "2" to number "3."

R6-5-5608(A)(1) Indented "a" and "b" to the 3rd level.

R6-5-5609(A) Changed statutory reference from ~~8-546.11(C)(12)~~ to 8-807(C)(12).

R5-5-5609(A) and (C) Changed who will receive and review requests for information . . . "shall send a written request for information to the ~~ACYF Program Administrator, or the Administrator's designee~~ Department Director, or the director's designee."

R6-5-5610(A) Changed statutory reference from ~~8-546.11(C)(14)~~ to 8-807(C)(15).

R6-5-5610(B)(1) Indented "a" and "b" to the 3rd level.

R6-5-5611 Corrected the rule reference from ~~R6-5-5-5611~~ to R6-5-5611.

R6-5-5612(B) and (D) Changed statutory reference from ~~8-546.11(C)(10), (D), or (F)~~ to 8-807(C)(10), (D), or (F).

R6-5-5612(C)(2) Changed statutory reference from ~~8-546.11(D), (F), and (G)~~ to 8-807 (D), (F), and (G).

Substantive Changes (Changes that resulted in a change or clarification in the meaning of a rule):

Based on comments from child advocates, public comment, as well as the Department's review and review by the Attorney General's Office the, Department made the following substantive corrections and changes to the rules.

Arizona Administrative Register
Notices of Final Rulemaking

R6-5-5601. Definitions

R6-5-5601 A comment was received that the definition of "CPS" was not clear in describing the organizational structure and function. The definition in R6-5-5601(4) has been changed to:

"CPS" means Child Protective Services, a program within the Administration for Children, Youth and Families, (ACYF) to receive and investigate allegations of child maltreatment and provide protective services as described in R6-5-5501(40)."

R6-5-5611 This rule has been renumbered to R6-5-5612 to permit the addition of a new rule.

R6-5-5611 To comply with a statutory change effective August 21, 1998, with a retroactive date of July 1, 1998, a new rule has been added that provides for the release of confidential information concerning an alleged victim of abuse, neglect or abandonment who has died.

R6-5-5612(B), (C), and (D) The fee the Department will charge for copies of records and files has been reduced from \$1.50 per page to 25¢ per page to give individuals the opportunity to receive authorized information at less cost.

R6-5-5612(E) This section has been deleted as the 25¢ fee per page will be charged in all cases as prescribed in R6-5-5612(B), (C), and (D).

11. A summary of the principal comments and the agency responses to them:

The Department received public comments regarding the issues summarized below. This section describes comments that were not adopted, and the Department's response to those comments. The response explains the Department's reasons for not making requested changes. In question #10 above, the Department described comments received where the response was to make the requested change.

R6-5-5601 (Protected individual) A comment was received that when it has been confirmed that a protected individual is the abuser, that person should no longer be considered protected by the rule. The Department must abide by state and federal statutes that protect individuals who are the subject of a CPS investigation. These laws do not exclude a person from privacy based on the outcome of an investigation. When the Department intends to substantiate a report, individuals have a right to appeal this decision prior to entry of the finding into the Central Registry.

R6-5-5601 (Redacting) One comment stated the Department should adopt language from Arizona Supreme Court Rule 123(c)(2)(C), that provides for a disclosure that records were redacted, identification of redacted records, including a description of the nature and length of matters redacted unless this would disclose confidential information, and the legal authority for the redaction. The Department has concluded that specific rules in this package accomplish the same purpose. This definition references blacking out personally identifiable information on protected individuals. Personally identifiable information, protected individuals and the types of confidential information to be redacted, are described in R6-5-5601. Adding a requirement to describe each item that was redacted would not provide the requester any further information and could possibly reveal personally identifiable information. This additional task would prevent the Department from releasing the information in a timely manner. Individuals requesting information are advised in these rules of the statutory authority and that personally identifiable information will be redacted pursuant to statute. This disclosure is also included on the request form used to obtain confidential information.

R6-5-5603 A comment was received that asking a person the purpose for the request should be deleted as it appears to give DES the ability to decide whether or not the purpose is acceptable. A.R.S. § 8-807 identifies individuals and circumstances under which confidential information may be released. The Department must make all efforts to determine whether or not the individual requesting information meets the statutory requirement and purpose.

R6-5-5603 One person felt that having an individual notarize the request form is burdensome. The Department must require a notarized signature as the requests for confidential information are submitted by mail. Verification of the identity of the requester must be obtained to prevent individuals not authorized by statute from obtaining CPS records and files.

R6-5-5606 One comment recommended that the time-frames for notifying an individual requesting a copy of a CPS report be shorter. It was suggested that if the Department does not have the information, written notice be provided within 7 calendar days, and the information provided to the person within 20 calendar days.

The Department has determined that responding to and releasing requests for information within 30 days is reasonable. This maximum time-frame permits the Department to make diligent efforts to provide requested reports and information quickly, while allowing more time if necessary. Each request requires a search of the CPS databases, printing, redacting and copying of each report and approval by a manager prior to release. The process time for each request is approximately 10 to 15 minutes. The cycle time is longer due to the volume of requests and other duties of

the individuals who process them. The implementation of the CPS appeal process for proposed substantiated investigation findings has substantially increased the volume of requests for reports. Each person is entitled to appeal this proposed finding and receive a copy of the CPS report. In FY 97, 14,394 reports were substantiated. The Department would not be able to comply with requests for this number of reports if shorter time-frames were imposed by rule.

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

Not applicable.

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

Not applicable.

14. Was this rule previously adopted as an emergency rule?

Not applicable.

15. The full text of the rules follows:

TITLE 6. ECONOMIC SECURITY

**CHAPTER 5. DEPARTMENT OF ECONOMIC SECURITY
SOCIAL SERVICES**

~~ARTICLE 23. SAFEGUARDING OF RECORDS AND INFORMATION~~ Repealed

Section

- R6-5-2301. ~~Objective~~ Repealed
- R6-5-2302. ~~Legal authority~~ Repealed
- R6-5-2303. ~~Definitions~~ Repealed
- R6-5-2304. ~~System of records to be safeguarded~~ Repealed
- R6-5-2305. ~~Types of information to be safeguarded~~ Repealed
- R6-5-2306. ~~Subpoena of record by court~~ Repealed
- R6-5-2307. ~~Access to records and disclosure of information~~ Repealed
- R6-5-2308. ~~Public information and publicity~~ Repealed
- R6-5-2309. ~~Violation and penalties~~ Repealed
- R6-5-2310. ~~Storage of case records or system of records~~ Repealed

~~ARTICLE 56. CONFIDENTIALITY AND RELEASE OF CPS RECORDS~~

Section

- R6-5-5601. Definitions
- R6-5-5602. Scope and Application
- R6-5-5603. Procedures for Requesting Information
- R6-5-5604. Procedures for Processing a Request for Information
- R6-5-5605. Release of Information in Situations Requiring Immediate Action or Service to a Child
- R6-5-5606. Release of Report and Investigation Findings
- R6-5-5607. Release of Summary Information to a Person Who Reported Suspected Child Abuse and Neglect
- R6-5-5608. Release of Information to a Research or Evaluation Project
- R6-5-5609. Release of Information to a Legislative Committee
- R6-5-5610. Release of Information to a State Official
- R6-5-5611. Release of Information to an Individual Who Requests Records and Files Concerning an Alleged Victim of Abuse, Neglect or Abandonment Who Has Died
- R6-5-5612. Fees

~~ARTICLE 23. SAFEGUARDING OF RECORDS AND INFORMATION~~ Repealed

R6-5-2301. Objective Repealed

The stipulation of policy for safeguarding records and the disclosure of information is mandated in federal and state statutes. Any information in records, registries, listing or data base information system is confidential. This information is extended to many people but each is equally accountable to the obligation to safeguard information. These regulations apply to all staff and employees of the Department of Economic Security, to members of the advisory councils, all agencies who contract or provide social services and county officers, representatives of social agencies, hospitals, and any educational facility to whom use of any information from any record is entrusted. This Article will identify all records and registries that are kept about individuals, state rules and regulations for safeguarding of records, and disclosure of information.

Arizona Administrative Register
Notices of Final Rulemaking

R6-5-2302. Legal authority Repealed

- A.** Title XX, IV-A, and IV-B. Title 42 U.S.C. § 602 provides as a condition for federal financial participation, the state shall "provide safeguards which restrict the use of disclosure of information concerning applicants and recipients to purposes directly connected with the administration of the program". Federal regulations set forth in 45 CFR § 205.50 must be followed.
- B.** A.R.S. § 46-135. Power to promulgate rules concerning confidential nature of records.
The state department shall establish such reasonable regulations as it deems necessary to protect confidential information. In no event shall the name of any recipient be made available for political or commercial purposes.
- C.** Adoption
A.R.S. § 8-120. Records; inspections; exception
"**A.** All files, records, reports and other papers compiled in accord with this article, where filed in or in possession of the court, an agency or any other person or association, shall be withheld from public inspection.
B. Such files, records, reports and other papers may be open to inspection by persons and agencies having a legitimate interest in the case and their attorneys and by other persons and agencies having a legitimate interest in the protection, welfare or treatment of the child if so ordered by the court."
- D.** Child welfare and placement
1. Foster care
A.R.S. § 8-519. Records and reports
"**A.** Each child welfare agency shall keep records regarding the children in its care as the division prescribes, and shall furnish to the division, upon request, such additional information as the division requires.
B. All records and information in the possession of the department or any child welfare agency regarding children and their parents or relatives shall be deemed confidential, and shall be disclosed only pursuant to rules by the division or by order of court.
C. A child welfare agency shall furnish a report of each placement or withdrawal of each child to the division."
2. Termination of parental rights
A.R.S. § 8-541. Records; inspections; exception
"**A.** All files, records, reports and other papers compiled in accord with this article, whether filed or in possession of the court, a child placement agency or other agency or association, shall be withheld from public inspection."
3. Protective services
A.R.S. § 8-546.03. Central registry
A. The State Department of Economic Security shall maintain a central registry of reports, investigations and evaluations made under this article. The registry shall contain the information furnished by protective service workers throughout the state.
B. Data shall be kept in the central registry until the child concerned reaches the age of 18 years.
C. Data and information in the central registry shall be confidential and shall be made available only with the approval of the director of economic security to the juvenile court, social agencies, public health and law enforcement agencies, licensed health practitioners, and health and educational institutions licensed or regulated by the state of Arizona.

R6-5-2303. Definitions Repealed

- A.** "Department". The Department of Economic Security (referred to as division in A.R.S. § 8-519 regarding foster care).
- B.** "Record". Any item, collection or grouping of information about an individual that is maintained by the Department including, but not limited to the individual's education, financial transactions, medical, social and psychological histories, criminal or employment history, that contains his name, or any number, symbol and other identifying particular used and assigned in the past to the individual such as a finger or voice print or a photograph.
- C.** "Statistical record". A record maintained for statistical research or reporting purposes only and not used in whole or in part in making any determination about an identifiable individual.
- D.** "System". A system of records under control of the Department from which information is retrieved by the name of the individual as well as by some identifying number, symbol or other identifying particular assigned to the individual. They will include central registries, payrolls and data base information system.
- E.** "Routine use". The disclosure of information without the consent of the subject individual of such information for a purpose which is compatible with the purpose for which it was collected.
- F.** "Individual". A living person who resides or has resided in the past within the state of Arizona or who is here temporarily, but who intends to make Arizona his permanent residence. This does not include aliens who are here illegally or are here on temporary work status.
- G.** "Subject individual". That individual to whom a record pertains.
- H.** "Disclosure". The availability or release of a record to anyone other than the subject individual.
- I.** "Maintain". To collect, use or disseminate when used in connection with the term "record". To have control over or responsibility for a system of records when used in connection with the term "system of records".
- J.** "Access". Availability of information or the record of an individual.

Arizona Administrative Register
Notices of Final Rulemaking

- ~~**K.** "Storage". That method designated by the Department to safeguard records that contain information of individuals and the location of where records shall be kept.~~
- ~~**L.** "Retention". The length of time a record will be maintained and information kept intact.~~
- ~~**M.** "Disposal". That method designed for destruction of closed records.~~

R6-5-2304. System of records to be safeguarded Repealed

The following system of records are kept by the Department:

- ~~1. Case records which may include but are not limited to the following information: applications— documents, field notes, reports of investigations, medical and psychiatric reports, correspondence, court reports, court orders, social studies, summaries and evaluations, foster home, day care home and adoptive home studies.~~
- ~~2. Child protective service central registry.~~
- ~~3. Social service data base information system.~~
- ~~4. Licensed foster home central registry.~~
- ~~5. Records of licensed group homes, licensed child care agencies and licensed child placing agencies.~~
- ~~6. Adoptive home certifications.~~
- ~~7. Pre-placement studies and listing of children available for adoption.~~
- ~~8. Listing of foster care placement and withdrawal of children.~~
- ~~9. Payrolls on foster care, day care, adoption subsidy, family planning, shelter care, day treatment and special education.~~

R6-5-2305. Types of information to be safeguarded Repealed

- ~~**A.** The names and addresses of applicants and recipients and the type of service provided;~~
- ~~**B.** Information related to the social and economic conditions or circumstances of a particular individual;~~
- ~~**C.** Agency evaluation of information about a particular individual;~~
- ~~**D.** Medical data, including diagnosis and past history of disease or disability concerning a particular individual;~~
- ~~**E.** All information, including records, applications, documents, case records, field notes, reports of investigations, medical reports, correspondence and evaluations or studies, concerning any applicant for or recipient of adoption and child placement services;~~
- ~~**F.** All data and information filed in the child protective service central registry;~~
- ~~**G.** All data and information filed in the licensed foster home central registry;~~
- ~~**H.** All data and information filed in the listing of foster care placements and withdrawal of children;~~
- ~~**I.** Data and information, such as names and addresses on the following payroll listings: day care, family planning, adoption subsidy, foster care, shelter care, day treatment, special education, institutional care—or any other printouts which list names and addresses;~~
- ~~**J.** All data and information of the social services information system;~~
- ~~**K.** Medical records of minors in cases of abortion, pregnancy, contraception, venereal disease, alcohol, drug and narcotic abuse or addiction;~~
- ~~**L.** Adoption records must be segregated from other Departmental records and may be viewed only by Departmental employees directly connected with the case unless otherwise ordered by the Court. The statutes relating to adoption require adoption records to be withheld from public inspection; the Department must zealously guard against adoption information becoming public. In closed adoption cases, the Department of Economic Security shall release information only by authority of a court order.~~

R6-5-2306. Subpoena of record by court Repealed

- ~~**A.** Information or records subpoenaed or ordered by the courts.
 - ~~1. No officer or employee of the Department shall testify or give evidence before any court or quasi-judicial proceeding concerning any applicant recipient, claimant or employee except as provided herein. If an officer or an employee of the Department is subpoenaed or ordered by the court to disclose information concerning any applicant, client or employee, the Legal Services Bureau must be notified promptly. No information shall be released except when authorized by the Legal Services Bureau. The Legal Services Bureau shall call to the attention of the court or quasi-judicial officer, the federal and state provisions against disclosure of information.~~
 - ~~2. If Department records and information are ordered by the court, the Legal Bureau will be notified immediately. The records will be photocopied and then the original case record will be submitted to the court. When the original case record is returned to the office, the photo copy will be destroyed.~~
 - ~~3. Under no circumstances is anyone to accept service of a subpoena unless he is the person named in the document. The acceptance of a subpoena for records will be the office manager.~~~~
- ~~**B.** Acceptance or nonacceptance of a subpoena is to be communicated immediately to the District Manager or Bureau Chief, depending on whether the individual involved is on the district or state level. Pertinent information about the situation and the subpoena, if accepted, will then be forwarded to the Legal Service Bureau as expeditiously as possible through proper channels.~~

Arizona Administrative Register
Notices of Final Rulemaking

~~C. When an individual requests information to be released to a court or to a hospital or health care where the information may be used in any adjudicatory procedure, the release will not be authorized. Records and information can be released only when subpoenaed or ordered by the court in the following circumstances:~~

- ~~1. Juvenile courts when concerned with dependency, incorrigibility or delinquency.~~
- ~~2. Superior courts when concerned with cases of mental health.~~
- ~~3. Hospital and health care facilities involved in any litigation regarding the individual.~~

R6-5-2307. Access to records and disclosure of information Repealed

~~A. No officer or employee shall release information concerning any individual applicant, recipient or client unless~~

- ~~1. The use or disclosure of information concerning applicants and recipients will be limited to purposes directly connected with establishing eligibility, determining amount of assistance and providing services for applicants or clients.~~
- ~~2. Written permission is obtained from the individual or parent or legal guardian thereof when request for information is made by an outside source.~~
- ~~3. An emergency situation arises and it is in the best interest of the applicant or recipient that information be disclosed. Written consent need not be obtained for the release of information. The information disclosed and to whom disclosure was made shall be recorded in the case record. The applicant or recipient shall be notified promptly of the request or disclosure.~~
- ~~4. Information is requested by persons or agency representatives who are subject to standards of confidentiality which are comparable as stated herein. Written consent need not be obtained for the release of the information. Information disclosed and to whom disclosure was made shall be recorded in the case record. The applicant or recipient shall be notified promptly of the request or disclosure.~~
- ~~5. Only that information necessary for the determination of eligibility for another program will be disclosed.~~

~~B. Reporting release of information~~

- ~~1. Information disclosed or released by the Department to other agencies or individuals shall be notified that the information they receive from the Department cannot be released to the clients, any other person or agency without written permission from the Department.~~
- ~~2. Only employees having an authorized and established purpose in a record shall have routine use of or the privilege of inspection to information in the record. A log will be kept on the whereabouts of all records and systems of records and to whom the record is released.~~
- ~~3. The information in the child protective services registry can only be released to Department staff directly connected with protective services. All other requests can only be honored by approval of the Department Director.~~

~~C. Persons authorized to have access to records, listings, or files:~~

- ~~1. Director of Department of Economic Security~~
- ~~2. Deputy Director of Department of Economic Security~~
- ~~3. Assistant Director of Field Services~~
- ~~4. Assistant Director of Program Services~~
- ~~5. Assistant Attorney Generals assigned to the Legal Services Bureau~~
- ~~6. Chief, Information and Legislative Services Bureau~~
- ~~7. Chief information officer~~
- ~~8. District managers~~
- ~~9. District social service consultants~~
- ~~10. Area managers~~
- ~~11. Chief, Social Services Bureau~~
- ~~12. Section managers and staff of Social Services Bureau~~
- ~~13. Managers of the local offices~~
- ~~14. Social services' supervisors~~
- ~~15. Local office social service staff~~
- ~~16. Management analyst, planner and research analyst employed by the Department~~
- ~~17. Special investigators~~
- ~~18. Internal auditors~~
- ~~19. Non-Department employees, conducting research projects with permission of the Department Director~~
- ~~20. Student, interns, etc. in field placement status~~
- ~~21. Special project personnel as approved by the Department Director.~~

~~D. Persons authorized to approve disclosure of information:~~

- ~~1. Director of Department of Economic Security~~
- ~~2. Deputy Director of Department of Economic Security~~
- ~~3. Attorneys assigned to the Legal Service Bureau~~
- ~~4. Assistant Director of Field Services~~
- ~~5. District managers~~
- ~~6. District social services consultants~~

Arizona Administrative Register
Notices of Final Rulemaking

7. Area managers
 8. Managers of local offices
 9. Social services supervisors
 10. Local office social service staff may release case information when authorized to do so by district managers
 11. Assistant director of Program Services
 12. Chief, Social Services Bureau
 13. Section managers of Social Services Bureau.
- E.** Release of information to applicant/client. Information contained in the Department's records shall not routinely be made available to applicant/client. However, where applicant/client requests a fair hearing as provided by Department regulations, or some form of court action has been instituted, the applicant/client and/or attorney may examine case records prior to the hearing.
- Exception: Medical, psychiatric and psychological records which could be harmful and have an adverse reaction to the client can only be released to a designated physician. The physician must be asked to evaluate the effect that access to the record would have on the individual client. The physician will interpret to the family and court. When the information is about a minor, age 12 years or older, that minor will have to sign the release in addition to the parents. The total case record may not be photocopied or taken from the office by the client or his attorney. If the attorney wants copies of items other than medical records, a fee of 10¢ a page may be charged.
- F.** Release of information upon request of the applicant/client
1. The Department must approve all requests by the applicant/client to release information before it may be disclosed. Authority to approve requests is vested in the same personnel authorized to release information.
 2. The release of information must state to whom (title and address), the purpose, the exact information to be released and the date. This information, if approved for release, must be sent within a 30-day period. There can be no blanket release signed by any individual.
 3. No employee or staff of the Department can release copies or information from reports received from federal agencies unless a release is signed by the affected individual or by the federal agency (examples: Social Security Administration, Bureau of Indian Affairs, Veterans Administration, Department of Labor, or Department of Agriculture).
 4. Medical records of minors regarding abortion, pregnancy, contraception, venereal disease, alcohol, drug and narcotic abuse or addiction between the ages 12 to 18 can only be released with permission of the minor or when ordered by the court. Then it can only be released to a physician.
- G.** Release of information upon request of the parent(s) of a minor. The Department must approve all requests by the parent(s) to release information before it may be disclosed. When the minor is a ward of the court, the court may approve disclosure. Authority to approve requests is vested in the same personnel authorized to release information. Requests must be signed by the parent(s) and filed in the case record (refer to R6-5-2307(E)).
- H.** Release of information to relatives or interested parties. The Department may not release or acknowledge that any individual is known to the Department.
- I.** Release of information to the parent(s). Information contained in the Department's records shall be made available to the parent(s) and his/her attorney when there is a fair hearing and to an attorney in a court action involving the minor. The minor of age 12 and over must sign and authorize the release of information. Medical records will not be made available.
- J.** Release of names and addresses to a legislative body. Names and addresses of clients can never be available for political or commercial purposes. Names and addresses can be made available to a legislative body or legislative committee that certifies that the information is needed for the purpose directly connected with:
1. Establishing eligibility;
 2. Determining amount of assistance;
 3. Providing services for applicants and clients;
 4. Any investigation, prosecution or criminal or civil proceeding conducted in connection with the administration of the social service program.
- The Department Director will approve all releases to a legislative body or legislative committee.
- K.** Release of name of clients to employers submitting a certification of receipt of aid to dependent children to an employer for purposes of claiming tax credit in public law 94-12, the Tax Reduction Act of 1974 is considered to be for a purpose directly connected with the administration of the social services program.

R6-5-2308. Public information and publicity Repealed

- A.** Public information office. Information of a general nature and statistical data not associated with any individual claimant, applicant, employer or employee shall be distributed by and through the Department's Public Information Office. The current Annual Report is maintained by and available for public distribution from the Public Information Office. The central office, local offices and contributing field offices shall maintain a small supply of these publications for distribution to the public upon request. Routinely all requests for statistical data not released should be referred to the Public Information Office.

Arizona Administrative Register
Notices of Final Rulemaking

- ~~**B.** Day care and foster home publicity. Publicity programs regarding day care and foster parents will be approved by the Department. The release of day care and foster parents' names can be made to the news media if the publicity meets the established procedure and the day care foster parents sign a release of information form.~~
- ~~**C.** Publicity for purposes of adoption. Pictures and facts about a child, except information that can easily identify the child and child's name and that of his natural parent(s) may only be published for purposes of adoption, subject to Department procedure for specific publicity programs.~~
- ~~**D.** Distribution of materials sent to clients. All materials sent or distributed to clients or medical vendors, including material enclosed in envelopes containing checks will be limited to those which are directly related to the administration of the program and will not have political implication. Under no circumstances shall the following material be sent: Holiday greetings, general public announcements, voting information, and alien registration notices, etc. Only material pertaining to official business directly connected with the administration of social services shall be sent or distributed to clients. All materials sent over signature shall be signed by officers and employees of the Department in their official capacity. Under no circumstances shall personal material be sent to clients.~~

R6-5-2309. Violation and penalties Repealed

- ~~**A.** Any staff or employee who makes any unlawful disclosure of confidential information to any person within the Department or outside sources will receive some form of disciplinary action. The severity of the violation could be grounds for immediate dismissal. When any employee knows of a violation, this must be reported to the immediate supervisor.~~
- ~~**B.** Penalties applied by statute
 - 1. Adoptions
A.R.S. § 8-128. Violation; penalty
"Any person who violates any provision of this article is guilty of a misdemeanor."
 - 2. A.R.S. § 8-542(B)
"A person who discloses information in violation of the provisions of this section or § 8-541 is guilty of a misdemeanor punishable by a fine not to exceed five hundred dollars or imprisonment in the county jail, for not to exceed six months, or both."
 - 3. 21 U.S.C. 1175, Confidentiality of alcohol and drug abuse patient records
"Penalty provided by law. Any person who violates any provision of the authorizing legislation or any provision of this part shall be fined not more than \$500 in the case of a first offense, and not more than \$5,000 in the case of each subsequent offense."~~

R6-5-2310. Storage of case records or system of records Repealed

- ~~**A.** Security of records
 - 1. All case records and systems of records must be safe guarded. Adequate security is the responsibility of all division, bureaus, and/or office managers within the Department where case records or systems of records are kept or maintained. The person in charge of office shall have prime responsibility for safeguarding all records kept in that office.
 - 2. Records and information which can identify specific applicants, recipients or clients that are sent through office mail shall be sent so that the identity will not be seen.
 - 3. All discarded material which has the names, addresses or other identifiable particulars shall be torn, cut or so destroyed, so that information cannot identify individuals.~~
- ~~**B.** Destruction of case records or systems of records
 - 1. Child protective services.
A.R.S. § 8-546.03(B)
"Data shall be kept in the central registry until the child concerned reaches the age of 18 years."
 - 2. Foster home and day care home records. All records of foster homes and day care homes are to be retained for five years following the expiration date of the last certificate issued by the Department.
 - 3. Out of town inquiries. These case records shall be destroyed two years after date of answer or closing; whichever is the latest.
 - 4. Adoption:
A.R.S. § 8-120(D)
"All files, records, reports and other papers not filed in or in the possession of the court shall be destroyed after a 20-year period."
 - 5. Licensed child placing agencies and child care institutions. Records will be destroyed five years after the expiration of the last license issued by the Department.
 - 6. All other case records will be destroyed five years after the date of closing, if client is living and three years after date of closing if client is dead. Retention must be extended beyond these periods whenever:
 - a. The federal fiscal audit and administration review has not been completed.
 - b. Specific records are involved in claims or expenditures questioned in any audit. These must be further maintained until necessary adjustments have been reviewed and cleared.
 - e. Records of clients where the Department is involved in any type of litigation with the client.~~

- ~~C.~~ The process of destruction of case records must be so that it is impossible for the record material to be identifiable. The person in charge of the records to be destroyed will notify by memorandum, all appropriate divisions of the scheduled date for destruction of the records.

ARTICLE 56. CONFIDENTIALITY AND RELEASE OF CPS RECORDS

R6-5-5601. Definitions

The definitions contained in A.R.S. §§ 8-531, 8-201, 8-807, R6-5-5501, and the following definitions apply in this Article:

1. "ACYF" means the Administration for Children, Youth and Families, an organizational unit within the Division of Children, Youth and Families, Department of Economic Security.
2. "Caregiver" means a child's parent, guardian, or custodian.
3. "Completed request" means a Request for Confidential Information form with all information completed as prescribed in R6-5-5603.
4. "CPS" means Child Protective Services, a program within the Administration for Children, Youth and Families, (ACYF) to receive and investigate allegations of child maltreatment and provide protective services as described in R6-5-5501(40)."
5. "CPS Administrator" means the DES Administrator responsible for operation of CPS, or that person's designee, which may include the ACYF Field Operations Manager, the CPS District Program Manager ("DPM"), the CPS Assistant District Program Manager (APM), or the CPS Local Office Manager.
6. "Department" means the Arizona Department of Economic Security, which is sometimes referred to as "DES" or "ADES".
7. "Estimated processing fee" means an amount a requester must pay to the Department before the Department copies and redacts requested records and files.
8. "Information" means data contained in a hard copy case file or electronic case record.
9. "Maltreatment" means alleged abuse, neglect, abandonment, or exploitation of a child.
10. "Person about whom a report is made" means an alleged abusive caregiver or other person, or a child victim age 12 or older.
11. "Personally identifiable information" means information which specifically identifies a protected individual and includes:
 - a. Name;
 - b. Address;
 - c. Telephone or fax number;
 - d. Photograph;
 - e. Fingerprints;
 - f. Physical description;
 - g. Place, address, and telephone number of employment;
 - h. Social security number;
 - i. Tribal affiliation and identification number;
 - j. Driver's license number;
 - k. Auto license number;
 - l. Any other identifier that is specific to an individual; and
 - m. Any other information that would permit another person to readily identify the subject of the information.
12. "Processing fee" means the final amount a requester must pay to the Department for copying and redacting requested records and files, before the Department will release the copied records and files.
13. "Protected individual" means a person who is the subject of a CPS investigation and includes:
 - a. An alleged victim.
 - b. An alleged victim's sibling.
 - c. A parent.
 - d. A foster parent.
 - e. A child living with the alleged victim.
 - f. The person who made the report of child maltreatment, and
 - g. Any person whose health or safety would be endangered by disclosure of CPS information.
14. "Redacting" means striking or blacking out personally identifiable information contained in CPS records or files on protected individuals so that no one can read the information.
15. "Requester" means an individual or organization that has made a public records request for information from a CPS record or file.
16. "Research requester" means an individual or organization that seeks CPS information for a research or evaluation project.
17. "Workday" means Monday through Friday excluding Arizona state holidays.

Arizona Administrative Register
Notices of Final Rulemaking

R6-5-5602. Scope and Application

- A.** This Article governs public records requests for CPS information and all requests made under A.R.S. § 8-807.
- B.** The Department shall handle any request or subpoena for information made by a party to a pending administrative proceeding, or civil, criminal, juvenile, probate, or domestic relations court proceeding, in accordance with the disclosure and discovery rules applicable to the particular proceeding or court.

R6-5-5603. Procedures for Requesting Information

- A.** A person who wishes to obtain information pursuant to A.R.S. § 8-807 shall comply with the requirements of this Section, and any applicable limitations and conditions in R6-5-5605, R6-5-5607, R6-5-5608, and R6-5-5609.
- B.** The requester shall send the Department a completed information request form, as provided in subsections (C) and (D). The form shall include the following information:
 - 1.** Requester's name, address, and telephone number;
 - 2.** Name and title of the person signing the form;
 - 3.** Name of the child victim who is the subject of the CPS report, with as much of the following information as the requester can provide on the child victim:
 - a.** Other possible spellings, names, or aliases for the child;
 - b.** Date of birth;
 - c.** The name of the child's caregivers; and
 - d.** The date of the CPS report or time-frame for the report;
 - 4.** Any other data that the requester believes will be likely to assist the Department in identifying the information requested, including the following:
 - a.** The name of the child's siblings;
 - b.** The child's social security number;
 - c.** The name of the CPS Specialist handling the case; and
 - d.** The location of the alleged maltreatment;
 - 5.** A description of the specific information needed;
 - 6.** A statement of the purpose for which the information is needed;
 - 7.** The notarized signature of the requester, unless the information is released pursuant to a court order; and
 - 8.** The address to which the requested information is to be mailed, or an indication of another method for handling the response.
- C.** The requester shall send the request to a local Department office or to the address indicated on the form.
- D.** A person seeking information pursuant to A.R.S. § 8-807(C)(10),(D),or (F), shall also send the Department a processing fee in an amount determined under R6-5-5612.

R6-5-5604. Procedures for Processing a Request for Information

- A.** Upon receipt of a request for information, the Department shall determine whether the request is complete. If the request is incomplete, the Department shall either:
 - 1.** Return the form to the requester with a statement explaining the additional information the Department needs to process the request; or
 - 2.** Contact the requester to obtain the missing information.
- B.** Upon receipt of a completed request, the Department shall stamp the receipt date on the form. The receipt date is the day that the receiving office designated on the form actually receives the completed request.
- C.** Within 30 days of the receipt date, the Department shall provide the requester with 1 of the following written responses:
 - 1.** A statement that the requested information does not exist;
 - 2.** The requested information;
 - 3.** A statement that the Department cannot provide the requested information within 30 days, the reason for the delay, and the anticipated time-frame for response; or
 - 4.** A statement that the Department cannot legally release the requested information, with the statutory citation and the reason for denial.

R6-5-5605. Release of Information in Situations Requiring Immediate Action or Service to a Child

- A.** When a person or entity entitled to receive records under A.R.S. § 8-807(C) requires information from a record or file in order to take immediate action on behalf of, or render service to, a child who is or may be the victim of maltreatment, the Department shall release the information without obtaining the form or fee required by R-5-5603.
- B.** Before releasing information pursuant to this Section, the Department shall verify that the person requesting information is a person entitled to receive information under A.R.S. § 8-807(C).
- C.** The Department shall:
 - 1.** Obtain the name and telephone number of the requester;
 - 2.** Call the requester to verify:
 - a.** That the person requesting information is a person entitled to receive information under A.R.S. § 8-807(C); and
 - b.** That the requester needs the information for a purpose described in subsection (A).

Arizona Administrative Register
Notices of Final Rulemaking

R6-5-5606. Release of Report and Investigation Findings

- A.** Pursuant to A.R.S. § 8-807(E), a person about whom a report is made who is not a party in a dependency or termination of parental rights proceeding may obtain a copy of a CPS report and investigation findings, including the following persons:
1. An adult about whom a CPS report has been made;
 2. A child victim age 12 or older;
 3. A child's parent or legal guardian.
- B.** The person requesting a copy of the CPS report and investigation findings shall submit a completed information request form which shall include the information listed in R-5-5603(B). Within 30 days of receipt of a completed information request form, the Department shall provide the requester with either:
1. A copy of the report and investigation findings, after redacting information as required by A.R.S. § 8-807(E) and (G);
or
 2. A written response indicating that the Department does not have the requested report or investigation findings.

R6-5-5607. Release of Summary Information to a Person Who Reported Suspected Child Abuse and Neglect

- A.** A person who reports alleged child maltreatment to CPS may contact CPS to determine the outcome of the report as permitted under A.R.S. § 8-807(H).
- B.** After receiving a request and before releasing information, the Department shall verify that the person requesting information was the person who made the report as follows:
1. Obtain the name and telephone number of the requester;
 2. Compare the requester's name with the name of the person listed as the reporter on the CPS report; and
 3. Call the requester and advise whether the Department can legally honor the request.
- C.** After verifying the identity of the requester, CPS shall give the person a summary of the outcome with the following information:
1. Disposition of the report;
 2. Investigation findings, if available; and
 3. A general description of the services offered or provided to the child and family.

R6-5-5608. Release of Information to a Research or Evaluation Project

- A.** A person seeking information for a research or evaluation project shall send a written request and provide information required for a complete request, under R6-5-5603. A complete research request shall also include the following information:
1. If the person works for a research organization:
 - a. The name of the organization, and
 - b. The organization's mission.
 2. A description of the research or evaluation project, and
 3. The funding source for the research or evaluation project.
- B.** Upon receipt of a completed request from a research requester, the Department shall advise whether the Department can legally honor the request, and the estimated amount of the processing fee required under R6-5-5612.
- C.** Upon receipt of the processing fee, the Department shall provide the requester with the expected time-frame for releasing the requested information.

R6-5-5609. Release of Information to a Legislative Committee

- A.** A legislative committee entitled to receive information under A.R.S. § 8-807(C)(12), shall send a written request for information to the Department Director, or the director's designee.
- B.** The written request shall include:
1. The name of the committee,
 2. The purpose for which the information is sought, and
 3. The date by which the committee needs the information.
- C.** The Department Director, or the director's designee, shall evaluate all requests for information and determine whether to release information to a legislative committee.
- D.** When releasing information to a legislative committee, the Department shall send the committee written notice that the information is confidential and shall not be further disclosed.

R6-5-5610. Release of Information to a State Official

- A.** An Arizona state official entitled to receive information pursuant to A.R.S. § 8-807(C)(15) shall send a written request to the Department Director.
- B.** The Director, or the director's designee, shall verify:
1. That the requesting state official is:
 - a. Responsible for administration of CPS, or
 - b. Responsible for oversight of CPS enabling or appropriating legislation, and
 2. That the requesting state official is seeking the information to carry out official functions.

Arizona Administrative Register
Notices of Final Rulemaking

R6-5-5611. Release of Information to a Person Who Requests Records and Files Concerning an Alleged Victim of Abuse, Neglect or Abandonment Who Has Died

- A.** An individual who requests records and files under A.R.S. § 8-807(C)(13), concerning an alleged victim of abuse, neglect, abandonment who has died, shall send the Department a completed request on each child.
- B.** Upon receipt of the request form the Department shall stamp the date and time of receipt and complete a record and location search.
- C.** The Department shall notify the requester in writing of the estimated processing fee required under R6-5-5612. If the requester does not want to proceed, the requester shall send the Department written notice to cancel the search.
- D.** Upon receipt of a cancellation notice, the Department shall return the estimated processing fee.
- E.** Upon receipt of the estimated processing fee, the Department shall prepare the records and files within 30 work days from receipt of the estimated processing fee and notify the requester of the final processing fee for records and file preparation.
- F.** After receipt of the final processing fee, the Department shall notify the requester and send the redacted records and files as indicated on the original request.

R6-5-5612. Fees

- A.** If a record production will result in a processing fee, the Department shall notify the requester of the estimated processing fee before copying any records. Within 10 days of the date of the estimate, the requester shall send the fee or advise the Department to terminate the request.
- B.** When providing information to the persons entitled to receive information pursuant to A.R.S. § 8-807(C)(10), (D), or (F), the Department shall charge a fee of 25¢ per page.
- C.** The fee per page covers the partial cost of:
 - 1. Staff time to research and collect the requested information;
 - 2. Staff time to review and redact information pursuant to A.R.S. § 8-807(D), (F), and (G);
 - 3. Administrative staff time to review and prepare the information to be submitted; and
 - 4. Costs of copying supplies such as paper, toner, and use of equipment.
- D.** The fee per page applies to both persons who obtain copies of files and persons who request to review files that must be redacted prior to review, pursuant to A.R.S. § 8-807(C)(10), (D), or (F).
- E.** After the Department has prepared information for release, the Department shall prepare an itemized billing statement showing the document preparation costs and fees the requester must pay before the Department can release the records and files.
- F.** The Department shall refund any prepaid estimated processing fees that exceed the final processing fee.

NOTICE OF FINAL RULEMAKING

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

PREAMBLE

<u>1. Section Affected</u>	<u>Rulemaking Action</u>
R12-1-102	Amend
Article 2	Amend
R12-1-202	Amend
Appendix A	Amend
Article 3	Amend
R12-1-301	Repeal
R12-1-301	Renumber
R12-1-301	Amend
R12-1-302	Renumber
R12-1-302	Amend
R12-1-303	Renumber
R12-1-303	Amend
R12-1-304	Renumber
R12-1-304	Amend
R12-1-305	Renumber
R12-1-305	Amend
R12-1-306	Renumber
R12-1-306	Amend

Arizona Administrative Register

Notices of Final Rulemaking

R12-1-307	Renumber
R12-1-308	Renumber
R12-1-308	Amend
R12-1-309	Renumber
R12-1-309	Amend
R12-1-310	Renumber
R12-1-310	Amend
R12-1-311	Renumber
R12-1-311	Amend
R12-1-312	Renumber
R12-1-312	Amend
R12-1-313	Renumber
R12-1-313	Amend
R12-1-314	Renumber
R12-1-314	Amend
R12-1-315	Renumber
R12-1-315	Amend
R12-1-316	Renumber
R12-1-316	Amend
R12-1-317	Renumber
R12-1-317	Amend
R12-1-318	Renumber
R12-1-318	Amend
R12-1-319	Renumber
R12-1-319	Amend
R12-1-320	Renumber
R12-1-320	Amend
R12-1-321	Renumber
R12-1-321	Amend
R12-1-322	Renumber
R12-1-322	Amend
R12-1-323	Renumber
R12-1-323	New Section
Schedule (Exhibit) A	Amend
Schedule (Exhibit) B	Amend
Schedule C	Repeal
Schedule (Exhibit) D	Amend
Schedule (Exhibit) E	Amend
Exhibit E	New Section
R12-1-407	Amend
R12-1-408	Amend
R12-1-409	Amend
R12-1-411	Amend
R12-1-415	Amend
R12-1-418	Amend
R12-1-419	Amend
R12-1-442	Amend
R12-1-449	New Section
R12-1-450	New Section
R12-1-511	Amend
R12-1-541	Amend
R12-1-606	Amend
R12-1-612	Amend
Article 7	Amend
R12-1-701	Amend
R12-1-702	Amend
R12-1-703	Repeal
R12-1-703	New Section
R12-1-704	Repeal

Arizona Administrative Register

Notices of Final Rulemaking

R12-1-704	New Section
R12-1-705	New Section
R12-1-706	New Section
R12-1-707	New Section
R12-1-708	New Section
R12-1-709	Reserved
R12-1-710	New Section
R12-1-711	New Section
R12-1-712	New Section
R12-1-713	New Section
R12-1-714	New Section
R12-1-715	Reserved
R12-1-716	New Section
R12-1-717	New Section
R12-1-718	New Section
R12-1-719	New Section
Exhibit A	New Exhibit
R12-1-801	Amend
R12-1-802	Amend
R12-1-803	Amend
R12-1-804	Amend
R12-1-805	Amend
R12-1-806	Amend
R12-1-902	Repeal
R12-1-903	Amend
R12-1-904.	Amend
R12-1-911	Amend
Article 10	Amend
R12-1-1001	Amend
R12-1-1002	Amend
R12-1-1003	Amend
R12-1-1004	Amend
R12-1-1005	Amend
R12-1-1006	Amend
R12-1-1007	Amend
R12-1-1008	Amend
R12-1-1209	Amend
R12-1-1210	Amend
R12-1-1211	Amend
R12-1-1212	Amend
R12-1-1213	Amend
R12-1-1214	Amend
R12-1-1215	Amend
R12-1-1216	Amend
R12-1-1217	Amend
R12-1-1218	Amend
R12-1-1219	Amend
R12-1-1220	Amend
R12-1-1222	Amend
R12-1-1301	Amend
R12-1-1302	Amend
R12-1-1303	Amend
R12-1-1304	Amend
R12-1-1305	Amend
R12-1-1306	Amend
R12-1-1307	Amend
R12-1-1308	Amend
R12-1-1309	New Section

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

General: A.R.S. §§ 30-654(B), 41-1073 to 1078

Specific: A.R.S. §§ 30-657, 30-671(B) 30-672, 30-681, 30-682, 30-683(C), 30-686, 30-687, 30-688, 30-693, and 30-696

3. The effective date of the rules:

May 12, 1999

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

Notice of Rulemaking Docket Opening: 3 A.A.R. 1990, July 25, 1997.

Notice of Proposed Rulemaking: 4 A.A.R. 2442, September 11, 1998.

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

Name: Dan Kuhl

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

Telephone: (602) 255-4845 ext. 233

Fax: (602) 437-0705

6. An explanation of the rule, including the agency's reasons for initiating the rule:

R12-1-102 The definition of "Background radiation" is modified to bring it in alignment with the law governing the Agency's rules.

The definition for "Exhibit" is added to explain name changes of listings that occur at the end of some of the articles in Title 12, Chapter 1.

The definition of "Temporary jobsite" is amended to limit a temporary jobsite to 6 months. This limitation was added to the definition on June 30, 1996 and inadvertently deleted in 1997. Therefore this is a correction only.

The definition of "TODE" is amended to correctly reference a subsection in R12-1-419.

A definition for "Workload" is added so persons affected by R12-1-202 will know what information is required with the x-ray registration application.

R12-1-202 Changes are made to the application, for registration of radiation producing machine requirements. Some are made for clarification purposes while others are made to improve safety. An applicant will be required to meet the particle accelerator safety standards in Article 9 prior to registering.

Article 2, Appendix A, Registration Forms Corrections are made to spelling and format. The requirement to provide credentials for the radiation safety officer and the physician operating the particle accelerator in the practice of radiation therapy is added. The authority to request this information is in R12-1-904(C)(2).

R12-1-301 This rule is repealed to eliminate the numbering problem that exists in Article 3. Because the terms "Decommissioning" and "Emergency Plan" are used in a single rule, their definitions are relocated in the rule where each term is used, R12-1-322 and R12-1-323, rather than the definition list in Article 1.

Note: The following Section numbers are the corrected numbers. Each number was originally a digit higher. (R12-1-302 through R12-1-323 becomes R12-1-301 through R12-1-322)

R12-1-301 This rule describes general requirements for ownership, control, and transfer of radioactive material. References to requirements in Article 7 and Article 15 are added for clarification purposes.

R12-1-302 This rule lists exemptions for source material licensing. Only clarification changes are made.

R12-1-303 Exemptions for licensing radioactive material other than source material are listed in this rule. Only clarification changes are made.

R12-1-304 A list of license types is presented. Only clarification changes are made.

R12-1-305 Requirements for source material general licenses are listed. Only format and clarification changes are made.

