

NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Due to time restraints, the Secretary of State's Office will no longer edit the text of proposed rules. We will continue to make numbering and labeling changes as necessary.

Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for adoption, amendment, or repeal of any rule. A.R.S. §§ 41-1013 and 41-1022.

NOTICE OF PROPOSED RULEMAKING

TITLE 2. ADMINISTRATION

CHAPTER 1. DEPARTMENT OF ADMINISTRATION

PREAMBLE

1. Sections Affected

R2-1-501
R2-1-502
R2-1-503
R2-1-504
R2-1-505

Rulemaking Action

Repeal
Repeal
Repeal
Repeal
Repeal

2. The specific authority for the rulemaking, including both the implementing and authorizing statutes.

Authorizing statute: A.R.S. § 41-703(3)

Implementing statute: A.R.S. § 41-1027(A)(1)

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

Notice of Rulemaking Docket Opening, 6 AAR 1915, May 26, 2000

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

Name: Mr. William E. Parker, Assistant Director

Address: ADOA Information Services Division
1616 West Adams St.
Phoenix, Arizona 85007

Telephone: (602) 542-2250

Fax: (602) 542-4272

5. An explanation of the rule, including the agency's reason for initiating the rule:

In October of 1985 the Arizona Department of Administration, Data Management Division promulgated rules for the planning and acquisition of automation technologies. The rules are contained in 2 A.A.C. 1, Article 5 of the Arizona Administrative Code (see A.A.C. R2-1-501 through R2-1-505). These rules have not been updated since 1985.

A.R.S. § 41-3504(A)(1)(f), enacted in 1996, transfers the authority to evaluate and approve or disapprove budget unit information technology plans to the Government Information Technology Agency. At the same time A.R.S. § 41-712 and A.R.S. § 41-714 were repealed effective July 1, 1997 and removed the planning and acquisition requirements and oversight requirements from the ADOA.

This rule repeal is necessary because the Government Information Technology Agency authority supersedes ADOA's authority.

6. 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

7. 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:

A showing of good cause is not applicable.

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

Exempt pursuant to A.R.S. § 41-1055(D)(3)

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

This is not applicable in this instance.

10. The time, place and nature of the proceedings for the adoption, amendment, or repeal of the rule:

No oral proceedings are scheduled on the repeal of these rules. An oral proceeding will be scheduled if a written request is submitted to the person identified in item 4 within 30 days after publication of this notice.

Comments regarding the repeal can be made to the person listed in item 4 of this document.

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

None

12. Incorporations by reference and location in the rules:

None

13. The full text of the rules follows:

TITLE 2. ADMINISTRATION

CHAPTER 1. ARIZONA DEPARTMENT OF ADMINISTRATION

ARTICLE 5. ~~AUTOMATION PLANNING AND ACQUISITION~~ REPEALED

Section

- R2-1-501. ~~Definitions~~ Repealed
R2-1-502. ~~Submission of plan~~ Repealed
R2-1-503. ~~Plan approval~~ Repealed
R2-1-504. ~~Modification of an approved plan~~ Repealed
R2-1-505. ~~Acquisition of automation equipment and services~~ Repealed

ARTICLE 5. ~~AUTOMATION PLANNING AND ACQUISITION~~ REPEALED

R2-1-501. ~~Definitions~~ Repealed

~~In this Chapter, unless the context otherwise requires:~~

- ~~1. "Agency" means any department, board, office, authority, commission, or any other state service organization served by the Department of Administration.~~
- ~~2. "Assistant Director" means the Assistant Director for the Department of Administration Data Management Division.~~
- ~~3. "Automation plan" means a document that describes the automation goals and objectives and defines the program of action to achieve the desired goals~~
- ~~4. "Computer equipment" means programmable electronic devices that can store, retrieve, and process data or text, including terminal devices and other peripheral units connected to used in support of the computer.~~
- ~~5. "Computer services" means services received from another person to assist with any function relating to the acquisition or use of computer equipment.~~
- ~~6. "Computer software" means computer programs, procedures, and related documentation associated with the operation of computer equipment.~~
- ~~7. "Data communications" means equipment or software used to transmit or receive data between computer equipment devices.~~
- ~~8. "Acquisition" relates to the procurement of all data processing, word processing, and data communications equipment services by purchase or lease, regardless of the funding source.~~

Arizona Administrative Register
Notices of Proposed Rulemaking

R2-1-502. Submission of plan Repealed

Each state agency shall submit a three year automation plan to the Department of Administration, Data Management Division by October 1st of each year. The three year period shall include the current fiscal year and at least the next two fiscal years. The plan shall be consistent with the State Automation Plan and shall include, as a minimum, the following major sections or it shall be considered incomplete and may be disapproved by the Assistant Director.

1. ~~Introduction. A brief description of the plan, including a discussion of the key events that have occurred since the last plan and that are expected to have a major impact on future plans.~~
2. ~~Accomplishments. A brief description of major accomplishments during the previous year.~~
3. ~~Agency goals. A brief description of agency plans or goals, that will have a substantial impact on automation and communication requirements.~~
4. ~~Assumptions. A list of assumptions upon which planning decisions are based.~~
5. ~~Specific automation objectives. A list of specific automation objectives with planned completion dates.~~
6. ~~Strategies. A brief description of the major steps necessary to accomplish the objectives.~~
7. ~~Appendices. Supplemental information such as equipment configuration charts, budget data and organizational charts.~~

R2-1-503. Plan approval Repealed

- ~~A. The Assistant Director shall approve or disapprove the plan, in writing, within 30 days of receipt. If disapproved, the Assistant Director shall set forth the reasons for disapproval.~~
- ~~B. If the plan is disapproved, a revised plan shall be resubmitted within 30 days of receipt of the disapproval notice.~~

R2-1-504. Modification of an approved plan Repealed

- ~~A. The Assistant Director shall be notified at least 30 days in advance of any proposed modifications that would change the estimated cost by \$25,000 or more in any fiscal year, or deviate from the primary planned technology and direction of automation within the agency from plans previously approved.~~
- ~~B. Within 30 days of receipt of any proposed modifications, the Assistant Director shall approve or disapprove the modifications in writing. If disapproved, the Assistant Director shall set forth the reasons for disapproval.~~

R2-1-505. Acquisition of automation equipment and services Repealed

- ~~A. State agencies shall make a written request to the Assistant Director for approval prior to the acquisition of computer equipment, computer software, communications equipment or computer services.~~
- ~~B. The Assistant Director shall acknowledge receipt of the acquisition request within five working days and shall approve or disapprove the request within 15 working days of receipt of the request. If the acquisition request is disapproved, the Assistant Director shall notify the requestor in writing setting forth the reason(s) for disapproval.~~
- ~~C. A decision by the Assistant Director to disapprove a request may be appealed to the Automation Oversight Committee pursuant to A.R.S. § 41-714(E).~~

NOTICE OF PROPOSED RULEMAKING

TITLE 4. COMMERCE, PROFESSIONS, AND OCCUPATIONS

CHAPTER 21. BOARD OF OPTOMETRY

PREAMBLE

1. Sections Affected

R4-21-101
R4-21-201
R4-21-203
R4-21-204
R4-21-205
R4-21-206
R4-21-207
R4-21-208
R4-21-209
Table 1
R4-21-304

Rulemaking Action

Amend
Amend
Amend
Amend
Amend
Amend
Amend
Amend
Amend
New Section
Amend
Amend

Arizona Administrative Register
Notices of Proposed Rulemaking

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

Authorizing statutes: A.R.S. §§ 12-2297, 32-1704, 41-1073

Implementing statutes: A.R.S. §§ 12-2297, 32-1706, 32-1722, 32-1724, 32-1726, 32-1728, 41-1075

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

Notice of Rulemaking Docket Opening: 5 A.A.R. 4267, November 5, 1999

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

Name: Dr. Jan McVey, President

Address: State Board of Optometry
1400 W. Washington, Room 230
Phoenix, Arizona 85007

Telephone: (602) 542-3095

Fax: (602) 542-3093

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

This rulemaking complies with SB1084 to establish a program for oral pharmaceutical use, including certification, continuing education, and course of study and completion requirements.

Articles 1 and 2 are revised for clarity and understanding, consolidation of like information, and to update the structure and grammar to meet the requirements of the Governor's Regulatory Review Council and the Style Manual of the Office of the Secretary of State.

R4-21-101. Definitions. The term for "certificate of special qualification" has been added and includes all segments of the field of optometry. The statute definitions for "pharmaceutical" and "pharmaceutical agent" are included and further defined to make clear that the terms include 3 separate categories: topical pharmaceutical agents, oral pharmaceutical agents, and anti-anaphylactic agents. The term "topical pharmaceutical agent" has been deleted, but is redefined under "pharmaceutical" and "pharmaceutical agent." The term "TPA certificate holder" is no longer used within the rules and has been deleted.

R4-21-201. Licensure. This Section provides the applicant with the requirements necessary to apply for licensure.

The dates in subsection (B)(3) have been revised to comply with the effective date of SB1084.

R4-21-203. Timeframes for Licensure, Renewal of License, Certificates of Special Qualification, and Course of Study Approval. This Section establishes the length of time the Board is required to issue a license.

The title of this Section has been changed to conform with new terminology, and the word "topical" has been removed from the phrase "pharmaceutical agent" in subsection (E)(5).

R4-21-204. License Renewal. This Section provides the applicant with the information necessary to renew a license, and establishes the number of hours for specific courses used for license renewal. The statute requirement specifying that the applicant must submit renewal information to the Board before August 31 of the renewal year has been added to the rule and clarification made of the specific "information" required.

R4-21-205. Course of Study Approval. This Section specifies how an accredited educational institution obtains approval for a course of study.

The Board requested the Pacific University College of Optometry, the Southern California College of Optometry, and Northeastern State University, College of Optometry, Oklahoma, to propose a course of study for oral pharmaceuticals. The Board then forwarded these documents to the Associate Dean of Curriculum, Theodore Tong, at the University of Arizona College of Pharmacy for review. Of the 2 proposals received, the Board obtained comprehensive content with regards to pharmacodynamics, pharmacotherapeutic principles – particularly with examining issues of drug-drug interactions, adverse drug reactions, and side effects. Each segment of the course contains adequate learning sessions that are specific and appropriate to develop prescribing abilities.

The course of study requirements in subsection (A) have been revised to include a minimum of 12 hours in pharmacologic principles, and specific requirements established for administering and passing a course of study.

R4-21-206. Pharmaceutical Agent Certificate of Special Qualification. This Section provides an optometrist with clear instructions for obtaining a Pharmaceutical Agent Certificate of Special Qualification. The Board is following the recommendation of the Pacific University College of Optometry to require that an optometrist obtain a CPR certi-

Arizona Administrative Register
Notices of Proposed Rulemaking

fication to qualify for this special qualification. If injectables are administered to counteract an anaphylactic reaction, standard CPR procedures may be necessary until emergency services arrive. Therefore, it is necessary for an applicant to possess CPR Certification.

The Board also requires that any documentation deemed confidential by the National Board or an issuing education institution be submitted directly to the Board by that entity.

The 15-day timeframe to file a written request to appeal a decision by the Board has been changed to comply with standard hearing guidelines.

R4-21-207. Submission of Fee; Issuance and Display of License; Surrender of License. This Section establishes when license fees must be paid to the Board, sets the requirements for licensure display, and requires the surrender of a license if ordered by the Board.

The Board reviews the examinations taken for licensure at the August Board meeting following the July examination. The Board notifies all applicants who pass the examination that the license issuance fee must be submitted before a license will be issued. Currently subsection (A) allows the applicant 60 days to submit the license issuance fee and another 60 days after receiving the fee for the Board to issue the license. These timeframes are not included in Table 1 and extend the overall timeframe. The 60 days allowed for fee submittal has been changed to 20 days, as allowed by Table 1. This timeframe should be adequate for fee submission, particularly since the application information has been submitted and the examination taken.

Currently, the Board issues licenses at their next Board meeting (September). Therefore, the timeframe allowing the Board an additional 60 days following receipt of payment is unnecessary.

R4-21-208. Continuing Education. This Section provides the criteria used by the Board to determine whether an education course or program will be approved. Currently subsection (B) allows pre-approved courses by specific educational institutions. The Board wishes to review all courses submitted for continuing education, therefore, subsection (B) no longer applies.