Arizona Administrative Register
Notices of Final Rulemaking

- R12-1-306 Listed are the requirements for general licenses other than source material. Only minor format, clarification, and rule reference changes are made.
- R12-1-307 Only the rule number is changed.
- R12-1-308 Requirements that must be met when filing an application for a specific license are listed. Subsection (C) now references a list of required information that must be provided with the application. The list is added as Exhibit (E) to this Article.
- R12-1-309 Requirements that must be met before the Agency will issue a specific license are listed. Listed are various references containing use requirements in this Article and other Articles in Chapter 1. Added are references to decommissioning requirements in R12-1-323 and specific use requirements contained in Articles 5, 7, and 17. These references are added to insure all safety issues are addressed.
- R12-1-310 Subsections (A) through (F), dealing with specific licensing requirements for radioactive material use in radiography and medicine, are moved to Articles 5 and 7, where these specialized uses are regulated. Requirements that must be met by broad scope license applicants remain in this rule. Also, reference changes are made due to the moving of the requirements mentioned above to other Articles and to Article 17, reference to which had been inadvertently deleted during past rulemaking.
- R12-1-311 Requirements affecting applicants desiring to manufacture, assemble, repair, or distribute commodities, products, or devices containing radioactive material are contained in this rule. The majority of changes are wording corrections and reference changes. Many changes involve incorporation-by-reference to update the rules. An exemption to manufacturing requirements is added in subsection (J), allowing nuclear pharmacies to provide radiopharmaceuticals to licensed recipients according to A.R.S. § 32-1904 .
- R12-1-312 This rule requires that the Agency issue a license if the applicant meets the application requirements and allows the Agency to incorporate additional safety requirements as license conditions. A precense inspection may be performed by the Agency to verify that all application requirements are met. Only minor word changes are presented.
- R12-1-313 Described are specific conditions and terms of licenses. Licensed activities governed by the Act, transfer requirements, and Agency notification of licensed program changes are dealt with in this rule. Only minor word changes are presented.
- R12-1-314 The expiration date of a license is described. A word change is made to improve clarity.
- R12-1-315 Requirements for renewing a license are listed. A minor word change is made.
- R12-1-316 The method for amending a license is described. A minor word change is made.
- R12-1-317 Under this rule the Agency is required to follow specific procedures in renewing or amending a license. A minor word change is made.
- R12-1-318 The rule details the steps that must be followed in transferring radioactive material to properly authorized recipients. Minor word changes are made.
- R12-1-319 Procedures for modification, revocation, and termination of licenses are listed. Minor word changes are made.
- R12-1-320 This rule is modified to better delineate the requirements that must be met when the Agency recognizes the license of a radioactive material user that wishes to enter the state to conduct licensed activities, licensed by another Agreement state or the Nuclear Regulatory Commission (NRC). Many word and reference changes are made.
- R12-1-321 The licensee is required to follow the rules in Article 15 when preparing radioactive material for transport. A minor word change is made.
- R12-1-322 Certain radioactive material users are required to have an emergency plan, preventing radiation exposure to the public. With the exception of adding the definition of "emergency plan" to this rule from the previous R12-1-301, repealed with this rule making package, only minor word changes are made to the rule.
- R12-1-323 A decommissioning plan and funding rule is added so that licensees possessing certain amounts of radioactive material sequester enough funds to insure that a contaminated facility or an inventory of radioactive material or waste can be cleaned up in a safe manner that is not costly to the State. This requirement is added by incorporating by reference the decommissioning requirement contained in the Code of Federal Regulations. This new rule is

Arizona Administrative Register
Notices of Final Rulemaking

a NRC compatibility requirement for all Agreement States. Currently, the Agency is ensuring that certain programs have a decommissioning plan by requiring it as a license condition, as authorized in A.R.S. § 30.654(B)(13).

Schedule C Moved to Article 7 as Exhibit A with the other requirements moved from R12-1-310 to Article 7.

Schedule D This schedule becomes Exhibit C.

Schedule E This schedule becomes Exhibit D.

Exhibit E A new Exhibit E is added. This schedule contains a listing of the information that must be provided by a radioactive material license applicant. The information is requested in a license application form as required in R12-1-308. This Exhibit is added as required by a recently passed law requiring agencies to list in their rules the information requested in a license or registration application.

R12-1-407 Six license categories are exempted from the record requirements in this rule due to the low hazard associated with their radiation use programs.

R12-1-408, R12-1-409, R12-1-411, and R12-1-415

These rules are concerned with radiation exposure limits. In each rule a correction is made to a rule reference, R12-1-419, and a wording correction is made in R12-1-409.

R12-1-418 Because of its importance, a subsection dealing with calibration of survey instruments is repealed because a separate new survey meter calibration rule, R12-1-449, is added. The requirement is buried in a rule that specifically deals with monitoring, an entirely different safety issue.

R12-1-419 This rule is the cornerstone for the standards that must be followed when determining which radiation workers are required to use personnel monitoring. The rule in its original form is incorrectly formatted. Rewording and format changes are made to the rule.

R12-1-442 A reference is added to clarify this rule that regulates the shipment of radioactive waste to a licensed disposal facility.

R12-1-449 This new rule requires the radiation user performing radiation surveys as part of a radiation safety program to calibrate survey instruments according to the specified standard. This requirement is moved from a subsection in R12-1-418 because of its importance in a safety program (see R12-1-418).

R12-1-450 A new rule is added regulating the use and inventory of sealed sources for unspecified use. These requirements are not new. They are currently addressed in license conditions and in Articles 3, 5, 7, and 17, which regulate sources of specific use.

R12-1-511 A minimum training level for enclosed radiography x-ray machine users is added to the industrial radiography application requirements. Other minor word changes are made.

R12-1-541 Changes are made to clarify the record-keeping requirements placed on cabinet and shielded room x-ray systems. Wording is changed to require shielded room x-ray machine operators to correctly use personnel monitoring (PM) devices. The current wording incorrectly requires radiography sealed sources to use PM devices.

R12-1-606 Minor changes are made to the fluoroscopic installation requirements. Unit conversions are added throughout the rule and wording changes are made to clarify the use of protective devices during fluoroscope operation. Personnel monitoring will no longer be required for operators of portable or mobile C-arm fluoroscopic x-ray machines.

R12-1-612 Radiation leakage record retention requirements for x-ray and electron therapy systems are modified. Machines having an energy range greater than 1 Mev must retain records for the life of the systems's operation. The information content of the therapy calibration report is explicitly defined. Qualifications are revised to more explicitly define minimal standards for individuals performing a calibration on a particle accelerators. The change aligns these qualifications with those of individuals calibrating teletherapy systems regulated in Article 7.

R12-1-701 With the major changes and additions to Article 7 the scope is now expanded to include the use of unsealed sources of radioactive material in the healing arts.

R12-1-702 This Section is amended to include definitions that will aid in understanding the requirements in other sections added to Article 7. Of particular interest is the change in definition of a misadministration from the definition now contained in R12-1-311(E). This proposed definition is consistent with the definition contained in 10 CFR 35, and is less stringent in terms of current reporting requirements.

Arizona Administrative Register
Notices of Final Rulemaking

R12-1-703 This Section contains the licensing requirements that were moved from R12-1-311. Included is a change in the standard for the allowable level of molybdenum-99 breakthrough in technetium generator eluate. The level will now be consistent with federal standards in 10 CFR 35. The old requirements in this Section are moved to R12-1-714

R12-1-704 This Section is added to describe the necessary supervision that is needed for use of radiation from radioactive material in the healing arts. Included is a definition for supervision, licensing requirements, and a requirement that a supervising physician be physically present during therapy procedures. This requirement is new and is added because of the potential safety hazards of use by an unqualified user. The old requirements in this Section are moved to R12-1-716.

R12-1-705 This Section is added. The rule requires all medical licensees to have a Radiation Safety Officer. Qualifications are not listed in this article. This requirement is added to address potential safety hazards.

R12-1-706 Parts of this Section contain new requirements. The Radiation Safety Committee required for all medical institutions in R12-1-703, must meet the requirements contained in this rule. With these additions the standards, formerly listed in R12-1-311, are now equivalent to those contained in 10 CFR 35. This requirement is added to address potential safety hazards.

R12-1-707 This rule requires each medical licensee to have in place a functioning Quality Management Program that will provide high confidence that radiation is administered as directed by the ordering physician. The Section is very broad, allowing each licensee to establish the standard and procedures employed to insure the high level of confidence. This requirement is added to address potential safety hazards.

R12-1-708 This requirement is not new; it is moved from R12-1-311(E). However, the standards requiring reporting are less stringent than those currently listed in Article 3. As previously noted in the R12-1-702 discussion, the proposed reporting requirement is based on a new definition for misadministration that is equivalent to the definition for misadministration in 10 CFR 35. This rule is made less stringent because of the low hazard associated with diagnostic procedures using radioactive material.

R12-1-710 This requirement, allowing visiting qualified physicians to supervise the use of radioactive material during periods when the authorized user is absent, is a new Section. However, it has been a condition of all medical licenses for a number of years. This authorization is added as a rule at this time to streamline licensing procedures.

R12-1-711 This Section is not new; it is moved from Article 3. However, its format is expanded to better define which radioactive sealed sources are acceptable for use by medical licensees. Licensees will now be able to possess calibration and reference sealed sources containing up to 15 mCi without listing them on their specific license.

R12-1-712 This new Section contains requirements that must be met by licensees that possess radioactive sealed sources. Included are inventory and authorized procedures. These requirements were previously addressed by license condition and are added at this time to streamline licensing.

R12-1-713 This is a new Section. Each medical licensee that administers radiopharmaceuticals is required to possess a dose calibrator and use it to measure the amount of radioactivity prior to administering a dose to a patient. This requirement is added to address potential safety hazards.

R12-1-714 Formerly R12-1-703, this Section addresses concerns associated with the use of sealed sources in the practice of brachytherapy. Of interest is the deletion of the specific leak testing requirements which duplicate requirements contained in R12-1-417.

R12-1-716 Formerly R12-1-704. Contained in this Section are requirements that must be met when practicing teletherapy.

R12-1-717 This is a new Section. Added are requirements for the use of remote after-loading brachytherapy devices. These devices have been prevalent in the medical therapy arena for about 10 years. The requirements listed in this Section have been addressed in license condition. The Section is added at this time to streamline licensing practices.

R12-1-718 This is a new Section. Requirements for performing stereotactic radiosurgery are added at this time to streamline licensing practices. These requirements have been addressed by license condition for about 1 year.

R12-1-719 This is a new Section. The release of patients containing radiopharmaceuticals is currently addressed by license condition. The standard in this Section will be consistent with 10 CFR 35, which allows release of radioactive patients with exposure levels higher than the current level accepted in license condition, provided certain administrative controls have been put in place. It is being added at this time to streamline licensing practices.

Arizona Administrative Register
Notices of Final Rulemaking

Exhibit A This exhibit is added to accommodate moving Groups I through V from Article 3 to Article 7. Minimal changes include the addition of carbon-11 to Group II, strontium-89 and samarium-153 to Group IV, and the addition of "product license application" (PLA) where appropriate in the Groups to accommodate licensing of new radiopharmaceuticals developed under this FDA approved category.

R12-1-801 Only minor changes are made to improve understandability of this statement that defines the scope of the rules contained in this Article.

R12-1-802 Only minor changes are made to the definitions needed for the understanding of the rules contained in this Article.

R12-1-803 This Section contains the requirements for the use of enclosed beam x-ray systems. Only minor changes are made to improve understandability.

R12-1-804 This Section contains the requirements for the use of open beam x-ray systems. Deleted are all references to radioactive material. Added is an exemption to the requirement that an interlock system be used, provided the listed criteria are met; a requirement for an interlock system if the x-ray tube can be removed from the system; and the requirement for the registrant to perform a radiation survey to demonstrate that levels in the vicinity of the open beam system do not exceed acceptable levels. Other changes are made to improve understandability.

R12-1-805 This Section contains administrative responsibilities that must be met by analytical x-ray operations. The wording is modified to improve understandability.

R12-1-806 Operation requirements for analytical x-ray systems. Major wording changes are made to clarify and strengthen the requirements listed in the rule. The requirement to maintain personnel monitoring records is deleted because the requirement already exists in Article 4.

R12-1-902 This Section is being repealed because the requirement to register a particle accelerator is addressed in Article 2 which is referenced in a new subsection of R12-1-903.

R12-1-903 General requirements for issuance of a registration for a particle accelerator are listed. A new reference to the requirements in Article 2 is added and the requirement to have a radiation safety committee is deleted because this Section deals with requirements affecting all accelerators. Also, a number of changes are made to improve understandability.

R12-1-904 This Section contains special requirements for users of particle accelerators in the practice of medicine. Added is a requirement for a radiation safety committee to oversee the use of particle accelerators for human research. This is not a new requirement; it is simply moved from R12-1-903. Also, qualifications are added for physicians and physicists wishing to qualify to use and calibrate particle accelerators for medical purposes. These standards are not new. Currently they are used to qualify users of teletherapy systems in Article 7. Other new requirements added to this Section include the need to have in place a quality management program as is described in R12-1-707, and the need to have a particle accelerator facility inspected by the Agency prior to initiation of patient treatment. Applicants have been providing descriptions of quality management programs with their applications for approximately 2 years, without complaint. Other changes are made to improve understandability.

R12-1-911 Radiation survey requirements for particle accelerator facilities are listed. Included, are new survey record retention requirements. Additional wording changes are made to improve understandability and clarity.

R12-1-1001 The purpose and scope of Article 10 are listed. Only minor wording changes are made.

R12-1-1002 Notice to worker posting requirements are listed. Minor rule reference changes are made with minimal wording changes.

R12-1-1003 The Section describes instructions that must be given to workers in areas of radiation. Minor word changes are made.

R12-1-1004 This Section stipulates individual notification requirements for those individuals exposed to radiation, entering or working in areas where radiation is used. Again, wording changes are made to improve understanding and clarity.

R12-1-1005 This Section allows a worker to have another individual represent the worker during an Agency inspection. Minor word changes are made for clarity.

R12-1-1006 This Section allows Agency inspectors to meet privately with licensee or registrant workers during an Agency inspection. Changes are made to improve clarity.

Arizona Administrative Register
Notices of Final Rulemaking

R12-1-1007 Under this Section a licensee or registrant worker may request an Agency inspection. Minor word changes are made.

R12-1-1008 If the Agency refuses to perform an inspection, requested according to R12-1-1007, the worker making the request for an inspection may request a review of the Agency's decision. Minor word changes are made.

R12-1-1209 A Notice of Violation will be provided to a licensee or a registrant following an inspection if an inspector finds violations during the inspection. The word "Division" is added to better define the proposed sanction and proposed civil penalty, if applicable. The Divisions are listed in R12-1-1215.

R12-1-1210 The Section describes action that can be taken by the Agency Director based on the response of the licensee or registrant receiving the violation. Rule references are changed to correspond with changes being referenced in Article 12. Some minor word changes are made to improve clarity; for example the addition of "initial" before the word "order."

R12-1-1212 A licensee or registrant may request a hearing upon receiving an initial order. To correctly reference the Board, the 1st letter is capitalized in subsection (B).

R12-1-1213 Listed are the 5 severity levels of violations. In subsections (A), (B), (C), and (E) the format of the listed criteria is changed to promote easier reference, and a statement is added to subsections (A)(2) and (3) to better differentiate the kind of information that must be available to affect the violation outcome. In subsection (C), the reference to the radiation protection program required in R12-1-407 is now correctly made. A licensee or registrant with a violation governed by subsection (C)(3) can be treated as a severity level IV violation if the radiation protection program previously discussed, is in place.

R12-1-1214 The mitigating factors that may affect the outcome of violations are listed. Subsection (A) is deleted because of the difficulty in discovering the listed criteria. The Director will be given more latitude in determining when a civil penalty should be reduced or waived. The remaining subsections contain wording changes to improve understandability.

R12-1-1215 Listed are the various license and registration divisions. The division lists are reformatted to improve ease of reference. New categories have been added to the division lists. Added are particle accelerator, research and development, laboratory, NORM (for a definition see "NARM" in Article 1) commercial disposal site, and low level waste disposal site. These license categories are defined in R12-1-1306. Added in subsection (D) are classifications of individuals who may use sources of radiation, but are not required to have a license or registration. These classifications are necessary because such individuals may act in an unsafe manner that requires the Agency to administer sanctions against them.

R12-1-1216 The schedule of civil penalties is listed in this Section. Minor word changes are made to improve clarity and to include registrants in subsection (C). The word "registrant" was inadvertently deleted during the original rulemaking.

R12-1-1217 This Section contains augmented consequences for violations that have the prescribed characteristics. Many changes are made to this rule to improve the practicality of the multitiered penalty system described in it.

R12-1-1218 The timing and method of payment of civil penalties is described in this Section. The word "final" is added to insure that the reader knows which order is of concern in the rule.

R12-1-1219 Unsafe conditions may result in a license or registration being revoked. If the conditions listed in this Section exist, the affected individual will have to show cause why the license or registration should not be revoked. "Show cause" is added to the Section heading to better describe the rule content and the word "suspended" is added to the penalty statements to provide the Agency with greater flexibility.

R12-1-1220 The Director may take escalated enforcement actions such as suspending or modifying a license or registration, or impounding a radiation source, if a violation meets the criteria in this Section. The wording is rearranged for ease of reference and to improve clarity.

R12-1-1222 Before the Agency initiates formal proceedings, a licensee or registrant may request an enforcement conference. The outcome of the conference, a consent agreement, is added to the rule wording so that a licensee or registrant understands the value of an enforcement conference in eliminating the need for formal proceedings that can be quite expensive.

R12-1-1223 The legislature has required that the Agency add time-frames during which the Agency will process license and registration applications, and requests for amendments to existing licenses and registrations. This was accomplished in December 1998. At this time the rule is amended to reference a new requirement in Article 13 that penalizes the applicant for not responding to Agency's application questions in a timely manner.

R12-1-1301 A single definition is listed. The definition for “combined” is modified to clarify how fee payments are handled when a combination license is issued by the Agency.

R12-1-1302 Definitions for each of the license and registration categories are listed. With this amendment a Category A license can be combined with any other type of license, and references to Article 3 subsections are corrected to agree with amendments that have occurred in Article 3. Added are license categories for:

a. Research and development, and laboratory categories that were inadvertently left out of the rule making when the categories were listed in 1993. There are many licensees of this type at this time.

b. A “NORM” commercial disposal site category is added to accommodate any future sites of this type. There are no licensees of this type at this time.

Other minor changes are made for clarification purposes, included is a change in rule title to reflect its content.

R12-1-1303 An applicant is required to pay the current fee upon submitting an application for license or registration. Minor word changes are made.

R12-1-1304 Each year licensees and registrants are required to pay an annual fee. Minor word changes are made.

R12-1-1305 The required method of payment is described. Minor word changes are made.

R12-1-1306 The fee table for all regulated categories is listed in the table. New fees for the new categories set forth in R12-1-1302 are listed. Other minor word changes are made to improve clarity.

R12-1-1307 Special license fees for reciprocity recognition, radioactive waste transfers, and a low-level radioactive waste site licensing are listed. The latter of the 3 is added as a new category to address safety concerns if an application is received for a waste site. Other minor word changes are made.

R12-1-1308 A fee for requested inspections is listed. The only change of consequence is the mileage charge from \$.25 per mile to the most current rate established by the Department of Revenue.

R12-1-1309 The Section adds the requirement for an applicant to respond to a deficiency letter in the specified time-frame. If not responded to in a timely manner, the application will be treated as if it has been abandoned. A new application and fee will be required.

7. **A reference to any study that the agency proposes to rely on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:**

None.

8. **A showing of good cause why the rule is 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.

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

Disposal site licensing fees:

R12-1-1302 A \$200,000 licensing fee is proposed for a naturally occurring radioactive material (NORM) commercial disposal site.

R12-1-1307 A \$3,000,000 licensing fee is proposed for a Low-level Radioactive Waste Disposal Site License. The fee is being justified using existing site licensing that occurred in California and other states.

Other Changes and Additions:

R12-1-311 Nuclear pharmacies will be allowed to function under Board of Pharmacy rules in dispensing certain radiopharmaceuticals per physician prescription, that are not approved by the FDA for commercial distribution and use. This should decrease cost while at the same time expediting patient care.

R12-1-323 The decommissioning rule could potentially add substantial cost to users of very large quantities of radioactive material, in that funds must be set aside at the time of application to insure that all radiation hazards are safely disposed of at termination of the program. Decommissioning must occur according to the prescribed schedule.

R12-1-1223 This Section is amended in an effort to decrease time and effort wasted on applicants who fail to respond in a timely manner to Agency requests for more information. See R12-1-1309 analysis provided below.

Arizona Administrative Register
Notices of Final Rulemaking

R12-1-1302 and R12-1-1306 Other new categories are added to insure radiation use is occurring in a safe manner. The cost is determined by factoring in the cost of application review, inspection, administrative costs, and degree of hazard associated with the specific radiation use. The following categories and associated annual costs are noted:

C16 Research and Development (R&D)\$750

C17 Laboratory (LAB)\$600

D19 NORM waste site\$200.000 (See above)

Note: R&D and LAB licensees are paying these fees at this time classified under the D18 category.

R12-1-1309 This could potentially cause an economic burden on an applicant if information is not provided to the Agency in 90 days from the date of the request. The applicant would be required to submit a new application with a 2nd application fee. There would also be delay in initiating any business activity involving the use of radiation.

Other changes and additions are made to improve clarity, consistency, and understanding of the rules. In Article 5, requirements are moved from Article 3 to better organize and portray the requirements. In Article 2 facility requirements are now stated in rule. In the past a description was requested on the registration application form. Also, a listing of needed specific and general license application information, currently requested on the application form, will be located in Exhibit E at the end of Article 3. The majority of changes are made as a result of 5-year-review reports, which are an on-going process to keep the rules current. The economic impact to all affected parties for these changes should be minimal.

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

Article 2:

1. Article 2 heading and R12-1-202 section heading, and subsection (B)

“Facilities” and “machine” are reinserted to improve understanding of the requirement.

2. R12-1-202(D)

Reference to R12-1-208 is added as originally listed in current rule. This reference was inadvertently omitted from the proposed rule changes.

Article 3:

1. In R12-1-310(A)(2)(b) ~~“If two or more radionuclides are possessed, the ratio of the quantity possessed to the applicable quantity specified in Schedule D, Column I, for that radionuclide shall be determined. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.”~~ This subsection is changed to the following language to improve clarity and consistency with the preceding subsection. The new language is: “The possession limit for multiple radionuclides is determined as follows: The sum of the ratios for all radionuclides possessed under the license shall not exceed unity (1). The ratio for each radionuclide is determined by dividing the quantity possessed by the applicable quantity in Exhibit C, Column I.” This change is also made in R12-1-310(A)(3)(b), except that the reference is made to Exhibit C, Column II.

2. In R12-1-322(A) the word “might” is removed from the definition of “emergency Plan”. The definition is changed to improve clarity and is not changed to require an offsite response as requested in a written comment from a citizen reviewer.

3. In R12-1-323(C) each licensee needing to submit a decommissioning funding plan will now be allowed to have 6 months to submit the plan. It is believed the 3 months listed in the proposed rule will not allow enough time for preparation of a plan.

4. In the title of Exhibit C the following underlined words are added for clarity and consistency: “Limits for Class B and C Broad Scope Licenses”.

Article 4:

1. In R12-1-419(B) a change is made in the wording so the personnel monitoring exemption proposed for low output fluoroscopy units is based on the 10% limit specified elsewhere in this rule. Also, “dosimeter” is replaced with “Individual monitoring device”. Both changes are made to maintain consistency in the rule that effects both radioactive material and x-ray users.

2. In R12-1-449(B)(2) the wording requiring the person doing the calibration to check a survey meter’s operation against a dedicated check source is deleted.

Arizona Administrative Register
Notices of Final Rulemaking

It is deleted to clarify the intent that check sources are used prior to use of a survey meter which is addressed in subsection (C), which is modified to require the meter be checked by the user after calibration and prior to use. Sometimes a survey meter will malfunction between calibrations and the user would not know it without checking the meter's operation against a known radiation source.

3 In R12-1-450(A) the wording is changed to allow a choice between the manufacturer's safety information and safety information provided by the applicant and approved by the Agency. The Agency will assist in deciding what safety concerns must be addressed. This change allows the licensee more flexibility in meeting a needed safety standard.

Article 6:

In R12-1-612(B)(3)(f) the language "in the therapy facility" is added in place of "at the therapy control panel" to give the registrant flexibility in their recordkeeping without compromising safety.

Article 7:

1. In R12-1-702 the word "intraluminal" is added to the definition of "brachytherapy" to better describe how the radiation sources are used to apply radiation to human disease.

In the definition "an" is replaced with "a" to correctly structure the sentence.

Added to the definition of "misadministration" is an additional statement under subsection (1)(d) that will further define a therapy misadministration. The language is similar to that listed under subsection (2)(d) that defines a diagnostic misadministration. The 2 subsections will be similar in that a certain dose level can be used for determining whether a misadministration has occurred. Language is added to the definition of "written directive" so that diagnostic standing procedures will be included. Currently, most nuclear medicine procedures are performed under this system of authority granted by the authorized user. It is impractical to expect a doctor to write an order for each and every procedure when the hazard associated with a diagnostic test is low. Because the intent of this rule is unchanged it is believed this is not a substantive change.

2. In R12-1-703(A)(3) the words "training and" are added before the word "experience" to correctly express the requirements that must be met by a physician who wants to be added to a radioactive material license as an authorized user.

3. In R12-1-703(B)(2)(a) the subsections are incorrectly designated with Arabic numbers instead of Roman numerals. This change is made to improve format.

4. In R12-1-704(B) the wording is changed to improve understandability. As originally drafted, a physician qualified to supervise must meet both standards listed in this subsection. The correction is made by adding "and is" between each standard.

5. In R12-1-707 the words "using radioactive material or the radiation from radioactive material for therapeutic purposes" is added between the words "licensee" and "shall" in the 1st line, so the requirement in the rule only effects therapeutic users of radiation. This change is made to bring the requirement in this rule in line with federal standards, as was the intent when the rule was originally drafted.

6. In R12-1-713 the wording is changed to clarify the requirement in this Section. The words "written directive" are deleted. A dose calibrator cannot be used to measure the amount of radioactivity prescribed and a written directive is not required for all procedures as implied by the language. Diagnostic procedures are often performed according to a standing order from an authorized user, as is the case when x-ray diagnostic procedures are performed.

7. In R12-1-714(A)(4) the wording is changed to allow a choice between the manufacturer's safety information and safety information provided by the applicant and approved by the Agency. The Agency will assist in deciding what safety concerns must be addressed.

8. In R12-1-714(C)(1) and (2) the words "A physician on a radioactive material license or qualified designee" is added in place of "the physician or other authorized user" so that the therapy survey required in the rule will be conducted by someone knowledgeable in survey procedures. The intent was that the doctor could select someone else to do the survey if that person was qualified. The doctor may not be available to do the survey. The surveys are often conducted by someone other than the authorized user.

The word "determine" is replaced with "measure" in subsection (C)(1) and (2). Also, the words "by measurement" are removed from the sentence in subsection (C)(1) after the word "inserted" so that understandability is maintained with the previously noted word change. These changes are made to improve clarity. Radiation levels are actually

Arizona Administrative Register
Notices of Final Rulemaking

measured, not determined as previously written. Lastly, the word “license” is added after “radioactive material” because it was inadvertently omitted when drafted.

9. In R12-1-714(D)(2) the words “A physician on a radioactive material license or qualified designee” is added for the same reason as noted in number 8 above. Also, the word “chart” is replaced with “patient records when the patient is undergoing brachytherapy”. The reason for this change is to insure the records are maintained in those incidents when patient charts are not available for recording the required information.

10. In R12-1-716(G)(1) the certifying organization “American Board of Medical Physicists in Radiation Oncology Physics” is added to the list of needed qualifications for those individuals calibrating teletherapy units. This organization was inadvertently omitted from the list of possible qualifications.

11. In R12-1-717(F)(1)(b), (b)(ii), and (b)(iii) changes are made to subsection (F)(1)(b) to correctly state the requirements in this subsection. In the 1st change all references to a beam are removed. There is no beam when an after-loader radiation source is exposed, and it is not possible to use a phantom as currently written in the rule. In subsection (F)(1)(b)(ii) “quantities of radiation” is replaced with “radiation levels” to correctly quantify radiation in the regulated areas around the radiation source. In subsection (F)(1)(b)(iii) “The intensity of the primary beam of radiation at a specified distance from the source” is replaced with “The activity of the source, using an Agency approved procedure and a calibrated Farmer chamber, or equivalent”. As it is written the radiation source in the after-loading device can not be properly calibrated.

12. In R12-1-719(A) the words “or an amount specified in license conditions” is added at the end of this subsection to accommodate any radiation levels that may result in an exposure greater than what is allowed in the rule. Users of radiation may need an exemption to this requirement so that a patient’s medical care is not compromised. In many cases special precautions can be used to prevent or limit unnecessary exposure to these types of patients.

13. In R12-1-719(B) and (D) the requirements associated with treatment of breast-feeding women and infants with radiopharmaceuticals were deleted because radiopharmaceutical therapy is no longer used on breast-feeding women.

14. In R12-1-719(C) there is confusion created by the use of “record of the basis for authorizing the release of an individual”, which can be alleviated by using this phraseology: “criteria used to authorize the release of an individual containing radioactive material”. The single statement in this subsection is split in 2 with the 2nd statement beginning with “The record shall be maintained” for 3 years.... It is believed these changes will improve the clarity.

15. In subsection (G) under Group IV of Exhibit A the amount of Iodine-131 that can be administered to patients treated outside of a hospital setting is increased from 30 to 33 millicuries to stay abreast of current standards. Current health physics calculations available in a federal regulation guide demonstrates there is minimal increase in hazard when a patient is released after treatment with 33 millicuries of Iodine-131.

Article 8:

In R12-1-804(I) “decommissioning” is replaced with “is no longer used” to improve understanding of the subsection.

Article 9:

1. In R12-1-904(B) a reference to R12-1-706 is added to make the language in this Section consistent with the requirements in Article 7. The current requirements in R12-1-904(B) are archaic and no longer consistent with current radiation safety committee requirements and protocol. It is believed this change is not substantive, because the proposed requirements are consistent with current state and federal standards, and consistent with the original intent.

2. In R12-1-911(B)(3) and (4) a beginning particle accelerator energy level of 30 Mev is added so that users of lower energy systems are not required to perform unnecessary surveys. Safety is not compromised below this level.

Article 10:

In R12-1-1006(A) and R12-1-1007(A) change “registration” to “registrant” and delete “and licenses” in the 1st subsection; and include “registration conditions” with the existing license conditions in the 2nd. These changes are made in an effort to maintain continuity for licensees and registrants in these requirements.

Article 12:

1. In R12-1-1213(A)(1)(c) and (B)(1)(c) the word “therapeutic” is added so that therapy users, using radiation in an amount greater than the amount prescribed in each subsection, are held accountable for the hazard associated with a mistaken therapy dose. There is no need to hold diagnostic users of radiation accountable because of the minimal hazard associated with the small amounts of radiation used.

2. In R12-1-1213(C)(1), R12-1-1213(C)(2), and R12-1213(C)(3) the following additions are made.

Arizona Administrative Register
Notices of Final Rulemaking

Added in the 1st part of the statement is “loss of control over a radiation source” which will include language that was inadvertently deleted during an earlier amendment process. A reference to “registration” is added to the 2nd subsection to maintain continuity with licensees in the rule; A reference to “registration” and “registrant” is added to the 3rd subsection to maintain continuity as is the case in the previous subsection; and “protection” is added to the 3rd subsection in place of “safety quality assurance” to maintain continuity with the language used in R12-1-407 which is referenced in this subsection. These changes are not substantive because the changes actually make the proposed amendment easier to understand while maintaining the rule’s integrity in regulating all users of radiation.

3. The underlined proposal in R12-1-1222(A) is deleted and the word “consists” is put into the requirement. It is now believed the proposed change is not needed. In subsection (B) “is” is added to complete the sentence.

Article 13:

The heading of R12-1-1302 is confusing when compared to the heading of R12-1-304. In the heading of R12-1-1302 the word “Types” is replaced with the word “Categories” to reflect the Section’s true content which is categories of licenses and registrations.

In closing, a number of very minor changes were made to this rule package to improve clarity and understandability. These changes are not listed because they do not affect the meaning or intent of the affected rules.

11. A summary of the principal comments and the Agency response to them:

1. Reinsert the word “facility” into Article 2 heading and R12-1-202, and make “machines” singular in same Section.

Agency response: Changes are made as recommended.

2. The definition for a broad scope license in R12-1-310 is not adequate

Agency response: A change is not needed for the following reasons:

a. The applicant must also meet the requirements in subsection (B) as well as meet the basic definition in subsection (A).

b. This category is further defined in R12-1-1302.

c. The current licensing system employed by the Agency has enough flexibility built into it to allow authorization of “Atomic Number 3 through 83” and the word “Any” for nonbroad scope licensed activities.

3. In R12-1-322 the word “might” in the definition for “Emergency Plan” is inappropriately used.

Agency response: The agency agrees this term may not be the best, but it is believed an emergency could occur that may not involve offsite response, and therefore no attempt should be made to change the definition to require offsite response. The word “may” will replace the word “might”.

4. Why is the multiplication factor 0.3 used when determining a whole body exposure from a collar badge as is required in R12-1-408? Additionally, why are there different factors used when 2 monitoring devices are worn?

Agency response: Studies have shown that 0.3 is the appropriate conversion when 1 badge is worn. When 2 are worn the sum of the 2 overestimate the exposure. The correction factors have been determined empirically and are as suggested by authorities in the field of radiation safety.

5. R12-1-450(A) and R12-1-714(A)(4) have not made any accommodations for old sources that do not or may not, have safety instructions available for them. The rule should provide a course of action for licensees possessing old sources with no safety instructions.

Agency response: A statement addressing this issue has been added to both Sections.

6. R12-1-511(2) is listed twice; remove 1 listing. Remove phrase “or if applicable, a program to provide instruction to enclosed radiography x-ray machine operators” from (1); and remove changes to (3) because they are vague.

Agency response: The Agency agrees with removal of the duplication, but disagrees with removal of the new wording because it is believed the wording is written in a clear and understandable manner.

7. There are no computer tomography (CT) x-ray rules and computerized tomography systems are not inspected by the Agency.

Agency response: The Agency is aware of this deficiency. CT rules will be promulgated in the next rulemaking project.

Arizona Administrative Register
Notices of Final Rulemaking

8. It is recommended that examples of “specific surgical applications” be listed in R12-1-606 to assist in regulating intensified fluoroscopes.

Agency response: The Agency is not in the habit of putting examples in rules. This would make the rule prohibitively large. For handling these kinds of issues the Agency has a relatively large staff and access to a number of regulation guides that address associated concerns.

9. Users of therapy simulators should be exempted from the requirements in R12-1-606.

Agency response: This request cannot be met at this time because the change would be substantive and would require new rulemaking. This requested change will be considered for a future rulemaking project.

10. In R12-1-612(B)(3)(f) there is no need for the calibration report to be at the therapy unit console, as long as it is available to the operator.

Agency response: The Agency agrees that a change is needed. A change will be made as requested. It is not substantive in nature and the safety intent of the rule is maintained.

11. There are no qualifications listed for a radiation safety officer in R12-1-705.

Agency response: Radiation Safety Officer credentials will not be added so that each applicant can be evaluated against the most current federal standards for this position. Recently, the federal standard changed for this position. Secondly, this change would be substantive in nature, requiring that a new rulemaking proposal be submitted.

12. There has been no accommodation made for someone other than the authorized user doctor named on a radioactive material license to do the required surveys in R12-1-714(C)(1).

Agency response: As stated in an earlier rule the physician named on the license is the supervisor for the radioactive material use. Therefore, he can designate duties like surveys to other qualified individuals. The words “qualified designee” will be added to the rule to meet this requested change.

13. In R12-1-714(D)(2) the patient’s chart is not always accessible to individuals wanting to add information about the therapy procedure being performed.

Agency response: The Agency agrees. A more general term “records” will be used in place of the term “chart”, as long as the information is recorded and available to interested parties during the therapy procedures.

14. The American Board of Medical Physicists in Radiation Oncology Physics should be included as a certifying body in R12-1-716(G)(1).

Agency response: The Board has been added to the list as requested. All accepted methods of qualifying were to be listed in the rule. Its deletion was an oversight.

15. R12-1-717(F)(1)(b) defines a required survey that can not be performed as stated in the rule. There is no primary beam and a patient phantom is never used when evaluating radiation levels associated with an after-loader therapy device.

Agency response: The Agency agrees to make the requested change. The requirement will now be stated in a realistic manner, applying the requirement to after loading devices, while taking into consideration how it is designed and intended to be used.

16. As in number 17, R12-1-717(F)(1)(b)(iii) should not contain a reference to a radiation beam. As previously stated these devices do not have a beam associated with their normal operation.

Agency response: The Agency agrees with this needed change. A change will be made indicating that the calibration performed will determine the quantity of radioactive material in the therapy source, not intensity of beam, which does not apply to this type of therapy unit.

17. R12-1-911(A), a survey meter is not needed in a particle accelerator facility.

Agency response: The Agency disagrees. A meter should always be available in a facility. This requirement is listed in the suggested state regulations published by the Conference of Radiation Control Program Directors (CRCPD).

18. R12-1-912(B) is no longer applicable to particle accelerator safety programs.

Agency response: This may be true, however, this is not new language and the Agency cannot change something that is not currently listed in the proposed rule changes. The Agency will consider this requested change when this rule is opened at a later date.

19. In R12-1-1006(A), “registration” should be “registrant” in the new language at the beginning of the sentence, and “registration” is added with the word “license” to maintain consistency in format. In R12-1-1007(B) “registration” is included with “license” because they both have conditions and therefore maintain consistency of format.

Agency response: Changes are made as suggested.

20. In R12-1-1213(C)(1)(c), add “diagnostic” in the statement with therapeutic doses.

Agency response: The Agency disagrees and will not make the change because an incorrect diagnostic dose of this size is not dangerous to the patient.

21. In R12-1-1213(C)(1)(c) a reference to “resulting in an excessive individual exposure” and “loss of control over a radiation source” should be added so all potential incidents are included.

Agency response: The 1st statement is already included while the 2nd is added as suggested.

22. In R12-1-1213(C)(3), add “registration” and “registrant”.

Agency response: Changes are made as suggested.

23. What is an “industrial radiation machine” as listed in R12-1-1215(A)(2), and should it be listed in a different Division?

Agency response: This category of use is defined in R12-1-1302. It is located in this Division because the hazard associated with this type of radiation use.

24. Civil penalties promote an adversarial approach to inspecting radiation users.

Agency response: The Agency has always had an “open door policy” when communicating about compliance issues with licensees and registrants. Often, if a user can show a good faith effort to correct a problem in a timely manner a violation may be mitigated. In a nutshell the licensee has to be looking at their radiation safety program when the Agency is not doing an inspection.

25. The civil penalties in R12-1-1216 are counterproductive in that they do not promote less radiation exposure to the public and radiation workers. They should be used only for the most serious deficiencies.

Agency response: The Agency disagrees. Civil penalties are used by many agencies both federal and state. The amounts are relatively low when compared to the Nuclear Regulatory Commission (NRC) and Department of Environmental Quality, and should only have a negative economic effect on the smallest of companies. Civil penalties were put into effect at the request of the NRC and state auditors. The amount collected annually is quite small compared to the Agency’s budget. Civil penalties are often applied to lesser offenses because it is believed they are indicators of a failing radiation safety program.

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

Not applicable.

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

10 CFR 32	R12-1-306(E)(3)	Page 105
10 CFR 32.26	R12-1-311(C)	Page 141
10 CFR 32.29	R12-1-311(C)	Page 141
10 CFR 32.53-56,	R12-1-311(E)	Page 149
and 32.101		
10 CFR 32.57, 58,	R12-1-311(F)(2)	Page 149
32.102 and 70.39		
10 CFR 32.61, 32.62		
and 32.101	R12-1-311(I)(2)	Page 153
10 CFR 30.35	R12-1-323(C)	Page 182
and 40.36		
10 CFR 30.36(g)(1)	R12-1-323(E)(1)	Page 183

10 CFR 30.36(i)	R12-1-323(E)(5)	Page 184
10 CFR 30.36(j)	R12-1-323(E)(6)	Page 184
10 CFR 32.72	R12-1-703(C)(2)(a)	Page 244
10 CFR 35	R12-1-704(C)	Page 253
10 CFR 32.72	Exhibit A	Page 276
10 CFR 35(J)	Exhibit A	Page 276
10 CFR 35.25	Exhibit A	Page 276
10 CFR 61	R12-1-1302(D)(11)	Page 333

14. Were the rules previously adopted as emergency rules?

No.

15. The full text of the rules follows:

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

ARTICLE 1. GENERAL PROVISIONS

Section

R12-1-102. Definitions

ARTICLE 2. RADIATION MACHINE FACILITY REGISTRATION OR LICENSING, INSTALLATION AND SERVICE REGISTRATION, AND MAMMOGRAPHIC FACILITY CERTIFICATION REGISTRATION AND CERTIFICATION OF IONIZING RADIATION MACHINE FACILITIES, REGISTRATION OF SERVICES, AND LICENSING OF NONIONIZING RADIATION MACHINE FACILITIES

Section

R12-1-202. Application Requirements for Registration or Certification of Ionizing and Nonionizing Radiation Machine Facilities: Notification

ARTICLE 3. LICENSING OF RADIOACTIVE MATERIAL LICENSING

Section

R12-1-301. ~~Definitions~~ Repealed

R12-1-302 <u>R12-1-301.</u>	Ownership, Control, or Transfer of Radioactive Material
R12-1-303 <u>R12-1-302.</u>	Source Material; Exemptions
R12-1-304 <u>R12-1-303.</u>	Radioactive Material Other than Source Material; Exemptions
R12-1-305 <u>R12-1-304.</u>	Types of Licenses <u>License Types</u>
R12-1-306 <u>R12-1-305.</u>	General <u>License Licenses</u> -- Source Material
R12-1-307 <u>R12-1-306.</u>	General <u>License Licenses</u> -- Radioactive Material Other than Source Material
R12-1-308 <u>R12-1-307.</u>	Repealed
R12-1-309 <u>R12-1-308.</u>	Filing Application for Specific Licenses
R12-1-310 <u>R12-1-309.</u>	General Requirements for the Issuance of Specific Licenses
R12-1-311 <u>R12-1-310.</u>	Special Requirements for Issuance of Certain Specific <u>Broad Scope Licenses for Radioactive Material</u>
R12-1-312 <u>R12-1-311.</u>	Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices Which Contain Radioactive Material
R12-1-313 <u>R12-1-312.</u>	Issuance of Specific Licenses
R12-1-314 <u>R12-1-313.</u>	Specific Terms and Conditions of Licenses
R12-1-315 <u>R12-1-314.</u>	Expiration of <u>License Licenses</u>
R12-1-316 <u>R12-1-315.</u>	Renewal of License
R12-1-317 <u>R12-1-316.</u>	Amendment of Licenses at Request of Licensee
R12-1-318 <u>R12-1-317.</u>	ARRA Action on Applications to Renew or Amend
R12-1-319 <u>R12-1-318.</u>	Transfer of <u>Radioactive Material</u>
R12-1-320 <u>R12-1-319.</u>	Modification, Revocation, and Termination of Licenses
R12-1-321 <u>R12-1-320.</u>	Reciprocal Recognition of Licenses For Byproduct, Source and Special Nuclear Material (In Quantities Not Sufficient to Form a Critical Mass)

Notices of Final Rulemaking

- ~~R12-1-322~~R12-1-321. Preparation of Radioactive Material For Transport
~~R12-1-323~~R12-1-322. The Need For an Emergency Plan For Response to a Release of Radioactive Material.
R12-1-323. Financial Assurance and Record Keeping for Decommissioning
Exhibit A. ~~Schedule A~~ Exempt Concentrations
Exhibit B. ~~Schedule B~~ Exempt Quantities
~~Schedule C~~ Groups of Medical Uses of Radioactive Material
Exhibit C. ~~Schedule D~~ Limits for Class B and C Broad Scope Licenses
Exhibit D. ~~Schedule E~~ Radioactive Material Quantities Requiring ~~(R12-1-340(G))~~ Consideration for an Emergency Plan
(R12-1-322) (~~R12-1-323~~)
Exhibit E. Application Information

ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

- R12-1-407. Radiation Protection Programs
R12-1-408. Occupational Dose Limits for Adults
R12-1-409. ~~Compliance with Requirements for~~ Summation of External and Internal Doses
R12-1-411. Determination of Internal Exposure
R12-1-415. Dose to an Embryo or / Fetus
R12-1-418. Surveys and Monitoring
R12-1-419. Conditions Requiring Individual Monitoring of External and Internal Occupational Dose
R12-1-442. Agency Inspection of Shipments of Waste
R12-1-449. Survey Instruments
R12-1-450. Sealed Source Requirements

ARTICLE 5. RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Section

- R12-1-511. License and Registration Application Requirements For Industrial Radiography
R12-1-541. Enclosed Radiography Using X-ray Machines

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

Section

- R12-1-606. Fluoroscopic Systems installations
R12-1-612. X-ray and Electron Therapy Systems with Energies of 1 MeV and Above

**ARTICLE 7. USE OF RADIONUCLIDES IN THE HEALING ARTS ~~USE OF SEALED RADIOACTIVE SOURCES~~
~~IN THE HEALING ARTS~~**

Section

- R12-1-701. Scope
R12-1-702. Definitions
R12-1-703. ~~Interstitial, Intracavitary, and superficial applications~~ Repealed
R12-1-703. License for Medical Use of Radioactive Material
R12-1-704. ~~Teletherapy~~ Repealed
R12-1-704. Supervision
R12-1-705. Radiation Safety Officer
R12-1-706. Radiation Safety Committee
R12-1-707. Quality Management Program
R12-1-708. Misadministration Reports and Records
R12-1-709. Reserved
R12-1-710. Visiting Authorized User
R12-1-711. Calibration and Reference Sources
R12-1-712. Sealed Sources
R12-1-713. Dose Calibrators
R12-1-714. Brachytherapy
R12-1-715. Reserved
R12-1-716. Teletherapy
R12-1-717. High Dose Rate Remote After-loading Brachytherapy Devices
R12-1-718. Gamma Stereotactic Radiosurgery
R12-1-719. Release of Individuals Containing Radiopharmaceuticals or Radioactive Sealed Sources from Restricted Areas
Exhibit A. Groups of Medical Uses of Radioactive Material

ARTICLE 8. RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY OPERATIONS

Section

- R12-1-801. Scope
- R12-1-802. Definitions
- R12-1-803. Enclosed Beam X-ray Systems ~~beam x-ray systems~~
- R12-1-804. Open Beam X-ray Systems ~~beam x-ray systems~~
- R12-1-805. Administrative Responsibilities ~~responsibilities~~
- R12-1-806. Operating Requirements ~~procedures~~

ARTICLE 9. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

Section

- R12-1-902. Reserved Registration Requirements
- R12-1-903. General Requirements for the Issuance of a Registration for Particle Accelerators
- R12-1-904. Special Registration Requirements for Medical Human Use of Particle Accelerators
- R12-1-911. Radiation Survey Requirements ~~monitoring requirements~~

ARTICLE 10. NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

Section

- R12-1-1001. Purpose and Scope ~~scope~~
- R12-1-1002. Posting of Notices for Workers ~~notices to workers~~
- R12-1-1003. Instructions to Workers ~~workers~~
- R12-1-1004. Notifications and Reports to Individuals
- R12-1-1005. Licensee, Registrant, and Worker Representation During Agency Inspection ~~Presence of representatives of licensees or registrants and workers during inspection~~
- R12-1-1006. Consultation with Workers During Inspections ~~workers during inspection~~
- R12-1-1007. Inspection Requests by Workers ~~workers for inspection~~
- R12-1-1008. Inspection ~~Inspections~~ not Warranted; Review ~~warranted; review~~

ARTICLE 12. ADMINISTRATIVE PROVISIONS

Section

- R12-1-1209. Notice of Violation
- R12-1-1210. Response to Notice of Violation
- R12-1-1211. Initial Orders
- R12-1-1212. Request for Hearing in Response to an Initial Order
- R12-1-1213. Severity Levels of Violations
- R12-1-1214. Mitigating Factors
- R12-1-1215. License and Registration Divisions
- R12-1-1216. ~~Base Schedule of Civil Penalties~~
- R12-1-1217. Augmentation of Civil Penalties
- R12-1-1218. Payment of Civil Penalties
- R12-1-1219. Additional Sanctions - Show Cause
- R12-1-1220. Escalated Enforcement
- R12-1-1222. Enforcement Conferences

ARTICLE 13. LICENSE AND REGISTRATION FEES

- R12-1-1301. Definition
- R12-1-1302. ~~Types of Licenses and Registrations~~ License and Registration Categories
- R12-1-1303. Fee for Initial License and Initial Registration
- R12-1-1304. Annual Fees for Licenses and Registrations
- R12-1-1305. Method of Payment
- R12-1-1306. Table Schedule of Fees
- R12-1-1307. Special License Fees
- R12-1-1308. Fee for Requested Inspections
- R12-1-1309. Abandonment of License or Registration Application

ARTICLE 1. GENERAL PROVISIONS

R12-1-102. Definitions

- “A₁” No change.
- “Absorbed dose” No change.

Notices of Final Rulemaking

“Accelerator”	No change.
“Accelerator produced material”	No change.
“Act”	No change.
“Activity”	No change.
“Adult”	No change.
“Agency”, or “AREA”	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.
“Background radiation” means radiation from cosmic sources; <u>not technologically enriched</u> naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material less than 10 times the quantities listed in Article 4, Appendix B, Table II; and global fallout as it exists in the environment from the testing of nuclear explosive devices. “Background radiation” does not include sources of radiation from radioactive materials regulated by the Agency.	
“Becquerel”	No change.
“Bioassay”	No change.
“Brachytherapy”	No change.
“By-product material”	No change.
“Calendar quarter”	No change.
“Calibration”	No change.
“Certified cabinet x-ray system”	No change.
“CFR”	No change.
“Chelating agent”	No change.
“Civil penalty”	No change.
“Collective dose”	No change.
“Committed dose equivalent”	No change.
“Committed effective dose equivalent”	No change.
“Curie”	No change.
“Current license”	No change.
“Deep-dose equivalent”	No change.
“Depleted uranium”	No change.
“Dose”	No change.
“Dose equivalent (H _T)”	No change.
“Dose limits”	No change.
“Dosimeter”	No change.
“Effective dose equivalent (H _E)”	No change.
“Effluent release”	No change.
“Embryo/fetus”	No change.
“Enclosed beam x-ray system”	No change.
“Enclosed radiography”	No change.
“Cabinet radiography”	No change.
“Shielded room radiography”	No change.
“Entrance or access point”	No change.
“Exhibit”	<u>For purposes of these rules, is equivalent in meaning to the word “Schedule” as found in previously issued rules, current license conditions and regulation guide.</u>
“Explosive material”	No change.
“Exposure”	No change.
“Exposure rate”	No change.
“External dose”	No change.
“Extremity”	No change.
“Eye dose equivalent”	No change.
“Fail-safe characteristics”	No change.
“Field radiography”	No change.
“Field station”	No change.
“Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC)”	

Notices of Final Rulemaking

licensed facilities”	No change.
“Generally applicable environmental radiation standards”	No change.
“Gray”	No change.
“Hazardous waste”	No change.
“Healing arts”	No change.
“Health care institution”	No change.
“High radiation area”	No change.
“Human use”	No change.
“Impound”	No change.
“Individual”	No change.
“Individual monitoring”	No change.
“Individual monitoring devices”	No change.
“Industrial radiography”	No change.
“Injection tool”	No change.
“Inspection”	No change.
“Interlock”	No change.
“Internal dose”	No change.
“Irradiate”	No change.
“Laser”	No change.
“License”	No change.
“Licensed material”	No change.
“Licensed practitioner”	No change.
“Licensee”	No change.
“Licensing State”	No change.
“Limits”	No change.
“Local components”	No change.
“Logging supervisor”	No change.
“Logging tool”	No change.
“Lost or missing licensed or registered source of radiation”	No change.
“Low-level waste”	No change.
“Major processor”	No change.
“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”	No change.
“Occupational dose”	No change.
“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”	No change.
“Pyrophoric liquid”	No change.
“Pyrophoric solid”	No change.

Notices of Final Rulemaking

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 safety officer”	No change.
“Radioactive marker”	No change.
“Radioactive material”	No change.
“Radioactivity”	No change.
“Radiographer”	No change.
“Radiographer’s assistant”	No change.
“Radiographic exposure device”	No change.
“Registrant”	No change.
“Registration”	No change.
“Regulations of the U.S. Department of Transportation”	No change.
“Rem”	No change.
“Research and Development”	No change.
“Restricted area”	No change.
“Roentgen”	No change.
“Safety system”	No change.
“Sealed source”	No change.
“Shallow dose equivalent”	No change.
“Shielded position”	No change.
“Sievert”	No change.
“Site boundary”	No change.
“Source changer”	No change.
“Source holder”	No change.
“Source material”	No change.
“Source material milling”	No change.
“Source of radiation”	No change.
“Special form radioactive material”	No change.
“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.
“Teletherapy”	No change.
“Temporary job site” means any location where sources of radiation are used other than the specified locations listed on a license document. <u>Storage of sources of radiation at a temporary jobsite shall not exceed 6 months unless the Agency has granted an amendment authorizing storage at that jobsite.</u>	
“Test”	No change.
“These rules”	No change.
“Total Effective Dose Equivalent” (TEDE) “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.	
“Total Organ Dose Equivalent” (TODE) “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 <u>R12-1-419(D)(1)(d)</u> R12-1-419(C)(1)(d) of these rules.	
“Unrefined and unprocessed ore”	No change.
“Unrestricted area”	No change.
“U.S. Department of Energy”	No change.
“Waste”	No change.
“Waste handling licensees”	No change.
“Week”	No change.
“Well-bore”	No change.
“Well-logging”	No change.

Notices of Final Rulemaking

“Whole body”	No change.
“Wireline”	No change.
“Wireline service operation”	No change.
“Worker”	No change.
“WL”	No change.
“WLM”	No change.
“Workload” means the degree of use of an x-ray or gamma-ray source per unit time.	
“Year”	No change.

ARTICLE 2. RADIATION MACHINE FACILITY REGISTRATION OR LICENSING, INSTALLATION AND SERVICE REGISTRATION, AND MAMMOGRAPHIC FACILITY CERTIFICATION REGISTRATION AND CERTIFICATION OF IONIZING RADIATION FACILITIES, REGISTRATION OF SERVICES, AND LICENSING OF NONIONIZING RADIATION MACHINE FACILITIES

R12-1-202. Application Requirements for Registration or Certification of Ionizing and Nonionizing Radiation Machine Facilities: Notification

- A. A person shall not ~~No person shall~~ receive, possess, use, or transfer a radiation machine except as authorized in pursuant ~~to~~ this Article.
- B. The owner or persons possessing ~~having possession of~~ any nonexempt radiation machine shall apply for registration of the machine with the Agency ~~such machine with the Agency~~ within 90 days following the effective date of this Article. Subsequent applications for registration shall be submitted within 30 days after its acquisition. ~~acquisition of such machine. The person applying for registration of a radiation producing machine shall use the appropriate form application shall be on the forms as prescribed in Appendix A of to~~ this Article.
- C. No change.
- D. In addition to the application forms, the applicant shall remit the appropriate registration or licensing fee listed in R12-1-1306. ~~remit the appropriate registration fee, pursuant to R12-1-1301, et seq.~~ and such other information as may be required to comply with R12-1-208.
- E. With the application forms for registration of radiation machines, except dental and mammography facilities, the applicant shall provide a scale drawing of the room in which a stationary x-ray system is located. The drawing shall denote the type of materials and the thickness (or lead equivalence) of each barrier of the room (walls, ceilings, floors, doors, windows). The drawing shall also denote the type and frequency of occupancy in adjacent areas including those above and below the x-ray room of concern (for example, hallways, offices, parking lots, and lavatories ~~toilets~~). Estimates of workload shall also be provided with the drawing.

Arizona Administrative Register
Notices of Final Rulemaking

Appendix A. Registration and Licensing Forms

ARRA-4IG

January 1996

ARIZONA RADIATION REGULATORY AGENCY

ATTACHMENT TO ARRA-4 FOR INDUSTRIAL GAUGE OR ANALYTICAL X-RAY SOURCE OF RADIATION
(does **NOT** include Industrial Radiography)

FACILITY NAME

REGISTRATION # (if available)

DATE

MACHINE INFORMATION
X-Ray Unit

Analytical ____ Industrial Gauge ____ This Machine is Mobile ____ or Fixed ____ Other ____

EQUIPMENT

	<u>MANUFACTURER / MODEL NO.</u>	<u>SERIAL NO.</u>	<u>MAX. KVP</u>	<u>MAX. MA.</u>	<u>PHYSICAL LOCATION</u>
Control Panel	_____				
Rad. Tube #1	_____				
Rad. Tube #2	_____				
Rad. Tube #3	_____				

ADDITIONAL SHIELDING INFORMATION
(Use additional pages, if necessary)

INSTRUCTIONS

1. Please provide a scale drawing of the facility, including construction material, and your calculations of the shielding needed to assure compliance with A.C.C. R12-1-408 and R12-1-416. The calculations should include the information required to assess the compliance with these regulations.
2. Please provide the specific instructions or procedures including any restrictions, such as beam stop usage, provided to the equipment operators.
3. Please note that R12-1-206(C) requires the transferor provide each registrant with the supplies and x-ray equipment as necessary to comply with the requirements of the rules relating to the use of the equipment transferred.

RETAIN A COPY FOR YOUR RECORDS

Arizona Administrative Register
Notices of Final Rulemaking

Appendix A. Registration and Licensing Forms *Continued*

ARRA-4IR

January 1996

ARIZONA RADIATION REGULATORY AGENCY

ATTACHMENT TO ARRA-4 FOR AN INDUSTRIAL RADIOGRAPHY X-RAY SOURCE OF RADIATION (<1,000 kVp)

FACILITY NAME

REGISTRATION # (if available)

DATE

TYPE PROGRAM

Cabinet _____

Fixed _____

Mobile _____

MACHINE INFORMATION

Fluoroscopic w/image Intensifier _____

Radiographic _____

Other _____

EQUIPMENT

	<u>MANUFACTURER / MODEL NO.</u>	<u>SERIAL NO.</u>	<u>MAX. KVP</u>	<u>MAX. MA.</u>	<u>PHYSICAL LOCATION</u>
Control Panel	_____	_____	_____	_____	_____
Rad. Tube #1	_____	_____	_____	_____	_____
Rad. Tube #2	_____	_____	_____	_____	_____
Rad. Tube #3	_____	_____	_____	_____	_____

ADDITIONAL SHIELDING INFORMATION

(Use additional pages, if necessary)

INSTRUCTIONS

1. Please provide a scale drawing of the facility, including construction material, and your calculations of the shielding needed to assure compliance with A.A.C. R12-1-408 and R12-1-416. If for temporary locations, please provide a copy of your operating and emergency procedures which contain the information required by R12-1-522.
2. Please provide the specific instructions including any restrictions provided to the radiographers.
3. Please note that R12-1-534 requires each registrant to maintain for each industrial x-ray radiography site:
 - a. A copy of the registration form;
 - b. Operating and emergency procedures;
 - c. Agency rules;
 - d. Survey records as required by R12-1-533 along with dosimetry records; and
 - e. The latest instrument calibration which indicates the applicability to the x-ray energies in use at the site.

RETAIN A COPY FOR YOUR RECORDS

Arizona Administrative Register
Notices of Final Rulemaking

Appendix A. Registration and Licensing Forms *Continued*

ARRA-4PA

January 1996

ARIZONA RADIATION REGULATORY AGENCY

ATTACHMENT TO ARRA-4 FOR A PARTICLE ACCELERATOR SOURCE OF RADIATION (>1 Mev)

FACILITY NAME

REGISTRATION # (if available)

DATE

CLASSIFICATION OF PERSONNEL IN CHARGE OF MACHINE

Health Physicist _____

Operator _____

Other _____

MACHINE INFORMATION

Betatron _____

Cyclotron _____

Van de Graaff
Graff _____

Linear _____

Other _____

This Machine is Mobile _____ or Fixed _____

EQUIPMENT

MANUFACTURER / MODEL NO.

SERIAL NO.

MAX. MVP

MAX. MA.

PHYSICAL LOCATION

ADDITIONAL SHIELDING INFORMATION

(Use additional pages, if necessary)

INSTRUCTIONS

1. Please provide a drawing of the facility, including construction material, and your calculations of the shielding needed to assure compliance with A.A.C. R12-1-408 and R12-1-416. If for temporary locations, please provide a copy of your operating and emergency procedures which contain the information required by R12-1-522.
2. Please provide the specific instructions including any restrictions provided to operators.
3. Please note that R12-1-1002 requires each registrant to maintain for each Particle Accelerator site:
 - a. A copy of the registration form;
 - b. Operating and emergency procedures;
 - c. Agency rules.

RETAIN A COPY FOR YOUR RECORDS

Arizona Administrative Register
Notices of Final Rulemaking

Appendix A. Registration and Licensing Forms *Continued*

ARRA-4PAR

January 1996

ARIZONA RADIATION REGULATORY AGENCY

ATTACHMENT TO ARRA-4 FOR AN INDUSTRIAL RADIOGRAPHY X-RAY SOURCE OF RADIATION (≥ 1 Mev)

FACILITY NAME _____

REGISTRATION # (if available) _____

DATE _____

CLASSIFICATION OF PERSONNEL IN CHARGE OF MACHINE

Health Physicist _____

Radiographer _____

Other _____

MACHINE INFORMATION

Betatron _____

Cyclotron _____

Van de Graaff
Graff _____

Linear _____

Other _____

This Machine is Mobile _____ or Fixed _____

EQUIPMENT

MANUFACTURER / MODEL NO.

SERIAL NO.

MAX. MVP

MAX. MA.

PHYSICAL LOCATION

ADDITIONAL REQUESTED SHIELDING INFORMATION

(Use additional pages, if necessary)

INSTRUCTIONS

1. Please provide a drawing of the facility, including construction material, and your calculations of the shielding needed to assure compliance with A.A.C. R12-1-408 and R12-1-416. If for temporary locations, please provide a copy of your operating and emergency procedures which contain the information required by R12-1-522.
2. Please provide the specific instructions including any restrictions provided to the radiographers.
3. Please note that R12-1-534 requires each registrant to maintain for each industrial x-ray radiography site:
 - a. A copy of the registration form;
 - b. Operating and emergency procedures;
 - c. Agency rules;
 - d. Survey records as required by R12-1-533 along with dosimetry records; and
 - e. The latest instrument calibration which indicates the applicability to the x-ray energies in use at the site.
4. Please provide the Radiation Safety Officer's name and his/her qualifications.

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Arizona Administrative Register
Notices of Final Rulemaking

Appendix A. Registration and Licensing Forms *Continued*

ARRA-4PAT

January 1996

ARIZONA RADIATION REGULATORY AGENCY

ATTACHMENT TO ARRA-4 FOR MEDICAL THERAPY PARTICLE ACCELERATOR SOURCE OF RADIATION ≥ 1 Mev

FACILITY NAME _____

REGISTRATION # (if available) _____

DATE _____

CLASSIFICATION OF PROFESSIONAL IN CHARGE OF MACHINE

General Practitioner _____

Health Physicist _____

Registered X-Ray Technologist _____

Radiologist _____

Non-Registered X-Ray Tech _____

Osteopath _____

Other _____

Medical Physicist _____

PARTICLE ACCELERATOR INFORMATION

Betatron _____

Cyclotron _____

Van de Graaff ~~Graff~~ _____

Other Medical therapy _____

medical LINAC _____

EQUIPMENT

MANUFACTURER / MODEL NO.

SERIAL NO.

MAX. Mev

MU/min or
MAX. MA.

PHYSICAL LOCATION

Photons _____

Electrons _____

Neutrons _____

ADDITIONAL SHIELDING INFORMATION

(Use additional pages, if necessary)

INSTRUCTIONS

1. Please provide a scale drawing of the facility, including construction material, and your calculations of the shielding needed to assure compliance with A.A.C. R12-1-408 and R12-1-416. The calculations shall meet the requirements specified in R12-1-603 (C)(2). For your assistance Regulatory Guide 11.5 is available to guide you in supplying these items. You may wish to submit the consultant design report for the facility instead.
2. Please provide the specific instructions including any restrictions provided to the equipment operators. Regulatory Guide 11.5 will assist you in completing this portion of the application.
3. Please note that R12-1-611(B) and (C) requires each registrant to maintain for each particle accelerator:
 - a. Prior to initiating treatment, a radiation protection survey of the facility is made and the record retained. A copy must be provided to the Agency;
 - b. A record of the calibrations of the Unit;
 - c. A record of the monthly spot checks must be maintained.
4. Please provide the names of the Radiation Safety Officer and the physician(s) with their qualifications to be listed on the registration as authorized users of the particle accelerator.

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Arizona Administrative Register
Notices of Final Rulemaking

Appendix A. Registration and Licensing Forms *Continued*

ARRA-4X

January 1996

ARIZONA RADIATION REGULATORY AGENCY

**ATTACHMENT TO ARRA-4 FOR THE REGISTRATION OF MEDICAL/DENTAL OR VETERINARIAN
DIAGNOSTIC X-RAY SOURCE OF RADIATION**

FACILITY NAME

REGISTRATION # (if available)

DATE

MACHINE INFORMATION

Diagnostic X-Ray

Fluoroscopic w/image Intensifier _____		Bone Densitometer _____
Fluoroscopic wo/image Intensifier _____	Tomographic _____	Cephalometric _____
Combination w/image Intensifier _____	Panographic _____	Intra Oral _____
Combination wo/image Intensifier _____	Radiographic _____	Other Dental _____
Computerized Axial Tomographic _____	Photofluorographic _____	Other Medical _____
This Machine is Mobile _____ Stationary _____ Portable _____ Transportable _____		

EQUIPMENT

	<u>MANUFACTURER/MODEL NO.</u>	<u>SERIAL NO.</u>	<u>MAX. KVP</u>	<u>MAX. MA.</u>	<u>PHYSICAL LOCATION</u>
Control Panel	_____				
Rad. Tube #1	_____				
Tube #2	_____				
Tube #3	_____				
Tube #4	_____				
Flouro. Tube #1	_____				
Flouro. Tube #2	_____				

ADDITIONAL SHIELDING INFORMATION
(Use additional pages, if necessary)

INSTRUCTIONS

1. Excluding dental and mammography units, please provide a scale drawing of the facility, including construction material, and your calculations of the shielding needed to assure compliance with A.A.C. R12-1-408 and R12-1-416. The calculations shall meet the standards specified in R12-1-603(C)(2). For your assistance Regulatory Guide 10.5 is available to guide you in supplying these items.
2. Please provide the specific instructions including any restrictions provided to the equipment operators. Regulatory Guide 10.5 will assist you in completing this portion of the application.
3. Please note that R12-1-604(B) requires each registrant to maintain for each x-ray machine:
 - a. Maximum rating of technique factors;
 - b. Aluminum equivalent filtration of the useful beam, including routine variations;
 - c. Records of surveys, calibrations, maintenance, modifications, and the names of persons who performed the service;
 - d. A copy of all correspondence with the Agency relating to the x-ray machine.
4. Please note that R12-1-206(C) requires transferor provide to each registrant, the supplies and x-ray machine necessary to comply with the requirements of the rules relating to the usage of the equipment transferred.

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Arizona Administrative Register
Notices of Final Rulemaking

Appendix A. Registration and Licensing Forms *Continued*

ARRA-4XT

January 1996

ARIZONA RADIATION REGULATORY AGENCY

ATTACHMENT TO ARRA-4 FOR MEDICAL THERAPY X-RAY SOURCE OF RADIATION <1 Mev

FACILITY NAME

REGISTRATION # (if available)

DATE

MACHINE INFORMATION

Medical Therapeutic X-Ray

< 150kVp _____

151 - 999kVp _____

EQUIPMENT

MANUFACTURER / MODEL NO.

SERIAL NO.

MAX. KVP

MAX. MA.

PHYSICAL LOCATION

Control
Panel

Therapy
Tube #1

Therapy
Tube #2

Therapy
Tube #3

ADDITIONAL SHIELDING AND CALIBRATION INFORMATION

(Use additional pages, if necessary)

INSTRUCTIONS

1. Please provide a scale drawing of the facility, including construction material, and your calculations of the shielding needed to assure compliance with A.A.C. R12-1-408 and R12-1-416. The calculations shall meet the standards specified in R12-1-603(C)(2). For your assistance, Regulatory Guide 11.5 is available to guide you in supplying these items. You may wish to submit the consultant design report for the facility instead.
2. Please provide the specific instructions including any restrictions provided to the equipment operators. Regulatory Guide 11.5 will assist you in completing this portion of the application.
3. Please note that R12-1-611(C), (D), and (E) require each registrant to maintain for each x-ray machine:
 - a. A record of the radiation protection survey of the facility;
 - b. A record of the calibrations of the Unit;
 - c. For Units > 150kVp, a record of the monthly spot check must be maintained;
4. Please provide a copy of 3(a) and 3(b) above when they are initially completed for this installation.

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ARTICLE 3. LICENSING OF RADIOACTIVE MATERIAL LICENSING

~~R12-1-301.~~ Definitions

- ~~A. "Decommissioning" means to remove a radioactive material use facility safely from service and to reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the radioactive material use license.~~
- ~~B. "Emergency Plan" means a procedure that will be followed when an accident occurs involving licensed radioactive material for which responses by offsite response organizations that might be needed such as police, fire, and medical organizations.~~

~~R12-1-302~~ R12-1-301. Ownership, Control, or Transfer of Radioactive Material

- ~~A. In addition to the requirements of this Article, all licensees are subject to the requirements of 12 A.A.C.1, Article 1, Article 4 and Article 10 of these Regulations. Licensees engaged in industrial radiographic operations are subject to the requirements of 12 A.A.C. 1, Article 5; and licensees using sealed sources radioactive material in the healing arts are subject to the requirements of ~~Article 6~~ 12 A.A.C. 1, Article 7; licensees transporting radioactive material are subject to the requirements contained in 12 A.A.C. 1, Article 15; ~~of these Regulations.~~~~
- ~~B. Ownership of radioactive material.~~ Notwithstanding any other provisions of this Article, any person may own radioactive material, provided that the ownership such ownership does not include the actual possession, custody, use or physical transfer of radioactive material or the manufacture or production of any article containing radioactive material without the applicable certification, license or registration unless appropriately licensed.
- ~~C. Authority to transfer possession or control by the~~ A manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer, or and disposal by all other persons is exempt are exempted from regulatory requirements may only obtain authority to transfer possession or control of the material be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. ~~Federal regulations adopted by reference in this Article are on file at the Office of the Secretary of State.~~

~~R12-1-303~~ R12-1-302. Source Material; Exemptions

- ~~A. Any person is exempt from this Article to the extent the that such person receives, possesses, uses, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20th of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.~~
- ~~B. Any person is exempt from this Article to the extent the that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material, provided that, ~~except as authorized in a specific license,~~ the such person does shall not refine or process the such ore except as authorized in a specific license.~~
- ~~C. Any person is exempt from this Article if the to the extent that such person receives, possesses, uses, or transfers:~~
- ~~1. Any quantities of thorium contained in:~~
 - ~~a. Incandescent incandescant gas mantles;~~
 - ~~b. Vacuum vaeuum tubes;~~
 - ~~c. Welding welding rods;~~
 - ~~d. Electric electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium;~~
 - ~~e. Germicidal germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting, provided that each lamp does not contain more than 2 grams of thorium; ~~or~~~~
 - ~~f. Rare rare earth metals, and compounds, mixtures, or and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of thorium and uranium these; or~~
 - ~~g. Individual individual neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;~~
 - ~~2. Source material contained in the following products:~~
 - ~~a. Glazed glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material by weight;~~
 - ~~b. Glassware glassware, glass enamel and glass enamel frit containing not more than 10 percent by weight source material by weight, but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass, glass enamel or ceramic used in construction;~~ or
 - ~~c. Piezoelectric piezoelectrie ceramic containing not more than 2 percent by weight source material by weight;~~
 - ~~3. Photographic film, negatives, and prints containing uranium or thorium;~~
 - ~~4. Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that the exemption contained in this subsection does not item shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of the finished any such product or part;~~
 - ~~5. Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, and stored or handled in connection with installation or removal of counterweights such counterweights, provided that:~~

- a. ~~The~~ counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee ~~according to~~ pursuant to 10 CFR Part 40;
 - b. ~~Each~~ counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM";
 - c. ~~Each~~ counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED"; ~~and~~
 - d. ~~The~~ exemption contained in this item ~~does not shall not be deemed to~~ authorize the chemical, physical, or metallurgical treatment or processing of any ~~such~~ counterweights other than repair or restoration of any plating or other covering; ~~and~~
 - e. The requirements specified in ~~R12-1-302.C.5 b. And e. subsections (C)(5)(b) and (c) do not apply to~~ need not be met by counterweights manufactured prior to December 31, 1969; provided, that ~~these counterweights such counterweights~~ are impressed with the legend, "CAUTION -- RADIOACTIVE MATERIAL -- URANIUM"; ~~as previously required by the Regulations.~~
6. Natural or depleted uranium metal used as shielding ~~and~~ constituting part of any shipping container; provided that:
 - a. ~~The~~ shipping container is conspicuously and legibly impressed with the legend "CAUTION -- RADIOACTIVE SHIELDING -- URANIUM", and
 - b. ~~The~~ uranium metal is encased in mild steel or equally fire resistant metal ~~with~~ of minimum wall thickness of ~~1/8 one-eighth~~ inch (3.2 mm).
 7. Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent ~~by weight~~ of thorium ~~by weight~~, and that the exemption contained in this item ~~does not shall not be deemed to~~ authorize either
 - a. ~~The~~ shaping, grinding, or polishing of a ~~thoriated~~ ~~such~~ lens or manufacturing processes other than the assembly of a ~~thoriated lens~~ ~~such~~ lens into optical systems and devices without any alteration of the lens, or
 - b. ~~The~~ receipt, possession, use, or transfer of thorium contained in contact lenses, ~~or in~~ spectacles, or ~~in~~ the eyepieces ~~of in~~ binoculars or other optical instruments;
 8. Uranium contained in detector heads ~~of for use in~~ fire detection units, provided that each detector head contains not more than 5 nanocuries (185 Bq) of uranium; or
 9. Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:
 - a. ~~The~~ thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide), and
 - b. The thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.
- D. ~~The~~ exemptions in ~~subsection (C) R12-1-302.C.~~ do not authorize the manufacture of any of the products described.

~~R12-1-304~~ R12-1-303. Radioactive Material Other than Source Material; Exemptions

A. Exempt concentrations

1. Except as provided in ~~R12-1-303.A.2~~ ~~subsection (A)(2)~~ ., ~~a~~ any person is exempt from this Article ~~if the to the extent that such~~ person receives, possesses, uses, transfers or acquires products or materials containing radioactive material in concentrations not in excess of those listed in Exhibit Schedule A.
2. ~~A~~ No person ~~may shall not~~ introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under ~~R12-1-303.A.1.~~ ~~subsection (A)(1)~~ or equivalent Regulations of the U.S. Nuclear Regulatory Commission NRC or any Agreement State or Licensing State, except in accordance with a specific license issued ~~under R12-1-311(A)~~ pursuant to ~~R12-1-311.A.~~ or ~~a~~ the general license prescribed provided in R12-1-320.

B. Exempt items

1. ~~Certain items containing radioactive material.~~ Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, ~~a~~ any person is exempt from this Chapter to the extent that ~~the person~~ receives, possesses, uses, transfers or acquires the following products:
 - a. Timepieces, ~~or~~ hands, or dials containing not more than the following specified quantities of material and not exceeding the following specified levels of radiation:
 - i. ~~925 MBq (25 millicuries)~~ ~~(925 M Bq)~~ of tritium per timepiece,
 - ii. ~~185 MBq (5 millicuries)~~ ~~(185 M Bq)~~ of tritium per hand,
 - iii. ~~555 MBq (15 millicuries)~~ ~~(555 M Bq)~~ of tritium per dial (bezels ~~when used are shall be considered as~~ part of the dial),
 - iv. ~~3.7 MBq (100 microcuries)~~ ~~(3.7 M Bq)~~ of promethium-147 per watch or ~~7.4 MBq (200 microcuries)~~ ~~(7.4 M Bq)~~ of promethium-147 per any other timepiece,
 - v. ~~740 kBq (20 microcuries)~~ ~~(740 k Bq)~~ of promethium-147 per watch hand or ~~1.48 MBq (40 microcuries)~~ ~~(1.48 M Bq)~~ of promethium-147 per other timepiece hand,
 - vi. ~~2.22 MBq (60 microcuries)~~ ~~(2.22 M Bq)~~ of promethium-147 per watch dial or ~~4.44 MBq (120 microcuries)~~ ~~(4.44 M Bq)~~ of promethium-147 per other timepiece dial (bezels ~~when used are shall be considered as~~ part of the dial),
 - vii. The levels of radiation from hands and dials containing promethium-147 ~~shall will~~ not exceed, when mea-

Arizona Administrative Register
Notices of Final Rulemaking

sured through 50 milligrams per square centimeter of absorber:

- (1) For wrist watches, 1.0 μ Gy (0.1 millirad) per hour (~~1.0 μ Gy/hr~~) at 10 centimeters from any surface of the watch,
 - (2) For pocket watches, 1.0 μ Gy (0.1 millirad) per hour (~~1.0 μ Gy/hr~~) at 1 centimeter from any surface,
 - (3) For any other timepiece, 2.0 μ Gy (0.2 millirad) per hour (~~2.0 μ Gy/hr~~) at 10 centimeters from any surface,
- viii. ~~37 kBq~~ (~~1 One microcurie~~) (~~37 k Bq~~) of radium-226 in time pieces manufactured prior to October 1, 1978;
- b. Lock illuminators containing not more than 555 MBq (15 millicuries) (~~555 M Bq~~) of tritium or not more than 74 MBq (2 millicuries) (~~74 M Bq~~) of promethium-147 installed in automobile locks. The levels of radiation from each lock illuminator containing promethium-147 shall ~~will~~ not exceed 10 μ Gy (1 millirad) per hour (~~10 μ Gy/hr~~) at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber;
 - c. Balances of precision containing not more than 37 MBq (1 millicurie) (~~37 M Bq~~) of tritium per balance or not more than 18.5 MBq (0.5 millicurie) (~~18.5 M Bq~~) of tritium per balance part;
 - d. Automobile shift quadrants containing not more than 925 MBq (25 millicuries) (~~925 MBq~~) of tritium;
 - e. Marine compasses containing not more than 27.75 GBq (750 millicuries) (~~27.75 G Bq~~) of tritium gas and other marine navigational instruments containing not more than 9.25 GBq (250 millicuries) (~~9.25 G Bq~~) of tritium gas;
 - f. Thermostat dials and pointers containing not more than 925 MBq (25 millicuries) (~~925 M Bq~~) of tritium per thermostat;
 - g. Electron tubes: Provided that each tube does not contain more than 1 of the following specified quantities of radioactive material:
 - i. 5.55 GBq (150 millicuries) (~~5.55 G Bq~~) of tritium per microwave receiver protector tube or 370 MBq (10 millicuries) (~~370 M Bq~~) of tritium per any other electron tube;
 - ii. 37 kBq (1 microcurie) (~~37 k Bq~~) of cobalt 60;
 - iii. 185 kBq (5 microcuries) (~~185 k Bq~~) of nickel 63;
 - iv. 1.11 MBq (30 microcuries) (~~1.11 M Bq~~) of krypton 85;
 - v. 185 kBq (5 microcuries) (~~185 k Bq~~) of cesium 137;
 - vi. 1.11 MBq (30 microcuries) (~~1.11 M Bq~~) of promethium-147;And provided further, that the level of radiation due to radioactive material contained in each electron tube does not exceed 10 μ Gy (1 millirad) per hour (~~10 μ Gy~~) at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber. The term "electron tubes" includes spark gap tubes, power tubes, gas tubes, including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical current.
 - h. Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, 1 or more sources of radioactive material provided that:
 - i. Each source contains no more than 1 exempt quantity set forth in Exhibit Schedule B of this Article, and
 - ii. Each instrument contains no more than 10 exempt quantities. For the purposes of this Paragraph, an instrument's source or sources may contain either 1 type or different types of radionuclide and an individual exempt quantity may be composed of fractional parts of 1 or more of the exempt quantities in Exhibit Schedule B of this Article, provided ~~the sum of the fractions do~~ that sum of such fractions shall not exceed unity.
 - iii. For the purposes of ~~this subsection (B)(1)(h) Paragraph~~ only, 185 kBq (50 nanocurie) (~~185 Bq~~) of americium-241 is considered an exempt quantity under Exhibit Schedule B of this Article.
 - iv. Spark gap irradiators containing not more than 37 kBq (1 microcurie) (~~37 k Bq~~) of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons per hour (11.4 liters/hr or 0.0114 m³/hr).
2. Resins containing scandium-46 and designed for sand consolidation in oil wells. ~~A Any~~ person is exempt from this Chapter ~~if the to the extent that such~~ person receives, possesses, uses, transfers or acquires synthetic plastic resins containing scandium 46 which are designed for sand consolidation in oil wells. ~~The described Such~~ resins shall ~~be have been~~ manufactured or imported according to a in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall ~~be have been~~ manufactured according to in accordance with the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer of ~~the described such~~ resins according to pursuant to licensing requirements equivalent to those in 10 CFR 32.16 and 10 CFR 32.17 of the U.S. Sections 32.16 and 32.17 or 10 CFR Part 32 of the Regulations of the Nuclear Regulatory Commission. This exemption does not authorize the manufacture of any resins containing scandium-46.
3. Self-luminous products
- a. ~~Self-luminous products containing tritium, krypton-85, or promethium-147.~~ Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, ~~a any~~ person is exempt from this Chapter ~~if the to the extent that such~~ person receives, possesses, uses, transfers or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred under a in accor-

Arizona Administrative Register
Notices of Final Rulemaking

~~in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission and described in pursuant to Section 32.22 of 10 CFR Part 32.22, and the which license authorizes the transfer of the products to persons who are exempt from regulatory requirements. This exemption does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.~~

b. ~~A Radium-226. Any person is exempt from this Chapter if the to the extent that such person receives, possesses, uses, or transfers articles containing less than 3.7 kBq (100 nanocuries)(3.7 k Bq) of radium-226, which were manufactured prior to October 1, 1978.~~

4. Gas and aerosol detectors containing radioactive material

a. Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, a ~~any~~ person is exempt from this Chapter ~~if the to the extent that such person receives, possesses, uses, transfers, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, provided that detectors containing radioactive material shall be have been manufactured, imported, or transferred according to a in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission and described in pursuant to Section 32.26 of 10 CFR Part 32.26, or equivalent regulations of an Agreement or Licensing State, and the license which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.~~

b. Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State ~~are shall be considered exempt under R12-1-303.B.4.a. subsection (B)(4)(a), provided that the device is labeled in accordance with the specific license authorizing distribution of the general licensed device, and provided further that the detectors they meet the requirements of R12-1-311.(C).~~

C. Exempt quantities

1. Except as provided in ~~R12-1-303.C.2. and 3. subsections (C)(2) and (3), a any person is exempt from these rules if the Regulations to the extent that such person receives, possesses, uses, transfers or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Exhibit Schedule B of this Article.~~

2. This ~~subsection Subsection R12-1-303.C.~~ does not authorize the production, packaging, or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

3. ~~Except as specified in this subsection, a No person may shall not, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Exhibit Schedule B of this Article, knowing or having reason to believe the described that such quantities of radioactive material will be transferred to persons exempt under R12-1-303.C. subsection (C) or equivalent Regulations of the U.S. Nuclear Regulatory Commission or any Agreement State or Licensing State. A person may transfer radioactive material for commercial distribution under a , except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission under pursuant to Section 32.18 of 10 CFR Part 32.18, or by the Agency according to pursuant to R12-1-311.(B.) which license states that the radioactive material may be transferred by the licensee to persons exempt under R12-1-303.C. this subsection or the equivalent Regulations of the U.S. Nuclear Regulatory Commission or any Agreement State or Licensing State.~~

R12-1-305 R12-1-304. Types of Licenses License Types

Licenses for radioactive materials are of ~~2 two~~ types: general and specific.

1. ~~For a general license, no application is required and no licensing document is issued. The Agency may require that a person file a certificate for a particular general license. The licensee is subject to all other applicable portions of this Chapter and any limitations of the general license. General licenses provided in this Article are effective without the filing of applications with the Agency or the issuance of licensing documents to the particular persons, although the filing of a certificate with the Agency may be required by the particular general license. The general license is subject to all other applicable portions of this Chapter and any limitations of the general license.~~

2. ~~For a specific license, a person submits an application to the Agency. The Agency issues a license if the person satisfies all of the requirements for a license. The licensee is subject to all applicable portions of this Chapter and any limitations contained in the licensing document. Specific licenses require the submission of an application to the Agency and the issuance of a licensing document by the Agency. The licensee is subject to all applicable portions of this Chapter, as well as any limitations specified in the licensing document. No change.~~

R12-1-306 R12-1-305. General License Licenses --Source Material

A. ~~This subsection establishes a A general license is hereby issued authorizing use and transfer of not more than 6.8 kg (15 pounds)(6.8 kg) of source material at any 1 time, for use in research, development, educational, commercial or operational purposes, by persons in the following categories: commercial and industrial firms, research, educational and medical institutions, and State and local government agencies; and provided that the person proceeding under , that no such person shall, pursuant to this general license, receives receive no more than a total of 68.2 kg (150 pounds)(68.2 kg) of source material in any 1 calendar year.~~

Arizona Administrative Register
Notices of Final Rulemaking

- B. Persons who receive, possess, use, or transfer source material under pursuant to the general license issued in ~~R12-1-305-A~~ subsection (A) are exempt from the provisions of 12 A.A.C. 1, Article 4 and Article 10, ~~of this Chapter~~ provided the to the extent that such receipt, possession, use, or transfer is within the terms of the such general license; provided, however, this exemption does not apply to any person that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued under pursuant to this Article part.
- C. Depleted uranium in industrial products and devices.
1. ~~This subsection establishes a A general license is hereby issued~~ to receive, acquire, possess, use or transfer, ~~in accordance with the provisions of R12-1-305.C.2., 3., 4. and 5.~~ depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.
 2. The general license in ~~R12-1-305.C.1. subsection (C)(1)~~ applies only to industrial products or devices which have been manufactured under a either in accordance with a specific license governed by issued to the manufacturer of the products or devices pursuant to R12-1-311.(M-), or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State authorizing which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.
 3. Depleted uranium
 - a. Persons who receive, acquire, possess, or use depleted uranium under pursuant to the general license established by ~~R12-1-305.C.1. subsection (C)(1)~~ shall file ARRA 23 43 "Registration Certificate -- Use of Depleted Uranium Under General License", with the Agency. The form, requesting the information in Exhibit E, shall be submitted within 30 days after the 1st receipt or acquisition of the such depleted uranium. The general licensee registration shall furnish on ARRA 23 ARRA 43 the following information.
 - i. Name, telephone number, name and address of the general licensee registrant;
 - ii. Location of use;
 - iii. ~~A a~~ statement that the general licensee registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in R12-1-305.C.1. subsection (C)(1) and designed to prevent transfer of the such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and
 - iv. ~~iii.~~ Name name or title (or both), address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in R12-1-305.C.3.a.ii subsection (C)(3)(a)(ii).
 - b. The general licensee registrant possessing or using depleted uranium under the general license established by ~~R12-1-305.C.1. subsection (C)(1)~~ shall report in writing to the Agency any changes in information originally furnished on by him in ARRA 23 43 "Registration Certificate -- Use of Depleted Uranium Under General License". The report shall be submitted within 30 days after the effective date of the described such change.
 4. A person who receives, acquires, possesses, or uses depleted uranium under pursuant to the general license established by ~~R12-1-305.C.1. subsection (C)(1)~~:
 - a. Shall not introduce the such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;
 - b. Shall not abandon the such depleted uranium;
 - c. Shall transfer the or dispose of such depleted uranium as prescribed in R12-1-318. only by transfer in accordance with the provisions of R12-1-318. In the case where If the transferee receives the depleted uranium under pursuant to the general license established by ~~R12-1-305.C.1. subsection (C)(1)~~, the transferor shall furnish the transferee with a copy of this rule regulation and a copy of the registration certificate. ARRA 13. In the case where If the transferee receives the depleted uranium under pursuant to a general license governed by a regulation of contained in the U.S. Nuclear Regulatory Commission's or Agreement State State's regulation that is equivalent to R12-1-305.C.1. subsection (C)(1), the transferor shall furnish the transferee a copy of this rule regulation and a copy of the registration certificate ARRA 13, accompanied by a letter note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially similar to the same as those in this rule regulation;
 - d. Within 30 days of any transfer, shall report in writing to the Agency the name and address of the person receiving the depleted uranium pursuant to such transfer; and
 - e. Shall not export the such depleted uranium except under in accordance with a license issued by the U.S. Nuclear Regulatory Commission in pursuant to 10 CFR Part 110.
 5. Any person receiving, acquiring, possessing, using, or transferring depleted uranium according to pursuant to the general license established by ~~R12-1-305.C.1. subsection (C)(1)~~ is exempt from the requirements of 12 A.A.C. 1, Articles 4 and 10 ~~of these Regulations~~ with respect to the depleted uranium covered by that general license.

Arizona Administrative Register
Notices of Final Rulemaking

~~R12-1-307~~ R12-1-306. General License Licenses -- Radioactive Material Other Than Source Material

- A. ~~This subsection establishes a certain devices and equipment. A general license is issued to transfer, receive, acquire, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer according to in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission under 10 CFR 31.3 pursuant to Section 31.3 of 10 CFR Part 31. This general license is subject to the provisions of 12 A.A.C. 1, Articles 1, 4, 10 and 12; of this Chapter and sections Sections R12-1-303-A.2-(A)(2), R12-1-313, R12-1-318, R12-1-319, and R12-1-321; of this Article and A.R.S. §§ 30-654(B)(13) 30-654.B.13, 30-657(A) and (B) 30-657.A and B, 30-681, and 30-685 through 30-689 of the Act.~~
1. Static elimination device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 microcuries) ~~(18.5 MBq)~~ of polonium-210 per device.
 2. Ion generating tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 microcuries) ~~(18.5 MBq)~~ of polonium-210 per device or a total of not more than 1.85 GBq (50 millicuries) ~~(1.86 GBq)~~ of hydrogen-3 (tritium) per device.
- B. Certain measuring, gauging or controlling devices
1. ~~This subsection establishes a general license for A general license is hereby issued to commercial and industrial firms; and to research, educational and medical institutions; individuals for conducting in the conduct of their business; and State or local government agencies to receive, acquire, possess, use or transfer radioactive material according to in accordance with the provisions of R12-1-306.B.2., 3. and 4. subsections (B)(2), (3), and (4), radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.~~
 2. The general license in ~~R12-1-306.B.1. subsection (B)(1)~~ applies only to radioactive material contained in devices which have been manufactured and labeled ~~according to in accordance with the specifications contained in a specific license issued by the Agency under pursuant to R12-1-311.D.(D) or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes distribution of devices to persons generally licensed by the NRC or an Agreement State. Regulations promulgated under the Federal Food, Drug, and Cosmetic Act, authorizing the use of radioactive control devices in food production require certain additional labeling prescribed in 21 CFR 179.21, thereon which is found in Section 179.21 of the Code of Federal Regulations, Title 21.~~
 3. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device according to pursuant to the general license in R12-1-306.B.1. subsection (B)(1):
 - a. ~~Shall shall~~ assure that all labels are affixed to the device at the time of receipt, each and bearing a statement that removal of the label is prohibited, maintain the labels are maintained on the device thereon and ~~shall~~ comply with all instructions and precautions provided by on the such labels;
 - b. ~~Shall shall~~ assure that the device is tested for leakage of radioactive material and proper operation of the actuation on-off mechanism and indicator, if any, at no longer than 6-month intervals or the intervals at such other intervals as are specified on in the label; however:
 - i. Devices devices containing only krypton need not be tested for leakage of radioactive material, and
 - ii. Devices devices containing only tritium or not more than 3.7 MBq (100 microcuries) ~~(3.7 MBq)~~ of other beta or and/or gamma emitting material or 370 kBq (10 microcuries) ~~(370 kBq)~~ of alpha emitting material; and and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;
 - iii. Devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose.
 - c. ~~Shall shall~~ assure that the tests required by ~~R12-1-306.B.3.b. subsection (B)(3)(b) and other testing, installation, servicing, and removal from installation involving shielding, containment or the radioactive material, materials, its shielding or containment, are performed:~~
 - i. According to in accordance with the instructions on any label provided by the labels, or
 - ii. By by a person holding a specific license from the Agency, the NRC, or an Agreement State or Licensing State to perform the specified such activities;
 - d. ~~Shall shall~~ maintain records showing compliance with the requirements of ~~R12-1-306.B.3.b. subsections (B)(3)(b) and (c), and R12-1-306.B.3.e.~~ The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal or other work concerning shielding, containment, or radioactive material. from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by ~~R12-1-306.B.3.b. subsection (B)(3)(b)~~ shall be maintained for 1 year after the next required leak test is performed or until the sealed source is disposed of or transferred or disposed of. Records of tests of the actuator on/off mechanism and indicator required by ~~R12-1-306.B.3.b. subsection (B)(3)(b)~~ shall be maintained for 1 year after the

Arizona Administrative Register
Notices of Final Rulemaking

next required test of the ~~actuator on/off~~ mechanism and indicator is performed or until the sealed source is ~~disposed of or transferred or disposed of~~. Records which are required by ~~R12-1-306.B.3.e. subsection (B)(3)(c)~~ shall be maintained for a period of 2 years from the date of the recorded event or until the device is ~~disposed of or transferred or disposed of~~;

- e. ~~Upon upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage of to,~~ the shielding of the radioactive material or the ~~actuation on-off~~ mechanism or indicator, or upon the detection of ~~185 Bq (5 nanocurie) (185 Bq)~~ or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding a specific license from the Agency, the NRC or an Agreement State or Licensing State to repair ~~the device such devices~~, or disposed of by transfer to a person authorized by a specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the Agency a report containing a brief description of the event and the remedial action taken;
- f. ~~Shall shall~~ not abandon the device containing radioactive material;
- g. ~~Except except~~ as provided in ~~R12-1-306.B.3.h. subsection (B)(3)(h)~~, shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the Agency, the NRC, or an Agreement State or Licensing State whose specific license authorizes the receipt of the device and, within 30 days after transfer of a device to a specific licensee shall furnish to the Agency a report to the Agency identifying containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;
- h. ~~Shall shall~~ transfer the device to another general licensee only:
 - i. ~~If where~~ the device remains in use at a particular location. ~~The In such case the~~ transferor shall give the transferee a copy of this ~~rule Regulation~~ and any safety documents identified ~~on in~~ the label of ~~on~~ the device and within 30 days ~~after of~~ the transfer, report to the Agency the manufacturer's name, ~~the and~~ model number of the device transferred, and the name and address of the transferee, and the name or position or both of ~~a contact person for the Agency an individual who may constitute a point of contact between the Agency and the transferee~~; or
 - ii. ~~Where where~~ the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee;
- i. ~~Shall shall~~ comply with the provisions of ~~R12-1-423 R12-1-443 and R12-1-444~~ for reporting radiation incidents, theft, or loss of licensed material, but ~~is shall be~~ exempt from the other requirements of 12 A.A.C. 1, Articles 4 and 10.