The information dealing with license renewal is more appropriate in the license renewal Section and has been moved to R4-21-204.

R4-21-210. Equipment and Supplies. This Section meets the requirements of A.R.S. § 32-1706(E) by requiring a licensee to maintain in the licensee's office medically necessary supportive equipment and supplies that are used in connection with the treatment of an anaphylactic reaction including oxygen equipment, airway maintenance equipment, or other necessary equipment consistent with the prevailing standard of care as specified by the Board.

Table 1. This Table establishes the timeframes used by the Board when issuing licenses and other approvals.

The "type of license" category has been updated to comply with this rulemaking, and the Initial Licensure by Examination or Reciprocity timeframe has been separated into 2 timeframes to allow for different administrative review periods required by R4-21-201 and A.R.S. § 32-1722.

The overall timeframe column has been moved to end of the Table for clarity and understanding.

R4-21-304. Vision Examination Standards; Records. This Section contains the incorporations by reference and affirms that the standards of care established by the American Optometric Association are practice guidelines which must be followed by Arizona optometrists.

The Section also establishes the information and length of time that records must be maintained by an optometrist. This Section is amended to comply with the 1999 legislative change to A.R.S. § 12-2297, which requires that records be maintained for 10 years.

6. A reference to any study that the agency relies on in its evaluation of or justification for the 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

7. 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

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

A. Estimated Costs and Benefits to the Board of Optometry.

Arizona Administrative Register
Notices of Proposed Rulemaking

No financial costs are realized by the implementation of this rulemaking. Other than adding a course of study in pharmaceutical agents and providing an optometrist a Pharmaceutical Agent Certificate of Special Qualification, the Department does not anticipate there will be any additional administrative functions.

During the past five years, the following licenses have been issued:

LICENSES/APPROVALS	1995	1996	1997	1998	1999
Optometrist					
New	28	18	42	30	42
Renewal	540	0	550	0	550
Courses	1	3	1	0	0

B. Estimated Costs and Benefits to Political Subdivisions.

Political subdivisions of this state are not directly affected by the implementation and enforcement of this rulemaking.

C. Businesses Directly Affected By the Rulemaking. (Optometrists, Physician Providers, Educational Institutions)

The Board's promulgation of this rulemaking provides current optometrists the opportunity to dispense, prescribe, and administer topical and oral pharmaceutical agents. Currently licensed optometrists may take a 12-hour course of pharmacological principles and apply to the Board for a Pharmaceutical Agent Certificate of Special Qualification.

Educational institutions will include this 12-hour curriculum as part of the 120-hour required course of study for optometry certificate of special qualification after August 6, 2000.

Updating certificates of special qualification to dispense, prescribe, and administer topical and oral pharmaceutical agents will allow optometrists to practice at the highest level of care and may ultimately benefit the patient through a more effective delivery of medication in certain circumstances.

An optometrist who obtains a Pharmaceutical Agent Certificate of Special Qualification will incur fees for taking appropriate courses and purchasing equipment to qualify to dispense, prescribe, and administer topical and oral pharmaceuticals, but the benefits should far outweigh the costs by allowing the optometrist to provide better quality health care to patients.

This rulemaking may negatively affect physician providers who currently receive referral for tertiary services. There is no way to forecast, however, the actual effect this rulemaking will have on these providers.

Participating educational institutions will benefit through increased revenues if they update their special courses of study in pharmaceutical agents.

D. Estimated Costs and Benefits to Private and Public Employment.

Private and public employment are not directly affected by the implementation and enforcement of this rulemaking.

E. Estimated Costs and Benefits to Consumers and the Public.

Currently an optometrist may diagnose a patient and prescribe a topical ocular medication. If a patient needs an ingested medication, the patient must use an additional provider to prescribe appropriate oral pharmaceutical agents, which the patient must then take to a pharmacy to be filled. This rulemaking allows an optometrist to initiate a total treatment plan to dispense, prescribe, and administer appropriate pharmaceutical agents, thereby providing the patient with one-stop quality healthcare.

F. Estimated Costs and Benefits to State Revenues.

This rulemaking will have no impact on state revenues.

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

Name: Dr. Jan McVey, President
Address: State Board of Optometry
1400 W. Washington, Room 230
Phoenix, Arizona 85007

Arizona Administrative Register
Notices of Proposed Rulemaking

Telephone: (602) 542-3095

Fax: (602) 542-3093

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

Date: July 25, 2000

Time: 9:00 a.m.

Location: State Office Building
1400 West Washington, B-1
Phoenix, Arizona 85007

Nature: Oral Proceeding

Written comments on the proposed rules or preliminary economic, small business, and consumer impact statement must be received by 5:00 p.m., July 25, 2000. Persons with a disability may request a reasonable accommodation, such as a sign language interpreter, by contacting the Board's coordinator, Dr. Jan McVey, President, at (602) 542-3095 (voice) or 1-800-367-3839 (TDD Relay). Requests should be made as early as possible to allow time to arrange the accommodation.

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

None

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

None

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

No

14. The full text of the rules follows:

TITLE 4. COMMERCE, PROFESSIONS AND OCCUPATIONS

CHAPTER 21. BOARD OF OPTOMETRY

ARTICLE 1. GENERAL PROVISIONS

Section

R4-21-101. Definitions

ARTICLE 2. LICENSING PROVISIONS

Section

R4-21-201. Licensure

R4-21-203. Timeframes for Licensure, Renewal of License, ~~TPA Certification~~ Certificates of Special Qualification, and Approval of Course of Study

R4-21-204. ~~Renewal of License~~ Renewal

R4-21-205. ~~Board approved Courses of Study~~ Course of Study Approval

R4-21-206. ~~Issuance of TPA Certificate to Optometry School Graduates Prior to July 17, 1993~~ Pharmaceutical Agent Certificate of Special Qualification

R4-21-207. Submission of Fee; Issuance and Display of License; Surrender of License

R4-21-208. Continuing Education ~~Requirements; Program Criteria and Procedures~~

R4-21-209. Equipment and Services

Table 1. Timeframes

ARTICLE 3. REGULATORY PROVISIONS

Section

R4-21-304. Vision Examination Standards; Records.

ARTICLE 1. GENERAL PROVISIONS

R4-21-101. Definitions

~~In this Chapter, unless otherwise specified, the following terms mean:~~ In addition to the definitions established in A.R.S. § 32-1701, the following terms apply to this Chapter:

1. “Accredited” means that an educational institution is officially approved by the New England Association of Schools and Colleges, Middle States Association of Colleges and Secondary Schools, North Central Association of Colleges and Schools, Northwest Association of Schools and Colleges, Southern Association of Colleges and Schools, Western Association of Schools and Colleges, or the American Optometric Association Council on Optometric Education to offer courses in optometry.
2. “Application” means forms designated as applications and all documents and additional information the Board requires to be submitted with an application.
3. “Board” means the Arizona State Board of Optometry state board of optometry. A.R.S. § 32-1701(1)
4. “Certificate of special qualification” means a document that allows the holder to practice in a specific area of optometry specified in A.R.S. § 32-1728.
- 4.5. “Incompetence” means:
 - a. Lack of professional skill or fidelity in performing the practice of optometry;
 - b. Treatment in a manner contrary to accepted optometric practices; or
 - c. Lack of physical or mental fitness to discharge professional duties.
- 5.6. “Licensure by examination” means an applicant has met the examination requirements of A.R.S. § 32-1724.
- 6.7. “Licensure by reciprocity” means an applicant has satisfied all of the requirements of A.R.S. § 32-1723.
- 7.8. “Low vision rehabilitation” means evaluation, diagnosis, management, and treatment, including the prescribing of corrective spectacles, contact lenses, prisms or filters; or the employment of any means for the adaptation of lenses.
- 8.9. “National Board” means the National Board of Examiners in Optometry.
- 9.10. “National Board Exam” means the optometry examinations administered by the National Board. ~~The Board may approve portions of the National Board exam for purposes of licensure.~~
11. “Pharmaceutical” or “pharmaceutical agent” means a prescription or nonprescription substance, or a schedule III controlled substance used for examination, diagnosis or treatment of conditions of the human eye and its adnexa. A.R.S. § 32-1701(5). Pharmaceutical and pharmaceutical agent includes the following categories:
 - a. “TPA” (topical pharmaceutical agent) means an externally-applied medication used to diagnose, treat, and manage disease of the eye and its adnexa.
 - b. “Oral pharmaceutical” means an ingested medicine used to diagnose, treat, and manage disease of the eye and its adnexa; and
 - c. “Anti-anaphylactic agent” means a self-injecting syringe delivering a 0.3 mg or 0.15 mg intramuscular dose of epinephrine for the emergency treatment of allergic reactions.
10. Topical pharmaceutical agent or TPA means an externally-applied medication used to diagnose, treat, and manage disease of the eye and its adnexa.
11. TPA certificate holder means an optometrist who has met the requirements of A.R.S. §§ 32-1722(A)(3) and 32-1728.
12. “Vision therapy” means an individualized treatment program prescribed to improve or rehabilitate conditions such as strabismus or amblyopia. Vision therapy is designed to help individuals learn, relearn, or reinforce specific vision skills, including eye movement control, focusing control, eye coordination, and the teamwork of the 2 eyes. It may include prescribing of corrective spectacles, contact lenses, prisms or filters, or the employment of any means for the adaptation of lenses.

ARTICLE 2. LICENSING PROVISIONS

R4-21-201. Licensure

- A. ~~An applicant~~ Any person applying for licensure by examination shall submit to the Board all of the following information on a form provided by the Board on the licensure application not later than 30 days prior to before the date of the licensing examination:
1. The applicant’s full name;
 2. The applicant’s place and date of birth;
 3. The applicant’s current residence;
 4. The applicant’s residence addresses for the past 10 years;
 5. The applicant’s educational background;
 6. The applicant’s previous optometric experience;
 7. The applicant’s previous optical experience;
 8. The applicant’s work experience or occupation for the past 10 years;
 9. A list of the applicant’s previous state board examinations;
 10. A list of the states in which the applicant is or has been licensed and, if a license is no longer valid, the reasons why;

Arizona Administrative Register
Notices of Proposed Rulemaking

11. Whether the applicant has ever been denied the right to take an examination for optometric licensure by any state;
 12. Whether the applicant has ever been refused an optometric license or renewal in any state;
 13. Whether the applicant has ever had a license or certificate of registration to practice optometry suspended or revoked by any optometric licensing agency, board, or equivalent;
 14. Whether any disciplinary action has ever been instituted against the applicant by any optometric licensing agency or equivalent, including any to determine whether the applicant's license to practice optometry should be suspended or revoked;
 15. Whether the applicant has ever been arrested for, pled guilty to, or been convicted of a felony or misdemeanor offense;
 16. Whether the applicant has been addicted to narcotic substances or habitually abused alcohol within the last 10 years;
 17. Whether the applicant is presently addicted to narcotic substances or habitually abuses alcohol;
 18. If the answer to any of the questions in subsections (A)(11) through (A)(17) is affirmative, a complete explanation of the details, including dates;
 19. The signed endorsements of 3 professional or business persons, unrelated to the applicant, who have known the applicant for at least the past 3 years;
 20. A sworn statement under oath by the applicant verifying the truthfulness of the information provided by the applicant; and
 21. A photograph of the applicant showing head and shoulders and measuring 2" by 3".
- B.** In addition to the requirements of subsection (A), an applicant for licensure ~~by examination~~ shall submit or arrange to have submitted:
1. A completed fingerprint card accompanied by a separate nonrefundable fee in the form of a cashier's check, certified check, or money order in an amount determined by and payable to the Arizona Department of Public Safety for the procurement of background information;
 2. The filing fee pursuant to A.R.S. § 32-1727;
 3. Evidence of the successful completion of an approved course of study prescribed by A.R.S. § 32-1722(A)(3) that includes the following:
 - a. An official transcript showing that the applicant has passed the course or courses, if the applicant graduated from a school of optometry on or after ~~April 6, 1993~~ August 6, 1999, or
 - b. A certificate of completion issued by the sponsoring institution specifying the subject matter and hours completed, if the applicant graduated from a school of optometry ~~prior to April 6, 1993~~ before August 6, 1999.
 4. An official transcript directly from the accredited institution from which the applicant graduated with a degree in optometry. The transcript need not be filed with the application, but shall be filed with the Board at least 10 days ~~prior to~~ before the examination date.
- C.** An applicant for licensure by reciprocity shall submit to the Board all of the information required by subsections (A) and (B) not later than 60 days ~~prior to~~ before the date of the licensing examination together with the following additional materials:
1. A State Certification form provided by the Board, completed by the agency responsible for licensing optometrists in the state from which the applicant is seeking reciprocity, that provides the following information:
 - a. Confirmation that the state accords similar reciprocity privileges to optometrists licensed in Arizona;
 - b. Confirmation that the applicant has been engaged in the practice of optometry in or under the authority of that state for at least 4 of the 5 years preceding the date of the application;
 - c. Explanation of the basis for and result of any disciplinary action taken against the applicant within the preceding 10 years, including censure, probation, suspension, or revocation of the applicant's license;
 - d. Description of any pending investigations or complaints regarding the applicant;
 - e. Statement that the applicant is in good standing to practice optometry in that state; and
 - f. Statement whether the applicant is known to have been licensed to practice optometry in any other state and, if so, the name of that state.
 2. The applicant's sworn and notarized statement on a form provided by the Board that affirms that the applicant satisfies each of the requirements of A.R.S. § 32-1723(A)(3), (4), and (6).
- D.** The Board shall permit only those applicants who complete an application and file transcripts ~~prior to~~ before the deadlines to take an examination.