- 4. The general license in ~~R12-1-306.B.1. subsection (B)(1)~~ does not authorize the manufacture of devices containing radioactive material.
- 5. The general license provided in ~~R12-1-306.B.1. subsection (B)(1)~~ is subject to the provisions of 12 A.A.C. 1, Articles 1, 3, 12, and 15 of this Chapter, and A.R.S. §§ 30-654(B)(13) 30-654.B.13, 30-657 (A) and (B) 30-657. A and B, 30-681, and 30-685 through 30-689 of the Aet.

C. Luminous safety devices for aircraft

- 1. ~~This subsection establishes a A~~ general license ~~for the receipt, acquisition, possession, and use of is hereby issued to receive, acquire, possess, and use~~ tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:
 - a. ~~Each each~~ device contains not more than 370 GBq (10 curies) (370 G Bq) of tritium or 11.1 GBq (300 millicuries) (11.1 G Bq) of promethium-147; and
 - b. ~~Each each~~ device has been manufactured, assembled or imported ~~according to a in accordance with a~~ specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled ~~according to in accordance with~~ the specifications contained in a specific license issued by the Agency or any Agreement State or Licensing State to the manufacturer or assembler of ~~the such device according to pursuant to~~ licensing requirements equivalent to those in 10 CFR 32.53 Section 32.53 of 10 CFR 32 of the Regulations of the U.S. Nuclear Regulatory Commission.
- 2. Persons who receive, acquire, possess, or use luminous safety devices ~~according to pursuant to~~ the general license in ~~R12-1-306.C.1. subsection (C)(1)~~ are exempt from the requirements of 12 A.A.C. 1, Article 4 and Article 10 except that they shall comply with the provisions of 423 R12-1-443 and R12-1-444.
- 3. This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.
- 4. This general license does not authorize the ownership, receipt, acquisition, possession or use of radioactive materials contained in instrument dials.
- 5. This general license is subject to the provisions of 12 A.A.C.1, Articles 1, 3, 12, and 15 of this Chapter, and A.R.S. §§ 30-654(B)(13), 30-657(A), 30-657(B) 30-654.B.13, 30-657.A, 30-657.B, 30-681, and 30-685 through 30-689 of the Aet.

Arizona Administrative Register
Notices of Final Rulemaking

D. Calibration and reference sources

1. ~~This subsection establishes a~~ A general license ~~for is hereby issued to~~ those persons listed below to receive, acquire, possess, use, and transfer, ~~according to in accordance with the provisions of R12-1-306.D.4. and 5. subsections (D)(4) and (5),~~ americium-241 in the form of calibration or reference sources:
 - a. Any person who holds a specific license issued by the Agency which authorizes the receipt, possession, use and transfer of radioactive material; and
 - b. Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes the receipt, possession, use and transfer of special nuclear material.
2. ~~This subsection establishes a~~ A general license ~~for ownership, receipt, possession, use and transfer of is hereby issued to own, receive, possess, use, and transfer~~ plutonium in the form of calibration or reference sources, ~~in accordance with the provisions of R12-1-306.D.4. and 5. to any person who holds a specific license issued by the Agency authorizing receipt, possession which authorizes him to receive, possess, use, and transfer of~~ radioactive material.
3. ~~This subsection establishes a~~ A general license ~~is hereby issued to~~ receive, possess, use and transfer radium-226 in the form of calibration or reference sources, ~~in accordance with the provisions of R12-1-306.D.4. and 5. to any person who holds a specific license issued by the Agency authorizing which authorizes the receipt, possession, use and transfer of~~ radioactive material.
4. The general licenses in ~~R12-1-306.D.1., 2. and 3. subsections (D)(1), (2), and (3)~~ apply ~~only~~ to calibration or reference sources which have been manufactured ~~according to in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission in pursuant to Section 32.57 of 10 CFR Part 32.57 or Section 70.39 of 10 CFR Part 70.39. The general licenses also apply to calibration or reference sources or~~ which have been manufactured ~~according to in accordance with the specifications contained in a specific license issued to the manufacturer by the Agency or any Agreement State or Licensing State according to pursuant to~~ licensing requirements equivalent to those contained in ~~Section 32.57 of 10 CFR Part 32.57 or Section 70.39 of 10 CFR Part 70.39 of the Regulations of the U.S. Nuclear Regulatory Commission.~~
5. The general licenses provided in ~~R12-1-306.D.1., 2. and 3. Subsections (D)(1), (2), and (3)~~ are subject to the provisions of ~~12 A.A.C. 1, Articles 1, 3, 4, 10, 12, and 15 of this Chapter and A.R.S. §§30-654(B)(13), 30-657(A), 30-657(B) 30-654.B.13, 30-657.A, 30-657.B, 30-681, and 30-685 through 30-689 of the Act.~~ In addition, persons who own, receive, acquire, possess, use, or transfer 1 or more calibration or reference sources ~~according to pursuant to~~ these general licenses:
 - a. ~~Shall shall~~ not possess at any 1 time, at any location of storage or use, more than ~~185 kBq (5 microcuries) (185 kBq)~~ of americium-241, ~~5 microcuries of plutonium or and 5 microcuries (185 kBq)~~ of radium-226 in ~~calibration or reference calibration and such~~ sources;
 - b. ~~Shall shall~~ not receive, possess, use, or transfer ~~a calibration or reference such~~ source unless the source, or the storage container, bears a label which includes ~~1 of the following statements statement~~ or a substantially similar statement which contains the information called for in 1 of the following statements, ~~as appropriate:~~
 - i. The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label. CAUTION -- RADIOACTIVE MATERIAL -- THIS SOURCE CONTAINS (name of the appropriate material) -- DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or importer

- ii. The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of any Licensing State. Do not remove this label.
CAUTION -- RADIOACTIVE MATERIAL -- THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

Name of manufacturer or importer

- c. ~~Shall shall~~ not transfer, abandon, or dispose of ~~a calibration or reference such~~ source except by transfer to a person authorized by a license from the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to receive the source;
 - d. ~~Shall shall~~ store ~~a calibration or reference such~~ source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and
 - e. ~~Shall shall~~ not use ~~a calibration or reference such~~ source for any purpose other than the calibration of radiation detectors or the standardization of other sources.
6. These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

E. Medical diagnostic uses

Arizona Administrative Register
Notices of Final Rulemaking

Receipt, possession, use, transfer, ownership or acquisition of carbon-14 urea capsules containing 1 microcurie of carbon-14 urea for "in vivo" human diagnostic use:

1. Except as provided in subsections (E)(2) and (3), a physician is exempt from the requirements for a specific license provided that each carbon-14 urea capsule for "in vivo" diagnostic use contains no more than 1 microcurie.
2. Any physician who desires to use the capsules for research involving human subjects shall obtain a specific license issued according to the specific licensing requirements in this Article.
3. Any physician who desires to manufacture, prepare, process, produce, package, repack, or transfer for commercial distribution carbon-14 urea capsules shall obtain a specific license from the Agency, issued according to the requirements in 10 CFR 32, 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of Secretary of State. This incorporation by reference contains no future editions or amendments.
4. Nothing in this subsection relieves physicians from complying with applicable FDA and other federal and state requirements governing receipt, administration, and use of drugs.
1. ~~A general license is hereby issued to any physician to receive, possess, transfer, or use the radioactive material set forth below for the stated diagnostic uses, provided, however, that a the use is in accordance with the provision of R12-1-306.E.2., 3. and 4, the radioactive material is in the form of capsules, disposable syringes, or other prepackaged individual doses; and the radioactive material has been manufactured in accordance with a specific license issued under pursuant to R12-1-311.G. by the Agency, the U.S. Nuclear Regulatory Commission, or any Agreement State or Licensing State authorizing distribution under the general license granted in this Paragraph or its equivalent:~~
 - a. ~~Iodine-131 as sodium iodide (NaI131) for measurement of thyroid uptake;~~
 - b. ~~Iodine-131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;~~
 - e. ~~Iodine-125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;~~
 - d. ~~Cobalt-57 for the measurement of intestinal absorption of cyanocobalamin;~~
 - e. ~~Cobalt-58 for the measurement of intestinal absorption of cyanocobalamin;~~
 - f. ~~Cobalt-60 for the measurement of intestinal absorption of cyanocobalamin; and~~
 - g. ~~Chromium-51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time.~~
2. ~~No physician shall receive, possess, use, or transfer radioactive material pursuant to the general license established by R12-1-306.E.1. until the physician has filed ARRA-5, "Certificate — Medical Use of Radioactive Material Under General License" with the Agency and received from the Agency a validated copy of the ARRA-5 with certification number assigned. The generally licensed physician shall furnish on ARRA-5 and such other information as may be required by that form:~~
 - a. ~~Name and address of the generally licensed physician;~~
 - b. ~~A statement that the generally licensed physician is a duly licensed physician authorized to dispense drugs in the practice of medicine in this State; and~~
 - e. ~~A statement that the generally licensed physician has appropriate radiation measuring instruments to carry out the diagnostic procedures which use radioactive material under the general license of R12-1-306.E. and that the physician is competent in the use of such instruments.~~
3. ~~A physician who receives, possesses, or uses a pharmaceutical containing radioactive material pursuant to the general license established by R12-1-306.F.1. shall comply with the following:~~
 - a. ~~The physician shall not possess at any one time, pursuant to the general license in R12-1-306.E.1. more than~~
 - i. ~~200 microcuries (3.7 M Bq) of iodine-131;~~
 - ii. ~~200 microcuries (3.7 M Bq) of iodine-125;~~
 - iii. ~~5 microcuries (185 k Bq) of cobalt-57;~~
 - iv. ~~5 microcuries (185 k Bq) of cobalt-58;~~
 - v. ~~5 microcuries (185 k Bq) of cobalt-60; and~~
 - vi. ~~200 microcuries (3.7 M Bq) of chromium-51;~~
 - b. ~~The physician shall store the pharmaceutical until administered in the original shipping container, or a container providing equivalent radiation protection;~~
 - e. ~~The physician shall use the pharmaceutical only for the uses authorized by R12-1-306.E.1.~~
 - d. ~~The physician shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age; and~~
 - e. ~~The physician shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Agency, the U.S. Nuclear Regulatory Commission or any Agreement State or Licensing State, or in any manner other than in the unopened, labeled shipping container, as received from the supplier, except by administering it to a patient.~~
4. ~~The generally licensed physician possessing or using radioactive material under the general license of R12-1-306.E.1. shall report in duplicate to the Agency any changes in the information furnished in the "Certificate — Medical Use of Radioactive Material Under General License", ARRA-5. The report shall be submitted within 30 days after the effective date of the such change.~~

Arizona Administrative Register
Notices of Final Rulemaking

~~5. Any person using radioactive material pursuant to the general license of R12-1-306.E.1. is exempt from the requirements of Article 4 and Article 10 of these Regulations with respect to the radioactive material covered by the general license.~~

F. General license for use of radioactive material for certain in vitro clinical or laboratory testing

1. ~~This subsection establishes a~~ A general license for ~~is hereby issued to~~ any physician, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, ~~in accordance with the provisions of R12-1-306.F.2., 3., 4., 5., and 6.,~~ the following radioactive materials in prepackaged units:
 - a. Iodine-125, in units not exceeding 370 kBq (10 microcuries) ~~(370 k Bq)~~ each for use in in vitro ~~in vitro~~ clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation from such material ~~therefrom~~, to human beings or animals.
 - b. Iodine-131, in units not exceeding 370 kBq (10 microcuries) ~~(370 k Bq)~~ each for use in in vitro ~~in vitro~~ clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation from such material ~~therefrom~~, to human beings or animals.
 - c. Carbon-14, in units not exceeding 370 kBq (10 microcuries) ~~(370 k Bq)~~ each for use in in vitro ~~in vitro~~ clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation from such material ~~therefrom~~, to human beings or animals.
 - d. Hydrogen-3 (tritium), in units not exceeding 1.85 MBq (50 microcuries) ~~(1.85 M Bq)~~ each for use in in vitro ~~in vitro~~ clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation from such material ~~therefrom~~, to human beings or animals.
 - e. Iron-59, in units not exceeding 740 kBq (20 microcuries) ~~(740 k Bq)~~ each for use in in vitro ~~in vitro~~ clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation from such material ~~therefrom~~, to human beings or animals.
 - f. Cobalt-57, in units not exceeding 370 kBq (10 microcuries) ~~(370 k Bq)~~ each for use in in vitro ~~in vitro~~ clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation from such material ~~therefrom~~, to human beings or animals.
 - g. Mock iodine-125 reference or calibration sources, in units not exceeding 1.85 kBq (50 nanocurie) ~~(1.85 k Bq)~~ of iodine-129 and 185 Bq (5 nanocurie) ~~(185 Bq)~~ of americium-241 each, for use in in vitro ~~in vitro~~ clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation from such material ~~therefrom~~, to human beings or animals.
2. ~~A No~~ person shall not acquire, receive, possess, use or transfer radioactive material according to ~~pursuant to~~ the general license established by ~~R12-1-306.F.1. subsection (F)(1)~~ until the person has filed ARRA-9, "Certificate -- In Vitro Testing with Radioactive Material Under General License", requesting the information listed in Exhibit E, with the Agency and received ~~from the Agency~~ a validated copy of ARRA-9 which shows the assigned with certification number assigned. The physician, clinical laboratory, or hospital shall furnish on ARRA-9, the following information: ~~the following information and such other information as may be required by that form:~~
 - a. Name, telephone number, and address of the physician, clinical laboratory, or hospital; and
 - b. ~~The location of use; and~~
 - c. A statement that the physician, clinical laboratory, or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material and that tests as authorized under the general license in R12-1-306.F.1. and that such tests will be performed only by personnel competent to in the use of the appropriate instruments and handle in the handling of the radioactive material.
3. A person who receives, acquires, possesses or uses radioactive material according ~~pursuant~~ to the general license established by ~~R12-1-306.F.1. subsection (F)(1)~~ shall comply with the following:
 - a. The general licensee shall not possess at any 1 time, ~~pursuant to the general license in R12-1-306.F.1.~~ in storage or use, a total amount of iodine-125, iodine-131, iron-59, or and/or cobalt-57 in excess of 7.4 MBq (200 microcuries), ~~or not~~ acquire or use in any 1 calendar month any more than ~~in excess of a total of~~ 18.5 MBq (500 microcuries) of these materials.
 - b. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
 - c. The general licensee shall use the radioactive material only for the uses authorized by ~~R12-1-306.F.1. subsection (F)(1).~~
 - d. The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it according to ~~pursuant to~~ a license issued by the Agency, the U.S. Nuclear Regulatory Commission, or any Agreement State or Licensing State, or not transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.
 - e. The general licensee shall not dispose of the mock iodine-125 reference or calibration sources described above except as authorized by ~~R12-1-434 R12-1-416.~~
4. The general licensee shall not receive, acquire, possess, or use radioactive material according ~~pursuant~~ to ~~R12-1-306.F.1. subsection (F)(1):~~

Arizona Administrative Register
Notices of Final Rulemaking

- a. Except as prepackaged units which are labeled according to ~~in accordance with~~ the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, or any Agreement State which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, cobalt-57, or mock iodine-125 for distribution to persons generally licensed under ~~R12-1-306.F. subsection (F)~~ or its equivalent federal law, and
- b. ~~Unless unless~~ 1 of the following statements, or a substantially similar statement which contains the same information ~~called for in one of the following statements~~, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:
 - i. This radioactive material may be acquired, received, possessed, and used only by physicians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation from such material ~~therefrom~~, to human beings or animals. The acquisition, receipt, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

Name of manufacturer

- ii. This radioactive material shall be acquired, received, possessed, and used only by physicians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation from such material ~~therefrom~~, to human beings or animals. The receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a Licensing State.

Name of manufacturer

5. ~~A The~~ physician, clinical laboratory or hospital possessing or using radioactive material under the general license ~~in of R12-1-306.F.1. subsection (F)(1)~~ shall report in writing to the Agency, any changes in the information furnished ~~on in the "Certificate - In Vitro Testing with Radioactive Material Under General License";~~ ARRA-9. The report shall be furnished within 30 days after the effective date of ~~the~~ such change.
6. Any person using radioactive material according to ~~pursuant to~~ the general license of ~~R12-1-306.F.1. subsection (F)(1)~~ is exempt from the requirements of 12 A.A.C. 1, Article 4 and Article 10 ~~of these Regulations~~ with respect to radioactive material covered by that general license, except that persons using mock iodine-125 sources described in ~~R12-1-306.F.1.g. subsection (F)(1)(g)~~ shall comply with the provisions of ~~R12-1-434 R12-1-416, and R12-1-423 R12-1-443 and R12-1-444~~ of these rules Regulations.
7. For the purposes of subsection (F), a licensed veterinary care facility is considered ~~shall be deemed to be~~ a "clinical laboratory".

G. Ice detection devices

1. ~~This subsection establishes a~~ A general license is hereby issued to receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 1.85 Mbq (50 µCi) 50 microcuries (1.85 M Bq) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured according to ~~in accordance with~~ the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer of ~~the~~ such device under ~~pursuant to~~ licensing requirements equivalent to those in ~~Section 32.61 or 10 CFR Part 32.61~~ of the Regulations of the NRC.
2. Persons who receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices according ~~pursuant~~ to the general license in ~~R12-1-306.G.1. subsection (G)(1):~~
 - a. ~~Shall shall~~, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating ~~to the device~~, discontinue use of the device until it has been inspected, tested for leakage, and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State to manufacture or service ice detection ~~such~~ devices; or shall dispose of the device according ~~pursuant~~ to the provisions of ~~R12-1-416 R12-1-434;-~~
 - b. ~~Shall shall~~ assure that all labels affixed to the device at the time of receipt, and which bear a statement prohibiting ~~which prohibits~~ removal of the labels, are maintained on the devices ~~thereon~~; and
 - c. ~~Are are~~ exempt from the requirements of 12 A.A.C. 1, Article 4 and Article 10, except the users of ice detection devices ~~that such persons~~ shall comply with the provisions of ~~416 and 423 R12-1-434, R12-1-443 and R12-1-444.~~
3. No change.
4. This general license is subject to the provisions of 12 A.A.C. 1, Articles 1, 3, 12, and 15 ~~of this Chapter~~, and A.R.S. §§ ~~30-654(B), 30-657(A), 30-657(B), 30-654.B.13, 30-657.A, 30-657.B, 30-681, and 30-685 through 30-689~~ of the Act.

Arizona Administrative Register
Notices of Final Rulemaking

~~R12-1-308~~ R12-1-307. Repealed.

~~R12-1-309~~ R12-1-308. Filing Application for Specific Licenses

- A. ~~An applicant Applications for a specific license licenses shall file be filed on an Agency application form, a form pre-~~scribed by the Agency. ~~The applicant Applications shall prepare the application be prepared in duplicate, 1 copy for trip-~~licate; two copies shall be filed with the Agency and the other ~~for shall be maintained~~ by the applicant.
- B. No change.
- C. Each application shall ~~contain the information specified in Exhibit (E) of this Article and~~ be signed by the applicant, ~~or licensee, or a person duly authorized to act for and on behalf of the applicant or licensee.~~
- D. An application for a license may include a request for a license authorizing ~~more than 1 activity authorized by R12-1-1302~~ one or more activities.
- E. In ~~the his~~ application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Agency, ~~provided the such~~ references are clear and specific.
- F. ~~The Agency shall make applications Applications and documents submitted to the Agency may be made~~ available for public inspection, ~~but except that the Agency may withhold any document or part of a document thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.~~

~~R12-1-310~~ R12-1-309. General Requirements for the Issuance of Specific Licenses

A license application ~~shall will~~ be approved if the Agency determines that:

1. ~~The the~~ applicant is qualified by reason of training and experience to use the material in question for the purpose requested, ~~according to in accordance with these rules, in Regulations in such a manner that will as to~~ minimize danger to public health and safety or property;
2. ~~The the~~ applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;
3. ~~The the~~ issuance of the license will not be inimical to the health and safety of the public;
4. ~~The the~~ applicant satisfies ~~all any~~ applicable special requirements in R12-1-310, R12-1-311, ~~and R12-1-323; R12-1-322, R12-1-323, 12 A.A.C. 1, Article 5, 7, and 17;~~ and
5. ~~The the~~ applicant demonstrates that a letter has been sent, return receipt requested, to the Mayor's office of the city, town, or, if not within an incorporated community, to the County Board of Supervisors ~~of the county~~ in which the applicant proposes to operate, which describes:
 - a. ~~The the~~ nature of the proposed activity involving radioactive material;
 - b. ~~The the~~ facility, including use and storage areas.

~~R12-1-311~~ R12-1-310. Special Requirements for Issuance of Certain Specific Broad Scope Licenses for Radioactive Material

- A.** Human use of radioactive material in institutions. In addition to the requirements set forth in R12-1-309, a specific license for human use of radioactive material in institutions will be issued only if:
1. The applicant has appointed a radiation safety committee to oversee the use of licensed material throughout the institution and to review the institution's radiation safety program. Membership of the committee shall include at least the following: an authorized user for each type of use permitted by the licensee, a representative of the nursing staff, a representative of the institution's management, and the Radiation Safety Officer.
 2. The applicant possesses adequate facilities for the clinical care of patients;
 3. Any physician designated on the application as an individual user has substantial experience in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients; and
 4. If the application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant's staff has substantial experience in the use of a variety of radioactive materials for a variety of human uses.
- B.** Specific licenses to individual physicians for human use of radioactive material
1. An application by an individual physician or group of physicians for a specific license for the human use of radioactive material may be approved if:
 - a. the applicant satisfies the general requirements specified in R12-1-309;
 - b. the application is for use in the applicant's practice in an office outside a medical institution;
 - c. the applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and
 - d. the applicant has substantial experience in the handling and administration of radio nuclides, and where applicable, the clinical management of radioactive patients.
 2. The Agency will not approve an application by an individual physician or group of physicians for a specific license to receive, possess, or use radioactive material on the premises of a medical institution unless:
 - a. The use of radioactive material is limited to:
 - i. the administration of radiopharmaceutical for diagnostic or therapeutic purposes;
 - ii. the performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered;

Arizona Administrative Register
Notices of Final Rulemaking

- iii. the performance of in vitro diagnostic studies, or
 - iv. the calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation and diagnostic instrumentation.
 - b. the physician brings the radioactive material with him/her and removes the radioactive material when he/she departs. (The institution cannot receive, possess, or store radioactive material other than the amount of material remaining in the patient); and
 - e. the medical institution does not hold a radioactive materials license under R12-1-310.A.
- C. Specific licenses for certain groups of medical uses of radioactive material**
- 1. Subject to the provisions of R12-1-310.C.2., 3. and 4., an application for a specific license pursuant to R12-1-310.A. or B. for any medical use or uses of radioactive material specified in one or more of Groups I to V, inclusive, of Schedule C of this Article will be approved for all of the materials within the group or groups in the application if:
 - a. The applicant satisfies the requirements of R12-1-310.A., B. and D.;
 - b. The applicant, or any physician designated in the application as an individual user, has adequate clinical experience in the types of uses included in the group or groups;
 - c. The applicant or the physicians and all other personnel who will be involved in the preparation and use of the radioactive material have adequate training and experience in the handling of radioactive material appropriate to their participation in the uses included in the group or groups;
 - d. The applicant's radiation detection and measuring instrumentation is adequate for conducting the procedures involved in the uses included in the group or groups;
 - e. The applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the uses included in the group or groups.
 - 2. Any licensee or registrant who is authorized to use radioactive material pursuant to one or more groups in R12-1-310.C.1. and Schedule C of this Article is subject to the following conditions:
 - a. For Groups I, II, IV and V, no licensee or registrant shall receive, possess, or use radioactive material as a radiopharmaceutical unless manufactured in the form to be administered to the patient, labeled, packaged, and distributed in accordance with a specific license issued by the Agency pursuant to R12-1-311.J., a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.72 of 10 CFR Part 32, a specific license issued by an Agreement State or a Licensing State pursuant to equivalent regulations.
 - b. For Group III, no licensee or registrant shall receive, possess, or use generators or reagent kits containing radioactive material or shall use reagent kits that do not contain radioactive material to prepare radiopharmaceuticals containing radioactive material, except:
 - i. Reagent kits not containing radioactive material that are approved by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State or Licensing State for use by persons licensed pursuant to R12-1-310.C. and Schedule C of this Article or equivalent regulations; or
 - ii. Generators or reagent kits containing radioactive material that are manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the Agency pursuant to R12-1-311.K., or a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Sec. 32.73 of 10 CFR Part 32, or a specific license issued by an Agreement State or a Licensing State pursuant to equivalent regulations.
 - iii. For Group III, any licensee or registrant who uses generators or reagent kits shall:
 - (1) Elute the generator or process radioactive material with the reagent kit, in accordance with instructions which are approved by the U.S. Nuclear Regulatory Commission, an Agreement State and are furnished by the manufacturer on the label attached to or in the leaflet or brochure which accompanies the generator or reagent kit;
 - (2) Before administration to patients, cause each elution or extraction of technetium-99m from a molybdenum-99/technetium-99m generator to be tested to determine either the total molybdenum-99 activity or the concentration of molybdenum-99. This testing shall be conducted according to written procedures and by personnel who have been specifically trained to perform the test;
 - (3) Prohibit the administration to patients of technetium-99m containing more than 1 microcurie (37k Bq) of molybdenum-99 per millicurie (37k Bq) of technetium-99m, or more than 5 microcuries (185 K Bqw) of molybdenum-99 per administered dose, at the time of administration; and
 - (4) Maintain for 2 years for Agency inspection, records of the molybdenum-99 test conducted on each elution from the generator and records of training given to personnel performing such tests.
 - iv. For Groups I, II and III any licensee using radioactive material for clinical procedures other than those specified in the product labeling (package insert) shall comply with the product labeling regarding:
 - (1) Chemical and physical form;
 - (2) Route of administration; and
 - (3) Dosage range.Provided, however, that specific alternative routes of administration may be approved pursuant to R12-1-103 upon application to the Agency describing the radiation safety merits of the proposed alternative.

Arizona Administrative Register
Notices of Final Rulemaking

3. Any licensee who is licensed pursuant to R12-1-310.C.1. for one or more of the medical use groups in Schedule C also is authorized to use radioactive material under the general license in R12-1-306.F. for the specified in vitro uses without filing Form AARA-9 as required by R12-1-306.F.2.; provided, that the licensee is subject to the other provisions of R12-1-306.F.
 4. Any licensee who is licensed pursuant to R12-1-310.C.1. for one or more of the medical use groups in Schedule C also is authorized, subject to the provisions of R12-1-310.C.4. and 5., to receive, possess, and use for calibration and reference standards:
 - a. Any radioactive material listed in Group I, Group II, or Group III of Schedule C of this Article with a half-life not longer than 100 days, in amounts not to exceed 15 millicuries (555 M Bq) total;
 - b. Any radioactive material listed in Group I, Group II, or Group III of Schedule C of this Article with half-life greater than 100 days in amounts not to exceed 200 microcuries (7.4 M Bq) total;
 - c. Technetium-99m in amounts not to exceed 30 millicuries (2.22 G Bq);
 - d. Any radioactive material, in amounts not to exceed 3 millicuries (222 M Bq) per source, contained in calibration or reference sources that have been manufactured, labeled, packaged, and distributed in accordance with:
 - i. A specific license issued by the Agency pursuant to R12-1-311.J.; or
 - ii. A specific license issued by the Nuclear Regulatory Commission pursuant to Section 32.72 of 10 CFR Part 32; or
 - iii. A specific license issued by an Agreement State or Licensing State pursuant to equivalent regulations.
 5. Sealed source testing
 - a. Any licensee or registrant who possesses sealed sources as calibration or reference sources pursuant to R12-1-310.C.4. shall cause each sealed source containing radioactive material, other than hydrogen-3, with a half-life greater than thirty days in any form other than gas to be tested for leakage and contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, the sealed source should not be used until tested, provided, however, that no leak tests are required when:
 - i. The source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material, or
 - ii. The sealed source is stored and is not being used; such sources shall, however, be tested for leakage prior to any use or transfer unless they have been leak tested within six months prior to the date of use or transfer.
 - b. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which contamination might be expected to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Agency.
 - c. If the leak test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee or registrant shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Articles 3 and 4 of these Regulations. A report shall be filed within 5 days of the test with the Agency describing the equipment involved, the test results, and the corrective action taken;
 6. Any licensee or registrant who possesses and uses calibration and reference sources pursuant to R12-1-310.C.4.d. shall:
 - a. Follow the radiation safety and handling instructions approved by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State and furnished by the manufacturer on the label attached to the source, or permanent container thereof, or in the leaflet or brochure that accompanies the source, and maintain such instruction in a legible and conveniently available form;
 - b. Conduct a quarterly physical inventory to account for all sources received and possessed. Records of the inventories shall be maintained for inspection by the Agency and shall include the quantities and kinds of radioactive material, location of sources, and the date of the inventory.
- D. Human use of sealed sources.** In addition to the requirements set forth in R12-1-309, a specific license for human use of sealed sources will be issued only if the applicant or, if the application is made by an institution, the individual user:
1. has specialized training in the diagnostic or therapeutic use of the sealed source considered, or has experience equivalent to such training, and
 2. is a physician.
3. Licenses issued pursuant to R12-1-310.D. are subject to the additional provisions of Article 7 of this Chapter.
- E. Misadministrations:**
1. Definition of a misadministration. For this part, misadministration means the administration of:
 - a. A radiopharmaceutical or radiation from a sealed source other than the one intended;
 - b. A radiopharmaceutical or radiation to the wrong patient;
 - c. A radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician;

Arizona Administrative Register
Notices of Final Rulemaking

- d. A diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent;
 - e. A therapeutic dose of a radiopharmaceutical differing from the prescribed dose by more than 10 percent; or
 - f. A therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent.
2. Reports of therapy misadministrations
- a. Immediate telephone report. When a administration involves any therapy procedure, the licensee shall notify the Agency by telephone. The licensee shall also notify the referring physician of the affected patient and the patient or a responsible relative (or guardian), unless the referring physician personally informs the licensee either that he will inform the patient, or that in his medical judgment, telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other respectively. These notifications shall be made within 24 hours after the licensee discovers the misadministration. (If the referring physician or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee shall not delay medical care for the patient because of this.)
 - b. Written report. Within 15 days after the initial therapy misadministration report to the Agency, the licensee shall report, in writing, to the Agency and to the referring physician and furnish a copy of the report to the patient or the patient's responsible relative (or guardian) if either was previously notified by the licensee under Subparagraph a. of this Paragraph. The written report shall include the licensee's name, the referring physician's name, a brief description of the event, the effect on the patient, the action taken to prevent recurrence, whether the licensee informed the patient or the patient's responsible relative (or guardian), and if not, why not. The report shall not include the patient's name or other information which could lead to identification by the patient.
3. Reports of diagnostic misadministrations. When a misadministration involves a diagnostic procedure, the licensee shall notify, in writing, the referring physician and the Agency. Licensee reports of diagnostic misadministrations are due within 10 days after the end of the calendar quarters (defined by March, June, September and December) in which they occur. These written reports shall include the licensee's name, the referring physician's name, a description of the event, the effect on the patient, and the action taken to prevent recurrence. The report should not include the patient's name or other information which could lead to identification of the patient.
4. Records of all misadministrations. Each licensee shall maintain, for Agency inspection, records of all misadministrations of radiopharmaceuticals or radiation from teletherapy or brachytherapy sources. These records shall 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 social security number, a brief description of the event, the effect on the patient, and the action taken to prevent recurrence. These records shall be preserved until the Agency authorizes their disposition.
- F. Use of sealed sources in industrial radiography.** In addition to the requirements set forth in R12-1-309, a specific license for use of sealed sources in industrial radiography will be issued only if:
- 1. The applicant provides an adequate program for training radiographers and radiographer's assistants and submits to the Agency a schedule or description of such program which specifies the:
 - a. initial training,
 - b. periodic training,
 - c. on-the-job training,
 - d. means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with the Agency regulations and licensing requirements, and the operating and emergency procedures of the applicant, and
 - e. means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant;
 - 2. The applicant has established and submits to the Agency satisfactory written operating and emergency procedures as needed to fulfill the requirements of Article 5 of these Regulations;
 - 3. The applicant will have an internal inspection system adequate to assure that Agency regulations, Agency license provisions, and the applicant's operating and emergency procedures are followed by radiographers and radiographer's assistants. The inspection system shall include the performance of internal inspections at intervals not to exceed three months and the retention of records of such inspections for two years;
 - 4. The applicant submits to the Agency a description of the overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and the responsibility for operation of the program;
 - 5. The applicant who desires to conduct his own leak tests has established adequate procedures to be followed in leak testing sealed sources for possible leakage and contamination and submits to the Agency a description of such procedures including:
 - a. Instrumentation to be used,
 - b. Method of performing tests, e.g., points on equipment to be smeared and method of taking smear, and
 - c. Pertinent experience of the person who will perform the test; and

Arizona Administrative Register
Notices of Final Rulemaking

6. ~~The applicant complies with appropriate provisions of Article 5.~~

G.A. The Agency shall issue 3 ~~three~~ classes of academic and industrial broad scope licenses, and only a single class A medical broad scope license.

1. A license is a broad scope class A license if it:

- a. Contains the exact wording "Any radioactive material with Atomic Number 3 through 83" or "Any radioactive material with Atomic ~~Number~~ ~~Numbers~~ 84 through 92" in License Item 6, and
- b. Contains the word "any" to authorize the chemical or physical form of ~~the~~ ~~those~~ materials in License Item 7.

The license may authorize the radioactive materials in multi-curie quantities, and may authorize other radioactive materials and forms in addition to those listed in subsection (A)(1)(a) ~~the above~~.

2. A broad scope class B license is any specific license which authorizes the possession and use of the radioactive materials specified in Exhibit C Schedule D ~~of 12 A.A.C. 1~~, Article 3 in any chemical or physical form and in quantities determined as follows:

- a. The possession limit, if only 1 radionuclide is possessed, is the quantity specified for that radionuclide in Exhibit C Schedule D, Column I, or
- b. The possession limit for multiple radionuclides is determined as follows: The sum of the ratios for all radionuclides possessed under the license shall not exceed unity (1). The ratio for each radionuclide is determined by dividing the quantity possessed by the applicable quantity in Exhibit C, Column I. If two or more radionuclides are possessed, the ratio of the quantity possessed to the applicable quantity specified in Schedule D, Column I, for that radionuclide shall be determined. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

3. A broad scope class C license is any specific license authorizing the possession and use of the radioactive materials specified in Exhibit C Schedule D ~~of 12 A.A.C. 1~~, Article 3 in any chemical or physical form and in quantities determined as follows:

- a. The possession limit, if only 1 radionuclide is possessed, is the quantity specified for that radionuclide in Exhibit C Schedule D, Column II, or
- b. The possession limit for multiple radionuclides is determined as follows: The sum of the ratios for all radionuclides possessed under the license shall not exceed unity (1). The ratio for each radionuclide is determined by dividing the quantity possessed by the applicable quantity in Exhibit C, Column II. If two or more radionuclides are possessed, the ratio of the quantity possessed to the applicable quantity specified in Schedule D, Column II, for that radionuclide shall be determined. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

B. The Agency shall approve:

41. An application for a class A broad scope license ~~will be approved~~ if:

- a. ~~The~~ ~~the~~ applicant satisfies the general requirements specified in R12-1-309; ;
- b. ~~The~~ ~~the~~ applicant has engaged in a reasonable number of activities involving the use of radioactive material. ~~(For purposes of this subsection, the requirement of "reasonable number of activities" can be satisfied by showing that the applicant has 5 years of five years' experience in the use of radioactive material. The Agency may accept less Less than 5 years of five years' experience may be acceptable if the applicant's qualifications are described in the application appear to be adequate for the scope of the proposed license;);~~ and
- c. ~~The~~ ~~the~~ applicant has established administrative controls and provisions relating to organization, ~~and~~ management, procedures, recordkeeping, material control, ~~and~~ accounting, and management review that are necessary to assure safe operations, including:
 - i. ~~Establishment~~ ~~the establishment~~ of a radiation safety committee composed of ~~such persons~~ as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material; ;
 - ii. ~~Appointment~~ ~~the appointment~~ of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; ; and
 - iii. ~~Establishment~~ ~~the establishment~~ of appropriate administrative procedures to assure:
 - (1): ~~Control~~ ~~control~~ of procurement and use of radioactive material; ;
 - (2): ~~Completion~~ ~~completion~~ of safety evaluations of proposed uses of radioactive material which take into consideration ~~matters such~~ ~~such matters~~ as the adequacy of facilities and equipment, training and experience of the user, ~~and~~ the operating or handling procedures; ; and
 - (3): ~~Review~~ ~~review~~, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with ~~R12-1-310(G)(4)(c)(iii)(2)~~ this subsection prior to use of the radioactive material.

52. An application for a class B broad scope license ~~will be approved~~ if:

- a. ~~The~~ ~~the~~ applicant satisfies the general requirements specified in R12-1-309; and

Arizona Administrative Register
Notices of Final Rulemaking

- b. ~~The~~ the applicant has established administrative controls and provisions relating to organization, ~~and~~ management, procedures, recordkeeping, material control, ~~and~~ accounting, and management review that are necessary to assure safe operations, including:
 - i. ~~Appointment~~ the appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; ; and
 - ii. ~~Establishment~~ the establishment of appropriate administrative procedures to assure:
 - (1) ~~Control~~ control of procurement and use of radioactive material; ;
 - (2) ~~Completion~~ completion of safety evaluations of proposed uses of radioactive material which take into consideration ~~matters such~~ such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating ~~or~~ of handling procedures; ; and
 - (3) ~~Review~~ review, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared ~~according to in accordance with R12-1-310(G)(5)(b)(ii)(2)~~ subsection (B)(2)(b)(ii) above prior to use of the radioactive material.

- 63. An application for a class C broad scope license ~~will be approved~~ if:
 - a. ~~The~~ the applicant satisfies the general requirements specified in R12-1-309; ;
 - b. ~~The~~ the applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:
 - i. ~~A~~ a college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; ; and
 - ii. ~~At~~ at least 40 hours of training and experience in the safe handling of radioactive material, ~~and in~~ the characteristics of ionizing radiation, units of ~~radiation~~ dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; ; and
 - c. ~~The~~ the applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, recordkeeping, material control and accounting, and management review necessary to assure safe operations.

7C. Unless specifically authorized, broad-scope licensees shall not: ~~Broad-scope licenses are subject to the following conditions:~~

- a. ~~Unless specifically authorized, persons licensed pursuant to R12-1-310(G)~~
 - i. ~~Conduct~~ conduct tracer studies in the environment involving direct release of radioactive material; ;
 - ii. ~~Acquire~~ acquire, receive, possess, use, or transfer devices containing ~~3.7 petabecquerel~~(100,000 curies) ~~(3.7 petabecquerel)~~ or more of radioactive material in sealed sources used for irradiation of materials; ;
 - iii. ~~Conduct~~ conduct activities for which a specific license ~~is~~ issued by the Agency ~~is required under any other Paragraph of R12-1-310 or R12-1-311, and 12 A.A.C. 1, Articles 5, 7, or 17; is required, or~~
 - iv. ~~Add~~ add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

bD. Each class A broad scope license issued under this section shall be subject to the condition that radioactive Radioactive material possessed under the class A broad scope license shall ~~may~~ only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

eE. Each class B broad scope license issued under this section shall be subject to the condition that radioactive Radioactive material possessed under the class B broad scope license shall ~~may~~ only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

dF. Each class C broad scope license issued under this section shall be subject to the condition that radioactive Radioactive material possessed under the class C broad scope license shall ~~may~~ only be used by, or under the direct supervision of, individuals who satisfy the requirements of R12-1-310(B)(3)(b) ~~R12-1-310(G)(6)(b)~~.