R4-21-203. Timeframes for Licensure, Renewal of License, ~~TPA Certification~~ Certificates of Special Qualification, and Approval of Course of Study Approval

- A.** For each type of license, renewal of license, certificate, or approval issued by the Board, the overall timeframe described in A.R.S. § 41-1072(2) is listed in Table 1.
- B.** For each type of license, renewal of license, certificate, or approval issued by the Board, the administrative completeness review timeframe described in A.R.S. § 41-1072(1) is listed in Table 1 and begins on the date the Board receives an application.

Arizona Administrative Register
Notices of Proposed Rulemaking

1. If the application is not administratively complete, the Board shall send a deficiency notice to an applicant.
 - a. The deficiency notice shall state each deficiency and the information needed to complete the application and documents.
 - b. Within the time provided in Table 1 for response to the deficiency notice, beginning on the mailing date of the deficiency notice, the applicant shall submit the missing information specified in the deficiency notice to the Board. The timeframe for the Board to finish the administrative completeness review is suspended from the date the Board mails the deficiency notice to the applicant until the date the Board receives the missing information.
 2. If the application is administratively complete, the Board shall send a written notice of administrative completeness to the applicant.
 3. If the application does not contain all of the components required by statute or this Chapter, the Board shall send a written notice to the applicant informing the applicant that the Board considers the application withdrawn. Fees are nonrefundable in accordance with A.R.S. § 32-1727(B).
- C. For each type of license, renewal of license, certificate, or approval issued by the Board, the substantive review timeframe described in A.R.S. § 41-1072(3) is listed in Table 1 and begins on the date as prescribed in subsection (D), depending on the manner in which the Board transmits the written notice of administrative completeness to the applicant.
1. During the substantive review timeframe, the Board may make 1 comprehensive written request for additional information. Within the time provided in Table 1 for response to a comprehensive written request for additional information, the applicant shall submit to the Board the requested additional information. The timeframe for the Board to finish the substantive review is suspended from the date calculated as prescribed in subsection (D), until the Board receives the requested additional information.
 2. Under A.R.S. § 32-1722(C), the Board may notice a hearing to obtain information on the character of any applicant for licensing or any aspect of the application. As part of a request for more information, the timeframe to finish the substantive review is suspended from the date the Board notices the hearing until the hearing is completed.
 3. The Board shall issue a written notice of denial of license, renewal of license, certificate, or approval if the Board determines that the applicant does not meet all of the substantive criteria required by statute or this Chapter.
 4. The Board shall issue a written notice informing the applicant that the Board considers the application withdrawn if the applicant does not submit the requested additional information within the timeframe in Table 1 unless the applicant requests formal denial in writing within 20 days. Fees are nonrefundable in accordance with A.R.S. § 32-1727(B).
 5. If the applicant meets all of the substantive criteria required by statute and this Chapter for licensure, renewal of license, certificate, or approval, the Board shall issue the license, renewal of license, certificate, or approval to the applicant. The Board shall issue a ~~topic~~ pharmaceutical agent certificate with a license to practice optometry.
- D. In computing any period of time prescribed in this Section, the day of the act, event or default after which the designated period of time begins to run shall not be included. The last day of the period shall be included unless it is Saturday, Sunday, or a state holiday, in which event the period runs until the end of the next day that is not a Saturday, Sunday, or a state holiday. The computation shall include intermediate Saturdays, Sundays, and holidays. The time period shall commence on the date of personal service, date shown as received on a certified mail receipt, or postmark date.

R4-21-204. ~~Renewal of License~~ Renewal

- A. ~~An applicant for a license renewal applicant shall, before August 31 of the biennial license renewal year, submit all of the renewal fee and the following information to the Board on a renewal form provided by the Board a form provided by the Board prior to August 31 of the year the license expires:~~
1. ~~Changes~~ Any change in the applicant's mailing address,
 2. ~~List~~ A list of all practice addresses and phone numbers,
 3. ~~Information regarding completion of the required continuing education~~ A list of continuing education courses and proof of attendance at 32 hours of Board-approved courses and programs in continuing education,
 4. ~~State~~ The State where the applicant currently practices and the date when the practice commenced,
 5. Whether the applicant is retired from the practice of optometry,
 6. Whether the applicant declines renewal of the license,
 7. Whether the applicant has been arrested or convicted of any misdemeanor or felony during the renewal period,
 8. ~~Sworn~~ The applicant's notarized statement ~~under oath signed by the applicant~~ verifying the truthfulness of the information provided, by the applicant, and
 9. Renewal fee.
- B. A license is void ~~under A.R.S. § 32-1726(A)~~ if an applicant does not submit a renewal application and renewal fee before August 31 of the year the license expires.

R4-21-205. ~~Board-approved Courses of Study~~ Course of Study Approval

- A. ~~An institution that provides a course of study in didactic education, pharmacology, and clinical training in the examination, diagnosis, and treatment of conditions of the human eye and its adnexa may be designated a college of optometry for~~

Arizona Administrative Register
Notices of Proposed Rulemaking

purposes of A.R.S. § 32-1722(A)(3) if it is accredited by the American Optometric Association Council on Optometric Education. Any accredited educational institution may apply to the Board for approval of a course of study covering didactic education, pharmacology, and clinical training in the examination, diagnosis, and treatment of conditions of the human eye and its adnexa, and prescribing, dispensing, and administering pharmaceutical agents. The school's authorized representative shall provide the following information on the application:

- ~~B.~~ A college of optometry shall apply to the Board for approval for a course of study as prescribed by A.R.S. § 32-1722(A)(3). The initial application for approval shall include the following information:
1. ~~Applicant's~~ The name and address of the accredited educational institution;
 2. Certification that the course is equivalent in scope and content to courses provided to ~~new~~ current graduates of the college;
 3. ~~Number~~ The names and qualifications of proposed faculty and staff; and
 4. ~~Course~~ A 120 hour course outline that shall include includes:
 - a. Didactic pharmacology and clinical training in the diagnosis and treatment of:
 - a.i. ~~Diagnosis and treatment of anterior~~ Anterior segment disease;
 - b.ii. ~~Diagnosis and treatment of posterior~~ Posterior segment disease;
 - e.iii. ~~Diagnosis and treatment of glaucoma;~~ Glaucoma; and
 - d.iv. ~~Diagnosis and treatment of systemic~~ Systemic diseases and emergencies, and with all pharmaceutical agents and the specific agents specified in A.R.S. § 32-1706(A), (B), (C) and (E).
 - b. A minimum of 12 hours of the pharmacologic principles in the side effects, adverse reactions, drug interactions, use of systemic antibiotics, analgesics, antipyretics, antihistamines, over-the-counter medications, and medications and procedures to counter the affect of adverse reactions.
 5. Evidence of accreditation by the American Optometric Association Council on Optometric Education.

~~C.B.~~ A college of optometry An accredited educational institution that offers a an approved course of study for purposes of A.R.S. § 32-1722(A)(3) shall grant a certificate of completion or its equivalent for the course when a student passes a closed book, proctored, written examination administered by the faculty. The written examination shall not be a take-home test with a score of at least 75%, covering prescribing, dispensing, and administering pharmaceutical agents, and is commensurate with doctoral candidates in colleges of optometry.

R4-21-206. Issuance of TPA Certificate to Optometry School Graduates Prior to July 17, 1993 Pharmaceutical Agent Certificate of Special Qualification

- ~~A.~~ An optometrist who graduated from an accredited school of optometry prior to July 17, 1993, who wishes to administer, dispense, and prescribe topical pharmaceutical agents shall submit a written request to the Board and shall cause to be submitted to the Board evidence that:
1. The optometrist has satisfactorily completed the Board-approved course of study required by A.R.S. § 32-1722(A)(3), by causing the issuing institution to submit:
 - a. An official transcript showing that the optometrist has passed the course; and
 - b. A certificate of completion specifying the subject matter and hours completed.
 2. The course of study meets the criteria listed in R4-21-205; and
 3. The optometrist has successfully passed the National Board's treatment and management of ocular disease examination or other National Board examination approved by the Board after July 17, 1993.
- ~~B.~~ An optometrist described in this Section, who is planning to enroll in a course of study in clinical pharmacology for the purposes of A.R.S. §§ 32-1722 or 32-1723 shall submit to the Board for review and approval, prior to enrollment, an outline of the course or courses, name of the sponsoring institution, names and qualifications of faculty or instructors, and evidence that the course of study meets the criteria for an approvable course of study in R4-21-205. A request for approval of a course shall be submitted to the Board not less than 60 days prior to the date the course is offered. The timeframes for the granting of a course approval are listed in R4-21-203.
- ~~C.~~ The Board shall issue a TPA certificate to an optometrist who meets the requirements of this Section that evidences that the optometrist is authorized to administer, dispense, and prescribe all topical pharmaceutical agents for the purpose of examining the eye and adnexa, and the diagnosis, treatment, and management of eye conditions.
- ~~A.~~ An optometrist who graduated from an accredited educational institution may apply for a pharmaceutical agent certificate of special qualification to prescribe, dispense, and administer pharmaceutical agents.
1. If the optometrist does not hold a TPA certificate of special qualification issued before August 6, 1999, the optometrist shall:
 - a. Meet the requirements of R4-21-205(A);
 - b. Provide the Board with a copy of current CPR certification; and
 - c. Request the National Board or the issuing educational institution to send the Board documentation showing the optometrist passed the National Board's Treatment and Management of Ocular Disease examination or other examination approved by the Board after July 17, 1993.
 2. If the optometrist holds a TPA certificate of special qualification issued before August 6, 1999, the optometrist shall:

Arizona Administrative Register
Notices of Proposed Rulemaking

- a. Request the issuing educational institution to send the Board a certificate of completion showing the optometrist passed a Board-approved course meeting the criteria specified in R4-21-205(A)(4)(b).
- b. Provide the Board with a copy of current CPR certification.
3. If the optometrist graduated after August 6, 1999 and is licensed by the Board, the optometrist shall provide the Board with a copy of current CPR certification.

~~D.B.~~ An optometrist who is denied certification in accordance with this Section or whose course of study is not approved by the Board may appeal the decision by filing a written request with the Board within ~~45~~ 30 days following receipt of the notice from the Board of denial of certification or disapproval. The hearing shall be conducted in accordance with A.R.S. Title 41, Chapter 6, Article 6.

R4-21-207. Submission of Fee; Issuance and Display of License; Surrender of License

A. An applicant shall submit the license issuance fee to the Board ~~the license issuance fee under A.R.S. § 32-1727~~ within 60 ~~60~~ 20 days following notification by the Board that ~~an~~ the applicant has met the qualifications for licensure. The Board shall issue a license at the next Board meeting within 60 days following receipt of payment, unless additional information is requested under A.R.S. § 41-1075.

B. License display.

1. An optometrist shall conspicuously display an optometry license or a Board-issued duplicate at all places where the optometrist is registered to practice optometry.
2. ~~In addition, each~~ Each optometrist ~~authorized to use diagnostic pharmaceutical agents or to administer, dispense, and prescribe all topical pharmaceutical agents shall similarly~~ shall display the appropriate Board-issued pharmaceutical agent certificate ~~or a Board-issued duplicate at each location.~~ An optometrist shall surrender to the Board all licenses, certificates, and duplicates upon disciplinary order of the Board.

R4-21-208. Continuing Education Requirements; Program Criteria and Procedures

~~A.~~ An optometrist applying for biennial license renewal shall include with the application a list of courses and a notarized affirmation by the licensee of attendance at 32 clock hours of Board-approved courses and programs in continuing education. ~~An optometrist who makes a materially false statement in the affirmation shall be subject to disciplinary action, including suspension or revocation of license.~~

~~B.~~ Continuing education courses approved by the Board for renewal of a license to practice optometry are:

1. Educational courses offered at the American Optometric Association Convention or offered at any American Optometric Association affiliate state association convention;
2. Seminars held by committees of the American Optometric Association or organized regional Optometric Extension Program Foundation seminars for educational purposes;
3. Postgraduate courses offered by accredited schools or colleges of optometry;
4. Postgraduate correspondence courses offered by an accredited college of optometry, provided that no more than 6 hours of continuing education credits are claimed in a single licensing renewal period; and
5. Other continuing education courses or programs that are based upon the following:
 - a. The program shall have optometric application and shall be available to all optometrists and students of optometry. All program instructors shall have expertise in the field in which they instruct:
 - i. Learning objectives shall be reasonably and clearly stated;
 - ii. Teaching methods shall be clearly stated and appropriate;
 - iii. Attendance shall be open to all optometrists and students of optometry; and
 - iv. Documentation of attendance shall be provided to those attending.
 - b. An optometrist applying for license renewal shall submit to the Board for approval 45 days prior to the date the course is offered a description of the program content, instructors, and their qualifications, the sponsor of the program, if any, the conditions of availability, and the time and place offered.

A. All continuing education courses or programs approved by the Board are based on the following:

1. The education has optometric application.
2. The education is available to all optometrists and students of optometry.
3. The instructor has expertise in the field in which the instructor is teaching.
4. The learning objectives are reasonably and clearly stated.
5. The teaching methods are appropriate and clearly stated, and
6. Documentation of attendance is provided to those attending.

B. An optometrist may apply to the Board for approval of continuing education, not otherwise authorized, by submitting to the Board 45 days before the date the course or program is offered, a description of the program content, instructors, and their qualifications, the sponsor of the program, if any, the conditions of availability, and the time and place offered.

C. The Board shall limit continuing education credit for correspondence courses, including computer, on-line education courses, to no more than 6 hours. Correspondence courses may include written, computer, and on-line education courses, but not more than 6 hours of correspondence courses may be used for license renewal.

Arizona Administrative Register
Notices of Proposed Rulemaking

- D.** ~~The Board shall limit continuing education credit for practice management or administration to no more than 4 hours. Not more than 4 hours of practice management and administration continuing education may be used for license renewal.~~
D.E. An optometrist shall not carry-over hours accumulated in any 1 biennial license period to a subsequent license period.
E. ~~An optometrist shall submit evidence of continuing education hours with the optometrist's biennial license renewal.~~

R4-21-210. Equipment and Supplies

An optometrist who holds a pharmaceutical agent certificate shall maintain the following equipment and supplies in the treatment room to counteract an anaphylactic reaction:

1. A telephone with access to an emergency medical number.
2. Auto-injectors of epinephrine.
3. Diphenhydramine hydrochloride (Benadryl).

Table 1. Timeframes (in calendar days)

Type of License	Administrative Review Timeframe	Time to Respond to Deficiency Notice	Substantive Review Timeframe	Time to Respond to Request for Additional Information	Overall Timeframe
Initial Licensure by Examination or Reciprocity R4-21-201 <u>A.R.S. § 32-1722</u>	30	20	60	20	90
<u>Initial Licensure by Reciprocity R4-21-201</u>	<u>60</u>	<u>20</u>	<u>60</u>	<u>20</u>	<u>120</u>
Renewal of License R4-21-204	60	20	30	20	90
Board Approved Course of Study R4-21-205	90	20	90	20	180
<u>Issuance of TPA Certification</u> <u>Certificates of Special Qualification</u> R4-21-206	60	20	60	20	120
Continuing Education Program Approval R4-21-208	60	20	60	20	120
Registration of nonresident dispenser of replacement soft contact lenses A.R.S. § 32-1773	60	20	60	20	120

R4-21-304. Vision Examination Standards; Records

- A.** An optometrist shall conduct eye examinations in accordance with the standards of care established by the following American Optometric Association practice guidelines which are incorporated by this reference and on file with the Secretary of State. The materials incorporated contain no later editions or amendments:
1. Comprehensive Adult Eye and Vision Examination, 1994, American Optometric Association, 243 N. Lindbergh Blvd., St. Louis, MO 63141-7881;
 2. Pediatric Eye and Vision Examination, 1994, American Optometric Association, 243 N. Lindbergh Blvd., St. Louis, MO 63141-7881;
 3. Care of the Patient with Diabetes Mellitus, 1994, American Optometric Association, 243 N. Lindbergh Blvd., St. Louis, MO 63141-7881;
 4. Care of the Patient with Amblyopia, 1994, American Optometric Association, 243 N. Lindbergh Blvd., St. Louis, MO 63141-7881;
 5. Care of the Patient with Primary Angle Closure Glaucoma, 1994, American Optometric Association, 243 N. Lindbergh Blvd., St. Louis, MO 63141-7881;
 6. Care of the Patient with Age-Related Macular Degeneration, 1994, American Optometric Association, 243 N. Lindbergh Blvd., St. Louis, MO 63141-7881;

Arizona Administrative Register
Notices of Proposed Rulemaking

7. Care of the Patient with Anterior Uveitis, 1994, American Optometric Association, 243 N. Lindbergh Blvd., St. Louis, MO 63141-7881;
 8. Care of the Adult Patient with Cataract, 1995, American Optometric Association, 243 N. Lindbergh Blvd., St. Louis, MO 63141-7881;
 9. Care of the Patient with Open Angle Glaucoma, 1995, American Optometric Association, 243 N. Lindbergh Blvd., St. Louis, MO 63141-7881;
 10. Care of the Patient with Ocular Surface Disease, 1995, American Optometric Association, 243 N. Lindbergh Blvd., St. Louis, MO 63141-7881;
 11. Care of the Patient with Conjunctivitis, 1995, American Optometric Association, 243 N. Lindbergh Blvd., St. Louis, MO 63141-7881;
 12. Care of the Patient with Strabismus: Esotropia and Exotropia, 1995, American Optometric Association, 243 N. Lindbergh Blvd., St. Louis, MO 63141-7881; and
 13. Care of the Patient with Retinal Detachment and Related Peripheral Vitreoretinal Disease, 1995, American Optometric Association, 243 N. Lindbergh Blvd., St. Louis, MO 63141-7881.
- B.** An optometrist shall establish and maintain a complete and legible record of each examination including all findings. The Board shall consider an illegible record to be an incomplete examination. An optometrist shall ensure that a patient record reflects the name of the person who makes each entry and is maintained for at least ~~5~~ 10 years after the last contact with a patient. The patient record shall include:
1. Complete case history;
 2. Visual acuity of each eye: entering, and best corrected;
 3. Ocular health examination;
 4. Assessment of intraocular and extraocular muscle function;
 5. Objective or subjective refraction of the eyes;
 6. Diagnosis, treatment, and disposition;
 7. The type and dosage of each use of a pharmaceutical agent used;
 8. Any final prescription given; and
 9. Any corrective procedure program prescribed.
- C.** An optometrist who discontinues practice for any reason shall arrange for patient records to be available to a patient for ~~5~~ 10 years and shall notify the Board of the permanent location of patient records from that practice ~~prior to~~ before discontinuing practice. An optometrist who acquires or succeeds to a practice or patient records of an optometrist who has discontinued practice shall maintain the records or make arrangements for the records to be available to a patient for ~~5~~ 10 years after the practice was discontinued.
- D.** An optometrist shall, upon written request of a patient, transmit a copy of the patient's requested records to any designated person. The optometrist may charge a fee to cover clerical and mailing costs. The optometrist shall maintain a record of the transfer for ~~5~~ 10 years from the date of the transfer.

NOTICE OF PROPOSED RULEMAKING

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

PREAMBLE

<u>1. Sections Affected</u>	<u>Rulemaking Action</u>
R12-1-102	Amend
R12-1-202	Amend
R12-1-206	Amend
Appendix A	Repeal
Appendix A	New Section
R12-1-303	Amend
R12-1-401	Amend
R12-1-402	Amend
R12-1-403	Amend
R12-1-404	Amend
R12-1-405	Amend
R12-1-406	Amend
R12-1-407	Amend

R12-1-408	Amend
R12-1-409	Amend
R12-1-410	Amend
R12-1-411	Amend
R12-1-412	Amend
R12-1-413	Amend
R12-1-415	Amend
R12-1-416	Amend
R12-1-417	Amend
R12-1-418	Amend
R12-1-419	Amend
R12-1-420	Amend
R12-1-421	Amend
R12-1-422	Amend
R12-1-423	Amend
R12-1-424	Amend
R12-1-425	Amend
R12-1-426	Amend
R12-1-427	Amend
R12-1-428	Amend
R12-1-429	Amend
R12-1-430	Amend
R12-1-431	Amend
R12-1-432	Amend
R12-1-433	Amend
R12-1-434	Amend
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R12-1-446	Amend
R12-1-447	Amend
R12-1-448	Amend
R12-1-449	Amend
R12-1-450	Amend
Article 5	Amend
R12-1-501	Amend
R12-1-502	Amend
R12-1-504	Amend
R12-1-505	Amend
R12-1-507	Amend
R12-1-508	Amend
R12-1-509	Amend
R12-1-510	Amend
R12-1-511	Amend
R12-1-512	New Section
R12-1-521	Amend
R12-1-522	Amend
R12-1-523	Amend
R12-1-524	Amend
R12-1-531	Amend
R12-1-533	Amend

Arizona Administrative Register
Notices of Proposed Rulemaking

R12-1-534	Amend
R12-1-541	Amend
R12-1-612	Repeal
R12-1-612	New Section
R12-1-702	Amend
R12-1-720	New Section
Article 9	Amend
R12-1-904	Amend
R12-1-905	New Section
R12-1-911	Amend
R12-1-912	Repeal
R12-1-913	New Section
R12-1-914	New Section
R12-1-1209	Amend

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

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

Implementing statutes: A.R.S. §§ 30-657(A), 30-671(B), 30-672.01, 30-673, 30-681, 30-683(C), 30-687(A), and 30-688(A)

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

Notice of Rulemaking Docket Opening: 5 A.A.R. 2880, August 20, 1999

Notice of Rulemaking Docket Opening: 6 A.A.R. 1580, April 28, 2000

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

Name: Daniel H. Kuhl
Address: Arizona Radiation Regulatory Agency
4814 South 40th Street
Phoenix, Arizona 85040
Telephone: (602) 255-4845, ext. 233
Fax: (602) 437-0705
E-mail: dkuhl@arra.state.az.us

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

Introductory Statement:

The majority of the changes are the result of a Five-Year Review of the rules contained in Article 4, completed in June 1999, and Article 5 which was completed in the fall of 1998. Many other changes are being made to remain compatible with Nuclear Regulatory Commission (NRC) standards and Conference of Radiation Control Program Directors (CRCPD) suggested rules, incorporate regulatory requirements that were previously addressed in license conditions, and make other changes to improve understanding of existing rules. The following is a summary of the NRC and CRCPD influenced changes, incorporated license conditions, and clarifications.