H: Measuring, gauging and controlling devices under specific licensure (Reserved)

I: Consultants (Reserved)

J: Uranium milling operations (Reserved)

R12-1-312 R12-1-311. Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices Which Contain Radioactive Material

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

- 1. In addition to the requirements set forth in R12-1-309, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another, to be transferred to persons exempt under R12-1-303(A)(1), shall be issued if: ~~R12-1-303.A.1. may be issued only if:~~
 - a. No change.
 - b. The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Exhibit A; Schedule A, ~~that~~ that concentration of the radioactive material in concentrations exceeding those in Exhibit Schedule A is not likely; ~~that~~ use of lower concentrations is not feasi-

- ble; and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.
2. Each person licensed under ~~R12-1-311.A.~~ this subsection shall file an annual report with the Agency which identifies ~~shall identify~~ the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; the name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each ~~such~~ product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made according to this subsection ~~pursuant to R12-1-311.A.~~ during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and ~~shall~~ be filed within 30 days after June 30 ~~thereafter~~.
- B. Licensing the distribution of naturally occurring and accelerator-produced radioactive material (NARM) in exempt quantities**
1. An application for a specific license to distribute NARM to persons exempted from these rules according to Regulations ~~pursuant to R12-1-303-C.(C)~~ will be approved if the applicant satisfies the requirements ~~requirement~~ of R12-1-309, and:
 - a. No change.
 - b. No change.
 - c. The applicant submits copies of prototype labels and brochures and the Agency approves the ~~such~~ labels and brochures.
 2. The license issued under ~~R12-1-311.B.1.~~ subsection (B)(1) is subject to the following conditions:
 - a. No change.
 - b. Each exempt quantity shall be separately and individually packaged. No more than 10 ~~such~~ packaged exempt quantities shall be contained in any outer package for transfer to persons exempt according to ~~pursuant to~~ R12-1-303-~~C.(C)~~. The outer package shall be such that the dose rate at the external surface of the package does not exceed 5 μ Sv (0.5 millirem) per hour ~~(5 μ Sv/hr)~~.
 - c. No change.
 - i. No change.
 - ii. No change.
 - d. In addition to the labeling information required by ~~R12-1-311.B.2.c.~~ subsection (B)(2)(c), the label affixed to the immediate container, or an accompanying brochure, shall
 - i. No change.
 - ii. No change.
 - iii. No change.
 3. Each person licensed under ~~R12-1-311.B.~~ subsection (B) shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under R12-1-303-~~C.(C)~~ or the equivalent regulations of a Licensing State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Agency. Each report shall cover the year ending June 30, and shall be filed within 30 days after June 30 ~~thirty (30) days thereafter~~. If no transfers of radioactive material have been made according to ~~pursuant to~~ ~~R12-1-311.B.~~ this subsection during the reporting period, the report shall so indicate.
- C. The Agency shall approve an Licensing the incorporation of NARM into gas and aerosol detectors. ~~An~~ application for a specific license authorizing the incorporation of radioactive material, other than source or byproduct material, into gas and aerosol detectors to be distributed to persons exempt under R12-1-303(B) ~~R12-1-303.B~~ will be approved if the application satisfies requirements equivalent to those contained in Section 32.26 of 10 CFR Part 32.26 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of the Secretary of State which shall not contain any future editions or references, and provided:**
1. The applicant satisfies the requirements of R12-1-309.
 2. The licensee files annual reports ~~Annual reports~~ as required by Section 32.29 of 10 CFR Part 32.29, 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of the Secretary of State, shall be filed with the Agency. This incorporation by reference contains no future editions or references.
- D. Licensing the manufacture and distribution of devices to persons generally licensed under R12-1-306-~~B.(B)~~**
1. The Agency shall approve an ~~An~~ application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under R12-1-306-~~B.(B)~~ or equivalent Regulations of the U.S. NRC, ~~or~~ an Agreement State, ~~will~~ or the Licensing State ~~will be approved~~ if:
 - a. The ~~the~~ applicant satisfies the general requirements of R12-1-309,
 - b. The ~~the~~ applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:
 - i. The ~~the~~ device can be safely operated by persons not having training in radiological protection;

Arizona Administrative Register
Notices of Final Rulemaking

- ii. ~~Under~~ under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive ~~in any period of one calendar quarter~~ a dose in excess of 10% of the limits specified ~~in the table of R12-1-402.A. in R12-1-408;~~ and
 - iii. ~~Under~~ under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:
 - ~~_~~ Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye 150 mSv(15 rem) (~~150 m Sv~~)
 - ~~_~~ Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter 2 Sv (200 rem) (~~2 Sv~~)
 - ~~_~~ Other organs 500 mSv (50 rem) (~~500 m Sv~~)
- c. No change.
- i. No change.
 - ii. The requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for ~~the such~~ testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and
 - iii. The information called for in 1 of the following statements in the same or substantially similar form:
 - (+) The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.
CAUTION -- RADIOACTIVE MATERIAL

(name of manufacturer or distributor)

~~(2)~~ The receipt, possession, use and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.
CAUTION -- RADIOACTIVE MATERIAL

(name of manufacturer or distributor).
- d. No change.
2. In the event the applicant desires that the device ~~undergo mandatory testing be required to be tested~~ at intervals longer than 6 months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, the application shall contain sufficient information to demonstrate that ~~the such~~ longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Agency ~~shall will~~ consider information which includes, but is not limited to:
- a. No change.
 - b. No change.
 - c. No change.
 - d. No change.
 - e. No change.
 - f. Maximum temperature withstood during prototype ~~tests test~~;
 - g. No change.
 - h. No change.
 - i. No change.
 - j. No change.
3. In the event the applicant desires that the general licensee under R12-1-306(B), or under equivalent ~~regulations Reg-~~ ~~ulations~~ of the NRC or an Agreement State or Licensing State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the application shall include written instructions to be followed by the general licensee, estimated calendar quarter doses associated with ~~the such~~ activity or activities, and bases for ~~the such~~ estimates. The submitted information shall demonstrate that performance of ~~the such~~ activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a ~~calendar quarter~~ dose in excess of 10% of the limits specified in ~~the table in R12-1-402.A. R12-1-408.~~

Arizona Administrative Register
Notices of Final Rulemaking

4. Each person licensed under ~~R12-1-311-D, subsection (D)~~ to distribute devices to general licensed persons shall:
 - a. Furnish a copy of the general license contained in R12-1-306-~~B-(B)~~ to each person to whom the individual, directly or through an intermediate person, transfers radioactive material in a device for use according to ~~pursuant to~~ the general license contained in R12-1-306-~~B-(B)~~.
 - b. Furnish a copy of the general license contained in the NRC or Agreement State's or Licensing State's regulation ~~Regulation~~ equivalent to R12-1-306-~~B-(B)~~, or alternatively, furnish a copy of the general license contained in R12-1-306-~~B-(B)~~ to each person to whom the individual, he directly or through an intermediate person, transfers radioactive material in a device for use according to ~~pursuant to~~ the general license of the NRC, ~~or the~~ Agreement State, or Licensing State. If a copy of the general license in R12-1-306-~~B-(B)~~ is furnished to ~~such~~ a person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. NRC, ~~or~~ Agreement State, or Licensing State under requirements substantially the same as those in R12-1-306-~~B-(B)~~.
 - c. Report to the Agency all transfers of ~~such~~ devices to persons for use under the general license in R12-1-306-~~B-(B)~~. The ~~Such~~ report shall identify each general licensee by name and address, an individual by name or ~~and~~ Xor position who serves as the contact person for ~~may constitute a point of contact between the Agency and~~ the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If 1 or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall identify ~~include identification of~~ each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under R12-1-306-~~B-(B)~~ during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and ~~shall~~ be filed within 30 days after the end of the quarter thereafter.
 - d. Report to the NRC all transfers of ~~such~~ devices to persons for use under the NRC general license in ~~Section 31.5 of 10 CFR Part 31.5~~.
 - e. Report to the responsible Agreement State or Licensing State agency all transfers of ~~such~~ devices to persons for use under a general license in an Agreement State's regulation ~~Regulations~~ equivalent to R12-1-306-~~B-(B)~~.
 - i. The report ~~Such reports reports~~ shall identify each general licensee by name and address, an individual by name or ~~and~~ Xor position who serves as the contact person for ~~may constitute a point of contact between the agency and~~ the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If 1 or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall identify ~~include identification of~~ each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which ~~such~~ a device is transferred to the generally licensed person.
 - ii. No change.
 - iii. No change.
 - f. Keep records showing the name, address, and the ~~point of contact~~ person for each general licensee to whom the distributor, he directly or through an intermediate person, transfers radioactive material in devices for use according to ~~pursuant to~~ the general license provided in R12-1-306-~~B-(B)~~, or equivalent Regulations of the NRC, ~~or~~ an Agreement State, or Licensing State. The records should show the date of each transfer, the isotope and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of this Section.
- E. The Agency shall approve an ~~Special requirements for the manufacture, assembly, or repair of luminous safety devices for use in aircraft. An~~ application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under R12-1-306(C), if the applicant satisfies: ~~R12-1-306.C. will be approved subject to the following conditions:~~
 1. The applicant satisfies the general requirements specified in R12-1-309; ~~;~~ and
 2. The applicant satisfies the requirements of Sections 32.53 through 32.56, and 32.101 of 10 CFR Part 32 32.53 through 32.56 and 32.101, 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of Secretary of State, or their equivalent. These incorporations by reference contain no future editions or amendments.
- F. The Agency shall approve an ~~Special requirements for license to manufacture calibration sources containing americium-241 or plutonium for distribution to persons generally licensed under R12-1-306(D). An~~ application for a specific license to manufacture calibration sources containing americium-241 or plutonium for distribution to persons generally licensed under R12-1-306-~~D, (D)~~ if the applicant satisfies: ~~will be approved subject to the following conditions:~~
 1. The applicant satisfies the general requirements ~~requirement~~ of R12-1-309; ~~;~~ and
 2. The applicant satisfies the requirements of 10 CFR 32.57, 32.58, 32.102, and 70.39, 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of Secretary of State, ~~Sections 32.57, 32.58, and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70~~ or their equivalent. These incorporations by reference contain no future editions or amendments.

Arizona Administrative Register

Notices of Final Rulemaking

- G. Manufacture and distribution of radioactive material for medical use under general license.** In addition to requirements set forth in R12-1-309, the Agency shall issue a specific license authorizing the distribution of radioactive material for use by physicians under the general license in R12-1-306.~~E.(E) will be issued~~ if:
1. The applicant submits evidence that the radioactive material is to be manufactured, labeled, and packaged under in accordance with a new drug application which the Commissioner of Food and Drugs, U.S. Food and Drug Administration has approved, or according to in accordance with a license for a biologic product issued by the FDA; and
 2. No change.
 - a. No change.
 - b. No change.
- H. The Agency shall approve an Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license.** An application for a specific license to manufacture or distribute radioactive material for use under the general license of R12-1-306.~~F.(F) will be approved~~ if:
1. The applicant satisfies the general requirements specified in R12-1-309.
 2. The radioactive material is to be prepared for distribution in prepackaged units of:
 - a. Iodine-125 in units not exceeding 370 kBq (10 microcuries)~~(370 k Bq)~~ each;
 - b. Iodine-131 in units not exceeding 370 kBq (10 microcuries)~~(370 k Bq)~~ each;
 - c. Carbon-14 in units not exceeding 370 kBq (10 microcuries)~~(370 k Bq)~~ each;
 - d. Hydrogen-3 (tritium) in units not exceeding 1.85 MBq (50 microcuries)~~(1.85 M Bq)~~ each;
 - e. Iron-59 in units not exceeding 740 kBq (20 microcuries)~~(740 k Bq)~~ each;
 - f. Cobalt-57 in units not exceeding 370 kBq (10 microcuries)~~(370 k Bq)~~ each;
 - g. Mock iodine-125 in units not exceeding 1.85 kBq (50 nanocuries) ~~nanocurie (1.85 k Bq)~~ of iodine-129 and 185 Bq (5 nanocuries) ~~nanocurie (185 Bq)~~ of americium-241 each.
 3. Each prepackaged unit bears a durable, clearly visible label:
 - a. Identifying the radioactive contents as to chemical form and radionuclide; and indicating that the amount of radioactivity does not exceed 370 kBq (10 microcuries)~~(370 k Bq)~~ of iodine-125, iodine-131, cobalt-57 or carbon-14; 1.85 MBq (50 microcuries)~~(1.85 M Bq)~~ of hydrogen-3 (tritium), 740 kBq (20 microcuries)~~(740 k Bq)~~ of iron-59; or mock iodine-125 in units not exceeding 1.85 kBq (50 nanocurie)~~(1.85 k Bq)~~ of iodine-129 and 185 Bq (5 nanocuries) ~~0.005 microcurie~~ of americium-241 each; and
 - b. Displaying the radiation caution symbol described in R12-1-428, R12-1-411.A.1. ~~and~~ the words, "CAUTION, RADIOACTIVE MATERIAL", and the phrase "Not for Internal or External Use in Humans or Animals".
 4. No change.
 - a. This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories, or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation from the radioactive material therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

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

Name of manufacturer
 5. The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information about as to the precautions to be observed in handling and storing the specified such radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source shall also contain directions to the licensee regarding the waste disposal requirements set out in R12-1-434, R12-1-416 of these Regulations.
- I. The Agency shall approve an Licensing the manufacture and distribution of ice detection devices.** An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under R12-1-306(G) if the applicant satisfies: ~~will be approved subject to the following conditions:~~
1. the applicant satisfies the general requirements of R12-1-309; and
 2. The the criteria of Sections 32.61, 32.62, and 32.101 of 10 CFR Part 32 10 CFR 32.61, 32.62, ans 32.101, 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of the Secretary of State, are met. These incorporations by reference contain no future editions or amendments.
- J. Manufacture and distribution of radiopharmaceuticals containing radioactive material for medical use under group a license issued according to 12 A.A.C. 1, Article 7.**

1. ~~The Agency shall approve an~~ An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed ~~under pursuant to R12-1-310.C. for the uses listed in Group I, II, IV or V of Schedule C of this Article 12 A.A.C. 1, Article 7~~ will be approved if:
 - a. The applicant satisfies the general requirements specified in R12-1-309; and
 - b. The applicant submits evidence that:
 - i. The radiopharmaceutical ~~containing radioactive material~~ will be manufactured, labeled, and packed ~~according to in accordance with~~ the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, ~~such as~~ a new drug application (NDA) approved by the Food and Drug Administration (FDA), ~~a biological product license issued by the FDA,~~ or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA; or
 - ii. The manufacture and distribution of the radiopharmaceutical ~~containing radioactive material~~ is not subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act.
 - c. The applicant submits information on the radionuclide; chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by group licensees; and
 - d. The label affixed to each package of the radiopharmaceutical contains information on the radionuclide; quantity, and date of assay; and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the Agency for distribution to persons licensed ~~according to pursuant to R12-1-310.C. and Schedule C, Group I, Group II, Group IV or Group V, as the requirements in 12 A.A.C. 1, Article 7 or an equivalent license or under equivalent licenses of the U.S. Nuclear Regulatory Commission or an Agreement State or Licensing State. The labels, leaflets, or brochures required by this paragraph supplement are in addition to~~ the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, ~~may be~~ combined with the labeling required by FDA.
 2. A radiopharmaceutical dispensed from a nuclear pharmacy according to A.R.S. §32-1904 is exempt from the requirements contained in subsection (J)(1). Labeling of such radiopharmaceuticals is governed by Board of Pharmacy rules and the conditions of a radioactive material license.
- K.** ~~The Agency shall approve an~~ Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing radioactive material. An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed ~~according to pursuant to R12-1-310.C. for the uses listed in Group III of Schedule C of this 12 A.A.C. 1, Article 7~~ will be approved if:
1. The applicant satisfies the general requirements ~~of specified in~~ R12-1-309;
 2. The applicant submits evidence that:
 - a. The generator or reagent kit is to be manufactured, labeled and packaged ~~according to in accordance with~~ the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, ~~such as~~ a new drug application (NDA) approved by the Food and Drug Administration (FDA), ~~a biologic product license issued by the FDA,~~ or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA; or
 - b. The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act.
 3. The applicant submits information on the radionuclide; chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;
 4. The label affixed to the generator or reagent kit contains information on the radionuclide, including quantity, and date of assay; and.
 5. No change.
 - a. No change.
 - b. A statement that this generator or reagent kit (as appropriate) is approved for use by persons licensed by the Agency ~~under pursuant to R12-1-310.C. and Schedule C Group III of Article 3-12 A.A.C. 1, Article 7 or under~~ equivalent licenses of the U.S. Nuclear Regulatory Commission or an Agreement State or Licensing State. The labels, leaflets, or brochures required by this subsection ~~supplement are in addition to~~ the labeling required by FDA and they may be separate from or, with the approval of FDA, ~~may be~~ combined with the labeling required by FDA.
- L.** Manufacture and distribution of sources or devices containing radioactive material for medical use
1. ~~The Agency shall approve an~~ An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed ~~under pursuant to R12-1-310.C. 12 A.A.C. 1, Article 7~~ for use as a calibration or reference source or for certain medical uses as sealed sources ~~may be approved if:~~
 - a. The applicant satisfies the general requirements in R12-1-309 ~~of this Article;~~
 - b. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of ~~the~~ radiation safety, including:

Arizona Administrative Register
Notices of Final Rulemaking

- i. No change.
 - ii. No change.
 - iii. No change.
 - iv. No change.
 - v. No change.
 - vi. No change.
 - vii. No change.
 - viii. Instruction for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for ~~the such~~ label may be summarized on the label and printed in detail on a brochure which is referenced on the label;
 - c. The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide; quantity, the date of assay, and a statement that the (name of source or device) is licensed by the Agency for distribution to persons licensed ~~under pursuant to R12-1-310.C. 12 A.A.C. 1, Article 7~~ or ~~under~~ equivalent licenses of the U.S. Nuclear Regulatory Commission or an Agreement State or a Licensing State, provided, ~~that such that~~ labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source.
2. In the event the applicant desires that the source or device ~~undergo mandatory testing~~ ~~be required to be tested~~ for leakage of radioactive material at intervals longer than 6 months, the application shall include sufficient information to demonstrate that the longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source. In determining the acceptable interval for test of leakage of radioactive material, the Agency ~~shall will~~ consider information that includes, but is not limited to:
- 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. Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass volume applications.
1. ~~The Agency shall approve an~~ ~~An~~ application for a specific license to manufacture industrial products and devices containing depleted uranium for use ~~under pursuant to R12-1-305(C)~~ or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State ~~may be approved~~ if:
 - a. The applicant satisfies the general requirements ~~specified in R12-1-309;~~
 - b. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive ~~in any period of one calendar quarter~~ a radiation dose in excess of 10 percent of the limits specified in ~~R12-1-408 R12-1-402.A.~~
 - c. No change.
 2. In the case of an industrial product or device whose unique benefits are questionable, the Agency ~~shall will~~ approve an application for a specific license under this paragraph only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.
 3. The Agency may deny any application for a specific license under this subsection if the end use(s) of the industrial product or device cannot be reasonably ~~foreseen~~ ~~fore seen~~.
 4. Each person licensed ~~pursuant to R12-1-311.M.1~~ ~~under subsection (M)(1)~~ shall:
 - a. Maintain the level of quality control required by the license in the manufacture of the industrial product or device ~~and~~ ~~and in~~ the installation of the depleted uranium into the product or device;
 - b. Label or mark each unit to:
 - i. ~~Identify~~ ~~identify~~ the manufacturer of the product or device, ~~and~~ the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and
 - ii. ~~State~~ ~~state~~ that the receipt, possession, use, and transfer of the product or device are subject to a general

Arizona Administrative Register
Notices of Final Rulemaking

- license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State;
- c. Assure that the depleted uranium, before being installed in each product or device, has been impressed with the following legend, clearly legible through any plating or other covering: "Depleted Uranium";
 - d. Furnish a copy of the general license contained in R12-1-305(C) and a copy of ~~ARRA-23~~ ~~ARRA-13~~ to each person to whom ~~he transfers~~ depleted uranium in a product or device ~~is transferred~~ for use ~~under a~~ pursuant to the general license contained in R12-1-305(C); ~~or~~ ~~or~~;
 - e. Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to R12-1-305(C) and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in R12-1-305(C) and a copy of ~~ARRA-23~~ ~~ARRA-13~~ to each person to whom ~~he transfers~~ depleted uranium in a product or device ~~is transferred~~ for use ~~under a~~ pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a document note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in R12-1-305(C);
 - f. Report to the Agency all transfers of industrial products or devices to persons for use under the general license in R12-1-305(C). ~~The~~ ~~Such~~ report shall identify each general licensee by name and address, an individual by name or position who serves as the ~~may~~ constitute a point of contact person for ~~between the Agency and the general licensee,~~ the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which ~~such~~ a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under R12-1-305(C) ~~(C)~~ during the reporting period, the report shall so indicate;
 - i. Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in ~~Section 40.25 of 10 CFR Part 40.25;~~ ~~or~~
 - ii. ~~Report~~ report to the responsible State agency all transfers of devices manufactured and distributed under subsection (M)(4)(f) pursuant to this paragraph for use under a general license in that state's regulations equivalent to R12-1-305(C); ~~;~~
 - iii. ~~The~~ ~~the~~ report required in subsection (M)(4)(f)(i) or (ii) (i) or (ii) above shall identify each general licensee by name and address, an individual by name or and/or position who serves as the ~~may~~ constitute a point of contact person for ~~between the agency and the general licensee,~~ the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which a ~~such~~ product or device is transferred to the generally licensed person; ~~;~~
 - iv. No change.
 - v. No change.
 - vi. Keep records showing the name, address, and ~~point of contact~~ person for each general licensee to whom ~~he transfers~~ depleted uranium in industrial products or devices ~~is transferred~~ for use ~~under a~~ pursuant to the general license provided in R12-1-305(C) or equivalent regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State. The records shall be maintained for a period of 2 years and ~~shall~~ show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the reporting ~~report~~ requirements of this Section.

R12-1-313 R12-1-312. Issuance of Specific Licenses

- A. Upon a determination that an application meets the requirements of the Act and the rules ~~regulations~~ of the Agency, the Agency shall ~~will~~ issue a specific license authorizing the proposed activity containing conditions and limitations as it deems appropriate or necessary.
- B. The Agency may incorporate in any license at the time of issuance, or thereafter by appropriate rule, ~~regulation,~~ or order, additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material ~~subject to this Chapter as it deems appropriate or necessary~~ in order to:
 1. No change.
 2. Require reports and the recordkeeping ~~keeping of records~~, and to provide for inspections of activities under the license as may be appropriate or necessary; and
 3. No change.
- C. ~~Prelicensing inspection.~~ The Agency may verify information contained in an application ~~applications~~ and secure additional information ~~deemed~~ necessary to make a reasonable ~~determination on~~ issuance of ~~as to whether to issue~~ a license and whether any special conditions should be attached to the license. ~~The Agency may inspect thereto by visiting~~ the facility or location where radioactive materials would be possessed or used, and discuss ~~by discussing~~ details of the proposed possession or use of the radioactive materials with the applicant or representatives designated by the applicant.

Arizona Administrative Register
Notices of Final Rulemaking

~~R12-1-314~~ R12-1-313. Specific Terms and Conditions of Licenses

- A. Each license issued ~~under pursuant to~~ this Article ~~is shall be~~ subject to all provisions of A.R.S. Title 30, Chapter 4 ~~the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.~~
- B. ~~A licensee shall not transfer, assign, or in any manner dispose of a~~ No license issued or granted under this Article ~~or a~~ and no right to possess or utilize radioactive material granted by any license issued ~~under pursuant to~~ this Article ~~shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information, finds find that the transfer is consistent with the Agency's statutes and rules, and gives in accordance with the provisions of the Act, and shall give its consent in writing.~~
- C. Each person licensed by the Agency ~~under pursuant to~~ this Article shall confine the use and possession of the material licensed to the locations and purposes authorized in the license.
- D. No change.
- E. No change.
 - 1. No change.
 - a. No change.
 - b. No change.
 - c. No change.
 - 2. No change.
 - a. No change
 - b. No change.
 - c. ~~The date of the filing of the petition was filed.~~

~~R12-1-315~~ R12-1-314. Expiration of License Licenses

Except as provided in R12-1-315(B), each specific license ~~expires shall expire~~ at the end of the day, in the month and year stated ~~on the license therein.~~

~~R12-1-316~~ R12-1-315. Renewal of License

- A. ~~An applicant shall file an application~~ Applications for renewal of a specific license ~~licenses shall be filed according to in accordance with~~ R12-1-308.
- B. In any case in which a licensee, not less than 30 days prior to expiration of the existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, the existing license ~~does shall~~ not expire until ~~a final determination the application has been finally determined~~ by the Agency.

~~R12-1-317~~ R12-1-316. Amendment of Licenses at Request of Licensee

~~An applicant shall file an application~~ Applications for amendment of a specific license ~~shall be filed by complying with in accordance with~~ R12-1-308 and ~~specifying shall specify the respects in which the licensee desires the license to be amended and the grounds for the amendment.~~

~~R12-1-318~~ R12-1-317. ARRA Action on Applications to Renew or Amend

In considering an application by a licensee to renew or amend ~~a specific the~~ license, the Agency ~~shall will~~ apply the criteria set forth in R12-1-309, ~~and~~ R12-1-310, or R12-1-311 as applicable.

~~R12-1-319~~ R12-1-318. Transfer of Radioactive Material

- A. ~~A licensee shall not~~ No licensee shall transfer radioactive material except as authorized ~~under pursuant to~~ this Section.
- B. Except as otherwise provided in the license and subject to the provisions of ~~R12-1-318.C. and D.~~ subsections (C) and (D), any licensee may transfer radioactive material:
 - 1. To the Agency; ~~only~~ after receiving prior approval from the Agency;
 - 2. No change.
 - 3. To any person exempt from the ~~rules regulations~~ in this Article to the extent permitted under ~~the such~~ exemption;
 - 4. To any person authorized to receive ~~radioactive such~~ material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Agency, the U.S. Nuclear Regulatory Commission, or any Agreement State or Licensing State, or to any person otherwise authorized to receive ~~radioactive such~~ material by the Federal Government or any agency ~~of the Federal Government thereof~~, the Agency, any Agreement State or Licensing State, or
 - 5. No change..
- C. No change.
- D. ~~The transferor shall use 1 or more of the following methods for the verification required by R12-1-318.C. subsection (C) are acceptable:~~
 - 1. The transferor ~~shall possess may have in possession~~, and read, a current copy of the transferee's specific license or registration certificate;

2. The transferor shall possess ~~may have in possession~~ a written certification by the transferee that ~~the transferee~~ ~~he~~ is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;
 3. For emergency shipments the transferor shall ~~may~~ accept oral certification by the transferee that ~~the transferee~~ ~~he~~ is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided, ~~that~~ the oral certification is confirmed in writing within ~~10 ten~~ days;
 4. The transferor shall ~~may~~ obtain information equivalent to that in subsection (D)(1) to (3) ~~other sources of information~~ compiled by a reporting service from official records of the Agency, the U.S. Nuclear Regulatory Commission, or the licensing agency of an Agreement State or Licensing State regarding as to the identity of any licensee, of licensees and the scope and expiration date of any license, registration, or certificate dates of licenses and registration; or
 5. When none of the methods of verification described in ~~R12-1-318.D.1. to 4.~~ subsections (D) (1) to (4) are readily available or when a transferor desires to verify that information received by 1 of ~~the above~~ such methods is correct or up-to-date, the transferor shall ~~may~~ obtain and record confirmation from the Agency, the U.S. Nuclear Regulatory Commission, or the licensing agency of an Agreement State or Licensing State that the transferee is licensed to receive the radioactive material.
- E. A transferor shall prepare and ~~Preparation for shipment and transport of radioactive material shall be as prescribed in~~ accordance with the provisions of 12 A.A.C. 1, Article 15 of this Chapter.

~~R12-1-320~~ R12-1-319. Modification, Revocation, and Termination of Licenses

- A. The terms and conditions of all licenses ~~are shall be~~ subject to amendment, revision, or modification and a ~~or the~~ license may be suspended or revoked by reason of amendments to the Agency's statutes or Act, ~~or by reason of rules, regulations,~~ and orders issued by the Agency.
- B. ~~The Agency may revoke, suspend, or modify any~~ Any license ~~may be revoked, suspended, or modified,~~ in whole or in part, for any material false statement in the application; ~~or any omission or misstatement statement~~ of fact required by statute, rule, or order ~~under provisions of the Act, or because of conditions revealed by the such application or statement of fact or any report, record, or inspection or other means that which would cause warrant the Agency to refuse to grant a license; or an original application, or any for violation of, or failure to observe any of the license terms and conditions, or the Agency's statutes, rules, or orders of the Act, or of the license, or of any rule, regulation, or order of the Agency.~~
- C. Except in cases of willfulness or those in which the public health, interest, or safety requires otherwise, the Agency shall not modify, suspend, or revoke a license ~~no license shall be modified, suspended, or revoked~~ unless, prior to the institution of proceedings ~~therefor,~~ facts or conduct which may warrant such action ~~shall~~ have been called to the attention of the licensee in writing and the licensee has ~~shall have~~ been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.
- D. The Agency may terminate a specific license upon written request ~~submitted by the licensee to the Agency in writing.~~

~~R12-1-321~~ R12-1-320. Reciprocal Recognition of Licenses ~~For Byproduct, Source and Special Nuclear Material (In Quantities Not Sufficient to Form a Critical Mass)~~

- A. A general license is established by the Agency to perform specific licensed activities in Arizona for a period not to exceed 180 days in any calendar year to any ~~Subject to these Regulations, any person who holds a specific license for activity involving the use of radioactive material from the U.S. Nuclear Regulatory Commission, Licensing State, or any Agreement State, issued by the agency with and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any calendar year provided that:~~
 1. The ~~license licensing document~~ does not limit the activity ~~authorized by such document~~ to specified installations or locations;
 2. The out-of-state licensee notifies the Agency in writing at least ~~3 three (3)~~ three (3) days prior to engaging in the licensed ~~such~~ activity. The ~~Such~~ notification shall indicate the location, period, and type of proposed possession and use within the State, and ~~shall~~ be accompanied by a copy of the pertinent licensing document. If, for a specific case, the ~~3 three (3)~~ day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Agency, obtain permission to proceed sooner. The Agency may waive the requirement for filing additional written notifications during the remainder of the calendar year, following ~~the~~ receipt of the initial notification from a person engaging in activities under the general license provided in ~~R12-1-320~~ this Section;
 3. The out-of-state licensee complies with all applicable statutes and rules ~~Regulations~~ of the Agency and with all the terms and conditions of the license, except those ~~any such~~ terms and conditions ~~which may be~~ inconsistent with applicable statutes and rules ~~Regulations~~ of the Agency;
 4. The out-of-state licensee supplies any ~~such~~ other information as the Agency requests ~~may request;~~ and
 5. The out-of-state licensee does ~~shall~~ not transfer or dispose of radioactive material possessed or used under the general license provided in this Section except by transfer to a person:

Arizona Administrative Register
Notices of Final Rulemaking

- a. ~~Specifically~~ specifically licensed by the Agency, or by the U.S. Nuclear Regulatory Commission to receive the radioactive such material; or
 - b. ~~Exempt~~ exempt from the requirements for a license for such material under R12-1-303(A).
- B.** Notwithstanding the provisions of ~~R12-1-320.A~~ subsection (A)(1), a general license is established by the Agency to manufacture, install, transfer, demonstrate, or service a device described in R12-1-306(B)(1) to any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission, Licensing State, or an Agreement State authorizing the same activities within areas subject to the jurisdiction of the licensing body, is hereby granted a general license to install, transfer, demonstrate or service the such a device in this State provided that:
1. ~~The person files a report~~ Such person shall file a report with the Agency within ~~30~~ ~~thirty~~ (30) days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each ~~such~~ report shall identify the each general licensee to whom the such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;
 2. The device has been manufactured, labeled, installed, and serviced according to ~~in accordance with~~ the applicable provisions of the specific license issued to the such person by the U.S. Nuclear Regulatory Commission or an Agreement State;
 3. The person entering the state ensures ~~Such person~~ shall assure that any labels required to be affixed to the device under rules ~~Regulations~~ of the authority which licensed manufacture of the device bear the following statement: a statement that "Removal of this label is prohibited"; and
 4. The holder of the specific license furnishes ~~shall furnish to each general licensee to whom the licensee transfers the device or on whose premises it is installed~~ a copy of the general license contained in R12-1-306(B), or equivalent rules of the agency ~~regulations of the agency~~ having jurisdiction over the manufacture or distribution of the device, to each general licensee to whom the licensee transfers the device or on whose premises the device is installed.
- C.** The Agency may withdraw, limit, or qualify the acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed under pursuant to a license such licensing document, upon determining that an such action is necessary ~~in order~~ to prevent undue hazard to public health and safety, or property.
- D.** ~~Licenses for naturally occurring and accelerator produced radioactive material:~~
1. Subject to this Chapter, any person who holds a specific license from any Licensing State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, shall be ~~is hereby granted a general license to conduct the activities authorized in the license such licensing document within this state for a period not in excess of 180 days in any calendar year provided that:~~
 - a. The license licensing document does not limit the activity authorized by the such document to specified installations or locations;
 - b. the out of state licensee notifies the Agency in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3-day period would impose an undue hardship on the out of state licensee, he may, upon application to the Agency, obtain permission to proceed sooner. The Agency may waive the requirement for filing additional written notifications during the remainder of the calendar year, following the receipt of the initial notification from a person engaging in activities under the general license provided in R12-1-320;
 - c. The out of state licensee complies with all applicable regulations of the Agency and with all the terms and conditions of the his licensing document, except those any such terms and conditions which may be inconsistent with applicable regulations of the Agency;
 - d. the out of state licensee supplies any such other information as the Agency request may request; and
 - e. the out of state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in R12-1-320 except by transfer to a person:
 - i. Specifically licensed by the Agency or by another Licensing State to receive such material; or
 - ii. exempt from the requirements for a license for radioactive such material under R12-1-303(A).
 2. Notwithstanding the provisions of R12-1-320.D.1., any person who holds a specific license issued by a Licensing State authorizing the holder to manufacture, transfer, install, or service a device described in R12-1-306(B)(1) within areas subject to the jurisdiction of the licensing body, is hereby granted a general license to install, transfer, demonstrate or service such a device in this State provided that:
 - a. Such person shall file a report with the Agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;
 - b. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by a Licensing State;

- e. ~~Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and~~
 - d. ~~The holder of the specific license to each general licensee to whom he transfers such device or on whose premises it is installed.~~
3. ~~The Agency may withdraw, limit, or qualify the acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.~~

~~R12-1-322~~ **R12-1-321. Preparation of Radioactive Material for Transport**

~~A~~ ~~No~~ licensee shall not deliver any radioactive material to a carrier for transport, unless the licensee complies with the provisions of 12 A.A.C. 1, Article 15.

~~R12-1-323~~ **R12-1-322. The Need for an Emergency Plan for Response to a Release of Radioactive Material.**

~~A.~~ For purposes of this rule "Emergency Plan" means a procedure that will be followed when an accident occurs involving licensed radioactive materials for which an offsite response may be needed from organizations, such as police, fire, or medical organizations.

~~A.B.~~ Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Exhibit D, "Radioactive Material Quantities Requiring Consideration for an Emergency Plan" Schedule E "Quantities of Radioactive Material Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," shall contain either:

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

~~B.C.~~ One or more of the following factors may be used to support an evaluation submitted under ~~Paragraph A.1. subsection (B)(1) of this Section:~~

- 1. No change.
- 2. No change.
- 3. The release fraction in the respirable size range would be lower than the release fraction shown in Exhibit D Schedule E: due to the chemical or physical form of the material;
- 4. The solubility of the radioactive material would reduce the dose received;
- 5. Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Exhibit D Schedule E;
- 6. Operating restrictions or procedures would prevent a release fraction as large as that shown in Exhibit D Schedule E; or
- 7. No change.

~~C.D.~~ An emergency plan for responding to a release of radioactive material submitted under ~~Paragraph A.2. of this Section subsection (B)(2)~~ shall include the following information:

- 1. ~~Facility description.~~ A brief description of the licensee's facility and areas near the site that could expose a member of the public to a dose equal to or greater than the levels expressed in ~~Paragraph A.1. of this Section subsection (B)(1).~~
- 2. ~~Types of accidents.~~ An identification of each type of radioactive materials accident for which protective actions may be needed.
- 3. ~~Classification of accidents.~~ A classification system for classifying accidents as alerts or site area emergencies.
- 4. ~~Detection of accidents.~~ Identification of the means of detecting each type of accident in a timely manner.
- 5. ~~Mitigation of consequences.~~ A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers on-site, and a description of the program for maintaining the equipment.
- 6. ~~Assessment of releases.~~ A brief description of the methods and equipment used to assess releases of radioactive materials.
- 7. ~~Responsibilities.~~ A brief description of the responsibilities of licensee personnel responsible for promptly notifying offsite response organizations and the Agency; also responsibilities for developing, maintaining, and updating the plan.
- 8. ~~Notification and coordination.~~ A commitment to and a brief description of the means to promptly notify offsite response organizations and request off-site assistance, including medical assistance for the treatment of contaminated and injured ~~injure~~ on-site workers when appropriate. A control point shall be established. The notification and coordination shall be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the Agency immediately after notification of the appropriate off-site response organizations and not later than 1 ~~one~~ hour after the licensee declares an emergency.

Arizona Administrative Register
Notices of Final Rulemaking

9. ~~Information to be communicated.~~ A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to off-site response organizations and to the Agency.
10. ~~Training.~~ A brief description of the frequency, performance objectives, and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical, and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.
11. ~~Safe shutdown.~~ A brief description of the means of restoring the facility to a safe condition after an accident.
12. ~~Exercises.~~ Provisions for conducting quarterly communications checks with off-site response organizations and biennial on-site exercises to test response to simulated emergencies. Quarterly communications checks with off-site response organizations shall include the verifying and updating of all necessary telephone numbers. The licensee shall invite off-site response organizations to participate in the biennial exercises. Their participation is not required. Exercises shall use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise, using individuals ~~without not having~~ direct implementation responsibility for the plan. Critiques of exercises shall evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques shall be corrected.
13. ~~Hazardous chemicals.~~ A certification that the applicant has met its responsibilities in A.R.S. §§ 26-341 through 26-353 (emergency Planning and Community Right-to-Know Act of 1986), if applicable to the applicant's activities at the proposed place of use of the radioactive material.

~~D-E.~~ No change.

R12-1-323. Financial Assurance and Record Keeping for Decommissioning

A. For purposes of this rule:

1. "Decommissioning" means to remove a radioactive material use facility safely from service and to reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the radioactive material use license.
2. "Byproduct material" as used in 10 CFR 30, means "radioactive material" which is defined in A.R.S. §30-651.
3. "Facility" means the entire site of radioactive material use, or any separate building or outdoor area where it is used.
4. "Appendix B to Part 30" as used in 10 CFR 30, means Appendix E in 12 A.A.C. 1, Article 4..
5. "Financial security" means having a net worth of not less than \$10,000.

B. When applying, each nongovernment applicant for a specific license authorizing the possession and use of radioactive material, and each nongovernment holder of a license to possess and use radioactive material issued before the effective date of this rule, shall submit to the Agency certification of financial security, as required in A.R.S. §30-672(H).

1. Each affected licensee shall submit certification of financial security no later than 3 months following the effective date of this rule.
2. Licensees required to meet the requirements in subsection (C) are exempt from the requirements in this subsection.

C. When applying, each applicant for a specific license authorizing the possession and use of radioactive material, and each holder of a license to possess and use radioactive material issued before the effective date of this rule, shall submit to the Agency a decommissioning funding plan or certification of financial assurance meeting the requirements in 10 CFR 30.35 or 40.36, 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of Secretary of State. This incorporation by reference contains no future editions or amendments. Each affected licensee shall submit the plan or certification no later than 6 months following the effective date of this rule.

D. Each licensee required to provide financial assurance for decommissioning a radioactive material facility under this rule shall maintain records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the Agency. The licensee shall maintain the following records during the decommissioning process:

1. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, and site. The licensee shall keep records identifying the involved radionuclides and associated quantities, forms, and concentrations.
2. As-built drawings showing modifications of structures and equipment in restricted areas where radioactive materials are used and stored, and locations of possible inaccessible contamination. If drawings are not available, the licensee shall provide appropriate records describing each location of possible contamination.
3. Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

E. Decommissioning procedures:

1. Upon expiration or termination of licensed activities, a licensee shall begin decommissioning its facility within 60 days of notifying the Agency of the decision to discontinue licensed activities, or within 12 months of the decision,

Arizona Administrative Register
Notices of Final Rulemaking

- submit to the Agency a decommissioning plan, as prescribed in 10 CFR 30.36(g)(1), 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of Secretary of State, containing no future editions or amendments, and begin decommissioning upon approval of the plan if the license has expired or no licensed activities have been conducted at the licensee's facility for a period of 24 months.
2. In addition to the notification requirements in subsection (E)(1), the licensee shall maintain in effect all decommissioning financial assurances required by this Section. The financial assurances shall be increased or may be decreased as appropriate to cover the cost estimate established for decommissioning in subsection (E)(1).
 - a. Any licensee who has not provided financial assurance to cover decommissioning shall do so 1 year from the effective date of this rule.
 - b. The licensee may reduce the amount of the financial assurance following approval of the decommissioning plan, provided the radiological hazard is decreasing and the licensee has the approval of the Agency.
 3. The Agency shall extend the time periods established in subsection (E)(1) if a new time period is in the best interest of public health and safety.
 - a. The licensee shall submit the request for the change no later than 30 days before the notification time frame specified in subsection (E)(1).
 - b. If appropriate, the schedule for decommissioning activities, specified in subsection (E)(1), shall not commence until the Agency has made a determination on the request described in subsection (E)(3)(a).
 4. Except as provided in subsection (E)(5), the licensee shall complete decommissioning of a facility as soon as practicable but no later than 24 months following the initiation of decommissioning; and except as provided in subsection (E)(5), when decommissioning involves the entire facility, the licensee shall request license termination as soon as practicable but no later than 24 months following initiation of decommissioning.
 5. The Agency shall approve a request for an alternate schedule for completion of decommissioning and license termination if the Agency determines that the alternative is warranted by consideration of the conditions specified in 10 CFR, 30.36(i), 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of Secretary of State, containing no future editions or amendments.
 6. As a final step in decommissioning, the licensee shall meet the requirements specified in 10 CFR Part 30.36(j), 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of Secretary of State, containing no future editions or amendments.

Exhibit A Schedule A

Exempt Concentrations

No change.

Exhibit B Schedule B

Exempt Quantities

No change.

Schedule C

Groups of Medical Uses of Radioactive Material

Group I. Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution and excretion. This group does not include uses involving imaging and tumor localizations.

1. ~~Iodine-123~~
2. ~~Iodine-125~~
3. ~~Iodine-131~~
4. ~~Cobalt-57~~
5. ~~Cobalt-58~~
6. ~~Cobalt-60~~
7. ~~Chromium-51~~
8. ~~Iron-59~~
9. ~~Potassium-42~~
10. ~~Sodium-24~~
11. ~~Technetium-99m~~

The above radioactive materials shall be used in the form of radiopharmaceuticals for which a "new drug application" (N.A.) or a "notice of claimed investigational exemption for a new drug" (IND) has been issued or accepted by the Food and Drug Administration (FDA). The radioactive material may be used for any procedures specified in the product labeling (package insert). The above radioactive materials shall be procured in the form of prepackaged individual doses.

Group II. Use of prepared radiopharmaceuticals diagnostic studies imaging and tumor localizations.

1. ~~Iodine-123~~
2. ~~Iodine-125~~
3. ~~Iodine-131~~

Arizona Administrative Register
Notices of Final Rulemaking

4. Selenium-75
5. Technetium-99m
6. Ytterbium-169
7. Indium-111
8. Indium-113m
9. Chromium-51
10. Fluorine-18
11. Gallium-67
12. Gold-198
13. Thallium-201

The above radioactive materials shall be acquired and used in the form of a prepared radiopharmaceutical for which a "new drug application" (N.A.) or a "notice of claimed investigational exemption for a new drug" (IND) has been accepted by the Food and Drug Administration (FDA). The radioactive material may be used for any procedures specified in the product labeling (package insert).

~~Group III. Use of generators and reagent kits for the preparation and use of radiopharmaceuticals containing radioactive material for certain diagnostic uses:~~

- ~~1. Molybdenum-99/Technetium-99m generators~~
- ~~2. Tin-113/Indium-113m generators~~
- ~~3. Technetium-99m (in bulk)~~

~~The above radioactive materials shall be acquired and used in the form of a prepared radiopharmaceutical for which a "new drug application" (N.A.) or a "notice of claimed investigational exemption for a new drug" (IND) has been accepted by the Food and Drug Administration (FDA). The radioactive material may be used for any procedures specified in the product labeling (package insert).~~

~~Group IV. Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety:~~

- ~~1. Iodine-131, in quantities of less than 30 millicuries~~
- ~~2. Phosphorus-32~~

~~The above radioactive materials shall be used in a radiopharmaceutical for which an (N.A.) or an (IND) has been issued or accepted by the Food and Drug Administration (FDA).~~

~~Group V. Use of prepared radiopharmaceuticals for certain therapeutic procedures that normally require hospitalization for purposes of radiation safety according to protocols approved by FDA.~~

- ~~1. Iodine-131~~
- ~~2. Gold-198~~

~~The above radioactive materials shall be used in a radiopharmaceutical for which an (N.A.) or an (IND) has been issued or accepted by the Food and Drug Administration (FDA).~~

Notices of Final Rulemaking

Exhibit C Schedule D

Limits for Class B and C Broad Scope Licenses (R12-1-310.G)

<u>Radioactive Material</u>	<u>Col. I curies</u>	<u>Col. II curies</u>
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1.
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1.
Cesium-134m	100	1.
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1.
Chromium-51	100	1.
Cobalt-57	10	0.1
Cobalt-58m	100	1.
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1.
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2 h)	10	0.1
Europium-152 (13 yr)	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1.
Gadolinium-153	1	0.1
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1.
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.1
Holmium-166	10	0.1
Hydrogen-3	100	1.
Indium-113m	100	1.
Indium-114m	1	0.1

Arizona Administrative Register

Notices of Final Rulemaking

Indium-115m	100	1.
Indium-115	1	0.1
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.1
Iodine-134	10	0.1
Iodine-135	1	0.1
Iridium-192	1	0.1
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.1
Krypton-85	100	1.
Krypton-87	10	0.1
Lanthanum-140	1	0.1
Lutetium-177	10	0.1
Manganese-52	1	0.1
Manganese-54	1	0.1
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.1
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.1
Nickel-65	10	0.1
Niobium-93m	1	0.1
Niobium-95	1	0.1
Niobium-97	100	1.
Osmium-185	1	0.1
Osmium-191m	100	1.
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1.
Platinum-193	10	0.1
Platinum-197m	100	1.
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1,000	10
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1.

Arizona Administrative Register

Notices of Final Rulemaking

Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85	1,000	10
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulfur-35	100	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1.
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1.
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-197	10	0.1
Vanadium-43	1	0.01
Xenon-131m	1,000	10
Xenon-133	100	1.
Xenon-135	100	1.
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1.

Arizona Administrative Register

Notices of Final Rulemaking

Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than source material, special nuclear material, or alpha emitting radioactive material not listed above;	0.1	0.001

Exhibit D SCHEDULE E

Radioactive Material Quantities Requiring Consideration for an Emergency Plan (~~R12-1-323~~ R12-1-322)

<u>Radioactive Material</u>	<u>Release Fraction</u>	<u>Quantity (Ci)</u>
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9 (20 mg)
Carbon-14 (<u>Non CO</u>)	.01	50,000
	<u>Non CO</u>	
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Gadolinium-153	.01	5,000
Germanium-68	.01	2,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Indium-114m	.01	1,000
Iodine-125	.5	10
Iodine-131	.5	10
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000

Arizona Administrative Register
Notices of Final Rulemaking

<u>Radioactive Material</u>	<u>Release Fraction</u>	<u>Quantity (Ci)</u>
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment beta-gamma	.001	10,000
Irradiated material, any form other than solid non- combustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
<u>Packaged packaged mixed waste, beta gamma</u>	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha	.0001	20

Combinations of radioactive materials listed above:

For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios ~~ratios~~ of the quantity of each radioactive material authorized to the quantity listed for that material in Exhibit D Schedule E ~~Schedule E~~ exceeds 1 ~~one~~.

NOTE: Waste packaged in Type B containers does not require an emergency plan.