Article 1: A new definition for "Annual" is added. This word is used frequently throughout the rules. The definition for "Eye dose equivalent" is replaced with "Lens dose equivalent". The definitions for "High radiation area" and "Individual monitoring device" are amended for clarification purposes. The definition for "Quarter" is deleted because it is in conflict with the definition for "Calendar quarter". The definition for "Radiographer assistant" is replaced with a definition for "Radiography trainee" because assistants will no longer be permitted to provide a service in Arizona, as noted by the number of changes in Article 5. The accepted standard of operation in most Agreement States is that radiographic operations be controlled by radiographers.

Article 2: In R12-1-202 a specific deadline is listed for applying for registration of a radiation producing machine. The contents of the application will contain the newly tabulated requested information in Appendix A at the end of the Article, instead of listing specific application forms. R12-1-206 is amended to clarify the requirements contained in subsection (A), and a new subsection (B) is added that requires registrants to notify the Agency within 15 days of any radiation machine being taken out of service. Other minor changes are made to R12-1-202 and R12-1-206 for clarification purposes.

Arizona Administrative Register
Notices of Proposed Rulemaking

Article 3: R12-1-303 is amended to prevent users of smaller sealed sources that are exempt from specific licensing requirements, from bundling the smaller sources to create a larger radiation source. Bundling would circumvent the specific licensing requirements associated with some larger sources and compromise the radiation safety inherent in the smaller sources, which was the basis for granting an exemption.

Article 4: In various rules referencing organ dose, “eye” dose is changed to “lens” dose to ensure that compatibility is maintained with NRC regulations. The organ of concern, when considering radiation exposure in the eye, is the lens. In R12-1-431 specific labeling requirements are listed for syringe and vial shields used to protect handlers from radiopharmaceutical radiation. R12-1-438 will authorize licensees to hold radioactive waste with a half-life of 120 days or less, for decay, provided the radioactive waste is held for 10 half-lives and is surveyed prior to disposal. In R12-1-449 users of pocket dosimeters, used to show compliance with Article 4, will be required to maintain them in proper operating condition. R12-1-450 is amended to require users of licensed and sealed radioactive sources to use sources manufactured in accordance with a specific license for their manufacture and to use the sources as intended by the manufacturer. Radioactive sealed sources shall not be opened, unless authorized by the Agency. The described changes to R12-1-438, R12-1-449, and R12-1-450 are made to license conditions that effect all similarly licensed radioactive material users in rule. Numerous other changes are made throughout the rules in Article 4 that improve clarity, understandability, and incorporated references.

Article 5: R12-1-505 is being amended to require industrial radiographers, using a camera with depleted uranium as shielding, to test the camera for leakage of depleted uranium from the camera housing, as well as leakage from the radioactive source housed in the camera. R12-1-512 is added as a new rule. It requires radiography licensees to have a qualified radiation safety officer. The rule specifies the duties of the radiation safety officer and the deadline for compliance with this new rule. R12-1-521 requires industrial radiographers to pass an exam that will qualify them as being certified. The exam will be given at the Agency and will cost approximately \$60. In R12-1-502, R12-1-510, R12-1-511, R12-1-521, R12-1-523, R12-1-525, and R12-1-531 “radiographer assistant” is replaced with “radiography trainee”. This change is made because the assistant category will no longer be allowed to work in Arizona. An individual will be allowed to be a trainee for 1 year before that person is required to qualify as a radiographer or no longer practice radiography activities. Numerous other changes are made throughout the rules in Article 5 that improve clarity, understandability, and incorporated references.

Article 6: For clarification purposes the contents of R12-1-612 are moved to R12-1-905, because Article 9 addresses concerns associated with high energy x-rays used in particle accelerators. New requirements affecting computerized tomographic system users will now be listed under R12-1-612. The proposed standards of operation are from suggested state regulations made available to state programs by the CRCPD.

Article 7: In R12-1-702 the definition of “misadministration” is modified to bring its content into alignment with the definition used by the NRC. It was the intent of the Agency to follow the NRC when the rule went into effect in May, however, the definition was incorrectly worded at that time. R12-1-720 is added to clarify the procedure that must be followed when radioactive waste is held for decay in storage. This authorization was previously addressed by license condition.

Article 9: As noted under Article 6, R12-1-905 will contain the requirements for users of high energy x-rays that were formerly located in R12-1-612. They are moved to Article 9 to improve the organization of the rules contained in Title 12. R12-1-912 is amended to inform registrants that release of radioactive material through a ventilation system cannot exceed the limits for radioactive material listed in Article 4. R12-1-913 is added to Article 9 to ensure that registrants notify the Agency and affected patients of any misadministration that occurs as a result of improper use of a particle accelerator. The radiation exposure action levels associated with the misadministration are the same levels specified in R12-1-702, which went into effect in May. The Article 7 action levels affect medical licensees that perform therapies using radionuclides. R12-1-914 is added for clarification purposes. The requirement to have an Agency representative inspect a new particle accelerator facility prior to the initiation of patient treatments, presently located in R12-1-904(G).

Article 12: R12-1-1209 is reformatted to improve conciseness and for clarification purposes, The Agency should not be required to list civil penalty amounts in correspondence to the radiation user following an inspection, if the Agency has no intention of imposing a civil penalty.

6. A reference to any study that the Agency relies 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, analysis of the study, and other supporting material:

None

Arizona Administrative Register
Notices of Proposed Rulemaking

7. 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

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

The changes to Article 2 should not pose a financial burden on radiation-producing machine users. The requirement to provide information concerning the use of radiation is already being imposed on radioactive material users. It is believed, however, that the Agency will see an increase in Agency administrative duties for processing the additional registration paperwork.

The prohibition of radioactive source bundling in Article 3 should effect few users in Arizona. At this time only one company is suspected of this activity. The company would have to acquire a quantity and form of radioactive material requiring a specific license and pay the associated licensing fee. This fee would most likely be less than \$1750 annually. The cost of the source that requires specific licensing must be balanced with the safety issues circumvented by using bundled, exempt radioactive sources.

The change in the disposal action level listed in R12-1-438 should actually save radioactive material users money because they will be allowed to store radioactive waste for decay, waste that is currently sent to a disposal site or waste broker. The current charge is approximately \$300 per cubic foot. The changes to R12-1-449 and R12-1-450 should not present any additional costs to the affected radiation users because the requirements are already being applied to them through license conditions. However, the maintenance of pocket dosimeters will affect registrants, but will impose no additional use conditions. The resulting additional cost for annual calibration is \$50 per dosimeter.

The changes to Article 5 will mean additional costs to industrial radiography users. Radiography involves possessing radiography cameras with depleted uranium shielding that will have to be leak tested along with the radioactive source in the camera. The additional cost should be less than \$15 for each additional leak test sample. The test will normally be performed twice each year. In R12-1-512 a Radiation Safety Officer (RSO) candidate will have to meet a higher training standard before the candidate will be authorized to oversee a radiography operation. The stricter standard may present some additional future cost to licensees and registrants. Current Radiation Safety Officers will not be asked to meet the new standard, but it will affect future candidates. The future cost of the proposed additional training and experience is unknown at this time. Also, the deletion of "radiographer assistant" in favor of "radiography trainee" may affect users because they will have to pay a higher salary to a radiographer than to a radiographer assistant. The difference is \$15-\$20/hour for a radiographer and \$10-\$15/hour for an assistant. The last additional cost affecting radiography concerns is the requirement to employ only certified radiographers. The Agency will assess a \$60 fee for the radiography certification exam. The moneys collected will go directly to the CRCPD for the cost of the test. A fee is not collected by the Agency for proctoring the exam. As a final note, there are 5 radiography licensees in Arizona employing less than 75 radiographers and radiography assistants.

Recently, there has been concern for patient safety, because of the potential for a large radiation dose given to patients under-going a computerized tomography (CT) x-ray examination. In an attempt to minimize the hazard, the Agency has developed CT rules in R12-1-612, modeled after the CRCPD suggested regulations. The addition of R12-1-612 may result in an additional cost to the registrant, if a physics expert based quality assurance program is not in place.

At this time it the driving force for a CT system regulation is the accreditation requirement placed on registrants by insurance providers. Because most medical institutions and major outpatient clinics are dependent on a portion of their income from insurance providers, they are maintaining their systems adequately. However, some outlying hospitals, small clinics, and some doctor's offices are not maintaining their CT's adequately. An interview of physics consultants servicing x-ray equipment in Arizona has determined that a CT "dosimetry survey" meeting the requirements in R12-1-612 would cost a registrant between \$200 and \$600. The "dosimetry survey" would include CT calibration and other quality assurance procedures performed between the physics expert's reviews, at intervals established by the physics expert.

It would appear the facility requirements contained in R12-1-612(B) would result in an additional expenditure by a CT registrant, however, most facilities are being constructed with communication and viewing systems. Their presence is being verified during Agency CT facility inspections being performed at this time. The review of the physicist's reports should not result in any additional cost to the Agency, however, the need to supply each inspector with appropriate equipment to perform a minimal verification dosimetry survey will cost the Agency approximately \$2,000.

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

Name: Daniel H. Kuhl

Arizona Administrative Register
Notices of Proposed Rulemaking

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

Telephone: (602) 255-4845, ext. 233

Fax: (602) 437-0705

E-mail: dkuhl@arra.state.az.us

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

An oral proceeding at the Agency is scheduled for Wednesday July 25, 2000, at 9:00 a.m. A person may submit written comments concerning the proposed rules by submitting them no later than 5:00 p.m. on July 25, 2000, to the following person:

Name: Aubrey V. Godwin, Director

Location: Arizona Radiation Regulatory Agency

Address: 4814 South 40th Street
Phoenix, Arizona 85040

Telephone: (602) 255-4845

Fax: (602) 437-0705

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

Not applicable

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

<u>Rule</u>	<u>Incorporation</u>
R12-1-206(C)	21 CFR 1020.30(d)
R12-1-403	ICRP Publication 23, "Reference Man"
R12-1-416(C)	40 CFR 190
R12-1-418(B)(1)	NIST Handbook 150
R12-1-432(4)	49 CFR 172.403 and 436 49 CFR 173. 403 and 421
R12-1-433(A)	10 CFR 71.4
R12-1-433(B)	49 CFR 172.403 and 436-172.440
R12-1-444(A)(4)	40 CFR 190
R12-1-502(C)(1)	ANSI Pub. N43.9-1991
R12-1-502(C)(2)(c)	10CFR 71.51

13. The full text of the rules follows:

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**

Section
R12-1-202. ~~Application Requirements for Registration, or Certification, and Licensing~~ of Ionizing and Nonionizing Radiation Machine Facilities; Notification

R12-1-206. ~~Assembly, Installation, Removal from Service, and Transfer~~ ~~Assembler and/or transfer obligation~~

Arizona Administrative Register
Notices of Proposed Rulemaking

Appendix A: Registration and Licensing Forms (Excluding Radioactive Material)
Appendix A: Application Information

ARTICLE 3. RADIOACTIVE MATERIAL LICENSING

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

ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

Section
R12-1-401. Purpose
R12-1-402. Scope
R12-1-403. Definitions
R12-1-404. Units and Quantities
R12-1-405. Form of Records
R12-1-406. Implementation
R12-1-407. Radiation Protection Programs
R12-1-408. Occupation Dose Amounts for Adults
R12-1-409. Summation of External and Internal Doses
R12-1-410. Determination of External Dose from Airborne Radioactive Material
R12-1-411. Determination of Internal Exposure
R12-1-412. Determination of Prior Occupational Dose
R12-1-413. Planned Special Exposures
R12-1-415. Dose Limits for ~~to~~ an Embryo or Fetus
R12-1-416. Dose Limits for Individual Members of the Public
R12-1-417. Testing for Leakage or Contamination of Sealed Sources
R12-1-418. Surveys and Monitoring
R12-1-419. Conditions Requiring Individual Monitoring of External and Internal Occupational Dose
R12-1-420. Control of Access to High Radiation Areas
R12-1-421. Control of Access to Very-high Radiation Areas
R12-1-422. Control of Access to Irradiators (Very-high Radiation Areas)
R12-1-423. Use of Process or Other Engineering Controls
R12-1-424. Use of Other Controls
R12-1-425. Use of Individual Respiratory Protection Equipment
R12-1-426. Security of Stored Sources of Radiation
R12-1-427. Control of Sources of Radiation Not in Storage
R12-1-428. Caution Signs
R12-1-429. Postings ~~Posting~~ Requirements
R12-1-430. Posting ~~Exceptions to Posting~~ Requirements
R12-1-431. Labeling Containers and Radiation Machines
R12-1-432. Labeling ~~Exemptions to Labeling~~ Requirements
R12-1-433. Procedures for Receiving and Opening Packages
R12-1-434. General Requirements for Waste Disposal
R12-1-435. Method for Obtaining Approval of Proposed Disposal Procedures
R12-1-436. Disposal by Release into Sanitary Sewerage System
R12-1-437. Treatment or Disposal by Incineration
R12-1-438. Disposal of Specific Wastes
R12-1-439. Transfer for Disposal and Manifests
R12-1-440. Compliance with Environmental and Health Protection Regulations
R12-1-441. Records of Waste Disposal
R12-1-442. Agency Inspection of Shipments of Waste
R12-1-443. Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation
R12-1-444. Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits
R12-1-445. Notification of Incidents
R12-1-446. Notifications and Reports to Individuals
R12-1-447. Vacating Premises
R12-1-448. Additional Reporting Requirements
R12-1-449. Survey Instruments and Pocket Dosimeters
R12-1-450. Sealed Sources ~~Source~~ Requirements

Arizona Administrative Register
Notices of Proposed Rulemaking

ARTICLE 5. ~~RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS~~

Section

- R12-1-501. Limits on Levels of Radiation for Radiographic Exposure Devices and Storage Containers
R12-1-502. Radiographic Equipment Standards and Equipment Failure Notification
R12-1-504. Radiation Survey Instruments
R12-1-505. Leak Testing, Repair, Tagging, Opening, Modification, and Replacement of Sealed Sources
R12-1-507. Utilization ~~Logs~~ logs
R12-1-508. Inspection and Maintenance of Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments
R12-1-509. Permanent ~~Sealed Source~~ Radiographic Installations
R12-1-510. Operating ~~Personnel~~ Requirements
R12-1-511. License and Registration Application ~~Requirements~~ for Industrial Radiography
R12-1-512. Radiation Safety Officer
R12-1-521. Radiographer and Radiography Trainee Qualifications, Radiographer Certification, and Audits ~~Requirements for Radiographers and Radiographer's Assistants~~
R12-1-522. Operating and Emergency Procedures ~~emergency procedures~~
R12-1-523. Personnel Monitoring Control
R12-1-524. Supervision of Radiography Trainees ~~radiographers' assistants~~
R12-1-531. Security
R12-1-533. Radiation Surveys ~~surveys~~ and Survey Records ~~survey records~~
R12-1-534. Records Required at Temporary Job Sites ~~required at temporary job sites~~
R12-1-541. Enclosed Radiography Using X-ray Machines

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

Section

- ~~R12-1-612. X-ray and Electron Therapy Systems with Energies of 1 MeV and Above~~
R12-1-612. Computerized Tomographic Systems

ARTICLE 7. USE OF RADIONUCLIDES IN THE HEALING ARTS

Section

- R12-1-702. Definitions
R12-1-720. Decay in Storage

ARTICLE 9. ~~RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS~~

Section

- R12-1-904. Special Registration Requirements for Medical Use of Particle Accelerators
R12-1-905. Medical Particle Accelerator Equipment, Facility and Shielding, and Spot Checks
R12-1-911. Radiation Surveys ~~Survey Requirements~~
R12-1-912. ~~Ventilation systems~~ Repealed
R12-1-913. Misadministrations
R12-1-914. Initial Inspections of Particle Accelerators Used in the Practice of Medicine

ARTICLE 12. ADMINISTRATIVE PROVISIONS

Section

- R12-1-1209. Notice of Violation

ARTICLE 1. GENERAL PROVISIONS

R12-1-102. Definitions

Terms defined in A.R.S. § 30-651 have the same meanings when used in this Chapter. The following terms have the definitions set forth below. Additional definitions used only in a certain Article will be found in that Article.

"A ₁ "	No change.
"Absorbed dose"	No change.
"Accelerator"	No change.
"Accelerator produced material"	No change.
"Act"	No change.
"Activity"	No change.
"Adult"	No change.

Arizona Administrative Register
Notices of Proposed Rulemaking

“Agency”, or “ARRA”	No change.
“Agreement State”	No change.
“Airborne radioactive material”	No change.
“Airborne radioactivity area”	No change.
“ALARA”	No change.
“Analytical x-ray equipment”	No change.
“Analytical x-ray system”	No change.
<u>“Annual” means done or performed yearly. For purposes of Chapter 1 any required activity done or performed within plus or minus 2 weeks of the annual due date is considered done or performed in a timely manner.</u>	
“Background radiation”	No change
“Becquerel”	No change.
“Bioassay”	No change.
“Brachytherapy”	No change.
“By-product material”	No change.
“Calendar quarter”	No change.
“Calibration”	No change
“Certifiable cabinet x-ray system”	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”	No change.
“Explosive material”	No change.
“Exposure”	No change.
“Exposure rate”	No change.
“External dose”	No change.
“Extremity”	No change.
<u>“Eye dose equivalent” means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeters (300 mg/cm²).</u>	
“Fail-safe characteristics”	No change.
“Field radiography”	No change.
“Field station”	No change.
“Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities”	No change.
“Generally applicable environmental radiation standards”	No change.
“Gray”	No change.
“Hazardous waste”	No change.
“Healing arts”	No change.
“Health care institution”	No change.

Arizona Administrative Register
Notices of Proposed Rulemaking

“High radiation area” means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1mSv) in 1 hour at 30 centimeters from ~~the any source of radiation source or 30 centimeters from any surface that the radiation penetrates~~ or from any surface that the radiation penetrates.

“Human use” No change.

“Impound” No change.

“Individual” No change.

“Individual monitoring” No change.

“Individual monitoring ~~device devices~~ or “individual monitoring equipment” means an instrument devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these rules, “dosimeter”, “personnel dosimeter”, and “personnel monitoring equipment” are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal (“lapel”) air sampling devices.

“Industrial radiography” No change.

“Injection tool” No change.

“Inspection” No change.

“Interlock” No change.

“Internal dose” No change.

“Irradiate” No change.

“Laser” No change.

“Lens dose equivalent” (LDE) means the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeters (300 mg/cm²).

“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.

Arizona Administrative Register
Notices of Proposed Rulemaking

“Pyrophoric solid”	No change.
“Qualified expert”	No change.
“Quality Factor”	No change.
“Quarter” (see <u>calendar quarter</u>)	means a period of time equal to 1/4 of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.
“Rad”	No change.
“Radiation”	No change.
“Radiation area”	No change.
“Radiation dose”	No change.
“Radiation machine”	means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.
“Radiation safety officer”	No change.
“Radioactive marker”	No change.
“Radioactive material”	No change.
“Radioactivity”	No change.
“Radiographer”	No change.
“Radiographer’s assistant”	means any individual who, under the personal supervision of a radiographer, uses sources of radiation, radiographic exposure devices, related handling tools, or survey instruments in industrial radiography.
“Radiographic exposure device”	No change.
“Radiography trainee”	means a person learning to use radiographic exposure devices, sealed sources and related handling tools, and survey instruments in industrial radiography.
“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.
“TEDE”	No change.
“Teletherapy”	No change.
“Temporary job site”	No change.
“Test”	No change.
“These rules”	No change.
“Total Effective Dose Equivalent” (TEDE)	No change.
“Total Organ Dose Equivalent” (TODE)	No change.
“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.

Arizona Administrative Register
Notices of Proposed Rulemaking

“Well-bore”	No change.
“Well-logging”	No change.
“Whole body”	No change.
“Wireline”	No change.
“Wireline service operation”	No change.
“Worker”	No change.
“WL”	No change.
“WLM”	No change.
“Workload”	No change.
“Year”	No change.

**ARTICLE 2. RADIATION MACHINE FACILITY REGISTRATION OR LICENSING,
INSTALLATION AND SERVICE REGISTRATION, AND
MAMMOGRAPHIC FACILITY CERTIFICATION**

R12-1-202. ~~Application Requirements for Registration, or Certification, and Licensing of Ionizing and Nonionizing Radiation Machine Facilities; Notification~~

- A. A person shall not receive, possess, use, or transfer a radiation machine unless an application has been submitted to the Agency, except as authorized in this Article.
- B. A person ~~The owner or persons~~ possessing a ~~any~~ nonexempt radiation machine shall apply for registration of the machine with the Agency within 30 days after its installation acquisition. The person applying for registration of a radiation producing machine shall use the application forms provided by the Agency. The applicant shall provide the information identified in Appendix A of this Article ~~the appropriate form in Appendix A of this Article.~~
- C. No change.
- D. No change.
- E. With the application form for registration of a radiation machine ~~forms for registration of radiation machines~~, except dental, bone mineral analyzer, 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). Estimates of workload shall also be provided with the drawing.
- F. Each registrant moving an existing radiation machine to a new locations in an existing facility or to a new facility shall provide to the Agency the information required by subsection (E).
- G. An applicant proposing to use a particle accelerator for medical purposes shall not use the particle accelerator until the Agency inspection required in R12-1-914 has been completed.

R12-1-206. ~~Assembly, Installation, Removal from Service, and Transfer Assembler and/or transfer obligation~~

- A. Any person who ~~sells, leases, transfers, lends, disposes,~~ assembles, or installs radiation machines in this state shall notify the Agency within 15 days of:
 - 1. The name and address of the person possessing the machine that was assembled or installed ~~persons who have received these machines;~~
 - 2. The manufacturer, model, and serial number of each radiation machine assembled or installed ~~transferred;~~ and
 - 3. The date each machine was assembled or installed ~~of transfer of each radiation machine.~~
- B. Any person that possesses a radiation machine registered by the Agency shall notify the Agency within 15 days of the machine being taken out of service. The notification shall contain the name and address of the person receiving the machine, if it is sold, leased, or transferred to another person; the manufacturer, model, and serial number of the machine; and the date the machine was taken out of service.
- ~~C.~~ B. In the case of diagnostic x-ray systems that which contain certified components, an assembler shall submit to the Agency a copy of the assembler’s report prepared in compliance with requirements in of the Federal Diagnostic X-ray Standard, 21 CFR 1020.30(d), 1999 Edition, published April 1, 1999 by the Office of the Federal Register, National Archives and Records Administration revised as of April 1, 1987, incorporated herein by reference and on file with the Agency and in the Office of the Secretary of State, containing no future editions or amendments shall be submitted to the Agency within 15 days following completion of the assembly. The Such report shall suffice in lieu of any other report by the assembler.
- ~~D.~~ C. A person shall not No person shall make, sell, lease, transfer, lend, assemble, service, or install radiation machines or the supplies used in connection with radiation machines such machines unless the such supplies and equipment when properly placed in operation and used, shall meet the requirements of these rules.

Arizona Administrative Register
Notices of Proposed Rulemaking

Appendix A. Registration and Licensing Forms *Continued*

ARRA-4

Rev. 04/11/96

INSTRUCTIONS

Amendments to Form ARRA-4 should be submitted on Form ARRA-4. Changes to the attachments do not require a Form ARRA-4, but only submit the attachment form as applicable.

Items 1-3, are self-explanatory. Be sure to include area code and all ZIP codes.

Item 4, list address(es) at which a source of radiation may be used other than the address listed in item 3. If statewide, county wide, or citywide, please so designate. Leave blank if the same as item 3.

Item 5, please classify the facility according to the usage for which this application is being filed. If more than 1 usage of sources of radiation occurs at this facility a separate application should be filed for each usage. You may make copies of the front of this form, if necessary.

Item 6, choose a facility subtype that best describes your facility.

Item 7, list the name and telephone number of the individual who is delegated responsibility for radiation control for the facility. If a committee has this responsibility, list the chairman and attach a list of the committee membership. In any case, an individual usually designated as the Radiation Safety Officer will have the day to day responsibility for the administration of the Radiation Safety Program of the facility. Changes to the Committee Membership of the Radiation Safety Officer may be sent to the Agency by letter or FAX.

Item 8, please indicate the legal structure of the applicant. **NOTE:** for all cases indicate the State, etc., under which the entity is organized and any Arizona Agent representing the entity.