Exhibit E

Application Information

1. Radioactive Material (RAM) Specific License Application Information

An applicant shall provide the following information in a specific license application before a license is issued to the applicant. The Agency shall provide an application form to an applicant with a guide, when possible, to insure that correct information is provided in the application:

<u>Name and mailing address of applicant</u>	<u>Use location</u>
<u>Contact person</u>	<u>Telephone number</u>
<u>Users of RAM</u>	<u>Training of users</u>
<u>Radiation Safety Officer identity (RSO)</u>	<u>Duties of RSO</u>
<u>Description of RAM and uses</u>	<u>Description of radiation detection/measurement instruments and their calibration</u>
<u>Personnel monitoring</u>	<u>Bioassay program</u>
<u>Facility description</u>	<u>Survey program</u>
<u>Leak test program</u>	<u>Records management program</u>
<u>Instruction to personnel</u>	<u>Waste disposal program</u>
<u>Emergency procedures</u>	<u>Procedures for ordering, receiving, and opening packages</u>
<u>Description of animal use</u>	<u>Licensing fee provided with application</u>
<u>Copy of letter-of-intent to local governing body</u>	<u>Description of ALARA and quality management programs</u>
<u>Description of transportation procedures</u>	<u>Certifying signature</u>
<u>Legal structure of licensee's operation</u>	
<u>Other licensing requirements listed in: R12-1-310, R12-1-311, R12-1-312, R12-1-511, R12-1-703, and R12-1-1721</u>	

2. Radioactive Material (RAM) General License Application Information

An applicant shall provide the following information on a registration certificate. The certificate will be validated and returned to the applicant if the information provided is complete.

<u>Name and address</u>	<u>Telephone number</u>
<u>Where will the radioactive material be used</u>	<u>Address of use location</u>
<u>Description of radioactive material use</u>	<u>Date</u>
<u>Authorizing signature and printed name</u>	<u>Position of person signing the form</u>

ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

R12-1-407. Radiation Protection Programs

- A. No change.
- B. No change.
- C. No change.
- D. Records.
 - 1. No change.
 - a. No change.
 - b. No change.

Notices of Final Rulemaking

2. The licensee or registrant shall retain the records required by ~~subsection subparagraph~~ (D)(1)(a) above for ~~3 three~~ years after the termination of the license or registration. The licensee or registrant shall retain the records required by ~~subsection subparagraph~~ (D)(1)(b) above for ~~3 three~~ years after the record is made.
3. The following licensees and registrants are exempt from the record requirements contained in this subsection:

<u>B6-General Medical</u>	<u>D15-Possession Only</u>
<u>C9-Gas Chromatograph</u>	<u>E2-X-ray Machine class B</u>
<u>C10-General Industrial</u>	<u>E3- X-ray Machine class C</u>

R12-1-408. Occupational Dose Amounts for Adults

- A. No change.
- B. No change.
- C. The assigned deep-dose equivalent and shallow-dose equivalent ~~is, shall be~~ for the portion of the body receiving the highest exposure, determined as follows:
 1. No change.
 2. When a protective apron is worn and monitoring is conducted as specified in ~~R12-1-419(B) R12-1-419(A)(4)~~, the effective dose equivalent for external radiation shall be determined as follows:
 - a. When only 1 individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25% of the limit specified in R12-1-408(A), the reported deep-dose equivalent value multiplied by 0.3 ~~is shall be~~ the effective dose equivalent for external radiation; or
 - b. When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation ~~is shall be~~ assigned the value of the sum of the deep-dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep-dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.
- D. No change.
- E. No change.
- F. The licensee or registrant shall reduce the dose that an individual may ~~be allowed to~~ receive in the current year by the amount of occupational dose received while employed occupationally as a radiation worker by all previous employers. See R12-1-412.

R12-1-409. Compliance with Requirements for Summation of External and Internal Doses

- A. If the licensee or registrant is required to monitor ~~according to pursuant to~~ both ~~R12-1-419(B) and (C) R12-1-419(A) and (B)~~, the licensee or registrant shall ~~add demonstrate compliance with the dose limits by summing~~ external and internal doses, ~~and use the sum to demonstrate compliance with dose limits~~. If the licensee or registrant is required to monitor only ~~according pursuant~~ to ~~R12-1-419(B)(A) or only pursuant to according to~~ ~~R12-1-419 (C) R12-1-419 (B)~~, then summation is not required to demonstrate compliance with ~~the~~ dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses ~~according pursuant~~ to subsections (B), (C), and (D) ~~below~~. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation but are subject to separate limits (See R12-1-408(A)(2)).
- B. ~~Intake by inhalation~~. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep-dose equivalent divided by the total effective dose equivalent limit, and 1 of the following, does not exceed unity (one):
 1. No change.
 2. No change.
 3. No change.
- C. ~~Intake by oral ingestion~~. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10% of the applicable oral ALI, the licensee or registrant shall account for this intake and include it in demonstrating compliance with the limits.
- D. ~~Intake through Wounds or Absorption through skin~~. The licensee or registrant shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for Hydrogen-3 and does not need to be evaluated or accounted for pursuant to this subsection.

R12-1-411. Determination of Internal Exposure

- A. No change.
 1. No change.
 2. No change.
 3. No change.
 4. No change.
- B. No change.
- C. No change.
 1. No change.

Notices of Final Rulemaking

- 2. No change.
- 3. No change.
- D. If the licensee or registrant chooses to assess intakes of Class Y material using the measurements given in subsection R12-1-411(A)(2) or (3), the licensee or registrant may delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by R12-1-444 or R12-1-445. This delay permits the licensee or registrant to make additional measurements basic to the assessments.
- E. If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours is shall be either:
 - 1. No change.
 - 2. No change.
- F. If the identity of each radionuclide in a mixture is known, but the concentration of 1 or more of the radionuclides in the mixture is not known, the DAC for the mixture is shall be the most restrictive DAC of any radionuclide in the mixture.
- G. When a mixture of radionuclides in air exists, a licensee or registrant may disregard certain radionuclides in the mixture if:
 - 1. The licensee or registrant uses the total activity of the mixture to demonstrate in demonstrating compliance with the dose limits in R12-1-408 and to comply in complying with the monitoring requirements in R12-1-419 R12-1-419(B), and
 - 2. No change.
 - 3. No change.
- H. No change.
 - 1. No change.
 - 2. For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.5 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B. The licensee or registrant may, as a sampling assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in R12-1-408(A)(1)(b) R12-1-406(A)(1)(b) is met.

R12-1-415. Dose to an Embryo or ~~+~~ Fetus

- A. A The licensee or registrant shall ensure that the dose to an embryo or ~~+~~ fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem). Records shall be maintained according to in accordance with R12-1-419(D)(4) and (5) R12-1-419(C)(4) and (5).
- B. The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman ~~so as~~ to satisfy the limit in subsection (A) above.
- C. The dose to an embryo or ~~+~~ fetus is shall be taken as the sum of:
 - 1. No change.
 - 2. The dose to the embryo or ~~+~~ fetus from radionuclides in the embryo or ~~+~~ fetus and radionuclides in the declared pregnant woman.
- D. If by the time the woman declares pregnancy to the licensee or registrant, the dose to the embryo or ~~+~~ fetus has exceeded 4.5 mSv (0.45 rem), the licensee or registrant is shall be deemed to be in compliance with subsection (A) above, if the additional dose to the embryo or ~~+~~ fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

R12-1-418. Surveys and Monitoring

- A. Each licensee or registrant shall make, or cause to be made, surveys that are necessary:
 - 1. For Are necessary for the licensee or registrant to comply with Article 4, and
 - 2. Under Are necessary under the circumstances to evaluate:
 - a. No change.
 - b. No change.
 - c. No change.
- ~~B.~~ The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured.
- B.C. All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with R12-1-408, with other applicable provisions of these rules regulations, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:
 - 1. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology, pursuant to NVLAP PROCEDURES published November 1990 as Edition NISTIR-4493 by the U. S. Department of Commerce, incorporated herein by reference and on file with the Secretary of State, containing no future editions or amendments; and
 - 2. No change.

Arizona Administrative Register
Notices of Final Rulemaking

~~C.D.~~ No change.

~~D.E.~~ Records.

1. Each licensee or registrant shall maintain records showing the results of surveys ~~and calibrations~~ required by this Section and R12-1-433(B). The licensee or registrant shall retain these records for ~~3~~ three years after the record is made.
2. No change.
 - a. No change.
 - b. No change.
 - c. No change.
 - d. No change.

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

A. Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this Article. ~~As a minimum:~~

B. ~~At a minimum each licensee or registrant~~ Monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

- ~~1. a-~~ Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10% of the limits in R12-1-408(A);
- ~~2. b-~~ Minors and declared pregnant women likely to receive, in 1 year from sources external to the body, a dose in excess of 10% of any of the applicable limits in R12-1-414 or R12-1-415;
- ~~3. e-~~ Individuals entering a high or very high radiation area; and
- ~~4. d-~~ Individuals working with open beam fluoroscopic systems capable of exposing the individuals to 10% of the limits in R12-1-408(A). The individual monitoring device shall be located on the person according to the following requirements: Individuals working with medical fluoroscopic equipment.

~~a.i-~~ An individual monitoring device used for the dose to an embryo or fetus of a declared pregnant woman, according to R12-1-415(A) pursuant to R12-1-408 (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 regulations~~, the value to be used for determining the dose to an embryo or fetus according to pursuant to R12-1-415 (C)(1), for occupational exposure to radiation from medical fluoroscopic equipment is shall be 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 her work environment by a qualified expert.

~~b.ii-~~ An individual monitoring device used for eye dose equivalent shall be located at the neck, or an unshielded location closer to the eye, outside the protective apron.

~~c.iii-~~ When only 1 individual monitoring device is used to determine the effective dose equivalent for external radiation according to pursuant to R12-1-408 (C)(2), it shall be located at the neck outside the protective apron. When a 2nd 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.).

~~C.B-At As~~ As a minimum, each licensee or registrant shall monitor, to determine compliance with R12-1-411, the occupational intake of radioactive material ~~by~~ and assess the committed effective dose equivalent to:

1. Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B; and
2. Minors and declared pregnant women likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.5 mSv (0.05 rem).

~~D.C-~~Records.

1. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring is required according to pursuant to this Section, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before January 1, 1994, need not be changed. These records shall include, when applicable:
 - a. The deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;
 - b. The estimated intake of radionuclides, see R12-1-409;
 - c. The committed effective dose equivalent assigned to the intake of radionuclides;
 - d. The specific information used to calculate the committed effective dose equivalent according to pursuant to R12-1-411 (C);
 - e. The total effective dose equivalent when required by R12-1-409; and
 - f. The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.
2. The licensee or registrant shall make entries of the records specified in ~~Paragraph C. 1-subsection (D)(1) above~~, at intervals not to exceed 1 year.

3. The licensee or registrant shall maintain at the inspection site the records specified in ~~Paragraph C. 1. subsection (D)(1) above,~~ on Agency Form Z (available from the Agency), in accordance with the instructions for Agency Form Z, or in clear and legible records containing all the information required by this subsection.
4. The licensee or registrant shall maintain the records of dose to an embryo or fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.
5. The licensee or registrant shall retain each required form or record for 3 ~~three~~ years after the Agency terminates each pertinent license or registration requiring the record.

R12-1-442. Agency Inspection of Shipments of Waste

Each shipment of waste to a ~~licensed~~ disposal facility, licensed under R12-1-1302(D)(11), is ~~shall be~~ subject to inspection by the Agency prior to shipment. The waste shipper shall notify the Agency not less than 5 ~~five~~ working days prior to the scheduled shipment of the intent to transport waste to the licensed land disposal facility.

R12-1-449. Survey Instruments

- A. Each licensee or registrant shall ensure that survey instruments used to show compliance with this Article have been calibrated before first use, annually, and following repair, unless otherwise specified in this Chapter.
- B. To satisfy the requirements of subsection (A), the licensee or registrant shall:
 1. For each scale to be calibrated, calibrate 2 readings separated by at least 50 percent of scale rating; and
 2. Conspicuously note on the instrument the apparent radiation level, in appropriate units for the type of survey instrument being used and the date of calibration.
- C. Each licensee or registrant shall check each survey instrument for proper operation with the dedicated check source after calibration and before each use.
- D. The licensee or registrant shall retain a record of each calibration required in subsection (A) for 3 years. The record shall include:
 1. A description of the calibration procedure; and
 2. A description of the source used, the certified dose rates from the source, the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.
- E. To meet the requirements of subsections (A),(B), and (C), the licensee or registrant may obtain the services of persons licensed or registered by the Agency, the NRC, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Licensing records of the service person authorization shall be maintained for 3 years by the licensee or registrant obtaining the service.

R12-1-450. Sealed Source Requirements

- A. Any licensee who possesses and uses sealed sources containing radioactive material shall follow the radiation safety and handling instructions approved by the Agency; or follow the radiation safety and handling instructions furnished by the manufacturer on the label attached to the source, on the permanent container of the sources or in the leaflet or brochure that accompanies the source, and maintain the instructions in a legible and conveniently available form. If the handling instructions, leaflet, or brochure is no longer available or a copy cannot be obtained from the manufacturer, the licensee shall notify the Agency that the source information is no longer available.
- B. Any licensee who possesses and uses calibration and reference sources shall, unless otherwise specified, conduct a physical inventory, at intervals not to exceed 6 months, to account for all sealed sources of radioactive material received and possessed under a radioactive material license. The records of the inventory shall be maintained for 3 years from the date of the inventory, and shall be available for inspection by the Agency. The information recorded shall include the kind and quantity of radioactive material, the model and serial number of the source or the device in which it is mounted, the location of the sealed source, the date of the inventory, and the signature of the person performing the inventory.
- C. Any licensee who possesses and uses sealed sources in the practice of medicine shall conduct a physical inventory according to the requirements in 12 A.A.C. 1, Article 7.

ARTICLE 5. RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

R12-1-511. License and Registration Application Requirements For Industrial Radiography

If a licensee has satisfied ~~In addition to~~ the licensing requirements set forth in R12-1-309, the Agency shall issue a specific license or registration for industrial radiography ~~will be issued only~~ if:

1. The applicant has provides a program to provide ~~providing~~ the instruction specified in R12-1-521 for radiographers and assistant radiographers. The applicant shall submit ~~and submits~~ to the Agency a schedule or description of the training program which specifies the:
 - a. No change.
 - b. No change.
 - c. No change.

- d. Means of testing to be used by the licensee or registrant to determine a radiographer's or assistant radiographer's knowledge and understanding of, and ability to comply with the Agency's rules and licensing requirements, and the operating and emergency procedures of the applicant
2. No change.
3. The applicant ~~has will have~~ an internal inspection program system adequate to assure that Agency rules, Agency license and registration provisions, and the applicant's operating and emergency procedures are followed by radiographers, ~~and radiographer's assistants~~. The inspection program system shall include ~~the performance of~~ internal inspections at intervals not to exceed 3 three months and inspection record retention ~~the retention of records of such inspections~~ for 2 two years;
4. The applicant submits to the Agency a description of the overall organizational structure of the instruction program ~~the industrial radiography program~~, including specified delegations of authority and ~~the~~ responsibility for operation of the program;
5. No change.
 - a. No change.
 - b. No change.
 - c. No change.
6. No change.

R12-1-541. Enclosed Radiography Using X-ray Machines

- A. No change.
 1. No change.
 2. Physical radiation surveys shall be performed with a survey instrument appropriate for the energy range and levels of radiation to be assessed and ~~which has been~~ calibrated within the preceding 12 months
- B. The registrant shall ensure that cabinet ~~Cabinet~~ x-ray systems not exempted in subsection (A) ~~above shall~~ comply with the recordkeeping requirements ~~all other applicable provisions~~ of this Article and the following special requirements:
 1. No change
 2. No change.
 3. No change
 4. The registrant shall make, or cause to be made, evaluations of each x-ray system to determine conformance with this Article, prior to placing such systems into use and thereafter at intervals not to exceed 3 three months. Records of such evaluations shall be retained for 2 two years, and
 5. Physical radiation surveys to satisfy the requirements of subsection (4) ~~paragraph (4) above~~ shall be performed only with instrumentation meeting the requirements of R12-1-504.
- C. The registrant shall ensure that shielded ~~Shielded~~ room x-ray systems ~~shall~~ comply with the recordkeeping ~~all other applicable~~ requirements of this Article and the following special requirements:
 1. No change.
 2. No change.
 3. Each access point shall be provided with 2 two interlocks, each on a separate circuit so that failure of 1 2 interlock will not affect the performance of the other;
 4. No change.
 5. The registrant shall make, or cause to be made, evaluations of each shielded room x-ray system prior to placing the system into use and thereafter at intervals not to exceed 3 months to determine conformation with this Article. Records of such evaluations shall be retained for 2 two years.
 6. No change.
 7. No change.
 8. No change.
 9. An individual shall not ~~No individual shall~~ occupy the interior of any shielded room ~~enclosed~~ x-ray system during production of radiation; and
 10. The registrant shall provide personnel monitoring devices that meet the requirements of R12-1-523(C) to to, and require the use of, by each shielded room x-ray machine operator, and require that each operator use the devices, ~~radiographer and radiographer's assistant appropriate personnel monitoring devices meeting the requirements of R12-1-523.~~
 11. The registrant shall maintain records of:
 - a. Quarterly inventories for mobile systems, as prescribed in R12-1-506;
 - b. Utilization of all systems, as prescribed in R12-1-507; and
 - c. Records shall be maintained for 3 years from the date of the inventory or utilization.

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

R12-1-606. Fluoroscopic Systems installations

- A. No change.

Arizona Administrative Register
Notices of Final Rulemaking

1. No change.
 2. No change.
 3. No change.
 4. No change.
 5. No change.
- B.** No change.
1. No change.
 2. No change.
 3. No change.
 4. No change.
 - a. No change.
 - b. No change.
 - c. Compliance with subsection R12-1-606(B)(4)(a) and (b) shall be determined with the image receptor positioned 35.5 centimeters (14 inches) from the panel or table top, at normal operating technical factors and with the attenuation block in the useful beam for systems with image intensification.
- 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. In a lateral-type fluoroscope, the exposure rate shall be measured at a point 15 centimeters (5.9 11.8 inches) from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters (5.9 11.8 inches) to the centerline of the x-ray table.
- D.** The source to skin distance shall not be less than: ~~Source to skin distance~~
- ~~1. The source to skin distance shall not be less than:~~
 - ~~1. a. 38 centimeters (15 inches) on stationary fluoroscopes installed after the effective date of this Section;~~
 - ~~2. b. 35.5 centimeters (14 inches) on stationary fluoroscopes which are in operation prior to the effective date of this Section; January 2, 1996.~~
 - ~~3. c. 30 centimeters (11.8 inches) on all mobile fluoroscopes; and~~
 - ~~4. d. 20 centimeters (8 7.9 inches) for image intensified fluoroscopes used for specific surgical application. The registrant shall follow any precautionary measures in the users operating manual ~~The users' operating manual must provide precautionary measures to be adhered to during the use of this device.~~~~
- E.** Each fluoroscopic installation shall be subject to all of the following requirements for the control of stray radiation: ~~Stray radiation protection~~
- ~~1. Each fluoroscopic installation shall be subject to all of the following requirements for the control of stray radiation:~~
 - ~~1. a. A shielding device of at least 0.25 millimeter lead equivalent shall be provided for covering the Bucky-slot during fluoroscopy;~~
 - ~~2. b. Except for fluoroscopy performed using portable or mobile C-arm systems or C-Arm PM devices and during surgical procedures, protective drapes, or hinged or sliding panels, of at least 0.25 millimeters lead equivalent, shall be provided between the patient and fluoroscopist to intercept scattered radiation which would otherwise reach the fluoroscopist and others near the machine, but drapes and panels shall not be substituted for ~~and devices shall not substitute for wearing of a protective apron; and~~~~
 - ~~3. c. Protective aprons of at least 0.25 millimeter lead equivalent shall be worn in the fluoroscopy room by each person, except the patient, whose body is likely to be exposed to 50 µSv/hr (5 mR/hr). ~~5mR/hr or more (50 µSv/hr).~~~~
- F.** No change.
1. No change.
 2. No change.
 3. No change.
 4. No change.
- G.** Systems Mobile fluoroscopes. In addition to the requirements of this Section, systems utilized for mobile fluoroscopy shall be provided with image intensification.

Arizona Administrative Register
Notices of Final Rulemaking

R12-1-612. X-ray and Electron Therapy Systems with Energies of 1 MeV and Above ~~electron therapy systems with energies of one MeV and above~~

- A. No change
1. No change.
 - a. No change.
 - b. No change.
 - c. ~~Leakage radiation measurements.~~ Leakage radiation measurements made at any point 1 meter from the path of the charged particle between its point of origin and the target, window or scattering foil shall meet the requirements of subsection(A)(1)(a) and (b) when computed as a percentage of the dose rate equivalent of the unattenuated useful beam measured at 1 meter from the virtual source. Leakage radiation measurements at each point shall be averaged over an area up to but not exceeding 100 square centimeters (15.5 square inches).
 - d. The registrant shall maintain, for inspection by the Agency, records which show leakage radiation measurements for the life of the operation ~~a period of 3 years from the date of the respective measurements.~~
 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. No change.
 - ii. No change.
 - iii. No change.
 - f. No change.
 - g. No change.
 - i. No change.
 - ii. No change.
 - iii. No change.
 - iv. ~~Interruption switches.~~ It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption the equipment shall go to termination condition.
 - v. ~~Termination switches.~~ It shall be possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions at any time from the operator's position at the treatment control panel.
 5. No change.
 - a. No change.
 - b. No change.
 - c. 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. Facility and shielding requirements.**
 - 1. In addition to protective barriers sufficient to ensure compliance with Article 4 of this Chapter, all of the following design requirements shall apply:
 - a. No change.
 - b. No change.
 - c. Windows, mirrors, operable closed-circuit television, or other equivalent viewing systems shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. ~~When the viewing system is by electronic means (e.g., television), an alternate viewing system shall be provided for use in the event of failure of the primary system;~~
 - d. No change.
 - e. No change.
 - f. No change.
 - 2. A qualified expert trained and experienced in the principles of radiation protection shall perform a radiation protection survey on all installations prior to 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. All installations shall have a protection survey made by, or under the direction of, a person trained and experienced in the principles of radiation protection prior to human use and after any change in the installation which might produce a radiation hazard. The person shall report his findings in writing to the individual in charge of the installation and a copy of this report shall be transmitted to the Agency.
 - 3. No changes.
 - a. No change.
 - b. No change.
 - c. Calibration of a particle accelerator shall be made by, or under the supervision of a person having met the qualification requirements specified in R12-1-904(F) trained and experienced in performing calibrations, 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. The calibration determinations above shall be provided in sufficient detail such that the absorbed dose to tissue in the useful beam may be calculated to within +/-5% width + 5 percent.
 - e. No change.
 - f. A copy of the current calibration report shall be available in the therapy facility ~~at the therapy control panel~~ for use by the operator, and the report shall contain the following information:
 - i. The action taken by the person performing the calibration if it indicates a change has occurred since the last calibration;
 - ii. A listing of the persons informed of the change in calibration results; and
 - iii. A statement as to the effect the change in calibration has had on the therapy doses prior to the current calibration finding.
- C. No change.**
 - 1. No change.
 - 2. No change.
 - 3. No change.
 - 4. No change.
 - 5. No change.
- D. No change.**
 - 1. ~~Only~~ No individual other than the patient shall be in the treatment room during irradiation.
 - 2. No change.
 - 3. No change.

Arizona Administrative Register
Notices of Final Rulemaking

**ARTICLE 7. USE OF RADIONUCLIDES IN THE HEALING ARTS ~~USE OF SEALED RADIOACTIVE SOURCES~~
~~IN THE HEALING ARTS~~**

R12-1-701. Scope

The provisions of this Article apply to all licensees who use sealed sources in the healing arts and are in addition to, and not in substitution for, other applicable provisions of these regulations.

This Article establishes requirements for the use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of radionuclides. These requirements provide for the protection of the public health and safety, and are in addition to, and not in substitution for, other requirements in this Chapter.

R12-1-702. Definitions

"Authorized user" means a physician licensed in Arizona to practice medicine and who is identified as:

1. An authorized user on an Agency, Nuclear Regulatory Commission (NRC), or Agreement State license that authorizes the specified medical use; or
2. A user in a medical use broad scope program, licensed by the Agency, NRC or Agreement State to select its own authorized users in accordance with the training standards contained in this Article.

A. "Brachytherapy" means a method of radiation therapy in which ~~a sealed~~ ~~an encapsulated~~ source or group of sealed sources is utilized to deliver beta or gamma radiation at a distance of up to a few centimeters, by surface, intracavitary, intraluminal, intercavitary or interstitial application.

"High dose rate afterloading brachytherapy" means the treating of human disease using the radiation from a radioactive sealed source containing more than 1 curie of radioactive material. The radioactive material is introduced into a patient's body using a device that allows the therapist to indirectly handle the radiation source during the treatment. For purposes of the requirements in this Article "pulse dose rate afterloading brachytherapy" is included in this definition.

"Medical institution" means an organization in which several medical disciplines are practiced.

"Medical use" means the intentional internal or external administration of radioactive material, or the radiation from it, to an individual under the supervision of an authorized user.

"Misadministration" means:

1. The administration of a radiopharmaceutical or the radiation from a sealed source, administered for therapy purposes and involving:
 - a. The wrong radiopharmaceutical or sealed source; or
 - b. The wrong patient; or
 - c. The wrong route of administration; or
 - d. A dose to an individual that differs from the prescribed dose by 20%; or
2. The administration of a diagnostic dose of a radiopharmaceutical involving:
 - a. The wrong patient, or
 - b. The wrong radiopharmaceutical, or
 - c. The wrong route of administration; or
 - d. A dose to an individual that exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ; or
3. A therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose differing from the final, prescribed total treatment dose by more than 10 percent.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of any such substance.

"Remote afterloading brachytherapy device" means a device used in radiation therapy that allows the authorized user to insert, from a remote location, a radiation source into an applicator that has been previously inserted in an individual requiring treatment.

"Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a dose.

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

"Written directive" means an order in writing for a specific individual, or a diagnostic standing procedure for a group of patients written by an authorized user and on file with the licensee. The order or standing procedure shall be dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation.

~~R12-1-703. Interstitial, intracavitary, and superficial applications~~

~~A.~~ ~~Accountability, storage and transit~~

1. ~~Except as otherwise specifically authorized by the Agency, each licensee shall provide accountability of sealed sources and shall keep a record of the issue and return of all sealed sources to their place of storage.~~

Arizona Administrative Register
Notices of Final Rulemaking

- ~~2. When not in use, sealed sources and applicators containing sealed sources shall be kept in a protective enclosure of such material and wall thickness as may be necessary to assure compliance with the provisions of Article 4 of this Chapter.~~
- ~~3. Each licensee shall conduct a quarterly physical inventory to account for all sources and devices received and possessed. Records of the inventories shall be maintained for inspection by the Agency and shall include the quantities and kinds of radioactive material, location of sources and devices, and the date of the inventory.~~
- ~~4. Each licensee shall follow the radiation safety and handling instructions furnished by the manufacturer on the label attached to the source, device or permanent container thereof, or in the leaflet or brochure which accompanies the source or device, and maintain such instructions in a legible and conveniently available form.~~
- ~~5. Physicians, when transporting sealed sources or applicators containing sealed sources for their own use in the practice of medicine, shall transport such sources or applicators in packages of sufficient growth to withstand the rigors of normal transport and sufficient shielding to comply with the requirements of Article 4 of this Chapter. Any other transport of sealed sources or applicators containing sealed sources shall comply with the provisions of Article 15.~~

B. Testing sealed sources for leakage and contamination

- ~~1. All sealed sources containing more than 100 microcuries (3.7M Bq) of radioactive material with a half life greater than thirty days shall be tested for leakage contamination prior to initial use and at intervals not to exceed six (6) months. If there is reason to suspect that a sealed source might have been damaged, or might be leaking, it shall be tested for leakage before further use.~~
- ~~2. Leak tests shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample or, in the case of radium, the escape of radon at the rate of 0.001 microcurie per 24 hours. Any test conducted pursuant to R12-1-703(B)(1) which reveals the presence of 0.005 microcurie or more of removable contamination or, in the case of radium, the escape of radon at the rate of 0.001 microcurie or more per 24 hours shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with applicable provisions of Article 4.~~
- ~~3. Sealed sources containing radium shall in addition be tested for the escape of radon gas. The test shall be capable of detecting the escape of radon at the rate of 1.0 nanocurie (37 Bq) per 24 hours.~~
- ~~4. Each licensee shall assure that sealed sources containing radium-226, cesium-137 or cobalt-60 (as wire) are not opened while in the licensee's possession unless specifically authorized by a license issued by the Agency.~~

C. Radiation surveys

- ~~1. The maximum radiation level at a distance of 1 meter (40 in.) from the patient in whom brachytherapy sources have been inserted shall be determined by measurement using a calibrated survey instrument. This radiation level shall be entered on the patient's chart and other signs posted as required under R12-1-703(D).~~
- ~~2. The radiation levels in the patient's room and the surrounding area shall be determined and recorded, and the record maintained for inspection by the Agency.~~
- ~~3. The licensee shall assure that patients treated with cobalt-60, cesium-137, iridium-192, or radium-226 implants remain hospitalized until a source count and a radiation survey of the patient, using a calibrated survey instrument, confirm that all radiation emitting implants have been removed.~~

D. Signs and records

- ~~1. In addition to the requirements of R12-1-411, the bed, cubicle or room of the hospital brachytherapy patient shall be marked with a sign indicating the presence of brachytherapy sources. This sign shall incorporate the radiation symbol and specify the radionuclide, the activity, date, and the individual(s) to contact for radiation safety instructions. The sign is not required if any of the exceptions in R12-1-412 of these regulations apply.~~
- ~~2. The following information shall be included in the patient's chart:
 - a. The radionuclide administered, number of sources, activity in millicuries and time and date of administration;
 - b. The exposure or dose rate at 1 meter, the time the measurement was made, and by whom;
 - c. The radiation symbol; and
 - d. The precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted under R12-1-402.~~

R12-1-703. License for Medical Use of Radioactive Material

A. In addition to the requirements set forth in R12-1-309, the Agency shall issue a specific license for medical use of radioactive material in medical institutions, which will be issued if:

1. The applicant has appointed a radiation safety committee, meeting the requirements in R12-1-706, that will oversee the use of licensed material throughout the medical institution and review the medical institution's radiation safety program;
2. The applicant possesses facilities for the clinical care of patients;
3. Any physician designated on the application as an authorized user has substantial training and experience in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients; and

Arizona Administrative Register
Notices of Final Rulemaking

4. If the application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant's staff has substantial experience in the use of a variety of radioactive materials for a variety of medical purposes.
- B.** Specific licenses to individual physicians for medical use of radioactive material:
1. The Agency shall approve an application by an individual physician or group of physicians for a specific license governing the medical use of radioactive material if:
 - a. The applicant satisfies the general requirements in R12-1-309;
 - b. The application is for use in the applicant's practice at an office outside of a medical institution;
 - c. The applicant has access to a medical institution with adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and
 - d. The applicant has substantial experience in the handling and administration of radionuclides, and where applicable, the clinical management of radioactive patients.
 2. The Agency shall not approve an application by an individual physician or group of physicians for a specific license to receive, possess, or use radioactive material on the premises of a medical institution unless:
 - a. The use of radioactive material is limited to:
 - i. The administration of radiopharmaceuticals for diagnostic or therapeutic purposes;
 - ii. The performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered;
 - iii. The performance of in vitro diagnostic studies, or
 - iv. The calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation, or diagnostic instrumentation;
 - b. The physician brings the radioactive material and removes the radioactive material upon departure; and
 - c. The medical institution does not hold a radioactive materials license under subsection (A).
- C.** Specific licenses for certain groups of medical uses of radioactive material
1. Subject to the provisions of subsections (C) (2), (3), and (4), the Agency shall approve an application for a specific license under subsections (A) or (B), for any medical use or uses of radioactive material specified in 1 or more of Groups I to V, inclusive, in Exhibit A of this Article for all of the materials within the group or groups in the application if:
 - a. The applicant satisfies the requirements of subsections (A), (B), and (D);
 - b. The applicant, or any physician designated in the application as an individual user meets the qualifications in R12-1-704;
 - c. All other personnel who will be involved in the preparation and use of the radioactive material have adequate training and experience in the handling of radioactive material appropriate to their participation in the uses included in the group or groups;
 - d. The applicant's radiation detection and measuring instrumentation is adequate for conducting the procedures involved in the uses included in the group or groups;
 - e. The applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the uses included in the group or groups.
 2. Any licensee or registrant who is authorized to use radioactive material according to 1 or more groups in subsection (C) (1), and Exhibit A of this Article is subject to the following conditions:
 - a. For Groups I, II, IV and V, a licensee or registrant shall not receive, possess, or use radioactive material as a radiopharmaceutical unless manufactured in the form to be administered to the patient, labeled, packaged, and distributed according to a specific license issued by the Agency under R12-1-311(J), a specific license issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.72, 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of Secretary of State (This incorporation by reference contains no future editions or amendments), or a specific license issued by an Agreement State or a Licensing State under equivalent rules.
 - b. For Group III, a licensee or registrant shall not receive, possess, or use generators or reagent kits that contain radioactive material to prepare radiopharmaceuticals containing radioactive material, except:
 - i. Reagent kits that do not contain radioactive material, approved by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State or Licensing State for use by persons licensed under subsection (C) and Exhibit A of this Article or equivalent regulations; or
 - ii. Generators or reagent kits that contain radioactive material which are manufactured, labeled, packaged, and distributed according to a specific license issued by the Agency under R12-1-311(K).
 - c. For Group III, any licensee who uses generators or reagent kits shall:
 - i. Elute the generator according to instructions furnished by the manufacturer or located on the generator label, leaflet, or brochure which accompanies the generator or reagent kit;
 - ii. Before administration to patients, or distribution to authorized recipients for administration to patients, cause each elution or extraction of technetium-99m from a molybdenum-99/technetium-99m generator to be tested to determine either the total molybdenum-99 activity or the concentration of molybdenum-99, according to written procedures and by personnel who have been specifically trained to perform the test;

Arizona Administrative Register
Notices of Final Rulemaking

- iii. Prohibit the administration or distribution for administration of technetium-99m that, at the expiration date and time shown on the container label, contains more than 5.6 kBq (0.15 microcuries) of molybdenum-99 per 37 MBq (1 millicurie) of technetium-99m. The licensee shall determine an action level for molybdenum-99/technetium-99m at elution so that the above concentration is not exceeded by radiopharmaceutical expiration. For example, the maximum concentration is 2.6 kBq (0.07 microcurie) per 37 MBq (1 millicurie) at elution for a dose that expires 6 hours later. The licensee shall ensure that the limits above are not exceeded for any single patient dose by checking the expiration time on the container label. The results of each test performed to detect and quantify molybdenum-99 contamination and records of training given to personnel performing these tests shall be maintained for 3 years for Agency inspection; and
- d. For Groups I, II, and III, any licensee using radioactive material for clinical procedures other than those specified in the product labeling or package insert shall do so according to an authorized user's directive. Any deviation from the product labeling shall be recorded. Records shall be maintained for Agency review for 3 years from the date of the administration of the radiopharmaceutical.
- 3. Any licensee who is licensed according to subsection (C)(1), for 1 or more of the medical use groups in Exhibit A also is authorized to use radioactive material under the general license in R12-1-306(F) for the specified in vitro uses without filing Form ARRA-9 as required by R12-1-306(F)(2); provided, that the licensee is subject to the other provisions of R12-1-306(F)
- 4. Any licensee who is licensed according to this Section is authorized to receive, possess, and use calibration and reference radioactive sealed sources in accordance with R12-1-711:
- D.** In addition to the requirements set forth in R12-1-309, the Agency shall issue a specific license for medical use of sealed sources only if the applicant or, if the application is made by a medical institution, the individual user has the qualifications listed in R12-1-704:

R12-1-704. Teletherapy Repealed

A. Equipment

- 1. ~~The teletherapy equipment housing shall be so constructed that, at one (1) meter (40 in.) from the source, the maximum exposure rate does not exceed ten (10) milliroentgens per hour (87u Sv/hr) when the beam control mechanism is in the "off" position. The average exposure rate measured at a representative number of points about the housing, each one (1) meter (40 in.) from the source, shall not exceed two (2) milliroentgens per hour (17u Sv/hr).~~
- 2. ~~For teletherapy equipment installed after May 15, 1967, the leakage radiation measured at one (1) meter from the source when the beam control mechanism is in the "on" position shall not exceed one (1) roentgen per hour (8.7m Sv/hr) or 0.1 percent of the useful beam exposure rate whichever is less.~~
- 3. ~~Adjustable or removable beam-defining diaphragms shall allow transmission of not more than five (5) percent of the useful beam exposure rate.~~
- 4. ~~The beam control mechanism shall be of a positive design capable of acting in any orientation of the housing for which it is designed to be used. In addition to an automatic closing device, the mechanism shall be designed so that it can be manually returned to the "off" position with a minimum risk of exposure.~~
- 5. ~~The closing device shall be so designed as to return automatically to the "off" position in the event of any breakdown or interruption of the activating force and shall stay in the "off" position until activated from the control panel.~~
- 6. ~~When any door to the treatment room is opened, the beam control mechanism shall automatically and rapidly restore the unit to the "off" position and cause it to remain there until the unit is reactivated from the control panel.~~
- 7. ~~There shall be at the housing and at the control panel a warning device that plainly indicates whether the beam is on or off and there shall be an independent radiation monitoring device which shall
 - a. ~~Continuously monitor the condition of the teletherapy beam and~~
 - b. ~~Provide a continuously visible signal to the operator.~~~~
- 8. ~~The equipment shall be provided with a locking device to prevent unauthorized use.~~
- 9. ~~The control panel shall be provided with a timer that automatically terminates the exposure after a preset time.~~
- 10. ~~Provision shall be made to permit continuous observation of patients during irradiation.~~
- B.** ~~No individual shall be in the treatment room during irradiation unless that individual is the patient. Mechanical restraining or supporting devices shall be used for positioning the patient, if necessary.~~
- C.** ~~Testing for leakage and contamination. Teletherapy sources shall be tested for leakage and contamination in accordance with the procedures described in R12-1-702(B). Tests of leakage shall be made by wiping accessible surfaces of the housing port or collimator while the source is in the "off" position and measuring these wipes for transferred contamination.~~
- D.** ~~Calibration requirements
 - 1. ~~Full calibration measurements shall be performed on each teletherapy unit:
 - a. ~~Prior to the first use of the unit for treating humans;~~
 - b. ~~Prior to treating humans:
 - i. ~~Whenever spot check measurements indicate that the output value differs by more than 5 percent from the value obtained at the last full calibration corrected mathematically for decay;~~
 - ii. ~~Following replacement of the radiation source or following reinstallation of the teletherapy unit in a new~~~~~~~~

Arizona Administrative Register
Notices of Final Rulemaking

- location;
 - iii. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
 - e. At intervals not exceeding one year.
 - 2. Full calibration measurements shall include determination of:
 - a. The exposure or dose rate, to an accuracy within ± 3 percent for the range of field sizes and for the range of distances (or for the axis distance) used in radiation therapy;
 - b. The congruence between the radiation field and the field indicated by the light beam localizing device;
 - c. The uniformity of the radiation field and its dependence upon the orientation of the useful beam;
 - d. Timer accuracy; and
 - e. The accuracy of all distance measuring devices used for treating humans.
 - 3. Reserved.
 - 4. The exposure rate or dose rate values shall be corrected mathematically for intervals not exceeding one month.
 - 5. Full calibration measurements and dose rate corrections shall be performed by an expert qualified by training and experience in accordance with R12-1-704(G)(1)
- E. Spot check measurements**
- 1. Spot check measurements shall be performed on each teletherapy unit at intervals not exceeding one month.
 - 2. Spot check measurements shall include determination of:
 - a. Timer accuracy;
 - b. The congruence between the radiation field and the field indicated by the light beam localizing device;
 - c. The accuracy of all distance measuring devices used for treating humans;
 - d. The exposure rate dose or a quantity related in a known manner to these rates for one typical set of operating conditions; and
 - e. The difference between the measurement made and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for decay).
 - 3. Spot check measurements shall be performed in accordance with procedures established by an expert qualified by training and experience in accordance with R12-1-704(G)(1). (A qualified expert need not actually perform the spot check measurements.) If a qualified expert does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by a qualified expert within 15 days.
- F. Dosimetry systems**
- 1. Full calibration measurements shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system shall have been calibrated within the previous two years and after any servicing that may have affected system calibration.
 - 2. Spot check measurements shall be performed using a dosimetry system that has been calibrated in accordance with R12-1-704(F)(1). Alternatively a dosimetry system used solely for spot check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with R12-1-704(F)(1). This alternative calibration method shall have been performed within the previous one year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.
- G. Expert qualifications. The licensee shall determine if a person is an expert qualified by training and experience to calibrate a teletherapy unit and establish procedures for (and review the results of) spot check measurements. The licensee shall determine that the qualified expert:**
- 1. Is certified by the American Board of Radiology in: Therapeutic Radiological Physics, Radiological Physics, Roentgen-Ray and Gamma-Ray Physics, or X-ray and Radium Physics; or
 - 2. Has the following minimum training and experience:
 - a. A Master's or Doctor's degree in physics, biophysics, radiological physics or health physics; and
 - b. One year of full-time training in therapeutic radiological physics; and
 - c. One year of full-time experience in radiotherapy facility, including personal calibration and spot check of at least one teletherapy unit.
 - 3. Licensees that have their teletherapy units calibrated by persons who do not meet these criteria for minimum training experience may request a license amendment excepting them from R12-1-704(G). The request should include the name of the proposed qualified expert, a description of his training and experience, including information similar to that specified in R12-1-704(G)(2), reports of at least one calibration and spot check program based on measurements personally made by the proposed expert within the last ten years, and written endorsement of the technical qualifications of the proposed expert from personal knowledge by a physicist certified by the American Board of Radiology in one of the specialties listed in R12-1-704(G)(1)

- H.** Records. The licensee shall maintain for inspection by the Agency: records of the measurements, tests, corrective actions, instrument calibrations made under R12-1-704(D) and (E) and records of the licensee's evaluation of the qualified expert's training and experience made under R12-1-704(G):
1. Records of
 - a. Full calibration measurements and
 - b. Calibration of the instruments used to make these measurements shall be preserved for five years and after completion of the full calibration.
 2. Records of
 - a. Spot check measurements and corrective actions and
 - b. Calibration of instruments used to make spot check measurements shall be preserved for five years after completion of the spot check measurements and corrective actions.
 3. Records of the licensee's evaluation of the qualified experts training and experience shall be preserved for five years after the qualified expert's last performance of a full calibration of the licensee's teletherapy unit.

R12-1-704. Supervision

- A.** For purposes of this rule "supervision" means the exercise of control over or direction of the use of radioactive material in the practice of medicine by an authorized user named on a radioactive material license. Supervision does not require a supervising physician's constant physical presence if the supervising physician can be easily contacted by radio, telephone, or telecommunication.
- B.** A physician may use radioactive material if he or she is licensed by the Arizona Board of Medical Examiners or Board of Osteopathic Examiners in Medicine and Surgery and is listed as an authorized user on a radioactive material license issued by the Agency, NRC, or Agreement State, authorizing the use of radioactive material for medical purposes.
- C.** A physician, having the training and experience listed in 10 CFR 35, 1998 Edition, published January 1, 1998, which is incorporated by reference and on file with the Agency and the Office of Secretary of State, or a physician under the supervision of a physician having the qualifications listed above, may use radioactive material for medical purposes. This incorporation by reference contains no future editions or amendments.
- D.** An authorized user, approved to prescribe radiopharmaceuticals for therapy purposes on a radioactive materials license, shall be physically present when a radiopharmaceutical is administered to a human being for therapeutic purposes.

R12-1-705. Radiation Safety Officer

A licensee shall appoint a Radiation Safety Officer who is responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed according to this Chapter and Agency approved procedures.

R12-1-706. Radiation Safety Committee

A medical institution Radiation Safety Committee shall meet the following requirements:

1. Administrative requirements:
 - a. Committee membership shall consist of at least 3 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.
 - b. The Committee shall meet at least once each calendar quarter, unless otherwise specified by license condition.
 - c. To establish a quorum and to conduct business, 1/2 of the Committee's membership shall be present, including the Radiation Safety Officer and the management representative.
 - d. The minutes of each Radiation Safety Committee meeting shall include:
 - i. The date of the meeting;
 - ii. Members present;
 - iii. Members absent;
 - iv. A summary of deliberations and discussions;
 - v. Recommended actions and the numerical results of all ballots; and
 - vi. A reference to the review required in R12-1-407.
 - e. The Committee shall provide each member with a copy of the meeting minutes, and retain 1 copy for 3 years.
2. Oversight; the Committee shall:
 - a. Review the radiation protection program for all sources of radiation as required in R12-1-407;
 - b. Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the Radiation Safety Officer; and
 - c. Establish the safety objectives of the quality management program required by R12-1-707.

R12-1-707. Quality Management Program

Each licensee, using radioactive material or the radiation from radioactive material for therapeutic purposes, shall establish and maintain a written quality management program so that radioactive material or radiation from it will be administered as

Arizona Administrative Register
Notices of Final Rulemaking

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 Committee or Radiation Safety Officer for licensees not required to have a Radiation Safety Committee.

R12-1-708. Misadministration Reports and Records

A. Reports of therapy misadministrations.

1. When a administration involves any therapy procedure, the licensee shall notify the Agency by telephone. The licensee shall also notify the referring physician of the affected patient and the patient or a responsible relative or guardian, unless the referring physician personally informs the licensee either that he or she will inform the patient, or that in his or her medical judgment, telling the patient or the patient's responsible relative or guardian would be harmful to 1 or the other, respectively. These notifications shall be made within 24 hours after the licensee discovers the misadministration. If the referring physician or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee shall not delay medical care for the patient because of notification problems.
2. Within 15 days after the initial therapy misadministration report to the Agency, the licensee shall report, in writing, to the Agency and to the referring physician and furnish a copy of the report to the patient or the patient's responsible relative or guardian, depending on who was previously notified by the licensee under subsection (A)(1). The written report shall include the licensee's name, the referring physician's name, a brief description of the event, the effect on the patient, the action taken to prevent recurrence, whether the licensee informed the patient or the patient's responsible relative or guardian, and if not, why not. The report shall not include the patient's name or other information that could lead to identification of the patient.

B. When a misadministration involves a diagnostic procedure, the licensee shall notify, in writing, the referring physician and the Agency. A licensee's report of a diagnostic misadministration is due within 10 days after the end of the calendar quarter (defined by March, June, September and December) in which the misadministration occurs. The written report shall include the licensee's name, the referring physician's name, a description of the event, the effect on the patient, and the action taken to prevent recurrence. The report shall not include the patient's name or other information that could lead to identification of the patient.

C. Each licensee shall maintain, for Agency inspection, records of all misadministrations of radiopharmaceuticals or radiation from teletherapy or brachytherapy sources. These records shall 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 social security number or other 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. These records shall be preserved until the Agency authorizes disposal.

R12-1-709. Reserved

R12-1-710. Visiting Authorized User

A. A licensee may permit any visiting authorized user to use licensed material for a medical purpose under the terms of the licensee's license for 60 days each year if:

1. The visiting authorized user has the prior written permission of the licensee's management and Radiation Safety Committee, if applicable;
2. The licensee has a copy of an Agency, Agreement State, Licensing State, or NRC license that identifies the visiting authorized user by name as a person authorized to use licensed material for medical purposes; and
3. Only those procedures for which the visiting authorized user is specifically authorized by an Agency, Agreement State, Licensing State, or NRC license are performed by that individual, and

B. A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in subsection (A).

C. A licensee shall retain a copy of the license specified in subsection (A)(2) for 3 years from the date of the last visit.

R12-1-711. Calibration and Reference Sources

Any person authorized by R 12-1-703 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, and reference purposes:

- A.** Sealed sources manufactured and distributed by persons specifically licensed under 12 A.A.C. 1, Article 3 or equivalent provisions of the NRC, Agreement State, or Licensing State and that do not exceed 1.1 GBq (30 millicuries) each;
- B.** Any radioactive material listed in Group I, Group II, or Group III of Exhibit A of this Article with a half-life not longer than 100 days, in amounts not to exceed 555 MBq (15 millicuries) total;
- C.** Any radioactive material listed in Group I, Group II, or Group III of Exhibit A of this Article with half-life greater than 100 days in amounts not to exceed 7.4 MBq (200 microcuries) total; and
- D.** Technetium-99m in individual amounts not to exceed 1.85 GBq (50 millicuries).

R12-1-712. Sealed Sources

A. Each medical and nuclear pharmacy licensee shall conduct a quarterly physical inventory to account for all radioactive sealed sources received and possessed. Records of the inventories shall be maintained for inspection by the Agency and

Arizona Administrative Register
Notices of Final Rulemaking

shall include the quantities, kinds of radioactive material, location of sources, the date of the inventory, and signature of the person performing the inventory.

B. A licensee shall use radioactive sealed sources for medical purposes as prescribed in R12-1-450(A).

R12-1-713. Dose Calibrators

A medical use licensee shall possess a dose calibrator and use it to measure the amount of radioactivity administered to a person and to insure that the amount given to the person is the authorized user's prescribed amount.

R12-1-714. Brachytherapy

A. Accountability, storage, and transit.

1. Except as otherwise specifically authorized by the Agency, each licensee shall keep a record of the issue and return of all sealed sources.
2. When not in use, the licensee shall keep sealed sources and applicators containing sealed sources in a protective enclosure of such material and wall thickness as is necessary to assure compliance with the provisions of 12 A.A.C. 1, Article 4.
3. Each licensee shall conduct a quarterly physical inventory to account for all brachytherapy sources and devices containing brachytherapy sources received and possessed. Records of the inventories shall be maintained for inspection by the Agency and shall include the quantities and kinds of radioactive material, location of sources and devices, and the date of the inventory.
4. Each licensee shall follow the radiation safety and handling instructions approved by the Agency; or follow the radiation safety and handling instructions furnished by the manufacturer on the label attached to the brachytherapy source, the device containing a brachytherapy source, the permanent container containing the brachytherapy source, or in the leaflet or brochure which accompanies the brachytherapy source or device, and maintain these such instructions in a legible and easily accessible form. If the handling instructions, leaflet, or brochure is no longer available or a copy cannot be obtained from the manufacturer, the Agency shall be notified the source information is no longer available.
5. A physician, transporting a brachytherapy source or applicator containing a brachytherapy source for his or her own use in the practice of medicine, shall transport the brachytherapy source or applicator according to the requirements in 12 A.A.C. 1, Article 15.

B. A licensee shall perform leak testing on brachytherapy sources for radioactive contamination as required in R12-1-417.

C. Radiation surveys.

1. A physician on a radioactive material license or qualified designee shall measure the maximum radiation level at a distance of 1 meter (40 in.) from the patient in whom brachytherapy sources have been inserted, using a calibrated survey instrument. This radiation level shall be entered on the patient's chart and other signs posted as required in subsection (D).
2. A physician on a radioactive material license or qualified designee shall measure and record the radiation level in the patient's room and the surrounding area. The licensee shall maintain the record for Agency inspection.
3. The licensee shall assure that patients treated with cobalt-60, cesium-137, iridium-192, or radium-226 implants remain hospitalized until a source count and a radiation survey of the patient, using a calibrated survey instrument, confirm that all radiation emitting implants have been removed.

D. Signs and records.

1. In addition to the requirements in R12-1-429, the licensee shall mark the bed, cubicle or room of the hospital brachytherapy patient with a sign indicating the presence of brachytherapy sources. This sign shall incorporate the radiation symbol and specify the radionuclide, activity, date, and individual to contact for radiation safety instructions. The sign is not required if any of the exceptions in R12-1-430 apply.
2. A physician on a radioactive material license or a qualified designee shall include the following information in the patient's records when the patient is undergoing brachytherapy:
 - a. The radionuclide administered, the number of sources, the activity in millicuries, and the time and date of administration;
 - b. The exposure or dose rate at 1 meter, the time the measurement was made, and by whom;
 - c. The radiation symbol; and
 - d. The precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted in R12-1-408.

R12-1-715. Reserved

R12-1-716. Teletherapy

A. A licensee shall use equipment that meets all of the following specifications:

1. The teletherapy equipment housing is constructed so that, at 1 meter (40 in.) from the teletherapy source, the maximum exposure rate does not exceed 100 μ Sv (10 mrem) per hour when the beam control mechanism is in the "off"

Arizona Administrative Register
Notices of Final Rulemaking

- position. The average exposure rate measure at a representative number of points about the housing, each 1 meter (40 in.) from the teletherapy source, does not exceed .20 μ Sv (2 mrem) per hour 1 meter (40 in.) from the source.
2. For teletherapy equipment installed after May 15, 1967, the leakage radiation measured at 1 meter from the source when the beam control mechanism is in the "on" position does not exceed 260 μ C/kg (1 R) per hour or 0.1 percent of the useful beam exposure rate whichever is less.
 3. Adjustable or removable beam-defining diaphragms allow transmission of not more than 5% of the useful beam exposure rate.
 4. The beam control mechanism is of a design capable of acting in any orientation of the housing. The mechanism is designed so that it can be manually returned to the "off" position with a minimum risk of exposure.
 5. The closing device is designed to return automatically to the "off" position in the event of any breakdown or interruption of power and stays in the "off" position until activated from the control panel.
 6. When any door to the treatment room is opened, the beam control mechanism automatically and rapidly restores the unit to the "off" position and causes it to remain there until the unit is reactivated from the control panel.
 7. There is at the housing and at the control panel a warning device that plainly indicates whether the beam is on or off and an independent radiation monitoring device which:
 - a. Continuously monitors the condition of the teletherapy beam and
 - b. Provides a continuously visible signal to the operator.
 8. The equipment has a locking device to prevent unauthorized use.
 9. The control panel has a timer that automatically terminates the exposure after a preset time.
 10. The equipment permits continuous observation of patients during irradiation.
- B.** The authorized user shall ensure that no individual is in the treatment room during irradiation unless that individual is the patient. Mechanical restraining or supporting devices shall be used for positioning the patient, if necessary.
- C.** The licensee shall test the teletherapy sources for leakage and contamination as required in R12-1-417. The licensee shall also wipe accessible surfaces of the housing port or collimator while the source is in the "off" position, measuring the wipe samples for transferred contamination.
- D.** Calibration requirements.
1. The licensee's expert, qualified by training and experience under subsection (G), shall perform full calibration measurements on each teletherapy unit:
 - a. Prior to the 1st use of the unit for treating humans.
 - b. Prior to treating humans:
 - i. Whenever spot-check measurements indicate that the output value differs by more than 5% from the value obtained at the last full calibration, corrected mathematically for decay;
 - ii. Following replacement of the radiation source or following reinstallation of the teletherapy unit in a new location; or
 - iii. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
 - c. At intervals not exceeding 1 year.
 2. Full calibration measurements include determination of:
 - a. The exposure or dose rate, to an accuracy within +/-3% for the range of field sizes and for the range of distances or the axis distance used in radiation therapy;
 - b. The congruence between the radiation field and the field indicated by the light beam localizing device;
 - c. The uniformity of the radiation field and its dependence upon the orientation of the useful beam;
 - d. Timer accuracy; and
 - e. The accuracy of all distance measuring devices used for treating humans.
 3. Reserved.
 4. The expert shall correct the exposure rate or dose rate values mathematically for intervals not exceeding 1 month.
- E.** Spot check measurements.
1. The licensee's expert or other authorized agent shall perform spot check measurements on each teletherapy unit at intervals not exceeding 1 month.
 2. Spot check measurements shall include determination of:
 - a. Timer accuracy;
 - b. The congruence between the radiation field and the field indicated by the light beam localizing device;
 - c. The accuracy of all distance measuring devices used for treating humans;
 - d. The exposure rate dose or a quantity related to this rate for 1 typical set of operating conditions; and
 - e. The difference between the measurement made and the anticipated output, expressed as a percentage of the anticipated output. (For example, the value obtained at last full calibration corrected mathematically for decay).
 3. The expert shall establish spot check measurement procedures. If the expert does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by the expert within 15 days.
- F.** Dosimetry systems.

1. The licensee's expert shall perform full calibration measurements using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system shall have been calibrated within the previous 2 years and after any servicing that may have affected system calibration.
 2. Spot check measurements shall be performed using a dosimetry system that has been calibrated as required in subsection (F)(1). Alternatively a dosimetry system used solely for spot check measurements may be calibrated by direct intercomparison with a system that has been calibrated according to the standards in subsection (F)(1). This alternative calibration method shall have been performed within the previous 1 year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.
- G.** The licensee shall determine if a person is an expert, qualified by training and experience to calibrate a teletherapy unit, establish procedures for spot check measurements, and review the results of such measurements. The licensee shall determine that the qualified expert:
1. Is certified by the American Board of Radiology in: Therapeutic Radiological Physics, Radiological Physics, Roentgen-Ray and Gamma-Ray Physics, or X-ray and Radium Physics; or the American Board of Medical Physicists in Radiation Oncology Physics; or
 2. Has the following minimum training and experience:
 - a. A Master's or Doctor's degree in physics, biophysics, radiological physics or health physics;
 - b. One year of full-time training in therapeutic radiological physics; and
 - c. One year of full-time experience in radiotherapy facility, including personal calibration and spot check of at least 1 teletherapy unit.
 3. Licensees, that have their teletherapy units calibrated by persons who do not meet the criteria in subsections (1) and (2) for minimum training experience, may request a license amendment excepting them from these training requirements. The request should include the name of the proposed qualified expert, a description of the expert's training and experience, including information similar to that specified in subsection (2), reports of at least 1 calibration and 1 spot check, based on measurements personally made by the proposed expert within the last 10 years, and a written endorsement of the expert's qualifications by a physicist certified by the American Board of Radiology in 1 of the specialties listed in subsection (1), based on personal knowledge.
- H.** The licensee shall maintain for inspection by the Agency: records of measurements, tests, corrective actions, and instrument calibrations made under subsections (D) and (E), and records of the licensee's evaluation of the qualified expert's training and experience under subsection (G).
1. The licensee shall preserve records of the following for 3 years after completion of each full calibration:
 - a. Full calibration measurements; and
 - b. Calibration of the instruments used to make the full calibration measurements.
 2. The licensee shall preserve records of the following for 3 years after completion of each spot check:
 - a. Spot check measurements and corrective actions; and
 - b. Calibration of instruments used to make spot check measurements.
 3. The licensee shall preserve records of the licensee's evaluation of the qualified expert's training and experience for 3 years after the qualified expert's last performance of a full calibration on the licensee's teletherapy unit.

R12-1-717. High Dose Rate Remote After-loading Brachytherapy Devices

- A.** Each after-loading irradiation facility shall have a system permitting continuous observation of the patient from outside the treatment room during patient irradiation.
- B.** The licensee shall post written emergency instructions at the after-loading irradiation device operator console. These instructions shall inform the device operator of the procedures to be followed if the source fails to return to the shielded position.
- C.** The licensee shall ensure that the after-loading irradiator facility has the following:
 1. Access to the room housing the after-loading irradiation device is controlled by a door at the entrance. The doors are normally closed.
 2. The entrance to the treatment room is equipped with an electrical interlock system that will cause the source to return to the shielded position immediately if the entrance door is opened. The interlock system is connected in such a manner that the source cannot be exposed until the entrance door is closed and the source "on-off" control is reset at the control panel.
- D.** The licensee shall test the electrical interlocks on the entrance door to the treatment room for proper operation at least once a month. Records of test results shall be maintained for 3 years for inspection by the Agency.
- E.** In the event of malfunction of the door interlock, the licensee shall lock the after-loading irradiation device in the "off" position and not use the after-loading, except as may be necessary to repair or replace the interlock system, until the interlock system is shown to be functioning properly.
- F.** Before initiation of a treatment program, and after each source exchange for the after-loading device:
 1. The licensee shall perform radiation surveys of the following locations:

Arizona Administrative Register
Notices of Final Rulemaking

- a. The after-loading device source housing, with the source in the shielded position. The maximum radiation level at 20 centimeters from the surface of the source housing shall not exceed 3 milliroentgens per hour.
 - b. All areas adjacent to the treatment room with the source in the exposed position. The survey shall clearly establish:
 - i. That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in R12-1-408 and R12-1-414.
 - ii. That radiation levels in unrestricted areas do not exceed the limits specified in R12-1-416.
 - iii. The activity of the source, using an Agency approved procedure and a calibrated Farmer chamber, or equivalent.
 - 2. The licensee shall retain records of the radiation surveys for 3 years for inspection by the Agency.
- G.** A person shall not perform the following work without written authorization by the Agency:
- 1. Installation and replacement of sources contained in an after-loading irradiation device; or
 - 2. Any maintenance or repair operation on the after-loading irradiation device involving work on the source driving unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.
- H.** Before making any changes to treatment room shielding, treatment room location, or use of the after-loading irradiation device which could result in an increase in radiation levels in unrestricted areas outside the treatment room, the licensee shall perform a radiation survey according to subsection (F)(1). A report describing each change, and giving the results of each survey shall be sent to the Agency.

R12-1-718. Gamma Stereotactic Radiosurgery

- A.** A licensee shall provide the manufacturer's written radiological safety and operating instructions to each person responsible for operation of a stereotactic radiosurgery system.
- B.** A person licensed by the Agency shall install the stereotactic radiosurgery system and perform all service and maintenance involving exposure to persons in the treatment room beyond normal "Beam-off" conditions.
- C.** In lieu of a direct source inventory, the licensee shall perform an indirect source inventory through completion of absolute calibrations of the radiation dose-rate at the intersection of all beam axes of the radiosurgery radiation unit on a 6 month basis. The magnitude of this dose-rate shall be compared with the appropriately decayed value of the initial or acceptance date, calibrated dose-rate at the intersection of all beam axes. This measured dose-rate serves as verification that all sources inserted into the gamma knife are still present.
- D.** A licensee shall ensure that a stereotactic radiosurgery facility has the following safeguards:
- 1. Access to the radiosurgery room is controlled by a door at each entrance. The doors are normally closed.
 - 2. Each entrance to the radiosurgery room is equipped with an electrical interlock system that will turn the unit's primary beam of radiation off immediately if any entrance door is opened. The interlock system is connected in such a manner that the machine's primary beam of radiation cannot be turned on until all treatment room entrance doors are closed and the beam "ON-OFF" control is reset at the control panel.
 - 3. In the event of malfunction of any door interlock, the radiosurgery system control is locked in the "OFF" position and not used, except as may be necessary to the repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.
 - 4. The radiosurgery room has a system permitting continuous observation of the patient from outside the radiosurgery room during patient irradiation.
 - 5. Written instructions, including the manufacturer's radiological safety and operating procedures, are available at the stereotactic radiosurgery controls. These instructions inform the operator of the procedure to be followed in the event of malfunction. These instructions caution individuals on how to avoid exposure to radiation in the treatment room and include specific instructions for:
 - a. Removing the patient from the treatment room;
 - b. Securing the room against unauthorized entry; and
 - c. Notifying the responsible physician or radiation safety officer.
- E.** The licensee shall test electrical interlocks on entrance doors to the radiosurgery room for proper operation at least once every 3 months. Records of test results shall be maintained for inspection by the Agency.
- F.** The licensee shall cease treatment of patients with the therapy unit if a safety related system of the unit is found inoperative, including couch or helmet drive mechanisms, positioning mechanisms, treatment timing systems, safety interlocks, or radiation field alarms.
- G.** Before initiation of a treatment program, and after each installation of radiosurgery sources.
- 1. The licensee shall perform radiation surveys of the following locations:
 - a. The radiosurgery system source housing. The maximum and average radiation levels at 1 meter from the nearest source with the device's shielding door closed, shall not exceed 10 milliroentgens per hour and 2 milliroentgens per hour, respectively, for any of the device's sources, when all sources are installed.

- b. Unrestricted areas adjacent to the treatment room, with the device's shielding door open. The survey shall be performed with a phantom in the primary beam of radiation and shall clearly establish that radiation levels in restricted and unrestricted areas do not exceed the limits specified in 12 A.A.C. 1, Article 4.
- 2. The licensee shall test the following safety equipment:
 - a. Electrical interlocks on entrance doors to the therapy treatment room;
 - b. The therapy source "ON-OFF" indicators, both at the source housing and on the system control panel; and
 - c. The radiosurgery system treatment timing device.
- H. After any changes made in treatment room shielding, treatment room location, or use of the stereotactic radiosurgery system which could result in an increase in radiation levels in unrestricted areas outside of the therapy treatment room, the licensee shall conduct a radiation survey according to subsection (G). A report describing the changes and giving the survey results shall be sent to the Agency no later than 30 days following completion of the changes.

R12-1-719. Release of Individuals Containing Radiopharmaceuticals or Radioactive Sealed Sources from Restricted Areas

- A. A licensee may authorize the release of any individual who has received radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem) or an amount specified in license conditions.
- B. The licensee shall provide the released individual with oral and written instructions, on recommended actions that will make doses to other individuals as low as is reasonably achievable, if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem).
- C. The licensee shall maintain a record of the criteria used to authorize the release of an individual containing radioactive material. The record shall be maintained for 3 years after the date of release if the total effective dose equivalent is calculated by using:
 - 1. The retained activity rather than the activity administered,
 - 2. An occupancy factor of less than 0.25 at 1 meter,
 - 3. The biological or effective half-life, or
 - 4. The shielding by tissue.

Exhibit A

Groups of Medical Uses of Radioactive Material

Group I.

- A. Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution, and excretion. This group does not include uses involving diagnostic study imaging, and tumor localization.
 - 1. Iodine-123
 - 2. Iodine-125
 - 3. Iodine-131
 - 4. Cobalt-57
 - 5. Cobalt-58
 - 6. Cobalt-60
 - 7. Chromium-51
 - 8. Iron-59
 - 9. Potassium-42
 - 10. Sodium-24
 - 11. Technetium-99m
- B. A licensee shall use a radioactive material listed in subsection (A) in the form of a radiopharmaceutical prepared for medical purposes that is:
 - 1. Obtained from a manufacturer or preparer licensed according to 10 CFR 32.72, 1998 Edition, published January 1, 1998, or equivalent Agreement State requirements. This incorporation by reference is on file with the Agency and the Office of Secretary of State, and contains no future editions or amendments; or
 - 2. Prepared by a nuclear pharmacist or a physician who is an authorized user on a radioactive material license, and meets the training and experience requirements in 10 CFR 35(J), or an individual under the supervision of either as specified in 10 CFR 35.25, 1998 Edition, published January 1, 1998, both references are incorporated by reference, and on file with the Agency and the Office of Secretary of State. These incorporations contain no future editions or amendments.

Group II.

- C. A use of prepared radiopharmaceuticals for diagnostic study, imaging, and tumor localization.
 - 1. Iodine-123
 - 2. Iodine-125
 - 3. Iodine-131
 - 4. Selenium-75

Arizona Administrative Register
Notices of Final Rulemaking

5. Technetium-99m
6. Ytterbium-169
7. Indium-111
8. Indium-113m
9. Chromium-51
10. Fluorine-18
11. Gallium-67
12. Gold-198
13. Thallium-201
14. Rubidium-82
15. Carbon-11

D. A licensee shall use a radioactive material listed in subsection (C) in the form of a radiopharmaceutical prepared for medical purposes that is:

1. Obtained from a manufacturer or preparer according to subsection (B)(1); or
2. Prepared by a nuclear pharmacist or a physician who is authorized according to subsection (B)(2)

Group III.

E. Use of generators and reagent kits for the preparation and use of radiopharmaceuticals containing radioactive material for certain diagnostic uses.

1. Molybdenum-99/Technetium-99m generators
2. Tin-113/Indium-113m generators
3. Technetium-99m (in bulk)
4. Rubidium-81/Krypton-81m

F. A licensee shall acquire and use a radioactive material listed in subsection (E) in the form of a radiopharmaceutical prepared for medical purposes that is:

1. Obtained from a manufacturer or preparer according to subsection (B)(1); or
2. Prepared by a nuclear pharmacist or a physician who is authorized according to subsection (B)(2)

Group IV.

G. Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety.

1. Iodine-131, in quantities less than 33 millicuries
2. Phosphorus-32
3. Strontium-89
4. Samarium-153

H. A licensee shall use a radioactive material listed in subsection (G) in the form of a radiopharmaceutical prepared for medical purposes that is:

1. Obtained from a manufacturer or preparer according to subsection (B)(1); or
2. Prepared by a nuclear pharmacist or a physician who is authorized according to subsection (B)(2)

Group V.

I. Use of prepared radiopharmaceuticals for certain therapeutic procedures that normally require hospitalization for purposes of radiation safety.

1. Iodine-131
2. Gold-198

J. A licensee shall use a radioactive material listed in subsection (I) in the form of a radiopharmaceutical prepared for medical purposes that is:

1. Obtained from a manufacturer or preparer according to subsection (B)(1); or
2. Prepared by a nuclear pharmacist or a physician who is authorized according to subsection (B)(2)

ARTICLE 8. RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY OPERATIONS

R12-1-801. Scope

The ~~rules regulations~~ in this Article establish requirements for the use of analytical x-ray ~~equipment machines, as defined in R12-1-802(A) by persons registering such machines under the provisions of R12-1-204 of these regulations.~~ The provisions of this ~~article supplement Article 8 are in addition to,~~ and not in substitution for, other applicable provisions of ~~this Chapter these regulations.~~

R12-1-802. Definitions

- ~~A.~~ Analytical x-ray equipment” means devices or machines equipment used for x-ray diffraction or x-ray induced fluorescence analysis.
- ~~B.~~ “Analytical x-ray system” means a group of components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials.

- ~~C.~~ "Enclosed beam x-ray system" means an analytical x-ray system constructed in such a way that access to the interior of the enclosure housing the x-ray source ~~during operation~~ is precluded during operation except through bypassing of interlocks or other safety devices to perform maintenance or servicing.
- ~~D.~~ "Fail-safe ~~characteristic characteristics~~" ~~means mean~~ a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.
- ~~E.~~ "Local ~~component components~~" ~~means mean~~ part of an analytical x-ray system and includes each area ~~areas~~ that is ~~are~~ struck by x-rays, such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but does ~~do~~ not include power supplies, transformers, amplifiers, readout devices, and control panels.
- ~~F.~~ "Normal operating procedures" means instructions or procedures including ~~necessary to accomplish the analysis. These procedures shall include~~, but are not limited to, sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data recording procedures which are related to radiation safety.
- ~~G.~~ "Open beam x-ray system" means an analytical x-ray system ~~in~~ which permits an individual to place some body part in the primary beam path during normal operation.
- ~~H.~~ "Primary beam" means radiation which passes through an aperture of the source housing on ~~by~~ a direct path from the x-ray tube ~~or a radioactive source located in the radiation source housing.~~

R12-1-803. Enclosed Beam X-ray Systems ~~beam x-ray systems~~

- A. Enclosed beam x-ray systems are exempt from other equipment requirements contained in this Article provided the enclosed of Article 8 of this Chapter, however:
 - ~~1. Enclosed beam x-ray systems are~~ shall be so designed and constructed so that radiation levels measured at 5 cm from any accessible surface of the enclosure housing the x-ray source do ~~shall~~ not exceed 5 μSv (0.5 mrem mR) ~~in 1 one~~ hour ~~(4.4 uSv/hr).~~
 - ~~2. A registrant using enclosed Enclosed beam x-ray systems shall comply with applicable provisions of R12-1-804(A), R12-1-805(B), and 12 A.A.C. 1, Article 4 of this Chapter.~~
- ~~CB.~~ A registrant shall provide individuals ~~Individuals~~ performing maintenance, servicing, or alignment procedures, where bypassing of interlocks or other safety devices to gain access to the interior of the enclosure is required, shall be provided with, and shall wear, with appropriate personnel monitoring devices (that is, wrist or finger badges). These individuals shall wear the devices while performing the work.
- ~~DC.~~ Intentional bypassing of safety devices shall be authorized in advance by the individual responsible for radiation protection. Bypassing Such bypassing shall be terminated as soon as the activity described in subsection (C) is completed, or the equipment shall be labeled as out-of-service with a conspicuous sign until repairs are completed. ~~possible.~~

R12-1-804. Open Beam X-ray Systems ~~beam x-ray systems~~

- A. A registrant shall label open beam x-ray systems ~~Open beam x-ray systems shall be labeled~~ with a readily discernable sign or signs bearing the radiation symbol and the words
 - 1. "CAUTION -- HIGH INTENSITY X-RAY BEAM", ~~or words having a similar warning intent,~~ on the x-ray source housing, and
 - 2. "CAUTION RADIATION -- THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" ~~or words having a similar warning intent,~~ near any switch that energizes ~~energizes~~ an x-ray tube if the radiation source is an x-ray tube; ~~or~~
 - 3. "CAUTION -- RADIOACTIVE MATERIAL", ~~or words having a similar intent, on the source housing if the radiation source is a radionuclide.~~
- B. A registrant shall ensure that an open beam x-ray system has ~~Open x-ray systems shall incorporate~~ all of the following warning devices; ~~:~~
 - 1. No change.
 - 2. Shutter status (Open-Closed) indicators near each port on the radiation housing for systems which control the primary beam; ~~in this way; and~~
 - 3. A clearly visible warning light labeled with the words "X-RAY ON", ~~or words having a similar warning intent, shall be located near:~~
 - a. ~~Near~~ any switch that energizes an x-ray tube, ~~and shall be illuminated only when the tube is energized; and; or~~
 - b. ~~In the case of a radioactive source, near any switch that opens a housing shutter, and shall be illuminated only when the shutter is open.~~
 - 4. The warning devices in subsections (1) through (3) shall be labeled so that their purpose is easily identified.
- C. A registrant shall ensure that any ~~Any~~ apparatus utilized in beam alignment procedures is ~~shall be~~ designed in such a way that excessive radiation will not strike the operator. Particular attention shall ~~should~~ be given to viewing devices, in order to ascertain that lenses and other transparent components attenuate the beam to an acceptable level.
- D. A registrant shall provide an ~~An~~ interlock device which prevents entry of any portion of an individual's body limbs, fingers, hands, wrists, etc. into the primary beam or causes the primary beam to be shut off upon entry into its path shall be

Arizona Administrative Register
Notices of Final Rulemaking

provided on all open-beam x-ray systems. A registrant may apply to the Agency for an exemption from the requirements of a safety device. An application for exemption shall include:

1. A description of the various safety devices that have been evaluated;
 2. The reason each device cannot be used; and
 3. A description of the alternative methods that will be used to minimize accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices, shall be utilized whenever feasible. When such a device is not feasible, alternate methods shall be provided to minimize the possibility of accidental exposure to the primary beam.
- E. On open-beam configurations installed after the effective date of these ~~rules~~ regulations, a registrant shall equip each port on the radiation source housing ~~shall be equipped~~ with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.
- F. A registrant shall equip each ~~Each~~ x-ray tube housing ~~shall be with an interlock that shuts off the tube if the tube is removed from the housing or if the housing is disassembled, so constructed that with all shutters closed, the leakage radiation measured at a distance of 2 in. (5 cm) from its surface is not capable of producing a dose equivalent in excess of 2.5 mrem (25 uSv) in one hour at any specified tube rating.~~
- G. A registrant shall supply each ~~Each~~ x-ray generator ~~shall be supplied~~ with a protective cabinet which limits leakage radiation measured at a distance of 5 cm (2 in) (2) in. (5 cm) from its surface so such that it is not capable of producing a dose equivalent in excess of 25 uSv (2.5 mrem).25 mrem (2.5 uSv) in 1 one hour.
- H. A registrant shall ensure that the ~~The~~ local components of an analytical x-ray system ~~are~~ shall be located and arranged and have ~~shall include~~ sufficient shielding or access control so such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present in the areas surrounding the local components, therein in excess of the dose limits given in R12-1-416 R12-1-405 of this Chapter. For systems utilizing x-ray tubes, these limits levels shall be met at any specified tube rating.
- I. A registrant shall perform a radiation survey of the local component group of each analytical x-ray system sufficient to demonstrate compliance with subsection (H). The survey shall be performed following installation, change in configuration, or maintenance, affecting the radiation levels in the areas surrounding the local component group. Records of surveys shall be maintained for 3 years or until the analytical x-ray system is no longer used, which ever is shorter.

R12-1-805. Administrative ~~Responsibilities~~ responsibilities

- A. A registrant shall designate an ~~An~~ individual at each facility who is ~~shall be designated to be~~ responsible for maintaining radiation safety. This individual, designated the ~~Radiation Protection Supervisor or Radiation Safety Officer, shall be responsible for the following:~~
1. Establish and maintain ~~Establishing and maintaining~~ operational procedures so that the radiation exposure of each worker is kept as far below the maximum permissible dose as is practical;
 2. Instruct ~~Instructing~~ all personnel who work with or near radiation producing machines in safety practices;
 3. Maintain ~~Maintaining~~ a system of personnel monitoring;
 4. Establish ~~Arranging for establishment~~ of radiation control areas, including placement of appropriate radiation warning signs or and/or devices;
 5. Provide a ~~Providing for~~ radiation safety inspection of radiation producing machines on a routine basis;
 6. Review ~~Reviewing~~ modifications to x-ray systems apparatus, including x-ray tube housing, cameras, diffractometers, shielding, and safety interlocks;
 7. Investigate and report ~~Investigating and reporting~~ to proper authorities any case of excessive exposure to personnel and take taking remedial action; and,
 8. Be ~~Being~~ familiar with all applicable ~~rules~~ regulations for control of ionizing radiation.
- B. An individual shall not be permitted to operate or maintain an open beam analytical x-ray system unless the individual has received instruction in and demonstrated competence in all of the following:
1. Identification of radiation hazards associated with the use of the equipment;
 2. Significance of all radiation warning and safety devices, interlocks incorporated into the equipment, or the reasons that devices or interlocks have not been installed on certain pieces of equipment and the extra precautions required in lieu of these precautions;
 3. Proper operating procedures for the equipment;
 4. Recognition of symptoms of acute localized radiation exposure;
 5. Proper procedure for reporting an actual or suspected exposure; and
- C. A registrant shall maintain records of instruction and competence for Agency inspection for 3 years from the date of course completion or demonstration.
- ~~No individual shall be permitted to act as an operator of a particular machine until such individual has received an acceptable amount of training in radiation safety as it applies to that machine and is approved by the Radiation Protection Supervisor or Radiation Safety Officer. Operators shall be responsible for:~~
1. ~~Keeping radiation exposure to himself and to others as low as is practical;~~
 2. ~~Being familiar with safety procedures as they apply to each machine;~~

Arizona Administrative Register
Notices of Final Rulemaking

3. ~~Wearing of personnel monitoring devices, if applicable; and,~~
4. ~~Notifying the Radiation Protection Supervisor or Radiation Safety Officer of known or suspected excessive radiation exposures to himself or others.~~

R12-1-806. Operating Requirements ~~procedures~~

- A. ~~A Radiation Safety Officer shall establish written~~ ~~Written~~ emergency procedures pertaining to radiation safety shall be established for each analytical x-ray system and post the procedures ~~x-ray producing apparatus by the Radiation Protection Supervisor and posted in a conspicuous location. The procedures shall include~~ ~~These shall list the telephone number number(s) of the Radiation Safety Officer. A registrant shall notify the Radiation Safety Officer~~ ~~Protection Supervisor and shall include the following actions to be taken in case of a known, or suspected, or suspected radiation exposure accident and arrange for medical examination for the person exposed individual. accident involving radiation exposure:~~
 1. ~~Notify Radiation Protection Supervisor, and~~
 2. ~~Arrange for medical examination.~~
- B. ~~A registrant shall provide normal operating procedures to all analytical x-ray equipment workers. An individual shall not operate analytical x-ray equipment in any manner other than that specified in the procedures unless the individual has obtained the Radiation Safety Officer's written approval. Personnel shall not expose any part of their body to the primary beam.~~
- C. ~~An individual shall not bypass a safety device or interlock unless the individual has obtained Radiation Safety Officer approval. The approval shall be for a specific period of time. When a safety device or interlock has been bypassed, the Radiation Safety Officer shall place a readily discernable sign on the radiation source housing, warning the reader of the unsafe condition. A registrant shall maintain the written record of the bypass approval for 3 years after the approval expires. Only properly trained maintenance personnel shall be permitted to install, repair, or make other than routine modifications to the x-ray generating apparatus and the tube housing apparatus complex.~~
- D. ~~Except as authorized in subsection (C), an individual shall not perform an operation involving removal of covers, shielding materials, or tube housings or modification of shutters, collimators, or beam stops without ascertaining that the tube is off and that it will remain off until all protective devices have been restored to the normal operating condition. An individual repairing analytical x-ray equipment shall use the main switch, rather than interlocks, for routine shutdown in preparation for repairs. Whenever possible, x-ray diffraction and spectrographic equipment should be placed in a room separate from other work areas.~~
- E. ~~The registrant shall secure unused ports on radiation source housings in the closed position, preventing unauthorized access to the radiation source.~~
- F. ~~Finger or wrist personnel monitoring devices shall be used by:~~
 1. ~~Operators of open beam analytical x-ray equipment not equipped with a safety device; and~~
 2. ~~Personnel performing maintenance procedures that require the presence of a primary x-ray beam when any local component is disassembled or removed.~~
- G. ~~The registrant shall test safety devices and warning devices for proper operation at intervals not to exceed 1 month. Records of tests shall be maintained for Agency inspection for 3 years following the completion of each test.~~
- E. ~~If, for any reason, it is necessary to temporarily intentionally alter safety devices, such as bypassing interlocks or removing shielding, such action shall be:~~
 1. ~~Specified in writing and posted near the x-ray tube housing so that other persons will know the existing status of the machine; and~~
 2. ~~Terminated as soon as possible.~~
- F. ~~Unused tube head ports shall be secured in the closed position; these shall be checked prior to use when the machine has been left unattended.~~
- G. ~~Personnel film badges or other monitoring devices shall be worn on the finger or wrist, rather than on the body.~~
- H. ~~Analytical x-ray equipment shall not be left unattended while the tube is energized unless:~~
 1. ~~An interlock device is provided to prevent accidental entry into the primary beam, and~~
 2. ~~The stray radiation at any accessible point at a distance of 10 inches from the tube housing or its containment, as measured with a monitoring instrument appropriate for the energy range generated, is no greater than 2 mR per hour.~~
- I. ~~Safety devices should be tested at least once per week and shall be tested at intervals not to exceed one month.~~
- J. ~~Records of personnel monitoring results and safety device tests shall be maintained for inspection by the Arizona Atomic Energy Commission.~~

ARTICLE 9. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

R12-1-902. Reserved ~~Registration Requirements~~

~~No person shall receive, possess, use, transfer, or acquire a particle accelerator except as authorized in a registration issued pursuant to these Rules or as otherwise provided for in these Rules. The general procedures for registration of particle accelerator facilities are included in Article 2 of these Rules.~~

Arizona Administrative Register
Notices of Final Rulemaking

R12-1-903. General Requirements for the Issuance of a Registration for Particle Accelerators

- A.** ~~The requirements in this section supplement the registration requirements in 12 A.A.C. 1, Article 2.~~
- B.** ~~In addition to the requirements of Article 2, a~~ The Agency shall approve a registration application for use of a particle accelerator ~~will be approved~~ only if the Agency determines that:
1. ~~The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested according to this Article, in accordance with this Article and Articles 4, and 10, of these rules regulations in such a manner as to minimize danger to public health and safety or property;~~
 2. ~~No change.~~
 3. ~~The issuance of the registration will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in R12-1-904 of these Rules;~~
 4. ~~No change.~~
 5. ~~The applicant's staff has substantial experience in the use of particle accelerators for the intended uses; and~~
 6. ~~If the applicant is a medical institution having an existing radiation safety committee, the committee shall be responsible for approving, in advance, proposals for uses of particle accelerators (For purposes of this rule a medical institution is defined as any organization dedicated to providing medical and surgical care for the sick on an over night basis); and~~
 - 67- ~~The applicant has an adequate training program for particle accelerator operators.~~

R12-1-904. Special Registration Requirements for Medical ~~Human~~ Use of Particle Accelerators

~~In addition to the requirements set forth in Article 2, a registration for use of a particle accelerator in the healing arts will be issued only if:~~

- A.** ~~The requirements in this Section supplement the registration requirements in R12-1-903.~~
- 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. Whenever deemed necessary by the Agency, the applicant has appointed a medical committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of a particle accelerator. Membership of the committee shall include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in depth dose calculations and protection against radiation.~~
- 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. Certified in:
 - a. Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; or
 - b. Radiation oncology by the American Osteopathic Board of Radiology; or
 - c. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
 - d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
 2. Engaged in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic techniques applicable to the use of a particle accelerator, 500 hours of supervised work experience, and a minimum of 3 years of supervised clinical experience.
 - a. To satisfy the requirement for instruction, the classroom and laboratory training shall include all of the following subjects.
 - i. Radiation physics and instrumentation;
 - ii. Radiation protection;
 - iii. Mathematics pertaining to the use and measurement of radiotherapy; and
 - iv. Radiation biology.
 - b. To satisfy the requirement for supervised work experience, training shall occur under the supervision of an authorized user at a medical institution and shall include:
 - i. Reviewing full calibration measurements and periodic spot checks;
 - ii. Preparing treatment plans and calculating treatment times;
 - iii. Using administrative controls to prevent misadministration;
 - iv. Implementing emergency procedures to be followed in the event of the abnormal operation of a particle accelerator; and
 - v. Checking and using survey meters.
 - c. To satisfy the requirement for a period of supervised clinical experience, training shall include 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:
 - i. Examining individuals and reviewing their case histories to determine their suitability for treatment, noting any limitations or contraindications;

- ii. Selecting the proper dose and how it is to be administered;
 - iii. Calculating the therapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses, as warranted by patients' or human research subjects' reaction to radiation; and
 - iv. Post-administration follow up and review of case histories.
- 2. ~~The individuals designated on the application as the users have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans.; and~~
 - 3. ~~The individual designated on the application as the user is a physician.~~
- D. With the application the applicant shall provide the name of each authorized user, and the training and experience that satisfies the requirements in subsection(C).
 - E. Each licensee 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.
 - F. Each particle accelerator shall be calibrated by an expert meeting the training and experience qualifications in R12-1-716(G).
 - G. The Agency shall inspect a particle accelerator before it is used to treat a human.

R12-1-911. Radiation Survey Requirements ~~monitoring requirements~~

- A. The registrant shall ensure that a portable survey instrument is available at all times in a particle accelerator facility. There shall be available at each particle accelerator facility, appropriate portable monitoring equipment which is operable and has been calibrated for the appropriate radiations being produced at the facility. Such equipment shall be tested for proper operation daily and calibrated at intervals not to exceed one year, and after each servicing and repair.
- B. A person experienced in the principles of radiation protection and installation design shall:
 - 1. Check operation of the portable survey instrument using a known radiation source prior to its use;
 - 2. Perform and document a radiation protection survey when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas;
 - 3. Perform surveys to determine the amount of airborne particulate radioactivity present in areas of airborne hazards in particle accelerator facilities of greater than 30 Mev;
 - 4. Perform periodic smear surveys to determine the degree of contamination in target and adjoining areas when the conditions described in subsection (B)(3) exist;
 - 5. Perform surveys as prescribed in the written procedures established by the Radiation Safety Officer of the particle accelerator facility.
- C. The registrant shall retain the following records:
 - 1. Records of any radiation protection survey required in subsection (B), and an associated facility description, required in R12-1-202(E), until the registration is terminated.
 - 2. Records of particle accelerator calibration, spot checks, personnel radiation safety system tests, and periodic radiation protection surveys until the registration is terminated.
- B. ~~A radiation protection survey shall be performed and documented by a person experienced in the principles of radiation protection and installation design when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.~~
- C. ~~All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair.~~
- D. ~~Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present in areas of airborne hazards.~~
- E. ~~Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination in target and other pertinent areas.~~
- F. ~~All surveys shall be made in accordance with the written procedures established by the Radiation Safety Officer of the particle accelerator facility.~~
- G. ~~Records of all radiation protection surveys, calibration results, instrumentation tests, and smear results shall be kept current and on file at each accelerator facility.~~

ARTICLE 10. NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

R12-1-1001. Purpose and ~~Scope~~ ~~scope~~

This Article establishes requirements for notices, instructions, and reports by licensees or registrants to individuals working for a licensee or registrant. The Article explains the engaged in work under a license or registration and options available to these such individuals in connection with ARRA AAEC inspections of licensees or registrants to ascertain compliance with the provisions of the Act and regulations, registrations and licenses issued thereunder regarding radiological working conditions. The rules regulations in this Article apply to all persons who receive, possess, use, own, or transfer sources of radiation licensed by or registered by with the ARRA, AAEC pursuant to the regulations in Article 2 and Article 3.

R12-1-1002. Posting of Notices for Workers ~~notices to workers~~

- A. Each licensee or registrant shall post current copies of the following documents:
 - 1. The ~~rules regulations~~ in this Chapter;
 - 2. The license, certificate of registration, conditions or documents incorporated into the license or registration by reference, and any amendments to the license or registration thereto;
 - 3. No change.
 - 4. Any notice of violation involving radiological working conditions, proposed imposition of a civil penalty, or order issued ~~under pursuant to 12 A.A.C. 1, Article 12 4,~~ and any response from the licensee or registrant.
- B. If posting of a document specified in ~~subsections (A)(1), (2), and (3).~~ R12-1-1002(A)(1), (2) or (3) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.
- C. No change.
- D. ~~Each licensee or registrant shall post documents~~ Documents, notices, or forms ~~posted, as required by this Section, so that they are conspicuous and pursuant to this Section shall~~ appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, ~~shall be conspicuous,~~ and shall replace any document if it is replaced if defaced or altered.
- E. Agency documents posted as required in ~~pursuant to subsection (A)(4)~~ R12-1-1002(A)(4) shall be posted within 2 two working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted within 2 two working days after dispatch from the licensee or registrant. ~~The Such~~ documents shall remain posted for a minimum of 5 five working days or until action correcting the violation has been completed, whichever is later.

R12-1-1003. Instructions to ~~Workers~~ workers

- A. The licensee or registrant shall inform all individuals working in or frequenting any portion of a restricted area of:
 - 1. The storage, transfer, or use of radioactive material or of radiation in ~~such portions of~~ the restricted area and the health protection problems associated with exposure to ~~such~~ radioactive material or radiation;
 - 2. No change.
 - 3. The applicable provisions of Agency ~~rules regulations~~ and licenses for the protection of personnel from exposures to radiation or radioactive material occurring in each restricted area ~~such areas~~;
 - 4. Their responsibility to report promptly to the licensee or registrant any condition which may lead to or cause a violation of Agency ~~rules regulations~~ and licenses, or unnecessary exposure to radiation or radioactive material;
 - 5. The appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and
 - 6. The radiation exposure reports which workers may request under pursuant to R12-1-1004.
- B. No change.