Item 9, please sign and date the application. Send application to: ARRA; 4814 South 40th Street; Phoenix, AZ 85040.

If you have any questions, please write to the above address or call 602-255-4845 ex. 3 FAX 602-437-0705.

PLEASE NOTE AN APPLICATION FOR A NEW RADIATION MACHINE FACILITY (NEVER REGISTERED/LICENSED BY THE APPLICANT) CANNOT BE PROCESSED UNTIL THE APPROPRIATE APPLICATION FEE IS RECEIVED. IN ACCORDANCE WITH R12-1-202 (C), THE APPLICANT OF AN EXISTING REGISTERED OR LICENSED FACILITY IS NOT TO POSSESS OR USE UNREGISTERED/UNLICENSED EQUIPMENT FOR MORE THAN 30 DAYS. (NOTE: A SCHEDULE OF APPLICATION FEES CAN BE FOUND IN R12-1-1306.)

No registration is complete unless the appropriate forms listing the equipment to be registered/licensed accompany this application. The following is a list of the appropriate forms to use when registering equipment.

<u>TYPE EQUIPMENT</u>	<u>ATTACHMENTS TO ARRA-4 APPLICATION</u>
Medical/Dental Diagnostic X-Ray units	ARRA-4X
Medical Therapy X-Ray (<1Mev)	ARRA-4XT
Medical Therapy X-Ray (≥ 1Mev)	ARRA-4PAT
Industrial Gauge	ARRA-4IG
Industrial Radiography (< 1,000 kVp)	ARRA-4IR
Industrial Radiography (≥ 1Mev)	ARRA-4PAR
All other Particle Accelerators	ARRA-4PA
Mammography	ARRA-13
Non-Ionizing Application	ARRA-1004
Tanning	ARRA-1005
Radio Frequency	ARRA-1030
Nonionizing User	ARRA-1050
Laser	ARRA-1070
MRI	ARRA-1090

Arizona Administrative Register
Notices of Proposed 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 _____	Tomographic _____	Bone Densitometer _____
Fluoroscopic wo/image Intensifier _____	Panographic _____	Cephalometric _____
Combination w/image Intensifier _____	Radiographic _____	Intra Oral _____
Combination wo/image Intensifier _____	Photofluorographic _____	Other Dental _____
Computerized Axial Tomographic _____		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 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 Proposed 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

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

ADDITIONAL 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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Arizona Administrative Register
Notices of Proposed 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 _____ Medical Physicist _____ Osteopath _____ Other _____

PARTICLE ACCELERATOR INFORMATION

Betatron _____ Cyclotron _____ Van de Graaff _____ Other Medical therapy _____ medical LINAC _____

EQUIPMENT

<u>MANUFACTURER / MODEL NO.</u>	<u>SERIAL NO.</u>	<u>MAX. Mev</u>	<u>MU/min or MAX. MA.</u>	<u>PHYSICAL LOCATION</u>
Photons _____	_____	_____	_____	_____
Electrons _____	_____	_____	_____	_____
Neutrons _____	_____	_____	_____	_____

ADDITIONAL 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 Proposed Rulemaking

Appendix A. Registration and Licensing Forms *Continued*

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 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.

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Arizona Administrative Register
Notices of Proposed 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 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.

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Arizona Administrative Register
Notices of Proposed 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 _____ Linear _____ Other _____

This Machine is Mobile _____ or Fixed _____

EQUIPMENT

<u>MANUFACTURER / MODEL NO.</u>	<u>SERIAL NO.</u>	<u>MAX. MVP</u>	<u>MAX. MA.</u>	<u>PHYSICAL LOCATION</u>
---------------------------------	-------------------	-----------------	-----------------	--------------------------

ADDITIONAL REQUESTED 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 Proposed 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 _____

Linear _____

Other _____

This Machine is Mobile _____ or Fixed _____

EQUIPMENT

MANUFACTURER / MODEL NO.

SERIAL NO.

MAX. MVP

MAX. MA.

PHYSICAL LOCATION

ADDITIONAL 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.

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Arizona Administrative Register
Notices of Proposed Rulemaking

Appendix A. Registration and Licensing Forms Continued

ARRA-1050
May 1994



ARIZONA RADIATION REGULATORY AGENCY

NONIONIZING RADIATION USER APPLICATION

INSTRUCTIONS - Complete one of these applications, to be included with a NONIONIZING RADIATION LICENSE APPLICATION, for each user to be authorized use on a new license or the renewal of an existing license. Use supplemental sheets where necessary. Retain a copy of this application for your records. Mail the original to: Arizona Radiation Regulatory Agency, 4814 South 40th Street, Phoenix, Arizona 85040.

1. NAME AND ADDRESS OF LICENSEE TELEPHONE NUMBER: _____	2. ADDRESS AT WHICH DEVICE(S) WILL BE USED _____
3. PERSON TO CONTACT REGARDING THIS APPLICATION TELEPHONE NUMBER: _____	4. THIS APPLICATION IS PART OF A(N): (Check appropriate item) <input type="checkbox"/> NEW LICENSE <input type="checkbox"/> RENEWAL OF LICENSE NO. _____ <input type="checkbox"/> AMEMDMENT TO LICENSE NO. _____

The operator has been trained and demonstrated competence in the safe use of this equipment.
A copy of safety rules has been provided to the operator.

The operator has been made aware of any restrictions in operating techniques required for the safe use of the devices.

A copy of the Arizona Administrative Code, Title 12, Chapter 1 is available for review by the operator, and the requirements of the applicable portions of the same have been reviewed with the operator.

Job Title of Operator: _____

Job Title of Supervisor of Operator: _____

Name of Operator: _____

Name of Safety Officer: _____

The Use Applicant or the Official executing this certificate on behalf of the License Applicant named in item 1, certifies that this application is prepared in conformity with Arizona Administrative Code, Title 12, Chapter 1, and that all information contained on the form, including any attachments, is true and correct to the best of his or her knowledge and belief. Further, the User Applicant or any official executing this certificate on behalf of the applicant agrees to conform to the Statutory and Administrative requirements of the State of Arizona and the Arizona Radiation Regulatory Agency.

(TYPE OR PRINT NAME OF OPERATOR)

BY: _____
(SIGNATURE OF OPERATOR)

(TITLE OF OPERATOR)

DATE: _____

(TYPE OR PRINT NAME OF CERTIFYING OFFICIAL)

BY: _____
(SIGNATURE OF CERTIFYING OFFICIAL)

(TITLE OF CERTIFYING OFFICIAL)

DATE: _____

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Arizona Administrative Register
Notices of Proposed Rulemaking

Appendix A. Registration and Licensing Forms Continued

ARRA-1070
May 1994



ARIZONA RADIATION REGULATORY AGENCY
LASER DATA FORM

INSTRUCTIONS - Complete all items in this data sheet for licensing a new facility or the renewal or amendment of an existing license. Use one data form for each regulated LASER. Retain a copy of this data sheet for your records. Attach this sheet to your NONIONIZING RADIATION LICENSE APPLICATION and mail to: Arizona Radiation Regulatory Agency, 4814 South 40th Street, Phoenix, Arizona 85040. Upon approval of this application, the applicant will receive a Nonionizing Radiation License issued in accordance with the requirements contained in the Arizona Administrative Code. This data form is for use by Laser facilities. Other facility types are required to use forms provided by the Agency.

1. NAME AND ADDRESS OF LICENSEE: TELEPHONE NUMBER: _____	2. ADDRESS AT WHICH DEVICE(S) WILL BE USED: _____
3. PERSON TO CONTACT REGARDING THIS DATA FORM TELEPHONE NUMBER: _____	4. THIS IS DATA FOR AN APPLICATION FOR: (Check appropriate item) <input checked="" type="checkbox"/> NEW LICENSE <input type="checkbox"/> RENEWAL OF LICENSE NO. _____ <input type="checkbox"/> AMEMDMENT TO LICENSE NO. _____
5. LASER INDENTIFYING INFORMATION: MANUFACTURER: _____ MODEL NUMBER: _____ SERIAL NUMBER: _____	6. LASER CLASS AND TYPE: LASER CLASS: _____ LASING MEDIUM (i.e., CO2 or YAG): _____ PRINCIPAL WAVELENGTH: _____

The Applicant or any official executing this certificate on behalf of the applicant named in item 1, certifies that this application is prepared in conformity with Arizona Administrative Code, Title 12, Chapter 1, and that all information contained on the form, including any attachments, is true and correct to the best of his or her knowledge and belief. Further, the Applicant and any official executing this certificate on behalf of the applicants behalf agrees to conform to the Statutory and Administrative requirements of the State of Arizona and the Arizona Radiation Regulatory Agency.

(TYPE OR PRINT NAME OF CERTIFYING OFFICIAL)

(TITLE OF CERTIFYING OFFICIAL)

BY _____
(SIGNATURE)

DATE: _____

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Arizona Administrative Register
Notices of Proposed Rulemaking

Appendix A

Application Information

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

Name and mailing address of applicant

Person responsible for radiation safety program

Type of facility

Legal structure and ownership

Radiation machine information

Shielding information

Equipment operator instructions and restrictions

Record of calibration for therapy units

Type of industrial radiography program, if applicable

Radiation Safety Officer name, if applicable

Contact person

Laser class and type, if applicable

Appropriate fee listed in Article 13 table

Other licensing and registration requirements listed in Articles 2, 6, 8, 9, and 14

Use location

Telephone number

Facility subtype

Signature of certifying agent

Equipment identifiers

Scale drawing

Classification of professional in charge

Protection survey results, if applicable

Physicist name and training, if applicable

Type of request: amendment, new, or renewal

MRI field strength, device cycle time, and principle frequency, if applicable

ARTICLE 3. RADIOACTIVE MATERIAL LICENSING

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

- A.** No change.
 - 1. No change.
 - 2. No change.
- B.** No change.
 - 1. No change.
 - a. No change.
 - i. No change.
 - ii. No change.
 - iii. No change.
 - iv. No change.
 - v. No change.
 - vi. No change.
 - vii. No change.
 - (1) No change.
 - (2) No change.
 - (3) No change.
 - viii. No change.
 - b. No change.
 - c. No change.
 - d. No change.
 - e. No change.
 - f. No change.
 - g. No change.

- i. No change.
 - ii. No change.
 - iii. No change.
 - iv. No change.
 - v. No change.
 - vi. No change.
 - h. No change.
 - i. No change.
 - ii. No change.
 - iii. No change.
 - iv. No change.
- 2. No change.
- 3. No change.
 - a. No change.
 - b. No change.
- 4. No change.
 - a. No change.
 - b. No change.
- C. Exempt quantities
 - 1. No change
 - 2. No change.
 - 3. No change.
 - 4. Sources containing exempt quantities of radioactive material shall not be bundled or placed in close proximity for the purpose of using the radiation from the combined sources in place of a single source, containing a licensable quantity of radioactive material.
 - 5. Possession and use of bundled or combined sources containing exempt quantities of radioactive material in unregistered devices by persons exempt from licensing is prohibited.

ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

R12-1-401. Purpose

- A. Article 4 establishes standards for protection against ionizing radiation resulting from activities conducted according pursuant to licenses or registrations issued by the Agency. These rules regulations are issued according pursuant to A.R.S. Title 30, Chapter 4, Arizona Revised Statutes, as amended.
- B. The requirements of Article 4 are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose equivalent to an individual, including radiation exposure doses resulting from all sources of radiation other than radiation prescribed by a physician in the practice of medicine, radiation received while voluntarily participating in a medical research program, and background radiation, does not exceed the standards for protection against radiation prescribed in this Article Article 4. However, this Article does not limit nothing in Article 4 shall be construed as limiting actions that may be necessary to protect health and safety.

R12-1-402. Scope

Except as specifically provided in other Articles of these rules regulations, Article 4 applies to persons licensed or registered by the Agency to receive, possess, use, transfer, or dispose of sources of ionizing radiation. The limits in Article 4 do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs.

R12-1-403. Definitions

- A. "ALI" means annual limit on intake, the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the Reference Man reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Appendix B, Table I, Columns 1 and 2, of Appendix B.
- B. "Class" means a classification scheme for inhaled material according to the material's its rate of clearance from the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, days Days, of less than 10 days, for Class W, weeks Weeks, from 10 to 100 days, and for Class Y, years Years, of greater than 100 days (See Introduction, Appendix B). For purposes of these rules regulations, "lung class" and "inhalation class" are equivalent terms.
- C. "DAC" means derived air concentration, the concentration of a given radionuclide in air which, if breathed by Reference Man the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of 1 one ALI.