R12-1-1004. Notifications and Reports to Individuals

- A. ~~A licensee or registrant shall report radiation~~ Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body ~~of an individual shall be reported~~ to the individual as specified in this Section. The information reported shall include data and results obtained under pursuant to Agency ~~rules regulations~~, orders, or license conditions, as shown in records maintained by the licensee or registrant ~~pursuant to Agency regulations~~. Each notification and report shall be in writing; include appropriate identifying data, such as the name of the licensee or registrant, the name of the individual, and the individual's social security number; include the individual's exposure information; and contain the following statement:
"This report is furnished to you under the provisions of 12 A.A.C. 1, the Arizona Radiation Regulatory Agency rules entitled 'Rules for the Control of Ionizing Radiation'. You should preserve this report for future reference".
- B. Each licensee or registrant shall provide annual notification of ~~advise such worker annually of the worker's~~ exposure to radiation or radioactive material for each worker, as shown in records maintained by the licensee or registrant under pursuant to R12-1-419(D).
- C. At the request of a worker formerly engaged in work controlled by the licensee or the registrant, each licensee or registrant shall furnish to the worker a report of the worker's exposure to radiation or radioactive material. ~~The Such~~ report shall be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later; the report shall cover, within the period of time specified in the request, each calendar quarter in which the worker's activities involved exposure to radiation from radioactive material licensed by, or radiation machines registered with the Agency; and the report shall include the dates and locations of work under the license or registration in which the worker participated during this period.
- D. Reports to individuals of their exposure to radiation shall be made according to R12-1-446. ~~When a licensee or registrant is required pursuant to R12-1-444, or, for implementing the provisions of R12-1-401, R12-1-413(C), R12-1-445, and Article 12 of this Chapter, to report to the Agency any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on the licensee's or registrant's exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the Agency.~~

R12-1-1005. Licensee, Registrant, and Worker Representation During Agency Inspection ~~Presence of representatives of licensees or registrants and workers during inspection~~

- A. No change.
- B. No change.
- C. ~~A worker authorized to consult with an Agency inspector under to R12-1-1006, may authorize another individual to represent the worker's interests during the Agency inspection. The~~ If, at the time of inspection, an individual has been authorized by the workers to represent them during Agency inspections, the licensee or registrant shall notify the inspectors of the worker's ~~such~~ authorization and shall give the worker's ~~workers'~~ representative an opportunity to accompany the inspectors during the inspection of physical working conditions.
- D. Each ~~worker's~~ ~~workers'~~ representative shall be routinely engaged in work under control of the licensee or registrant or shall have received instructions ~~under as specified in Section R12-1-1003.~~
- E. Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with ~~the conduct of the inspection.~~ However, only 1 ~~worker's~~ ~~workers'~~ representative at a time may accompany the inspectors.
- F. With the approval of the licensee or registrant and the ~~worker's~~ ~~workers'~~ representative an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the ~~worker's~~ ~~workers'~~ representative, shall be afforded the opportunity to accompany Agency inspectors during the inspection of physical working conditions.
- G. Notwithstanding the other provisions of this Section, Agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information the ~~worker's~~ ~~workers'~~ representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, any individual who accompanies an inspector may have access to such information only if authorized ~~otherwise so authorized,~~ by the classifying agency.

R12-1-1006. Consultation with Workers During Inspections ~~workers during inspections~~

- A. ~~A licensee or registrant shall afford Agency inspectors talking to a licensee or registrant representative the opportunity to~~ Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Agency ~~rules, licenses, and registrations~~ ~~regulations and licenses~~ to the extent the inspectors deem consultation necessary for ~~conducting the conduct of~~ an effective and thorough inspection.
- B. During the course of an inspection, any worker may privately bring ~~privately~~ to the attention of the inspectors, either orally or in writing, any past or present condition which ~~the worker~~ ~~he~~ has reason to believe may have contributed to or caused any violation of the Act, these ~~rules, or a license or registration condition,~~ ~~regulations, or license condition,~~ or any unnecessary exposure of an individual to radiation from licensed radioactive material or a registered radiation machine under the licensee's or registrant's control. ~~If this notification is in writing, the worker~~ Any ~~such notice in writing~~ shall comply with the requirements of R12-1-1007(A).
- C. The provisions of ~~R12-1-1006(B)~~ ~~R12-1006(B)~~ shall not be interpreted as authorization to disregard instructions required ~~by pursuant to Section R12-1-1003.~~

R12-1-1007. Inspection Requests by Workers ~~workers for inspection~~

- A. Any worker or representative of workers who believes that a violation of the Act, these ~~rules, regulations or license, or~~ ~~registration~~ conditions exists, or has occurred with regard to radiological working conditions in which the worker is engaged, may request an inspection of the facility by the Agency. Any ~~such~~ request shall be in writing, addressed to the Director, ~~and shall~~ set forth the specific grounds for the request and shall be signed by the worker or representative of the workers. ~~The Agency shall provide a~~ A copy shall be provided to the licensee or registrant ~~by the Agency~~ no later than at the time of inspection except that, upon the request of the worker, ~~the Agency shall protect the worker's~~ ~~his~~ name and the name of individuals referred to ~~in the request therein shall be protected by the Agency~~ to the extent authorized by law, except for good cause shown.
- B. If, upon receipt of a request for inspection ~~such notice~~, the Agency's Director determines that there are reasonable grounds to believe that the alleged violation exists or has occurred, ~~the Director~~ ~~he~~ shall initiate an inspection ~~cause an inspection to be made~~ as soon as practicable, to determine if ~~the~~ ~~such~~ alleged violation exists or has occurred. Inspections performed under pursuant to this subsection need not be limited to matters referred to in the complaint.
- C. ~~A~~ No licensee or registrant shall not discharge or in any manner discriminate against any worker because ~~the~~ ~~such~~ worker has filed any complaint or caused to be instituted any proceeding under these rules ~~regulations~~ or has testified or is about to testify in ~~the instituted~~ ~~any such~~ proceeding or because ~~the worker exercises,~~ ~~of the exercise by such worker~~ on behalf of ~~the worker~~ ~~himself~~ or others, ~~of~~ any option afforded by this Article.

R12-1-1008. Inspection Inspections not Warranted; Review warranted; review

If the Agency determines, with respect to a complaint under R12-1-1007, that an inspection is not warranted or there are no reasonable grounds to believe that a violation exists or has occurred, the Agency shall notify the complainant in writing of ~~the~~ ~~such~~ determination. The complainant may obtain review of ~~the~~ ~~such~~ determination by submitting a written request for hearing

Arizona Administrative Register
Notices of Final Rulemaking

to the Agency. The Agency shall ~~who will~~ provide for a hearing before the Radiation Regulatory Hearing Board under 12 A.A.C. 1, Article 12 ~~in accordance with Article 12 of this Chapter~~ and A.R.S. Title 41, Chapter 6, Article 1.

ARTICLE 12. ADMINISTRATIVE PROVISIONS

R12-1-1209. Notice of Violation

- A. No change.
- B. No change.
- C. The notice shall also specify the License or Registration Division, any proposed sanction and the amount of any proposed civil penalty, unless the civil penalty is ~~proposed to be waived~~ as authorized in pursuant to R12-1-1216(C).

R12-1-1210. Response to Notice of Violation

- A. Except as provided in subsection (D), within 30 ~~calendar~~ calendar days of the date of the notice, or other time specified in the notice therein, the person charged with the violation shall submit a written response which includes a description of:
 - 1. The actions taken to achieve compliance and the results of the actions; therein; or
 - 2. The actions which are proposed to be taken and the date when full compliance is expected to be achieved; and
 - 3. No change.
- B. If the person charged with a violation submits a timely response, the Director, in consideration of the answer and the severity level of the violation, shall do 1 one of the following:
 - 1. Issue an initial order conditionally imposing the full amount of the proposed civil penalty and any other sanctions proposed;
 - 2. Issue an initial order conditionally mitigating or waiving the proposed civil penalty under pursuant to ~~R12-1-1214(B)~~ R12-1-1214(C);
 - 3. Waive the penalty as authorized under pursuant to R12-1-1216(C);
 - 4. Enter into a consent agreement as authorized under pursuant to ~~R12-1-1222~~ R12-1-1221.
- C. If an adequate and timely response is not received to the notice, the Director shall issue an initial order conditionally imposing any or all sanctions and civil penalties proposed in the notice of violation. If no civil penalty was proposed, the initial order may impose the base civil penalty scheduled in R12-1-1216.
- D. No change.

R12-1-1211. Initial Orders

- A. Initial orders are ~~shall be~~ valid for 30 20 calendar days after the date of the order, or until the such other time specified in the order, during which time the person charged may:
 - 1. Pay the civil penalty proposed and accept any proposed sanction, or
 - 2. Request a hearing before the Board.
- B. No change.

R12-1-1212. Request for Hearing in Response to an Initial Order

- A. In a request for a hearing, a person charged with a violation shall include a statement of the issues and the explanations and the arguments supporting denial of the violation or demonstrating extenuating circumstances, errors in notice, or any other reasons for not imposing the civil penalty, sanction, or both. A request for a hearing shall include a statement of the issues relied on by the person charged and whatever explanations and arguments the person charged may have to support a denial of the violation charged or demonstrate extenuating circumstances, errors in the notice, or other reason why the civil penalty and/or sanctions should not be imposed.
- B. The statement shall identify all issues. The failure to include an issue may, at the option of the Board board, foreclose consideration of that issue. If a statement is not provided or is insufficient the Board may summarily determine the issues.
- C. No change.
- D. No change.

R12-1-1213. Severity Levels of Violations

- A. The following violations are classified as severity level I violations:
 - 1. Any failure, malfunction, or insufficiency of a safety system which may result in
 - a. An individual exposure,
 - b. A concentration of radionuclides, or
 - c. A radiation level,in excess of 10 times the limits specified in 12 A.A.C.1, or 10 times the prescribed therapeutic patient dose; resulting in an individual exposure, concentration of radionuclides, radiation level or loss of control over a radiation source which may result in a radiation level in excess of ten times the limits specified in this Chapter, or ten times the prescribed patient dose.
 - 2. ~~Inaccurate or incomplete information~~

- a. Any inaccurate or incomplete information that is intentionally provided by a licensee or registrant official to the Agency ~~deliberately with the knowledge of a licensee or registrant official, and if the information had been complete and accurate at the time it was provided, that the information is incomplete or inaccurate, or~~
 - b. ~~If the information, had it been complete and accurate at the time provided,~~ would have likely resulted in action such as an immediate order required to protect the public health and safety.
3. ~~False information~~
- a. Any information that the Agency requires be kept by a licensee or registrant that is incomplete or inaccurate because of falsification by or with the knowledge of a licensee or registrant official, and if the information had been complete and accurate at the time it was ~~or~~
 - b. ~~If the information, had it been complete and accurate when~~ reviewed by the Agency, would have likely resulted in action such as an immediate order required to protect the public health and safety.
4. Any concealment or attempted concealment of a severity level I violation of the Act, 12 A.A.C.1 ~~this Chapter~~ or a license condition. This ~~is shall be~~ a separate violation ~~and~~ in addition to the original violation.
5. Any concealment or attempted concealment of a severity level II violation of the Act, 12 A.A.C.1 ~~this Chapter~~ or a license condition. This violation shall ~~be expressed as an~~ increase of the severity level of the original violation by 1 level.
6. For the purposes of subsections (2) and (3) above the term "licensee or registrant official" means the owner, a partner, a corporate officer, a radiation safety officer, the individual signing an application for a license or registration, or the chairman of any radiation safety committee supervising the radiation safety program of the licensee or registrant.
- B.** The following violations are classified as severity level II violations:
- 1. Any failure, malfunction, or insufficiency of a safety system which may result in
 - a. An individual exposure,
 - b. A concentration of radionuclides, or
 - c. A radiation level,~~in excess of 2 times the limits specified in 12 A.A.C.1, or 2 times the prescribed therapeutic patient dose resulting in an individual exposure, concentration of radionuclides, radiation level or loss of control over a radiation source which may result in a radiation level in excess of two times the limits specified in this Chapter, or two times a prescribed therapeutic patient dose or three times a diagnostic patient dose.~~
 - 2. No change.
 - 3. Any concealment or attempted concealment of a severity level III violation of the Act, 12 A.A.C.1, this Chapter or a license condition by a licensee or registrant official as defined in subsection (A)(6) ~~above~~. This violation shall ~~be expressed as an~~ increase of the severity level of the original violation by 1 level.
 - 4. No change.
- C.** The following violations are classified as severity level III violations:
- 1. Any failure, malfunction, or insufficiency of a safety system, or loss of control over a radiation source, which may result in:
 - a. An individual exposure,
 - b. A concentration of radionuclides, or
 - c. A radiation level~~in excess of the limits specified in 12 A.A.C.1, or 20% higher than the prescribed therapeutic patient dose, resulting in an individual exposure, concentration of radionuclides, radiation level or loss of control over a radiation source which may result in a radiation level in excess of the limits specified in this Chapter, or greater than 20% of a prescribed therapeutic patient dose.~~
 - 2. Any concealment or attempted concealment of a severity level IV or V violation of the Act, 12 A.A.C.1, this Chapter or a registration or a license condition. This violation shall ~~be expressed as an~~ increase of the severity level of the original violation by 1 level.
 - 3. Any violation of the safety requirements for the use, storage, disposal or the preparation for transportation of sources of radiation, as prescribed in the Act, 12 A.C.C.1, this Chapter or in a license or registration condition, provided the violation does not meet the criteria for a severity level I or II violation and the licensee or registrant does not maintain a radiation protection safety quality assurance program meeting the requirements of R12-1-407 R12-1-1214(A).
 - 4. Any factually incorrect statement, ~~except an accidental misstatement as described in R12-1-1214(B)~~, upon which the Agency relied or would have relied in consideration of any action.
 - 5. Any unlawful attempt to interfere with the progress of an inspection by the Agency.
 - 6. The acquisition of any source of radiation without the applicable current registration or license, unless otherwise authorized by these rules; or use of the source outside the scope of the current registration or license.
 - 7. No change.
- D.** The following violations are classified as severity level IV violations.
- 1. No change.

Arizona Administrative Register
Notices of Final Rulemaking

2. Any violation of the safety requirements for the use, storage, disposal, or preparation for transportation of sources of radiation, prescribed in the Act, 12 A.A.C.1, or in a license or registration condition, provided the violation does not meet the criteria for a severity level I, II or III violation;
 3. Failure to maintain records of mammography quality control tests, listed in Appendix B of 12 A.A.C.1, Article 6.
 2. ~~Any failure of a registrant or licensee to comply with the record keeping or reporting requirements in the Act, rules or any license condition, if as a result of the failure, compliance with a safety requirement cannot be demonstrated.~~
 4. Any failure to comply with the reporting requirements in the Act or 12 A.A.C.1.
- E. The following violations are classified as severity level V violations:
1. Failure of a registrant or a licensee to comply with the record keeping requirements of:
 - a. The Act.
 - b. 12A.A.C.1; or
 - c. A registration or facility certification, or license condition, provided that all safety requirements prescribed in the Act, 12 A.A.C.1, or in a license or registration condition are met or otherwise demonstrated.
 2. If compliance with all safety requirements cannot be demonstrated by the registrant or licensee the failure to comply with the record keeping requirements is classified as a level IV violation.
- E. ~~The following violations are classified as severity level V:~~
1. ~~Any violation of the safety requirements for the use, storage, disposal or the preparation for transportation of sources of radiation, as prescribed in the Act, this Chapter or in a license condition, provided the violation does not meet the criteria for a severity level I or II violation and the licensee or registrant maintains a radiation safety program meeting the mitigating factors of R12-1-1214(A).~~
 2. ~~A failure of a registrant or licensee to comply with the record keeping or reporting requirements in the Act, this Chapter or any license condition, if compliance with all safety requirements can be otherwise demonstrated.~~

R12-1-1214. Mitigating Factors

- A. ~~The Agency may refrain from issuing a Notice of Violation for a Severity Level V violation that is documented in an inspection report provided the report includes a brief description of the corrective action and that the violation meets all of the following:~~
1. ~~It was not a violation that could reasonably be expected to have been prevented by the licensee's or registrant's corrective action for a previous violation or a previous licensee or registrant finding;~~
 2. ~~It was or will be corrected within the time given for correction, by specific corrective action committed to by the licensee or registrant by the end of the inspection, including immediate corrective action and comprehensive corrective action to prevent recurrence;~~
 3. ~~It was not a willful violation.~~
- B.A.** ~~The Agency may refrain from issuing a Notice of Violation for Severity Level IV or V violations identified by the registrant or licensee provided the severity level IV or V violations are identified in an inspection report, ~~and~~ the report includes a brief description of the corrective action, and that the violation meets all of the following criteria:~~
1. ~~It was identified by the licensee, as a result of an event discovered by the licensee or registrant;~~
 2. ~~It was not a violation that could reasonably be expected to have been prevented by the licensee's or registrant's corrective action for a previous violation or a previous licensee or registrant finding;~~
 3. ~~It was or will be corrected within a reasonable time, by specific corrective action committed to by the registrant or licensee or registrant by the end of the inspection. The corrective action shall include comprehensive measures that will prevent reoccurrence; ~~including immediate corrective action and comprehensive corrective action to prevent recurrence;~~~~
 4. ~~It was not a willful violation or if it was willful;~~
 - a. ~~The violation was reported to the Agency;~~
 - b. ~~The violation appears to be the isolated action of an employee without management involvement and the violation was not caused by lack of management oversight;~~
 - c. ~~Significant remedial action was taken by the licensee or registrant, demonstrating such that it demonstrates the seriousness of the violation to all affected personnel.~~
- B.C.** ~~The Director may ~~shall~~:~~
1. ~~Reduce the scheduled civil penalty, including any augmentation, by 50% for the discovery, remedy, and voluntary reporting of a severity level I or II ~~severity level I, II or III~~ violation by the registrant or licensee; or -~~
 2. ~~Waive the scheduled civil penalty, including augmented civil penalties, for the discovery, remedy, and voluntary reporting of a severity level III, IV, or V ~~severity level IV or V~~ violation by the registrant or licensee. For the purposes of this rule, "voluntary reporting" means that the the registrant or licensee has notified the Agency of a violation, the reporting of which, may or may not be required under 12A.A.C.1~~

R12-1-1215. License and Registration Divisions

- A. ~~Each registrant or license type is ~~shall be~~ classified into 1 ~~one of 3~~ ~~three~~ administrative sanction divisions.~~
1. Division I licenses and registrations:

Arizona Administrative Register

Notices of Final Rulemaking

Broad Academic Class A
Broad Academic Class B
Broad Academic Class C
Broad Industrial Class A
Broad Medical
Distribution
Class C Laser Facility
Fixed Gauge Class A
Industrial Radiography Class A
Low Level Radioactive Waste Disposal Site
NORM Commercial Disposal Site

2. Division II licenses and registrations:

Broad Industrial Class B
Broad Industrial Class C
Class B Industrial Radiofrequency Facility
Class B Laser Facility
Class C Industrial Radiofrequency Facility
Fixed Gauge Class B
Health Physics Class A
Self Shielded Irradiator
Industrial Radiation Machine
Industrial Radiography Class B
NORM Commercial Disposal Site

3. Division III licenses and registrations:

Class A Laser Facility
Class A Industrial Radiofrequency Facility
Depleted Uranium
Class C
Gas Chromatograph
General Depleted Uranium
General Industrial
General Medical
General Veterinary Medicine
Health Physics Class B
Laboratory
Radioactive waste transfer-for-disposal

Major Accelerator Facility
Medical Materials Class A
Medical Teletherapy
Nuclear Laundry
Nuclear Pharmacy
Open Field Irradiator
Secondary Uranium Recovery
Waste Processor Class A
Well Logging
X-Ray Machine Class A

Laser Light Show
Limited Academic
Medical Imaging Facility
Medical Laser
Medical Materials Class B
Medical Radiofrequency Device Facility
Research and Development

Tanning Facility
Waste Processor Class B
X-Ray Machine Class B

Leak Detector
Limited Industrial
Medical Materials

Other Radiation Machine
Portable Gauge
Possession Only
Unclassified
Veterinary Medicine
X-ray Machine Class C
Reciprocal

1. ~~Division I licenses and registrations shall be Broad Academic Class A; Broad Academic Class B; Broad Academic Class C; Broad Medical; Medical Materials Class A; Medical Teletherapy; Broad Industrial Class A; Fixed Gauge Class A; Industrial Radiography Class A; Open Field Irradiator; Well Logging; Distribution; Nuclear pharmacy; Nuclear Laundry; Secondary Uranium Recovery; Low Level Radioactive Waste Disposal Site; Waste Processor Class A; X ray Machine Class A; Major Accelerator Facility; Class C Laser Facility;~~

2. ~~Division II licenses and registrations shall be Limited Academic; Medical Materials Class B; Broad Industrial Class B; Broad Industrial Class C; Fixed Gauge Class B; Industrial Radiography Class B; Self Shielded Irradiator; Health Physics Class A; Waste Processor Class B; X ray Machine Class B; Industrial Radiation Machine; Tanning Facility; Class B Laser Facility; Medical Laser Facility; Medical Radiofrequency Device Facility; Laser Light Show; Medical Imaging Facility; Class B Industrial Radiofrequency facility; Class C Radiofrequency Facility.~~

3. ~~Division III licenses and registrations shall be Medical Materials Class C; General Medical; Limited Industrial; Portable Gauge; Leak Detector; Gas Chromatograph; General Industrial; Depleted Uranium; General Depleted Uranium; Veterinary Medicine; General Veterinary Medicine; Health Physics Class B; Possession Only; X ray Machine Class C; Class A Laser Facility; Class A Radiofrequency Facility; Other Radiation Machine; Unclassified.~~

B. Any person required by the Act to register the use of a general license with the Agency, or to obtain a specific license from the Agency, ~~is shall be~~ considered a licensee of the appropriate type notwithstanding the failure of the person to register or obtain a license.

C. Out-of-state licensees issued a general license for reciprocal recognition ~~under pursuant to R12-1-321 R12-01-321~~ are ~~shall be~~ classified in accordance with an appropriate specific license type defined in R12-1-1302.

D. For administrative purposes, the following individuals are classified with the Division III licensees and registrants in subsection (A)(3):

1. Any individual not required to register the use of a general license;

2. Any individual not required to obtain a specific license;

Arizona Administrative Register
Notices of Final Rulemaking

3. Any individual not required to register a source of radiation who violates the Act or 12A.A.C.1; and
4. Any x-ray machine servicing registrant.

For the purposes of this Article, an individual who is not required to register the use of a general license or to obtain a specific license shall be classified as a Division III licensee.

R12-1-1216. Base Schedule of Civil Penalties

A. Except as augmented by R12-1-1217, the schedule of civil penalties ~~is shall~~ be as follows:

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

B. Payment of civil penalties for severity level I and severity level II violations may not be avoided merely by rectifying the condition; however, the Board may mitigate or waive the penalty upon determining a violation meets all of the following:

1. It was not a violation that could reasonably be expected to have been prevented by the licensee's or registrant's corrective action for a previous violation or a previous licensee or registrant finding;
2. It was or will be corrected within the time given for corrections, by specific corrective action committed to by the licensee or registrant by the end of the inspection, which includes including immediate corrective action and comprehensive measures corrective action to prevent recurrence;
3. It was not a willful violation.

C. The Director or Board shall waive payment ~~Payment~~ of penalties for severity level ~~levels~~ III through severity level V violations ~~will be waived by the Director or the Board~~ provided:

1. The violation is not subject to augmentation under pursuant to R12-1-1217, and
2. The registrant or licensee submits a timely and adequate response to the notice, rectifies the conditions which appear to have caused the violation, and ~~otherwise~~ complies with the Act, 12 A.A.C.1, registration, this Chapter, and license conditions, or takes steps acceptable to the Director to ensure compliance.

R12-1-1217. Augmentation of Civil Penalties

A. A continuing violation ~~is shall~~, for the purposes of calculating the proposed civil penalty, ~~be~~ considered a separate violation for each day it continues of its continuance. The 2nd (or successive) day of a continuing violation ~~is not shall not be~~ considered a repeat violation of the violation occurring on the 1st first day.

B. If a 2nd severity level I violation is committed within 5 five years, the Agency shall increase the base scheduled civil penalty ~~shall be increased~~ by 100%, provided the license is not revoked under pursuant to R12-1-1219.

C. If a ~~2nd second~~ severity level II violation is committed within a period of 5 five years, the Agency shall increase the base scheduled civil penalty ~~by shall be increased~~ 50%, provided the registration or license is not revoked under pursuant to R12-1-1219.

D. If a severity level III violation is repeated within 5 five years, the Agency shall increase the base scheduled civil penalty ~~by shall be increased~~ 50%. ~~The penalty may not be avoided merely by achieving compliance.~~ If the same severity level III violation is repeated a 2nd second time within 5 five years, the base scheduled civil penalty shall be increased by 100%, provided the registration or license is not revoked under pursuant to R12-1-1219.

E. If a severity level IV violation is repeated within 5 five years, the Agency shall propose the base scheduled civil penalty ~~shall be proposed.~~ ~~The penalty may not be avoided merely by achieving compliance.~~

1. If the same violation occurs 3 times, ~~is repeated a second time~~ within 5 five years, the Agency shall increase the base scheduled civil penalty ~~shall be increased~~ by 50%. ~~The penalty may not be avoided merely by achieving compliance.~~

2. If the same violation ~~occurs 4 times is repeated a third time~~ within 5 five years, the Agency shall increase the base scheduled civil penalty shall be increased by 100%, provided the registration or license is not revoked under pursuant to R12-1-1219.
- ~~F. If a severity level V violation is repeated within five years, the base scheduled amount of the civil penalty shall be proposed. The penalty may be avoided by prompt and effective actions to achieve compliance. If the violation is repeated more than once within five years, the scheduled amount of the civil penalty shall be increased by 50% for each subsequent violation and may not be avoided merely by achieving compliance.~~
- ~~E. If greater than 3 severity level V violations are observed during 2 consecutive inspections, the Agency shall impose a civil penalty for each violation. The base civil penalty for each violation is the base scheduled civil penalty assessed for a severity level V violation. If the inspection shows repetition of a violation the base civil penalty for each repeat violation is the base scheduled civil penalty assessed for a severity level IV violation. Subsection (E) does not apply to penalties under this subsection.~~
- ~~G. Other rights and procedures are not shall not be affected by the repeat nature of a the violation. In no case shall a civil penalty be proposed which exceeds the limits specified in A.R.S. § 30-687(C).~~
- ~~H. A person may avoid the The penalties in subsections (D),(E) and (F) and (E) above, may be avoided by demonstrating showing to the Director in the response to the to proposed civil penalty that the violation meets all of the following criteria:~~
 1. It was not a violation that could reasonably be expected to have been prevented by the licensee's or registrant's corrective action for a previous violation or a previous licensee or registrant finding;
 2. It was or will be corrected within the time given for correction, by specific corrective action committed to by the licensee or registrant by the end of the inspection, which includes including immediate corrective action and comprehensive measures corrective action to prevent recurrence;
 3. It was not a willful violation.
- ~~I. Notwithstanding any other provision of this section, the Agency shall not impose a no penalty that exceeds shall exceed a maximum of \$5,000 five thousand dollars for each violation for each day up to a maximum of \$25,000 for any 30-day twenty five thousand dollars for any thirty day period.~~

R12-1-1218. Payment of Civil Penalties

- ~~A. A person shall pay Payment of civil penalties imposed under this Article shall be made by certified check or money order payable to the Agency, and mailed or delivered to the Agency at the address shown on the notice of violation.~~
- ~~B. Payment of a civil penalty is Payment shall be due 30 calendar days after the effective date of the final order imposing the civil penalties, unless an alternate payment schedule is agreed upon before that date. A No payment schedule shall not extend beyond 1 one year after the due date.~~

R12-1-1219. Additional Sanctions - Show Cause

- ~~A. If a severity level I violation is repeated or if any 2nd second severity level I violation is committed within 10 ten years, the Agency shall require the registrant or licensee shall be required to show cause why the license should not be suspended or revoked.~~
- ~~B. If any 2nd second severity level II violation is committed within 5 five years, or if a severity level II violation involving radioactive effluent releases, excessive radiation levels, or radiation overexposure to an individual is committed within 5 five years of a similar severity level I violation, the Agency shall require the registrant or licensee shall be required to show cause why the license should not be suspended or revoked.~~
- ~~C. If repeated or different severity level III violations are committed on 3 three separate occasions within any 5 five year period, the Agency may require the registrant or licensee shall be required to show cause why the license should not be suspended or revoked.~~

R12-1-1220. Escalated Enforcement

- ~~A. The Director may issue an order to suspend or modify a registration or license, or impound a radiation source for impounding the radiation source or suspending or modifying the registration or license at the same time as or prior to issuing a notice of violation for:~~
 1. Any severity level I violation, or
 2. Any of the following occurring within a 5 five year period:
 - a. A repeat severity level II violation,
 - b. A different 2nd second severity level II violation, or
 - c. A severity level II violation after a severity level I violation.
- ~~B. The Director may issue an order impounding the radiation source or suspending or modifying the registration or license at any time upon determining that conditions exist which cause a potential for a severity level I or severity level II violation.~~
- ~~C. The Agency shall hold hearings according to Hearings shall be held in accordance with A.R.S. § 30-688.~~
- ~~D. An order to impound a radiation source, or an order to suspend, or modify a registration or a license of impoundment or registration license suspension or modification shall remain in effect until the order is suspended or modified by the Board according pursuant to A.R.S. § 30-688.~~

Arizona Administrative Register
Notices of Final Rulemaking

R12-1-1222. Enforcement Conferences

- A. An enforcement conference ~~consists shall consist~~ of a meeting in person between management personnel of the registrant or licensee and the Agency.
- B. The enforcement conference ~~is shall be~~ informal, however the Agency shall make a record of items discussed and decisions reached ~~shall be made~~. Statements made at the conference shall not be introduced in evidence at a formal hearing unless all parties have consented.
- C. Based on the results of the conference, the Agency may:
 - 1. Dismiss the notice of violation; ~~or;~~
 - 2. Enter into a consent agreement; or
 - 3. ~~2.~~ Continue with, or initiate, formal proceedings.

ARTICLE 13. LICENSE AND REGISTRATION FEES

R12-1-1301. Definition

“Combined” means the ~~Agency has granted authorized activities granting of the authorities~~ contained in 2 two or more license types in a single license document, ~~and requiring the payment only of a single license fee for the more expensive license of the planned combination~~ license of the highest cost type of licenses combined.

R12-1-1302. License and Registration Categories ~~Types of Licenses and Registrations~~

- A. Category A licenses ~~are shall be~~ those specific licenses which authorize a school, college, university, or other teaching facility to possess and use radioactive materials for instructional or research purposes. ~~A category A license may not be combined with any other type of license.~~
 - 1. A broad academic class A license is any category A license which meets the specifications of R12-1-310(A)(1) ~~R12-1-310(G)(1)~~.
 - 2. A broad academic class B license is any category A license other than a broad academic class A license which meets the specifications of R12-1-310(A)(2) ~~R12-1-310(G)(2)~~.
 - 3. A broad academic class C license is any category A license other than a broad academic class A or B license which meets the specifications of R12-1-310(A)(3) ~~R12-1-310(G)(3)~~.
 - 4. A limited academic license is any category A license which authorizes only those radioisotopes, forms, and quantities individually specified in the license.
- B. Category B licenses ~~are those shall consist of~~ specific or general licenses which authorize the application of radioactive material or the radiation ~~from it therefrom~~ to a human being for medical diagnostic, therapeutic, or research purposes, or the use of radioactive material in medical laboratory testing. Except for a type B6, general medical license, the Agency shall not combine a category B license ~~may not be combined~~ with a license of any other category.
 - 1. A broad medical license is any category B license which meets the specifications of R12-1-310(A)(1) ~~R12-1-310(G)(1)~~ and meets the requirements of 12 A.A.C. 1, Article 7 ~~rather than the requirements of R12-1-310(G)(2)~~. A broad medical license may authorize any medical use other than teletherapy.
 - 2. A medical materials class A license is any specific category B license, other than a broad medical license, which authorizes the use of radiopharmaceuticals and sealed sources containing radioactive materials for a therapeutic purpose in quantities which require hospitalization of the patient for radiation safety purposes. The license may authorize other radioactive materials and other medical uses, except teletherapy, ~~in addition to the above.~~
 - 3. No change.
 - 4. No change.
 - 5. A medical teletherapy license is a specific category B license which solely authorizes radioisotopes in the form of multi-curie sealed sources for use in external beam therapy. The Agency shall not combine a ~~A~~ medical teletherapy license ~~may not be combined~~ with any other type of category B license.
 - 6. No change.
- C. Category C licenses ~~are those shall consist of~~ specific or general licenses authorizing the use of radioactive materials in any activity other than those authorized by a category A, B, or D license. Except as specifically authorized in this Section, The Agency shall not combine a category C license ~~may not be combined~~ with any other type of license.
 - 1. A broad industrial class A license is any category C license which meets the specifications of R12-1-310(A)(1) ~~R12-1-310(G)(1)~~. The Agency may combine a ~~A~~ broad industrial class A license ~~may be combined~~ with any other category C license except industrial radiography, open field irradiator, or well logging licenses.
 - 2. A broad industrial class B license is any category C license other than a broad industrial class A license which meets the specifications of R12-1-310(A)(2) ~~R12-1-310(G)(2)~~. The Agency may combine a ~~A~~ broad industrial class B license ~~may be combined~~ with any other category C license except industrial radiography, open field irradiator, or well logging licenses.
 - 3. A broad industrial class C license is any category C license other than a broad industrial class A or B license which meets the specifications of R12-1-310(A)(3) ~~R12-1-310(G)(3)~~. The Agency may combine a ~~A~~ broad industrial class C license ~~may be combined~~ with any other category C license except industrial radiography, open field irradiator, or well logging licenses.

Notices of Final Rulemaking

4. No change.
 5. A portable gauge license is a specific category C license which authorizes radioactive materials in the form of sealed sources for use in measuring or gauging devices designed and manufactured to be transported to the location of use. The Agency may combine a ~~A~~ portable gauge license ~~may be combined~~ with any broad scope industrial license or a fixed gauge class A license.
 6. A fixed gauge class A license is a specific category C license which authorizes the possession of 50 or more measuring or gauging devices containing radioactive materials, ~~and~~ where each device is permanently mounted for use at a single location.
 7. A fixed gauge class B license is a specific category C license which authorizes the possession of 1 through 49 measuring or gauging devices containing radioactive materials, ~~and~~ where each device is permanently mounted for use at a single location.
 8. No change.
 9. No change.
 10. No change.
 11. No change.
 12. No change.
 13. No change.
 14. A self-shielded irradiator license is a specific category C license authorizing the use radioisotopes in the form of sealed sources for irradiation of materials in a shielding device from which the sources are not removed during irradiation. The Agency may combine a ~~A~~ self-shielded irradiator license ~~may be combined~~ with any broad industrial ~~broad~~ license.
 15. No change.
 16. A research and development license is a specific category C license which authorizes a licensee to utilize radioactive material in unsealed and sealed form for industrial, scientific, or biomedical research, not including administration of radiation or radioactive material to human beings.
 17. A laboratory license is a specific category C license which authorizes a licensee to perform specific in-vitro or in-vivo medical or veterinary testing, while possessing quantities of radioactive material greater than the general license quantities authorized in R12-1-306.
- D.** Category D licenses are the following specific radioactive material licenses. Except for type D4, depleted uranium; type D8 and D9, health physics; and type D14, additional facilities licenses, the Agency shall not combine a category D license ~~may not be combined~~ with any other license.
1. A distribution license is one which, ~~except as noted,~~ authorizes the commercial distribution of radioactive materials or radioisotopes in products to persons holding an appropriate general or specific license. The Agency shall ensure that a distribution license does not:
 - a. Authorize ~~A distribution license shall not authorize~~ distribution of radiopharmaceuticals or distribution to persons exempt from regulatory control; or
 - b. Authorize ~~A distribution license shall not authorize~~ any other use of the radioactive material. An appropriate category C license ~~is~~ shall be required for possession of radioisotopes and their incorporation into products.
 2. No change.
 3. No change.
 4. A depleted uranium license is one which authorizes the use of depleted uranium as a concentrated mass or as shielding for other radiation sources within a device or machine. The Agency may combine ~~A~~ depleted uranium license ~~may be combined~~ with a medical teletherapy license; a broad industrial A, B or C license; a portable gauge license; a fixed gauge class A or B license; an industrial radiography class A or B license; or a self-shielded irradiator license..
 5. No change.
 6. No change.
 7. No change.
 8. A health physics class A license is one which authorizes the use of radioactive materials for performing ~~to perform~~ instrument calibrations, ~~the processing of~~ leak test or environmental samples, or providing ~~the provision of~~ radiation dosimetry services.
 9. No change.
 10. A secondary uranium recovery license is one which authorizes the extraction of natural uranium or thorium from an ore stream or tailing which is being or has been processed primarily for the extraction of another mineral. The Agency shall not combine a ~~A~~ secondary uranium recovery license ~~may not be combined~~ with any other license.
 11. A low-level, radioactive waste, ~~land~~-disposal facility license is ~~1 one~~ which is issued for a "~~land~~ disposal facility" as that term is used in R12-1-439 and R12-1-442 ~~R12-1-430 and R12-1-431~~; is constructed and operated according to the requirements in ~~in accordance with~~ 10 CFR 61, 1998 ~~1996~~ Edition, published January 1, 1998 ~~1996~~, incorporated by reference and on file with the Agency and the Office of the Secretary of State, containing no future editions or amendments; and has ~~having~~ a closure or long-term care plan meeting the requirements of 10 CFR 61.

12. A waste processor class A license is one authorizing the incineration, compaction, repackaging, or any other treatment or processing of low-level radioactive waste prior to transfer to another person authorized to receive or dispose of the waste. The Agency shall not combine a A waste processor class A license may not be combined with any other license.
 13. A waste processor class B license is one which authorizes a waste broker to receive prepackaged, low-level radioactive waste from other licensees; combine the waste into shipments; and transfer the waste without treating or processing the waste in any manner and without repackaging except to place damaged or leaking packages into overpacks. The Agency shall not combine a A waste processor class B license may not be combined with any other license.
 14. No change.
 15. A possession-only license is a license of any other category which authorizes only the possession in storage, but no use of, the authorized materials. A license which has been suspended as an enforcement action is not shall not be considered a possession-only license.
 16. No change.
 17. A radioactive waste transfer-for-disposal license is an authorization for the generator of radioactive waste to transfer the radioactive waste for disposal at a licensed disposal site under R12-1-439 and R12-1-442. This license is subject to a special fee as provided by R12-1-1307 but is exempt from annual fees.
 18. No change.
 19. A NORM commercial disposal site license is one that authorizes the receipt of waste material contaminated with naturally occurring radioactive material from other licensees for permanent disposal, provided the concentration of the radioactive material does not exceed 74kBq (2,000 picocuries)/gram.
- E. Category E registrations and licenses are those that register the possession of x-ray equipment or license the use of non-ionizing radiation producing equipment a radiation machine under pursuant to 12 A.A.C. 1, Article 2 or 14 of this Chapter. The Agency shall not combine Category E registrations or licenses may not be combined with any other registration or license.
1. An X-ray machine class A registration is one authorizing the possession of X-ray machines and particle accelerators in a hospital or other facility offering inpatient care.
 2. An X-ray machine class B registration is one authorizing the possession of X-ray machines and particle accelerators in a medical, osteopathic, or chiropractic office or clinic not offering inpatient care; or the possession of X-ray machines in a school, college, university, or other teaching facility.
 3. No change.
 4. No change.
 5. No change.
 6. No change.
 7. A class A laser facility license is one which authorizes the operation of 1 to 10 one to ten laser systems subject to R12-1-1433.
 8. No change.
 9. No change.
 10. No change.
 11. No change.
 12. No change.
 13. No change.
 14. A class A industrial radiofrequency device facility license is one authorizing 1 to 5 one to five radiofrequency heat sealers or industrial microwave ovens.
 15. No change.
 16. No change.
 17. No change.

R12-1-1303. Fee for Initial License and Initial Registration

An applicant shall remit for a new license or new registration. An application for a new license or registration shall be accompanied by the appropriate fee as prescribed in R12-1-1306, except that the fee will be prorated on a quarterly basis for applications submitted after March 31.

R12-1-1304. Annual Fees for Licenses and Registrations

- A. No change.
- B. No change.
- C. If a licensee or registrant fails to pay the annual fee by January 1, the license is shall be deemed not current.
- D. If a licensee or registrant fails to pay the annual fee by April 1, the Agency shall apply administrative sanction provisions of 12 A.A.C. 1, Article 12 of this Chapter shall be applied.

Notices of Final Rulemaking

R12-1-1305. Method of Payment

- A. ~~An applicant licensee or registrant shall pay fees~~ Payment of fees shall be by check or money order, payable to the “State of Arizona” at the address shown on the application, license, registration, or renewal notice.
- B. No change.

R12-1-1306. ~~Table Schedule of Fees~~

- A. The application and annual fee for each category type are as shown in Table 13-1.

Table 13-1

Category	Type	Annual fee
A1. Broad academic class A	\$2,600
A2. Broad academic class B	\$1,500
A3. Broad academic class C	\$1,200
A4. Limited <u>academic</u>	\$600
B1. Broad medical	\$1,650
B2. Medical materials class A	\$1,400
B3. Medical materials class B	\$1,000
B4. Medical materials class C	\$500
B5. Medical teletherapy	\$1,650
B6. General medical	\$75
C1. Broad industrial class A	\$2,200
C2. Broad industrial class B	\$1,600
C3. Broad industrial class C	\$1,250
C4. Limited industrial	\$500
C5. Portable gauge	\$500
C6. Fixed gauge class A	\$800
C7. Fixed gauge class B	\$500
C8. Leak detector	\$500
C9. Gas chromatograph	\$300
C10. General industrial	No Fee
C11. Industrial radiography class A	\$1,650
C12. Industrial radiography class B	\$1,500
C13. Open field irradiator	Full Cost
C14. Self-shielded irradiator	\$600
C15. Well logging	\$1,750
C16. <u>Research and Development</u>	<u>\$750</u>
C17. <u>Laboratory</u>	<u>\$600</u>
D1. Distribution	\$2,150
D2. Nuclear pharmacy	\$2,150
D3. Nuclear laundry	\$2,250
D4. Depleted uranium	\$100
D5. General depleted uranium	\$75
D6. Veterinary medicine	\$500
D7. General veterinary medicine	\$75
D8. Health Physics class A	\$600
D9. Health physics class B	\$450
D10. Secondary uranium recovery	\$4,000
D11. Low-level radioactive waste	
 Disposal Site	<u>(3) Full Cost</u>
D12.	Waste processor class A . .	\$2,250
D13.	Waste processor class B . .	\$500

Arizona Administrative Register

Notices of Final Rulemaking

D14.	Additional facility	(1)
D15.	Possession only	(2)
D16.	<u>Reciprocal</u>	(3)
D17.	<u>Radioactive waste transfer-for-disposal</u>	(3)
D18.	Unclassified	Full Cost
D19.	<u>Norm commercial disposal site</u>	<u>\$200,000</u>
E1.	X-ray machine Class A (per tube)	\$64
E2.	X-ray machine class B (per tube)	\$44
E3.	X-ray machine class C (per tube)	\$36
E4.	Industrial radiation machine (per device)	\$36
E5.	Major accelerator facility .	Full Cost
E6.	Tanning facility (per device)	\$24
E7.	Class A laser facility	\$150
E8.	Class B laser facility	\$350
E9.	Class C laser facility	\$600
E10.	Laser light show	\$350
E11.	Medical laser facility (per laser system)	\$40
E12.	Medical RF device facility (per unit)	\$40
E13.	Medical imaging facility (per unit)	\$50
E14.	Class A industrial radiofrequency facility	\$60
E15.	Class B industrial radiofrequency facility	\$180
E16.	Class C industrial radiofrequency facility	\$300
E17.	Other radiation machine . .	Full Cost

- Notes: (1) 20% of the base fee for each additional site, not to exceed 100% additional for all sites.
 (2) 50% of the annual fee for the license type required for full use of the stored radioactive materials.
 (3) See R12-1-1307.

- B.** The annual fee for a license or registration for which the scheduled fee is "Full Cost" ~~is shall be~~ approximately 18% of the full actual cost to the Agency for the personnel, consultants, facilities, equipment, supplies, and transportation used in evaluating the original application. The cost of all ~~All~~ applications for amendments and all regular inspections during the ~~5~~ five-year normal life of the license or registration, is calculated as follows:
1. The application fee ~~is shall be~~ based on estimates of the cost which are shall in turn be based on consideration of (in order of preference):
 - a. No change.
 - b. No change.
 - c. No change.
 2. Annual fees for the ~~2nd second~~ through ~~4th fourth~~ years are shall be determined by recalculation of the estimate made under subsection (B)(1) pursuant to paragraph (1) above, considering the actual cost based on experience in previous years and any revision of the estimated future costs.
 3. The fee for the ~~5th fifth~~ year is shall be 22.5% of the total actual cost to the Agency to issue and service the license or registration over the ~~1st first 4 four~~ years of the license.

R12-1-1307. Special License Fees

- A.** The fee for a Type D16 license providing reciprocal recognition under R12-1-320 of a radioactive materials license issued by the U.S. NRC or another state is ½ shall be one-half of the annual fee for an Arizona license of the appropriate type. The fee is shall be due and payable at the time reciprocity is requested, and the general license does shall not become current until the fee is paid.

Notices of Final Rulemaking

- B.** The fee for a Type D17 radioactive waste transfer-for-disposal license is ~~any person requiring certification of the packaging of Low-level Radioactive Waste for disposal shall be~~ \$2.50 per cubic foot of waste transferred, including packaging.

 - 1. A standard 55-gallon drum waste package ~~is shall be~~ considered to be 7 1/2 cubic feet of waste.
 - 2. The fee ~~is shall be~~ due at the time the waste is shipped, unless a prior written agreement between the licensee and the Agency is in effect. The total fee due shall be paid to the Agency in accordance with R12-1-1305(A).
- C.** For a low-level radioactive waste disposal site the initial application fee is \$3,000,000. The annual fee for the 2nd through 5th years is \$3,000,000. The Agency shall promulgate a new fee rule for years subsequent to year 5. Based on data gathered during the 1st 5 years, the Agency shall set a reasonable fee after consideration of the following factors:

 - 1. Unrecovered costs which the Agency may charge under A.R.S. §30-654(B)(18).
 - 2. Actual costs incurred by the Agency.

R12-1-1308. Fee for Requested Inspections

- A.** A licensee or registrant may request an inspection of its facility at any time. The Agency ~~shall will~~ bill the licensee or registrant 90% of the full cost of the inspection, based on personnel time for preparation, travel, on-site inspection, review of findings, and preparation of a report, charged at \$25 per hour and mileage charged at 25¢ per mile.
- B.** No change.

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

R12-1-1309. Abandonment of License or Registration Application

- A.** Any license or registration application for which the applicant has been provided a written notification of deficiencies in the application and for which the applicant does not make a written attempt to supply the requested information or request an extension in writing within 90 days of the date of the written notice of deficiencies, is considered abandoned and will not be processed.
- B.** If an applicant does not act in the time-frame specified in subsection(A), the applicant shall submit a new application with the appropriate fee.