Arizona Administrative Register
Notices of Proposed Rulemaking

For purposes of these ~~rules~~ regulations, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Appendix B, Table I, Column 3, of Appendix B.

- ~~D.~~ “DAC-hour” means derived air concentration-hour, the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).
- ~~E.~~ “Declared pregnant woman” means a woman who has voluntarily informed the licensee or registrant in writing of the pregnancy and the estimated date of conception. ~~her employer, in writing, of her pregnancy and the estimated date of conception.~~
- ~~F.~~ Deterministic effect” [see “Nonstochastic effect”].
- ~~G.~~ “Dosimetry processor” means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose received by a persons wearing delivered to the monitoring devices.
- ~~H.~~ “Inhalation class” [see “Class”].
- ~~I.~~ “Lung class” [see “Class”].
- ~~J.~~ “Nonstochastic effect” means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these rules regulations, “deterministic effect” is an equivalent term and “threshold” means a dose level at which a specific health effect can be expected to occur.
- ~~K.~~ “Planned special exposure” means an infrequent exposure to radiation received while employed, but separate from and in addition to the annual occupational dose limits.
- ~~L.~~ “Probabilistic effect” [see “Stochastic effect”].
- ~~M.~~ “Reference Man” means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of ~~the~~ Reference Man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, “Report of the Task Group on Reference Man,” published in 1975 by Pergammon Press, incorporated ~~herein~~ by reference and on file with the Agency and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.
- ~~N.~~ “Respiratory protective equipment” means an apparatus, such as a respirator, used to reduce an individual’s intake of airborne radioactive materials.
- ~~O.~~ “Sanitary sewerage” means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.
- ~~P.~~ “Stochastic effect” means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without a threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these rules regulations, “probabilistic effect” is an equivalent term.
- ~~Q.~~ “Very high radiation area” means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a radiation source of radiation or 1 meter from any surface that the radiation penetrates.
(At very high doses received at high dose rates, units of absorbed dose, the gray and rad should be used, gray and rad, are appropriate, rather than units of dose equivalent, the sievert and rem)
- ~~R.~~ “Weighting factor” w_T for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30 ^a
Whole Body	
	1.00 ^b

^a 0.30 results from 0.06 for each of 5 “remainder” organs, excluding the skin and the lens of the eye, that receive the highest doses.

Arizona Administrative Register
Notices of Proposed Rulemaking

^b For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved by the Agency on a case-by-case basis ~~until such time as specific guidance is issued.~~

R12-1-404. Units and Quantities

- A. Each licensee or registrant shall use the Standard International (SI) ~~SI~~ units becquerel, gray, sievert, and coulomb per kilogram, or the special units curie, rad, rem, and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this Article 4.
- B. The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this Article 4, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens eye dose equivalent, deep dose equivalent, or committed effective dose equivalent.

R12-1-405. Form of Records

A licensee or registrant shall ensure that each ~~Each~~ record required by this Article 4 ~~shall be~~ legible throughout the specified retention period. The record shall be the original, ~~or~~ a reproduced copy, or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. As an alternative the record may be stored in electronic media capable of ~~with the capability for~~ producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. A licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

R12-1-406. Implementation

- ~~A.~~ Any existing license or registration condition that is more restrictive than this Article 4 remains in force until amendment or renewal of the license or registration.
- ~~B.~~ If a license or registration condition exempts a licensee or registrant from a provision of Article 4 in effect on or before January 1, 1994, it also exempts the licensee or registrant from the corresponding provision of Article 4, until an amendment or renewal of the license or registration modifies or removes this condition.
- ~~C.~~ If a license or registration condition cites provisions of Article 4 in effect prior to January 1, 1994, which do not correspond to any provisions of Article 4, the license or registration condition remains in force until an amendment or renewal of the license or registration modifies or removes this condition.

R12-1-407. Radiation Protection Programs

- A. No change.
- B. The licensee or registrant shall use, to the extent practical ~~practicable~~, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).
- C. No change.
- D. No change.
 - 1. No change:
 - a. No change.
 - b. No change.
 - 2. No change.
 - 3. No change.

R12-1-408. Occupational Dose Amounts for Adults

- A. Each ~~The~~ licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures required in pursuant to R12-1-413, to the following dose limits:
 - 1. No change.
 - a. No change.
 - b. No change.
 - 2. The annual limits to the lens of the eye, to the skin, and to the extremities which are:
 - a. A lens ~~An eye~~ dose equivalent of 0.15 Sv (15 rem), and
 - b. No change.
- B. No change.
- C. The assigned deep dose equivalent and shallow dose equivalent is for the portion of the body receiving the highest exposure determined as follows:
 - 1. The deep dose equivalent, lens eye dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

Arizona Administrative Register
Notices of Proposed Rulemaking

2. When a protective apron is worn and monitoring is conducted as specified in R12-1-419(B), the effective dose equivalent for external radiation shall be determined as follows:
 - a. When only ~~1 one~~ individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25% ~~percent~~ of the limit specified in R12-1-408(A), the reported deep dose equivalent value multiplied by 0.3 is the effective dose equivalent for external radiation; or
 - b. No change.
- D. No change.
- E. No change.
- F. No change.

R12-1-409. Summation of External and Internal Doses

- A. If ~~a the~~ licensee or registrant is required to monitor according to R12-1-419(B) and (C), the licensee or registrant shall add 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 to R12-1-419(B) or only according to R12-1-419(C), summation is not required to demonstrate compliance with dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses according to subsections (B), (C), and (D). 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. 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 (~~1 one~~):
 1. The sum of the fractions of the inhalation ALI for each radionuclide, or
 2. The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or
 3. The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using applicable ~~appropriate~~ biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T , and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10% of the maximum weighted value of $H_{T,50}$, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.
- C. 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. 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 according pursuant ~~to~~ this subsection.

R12-1-410. Determination of External Dose from Airborne Radioactive Material

- A. Each licensee or registrant Licensees or registrants shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See Appendix B, footnotes 1 and 2.
- B. No change.

R12-1-411. Determination of Internal Exposure

- A. For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, each the licensee or registrant shall, when required according pursuant ~~to~~ R12-1-419, take suitable and timely measurements of:
 1. Concentrations of radioactive materials in air in work areas;
 2. Quantities of radionuclides in the body;
 3. Quantities of radionuclides excreted from the body; or
 4. Combinations of these measurements.
- B. No change.
- C. No change.
 1. No change.
 2. No change.
 3. No change.
- D. No change.
- E. No change.
 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 the most restrictive DAC of the any ~~the~~ radionuclide in the mixture.

Arizona Administrative Register
Notices of Proposed Rulemaking

- 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 compliance with the dose limits in R12-1-408 and ~~to~~ comply with the monitoring requirements in R12-1-419, ~~and~~
 2. The concentration of any radionuclide disregarded is less than 10% of its DAC, and
 3. The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30%.
- H.** When determining the committed effective dose equivalent, the following information may be considered:
1. In order to calculate the committed effective dose equivalent, the licensee or registrant may assume that the inhalation of 1 ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.
 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 Appendix B, Table I. The licensee or registrant may, as a simplifying 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) is met.

R12-1-412. Determination of Prior Occupational Dose

- A.** For each individual who may enter ~~a~~ the licensee's or registrant's restricted area and is likely to receive, in a year, an occupational dose requiring monitoring ~~according pursuant~~ to R12-1-419, the licensee or registrant shall:
1. Determine the occupational radiation dose received during the current year; and
 2. Attempt to obtain the records of lifetime cumulative occupational radiation dose.
- B.** ~~Before~~ ~~Prior to~~ permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:
1. No change.
 2. All doses in excess of the limits received during the lifetime of the individual, including doses received during accidents and emergencies, ~~received during the lifetime of the individual~~; and
 3. All lifetime, cumulative, occupational radiation doses.
- C.** In complying with the requirements of subsection (A) ~~above~~, a licensee or registrant ~~shall may~~:
1. Accept, as a record of the occupational dose that the individual received during the current year, a written and signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and
 2. No change.
 3. No change.
- D.** No change.
1. The licensee or registrant shall record the exposure history, as required by subsection (A) ~~above~~, on Agency Form Y (available from the Agency) or a similar ~~other~~ clear and legible record; of all the information required by this subsection. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report for ~~in~~ preparing Agency Form Y or its equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on Agency Form Y or its equivalent indicating each period ~~the~~ periods of time for which there is no data ~~are not available~~.
 2. ~~The licensee or registrant is~~ ~~Licensees or registrants are~~ not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed ~~according pursuant~~ to the rules ~~regulations~~ in Article 4 in effect before January 1, 1994. Occupational ~~Further, occupational~~ exposure histories obtained and recorded on Agency Form Y or its equivalent before January 1, 1994, would not have included effective dose equivalent but may be used in the absence of specific information on the intake of radionuclides by the individual.
 3. If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall ~~assume~~:
 - a. In establishing administrative controls under ~~pursuant to~~ R12-1-408(F) for the current year, reduce ~~that~~ the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and
 - b. Not subject ~~That~~ the individual to ~~is not available for~~ planned special exposures.
 4. The licensee or registrant shall retain current and prior records on Agency Form Y or its equivalent for 3 years after the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Agency Form Y or its equivalent for 3 years after the record is made.

Arizona Administrative Register
Notices of Proposed Rulemaking

R12-1-413. Planned Special Exposures

- A. A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in R12-1-408, provided that each of the following conditions is satisfied:
1. No change.
 2. No change.
 3. No change.
 - a. Informed in writing of the purpose of the planned special exposure; operation; and
 - b. Informed in writing of the estimated doses, ~~and~~ associated potential risks, and specific radiation levels or other conditions that might be involved in performing the task; and
 - c. Instructed in the measures to be taken to keep the dose ALARA ~~in accordance with R12-1-407(B)~~, considering other risks that may be present.
 4. ~~Before~~ Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall ascertain ~~ascertains~~ prior doses as required by R12-1-412(B) ~~during the lifetime of the individual~~ for each individual involved.
 5. Subject to R12-1-408(B), the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses that exceed ~~in excess of the limits to exceed~~:
 - a. No change.
 - b. No change.
 6. The licensee or registrant maintains records ~~of the conduct~~ of a planned Special exposure in accordance with subsections (B) and (C) ~~below~~ and submits a written report to the Agency within 30 days after the date ~~following~~ any planned special exposure conducted in accordance with this Section, informing the Agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by subsection (B) ~~below~~.
 7. The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days after ~~from~~ the date of the planned special exposure. The dose from a planned special exposure ~~exposures~~ shall not be considered in controlling future occupational dose of the individual according pursuant to R12-1-408(A) but shall be included in evaluations required by subsections (A)(4) and (5) ~~paragraphs A.4. and 5, above~~.
- B. No change.
1. For each ~~use of~~ planned special exposure ~~exposures~~, the licensee or registrant shall maintain records that describe:
 - a. No change.
 - b. No change.
 - c. No change.
 - d. No change.
 - e. What precautions were taken to assure that doses were minimized ~~maintained~~ in accordance with R12-1-407(B),
 - f. What individual and collective doses were expected ~~to result~~,
 - g. No change.
 - h. The process through which ~~That~~ the employee involved in the planned special exposure has been informed in writing of the information contained in subsection (A)(3) ~~paragraph (A)(3), above~~.
 2. The licensee or registrant shall retain the records for 3 years after the Agency terminates each pertinent license or registration ~~requiring these records~~.

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

- A. The licensee or registrant shall ensure that the dose equivalent 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 R12-1-419(D)(4) and (5).
- B. No change.
- C. The dose equivalent to an embryo or fetus is the sum of:
1. The deep dose equivalent to the declared pregnant woman; and
 2. The dose equivalent to the embryo or fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.
- D. If by the time the woman declares pregnancy to the licensee or registrant, the dose equivalent to the embryo or fetus has exceeded 4.5 mSv (0.45 rem), the licensee or registrant is deemed to be in compliance with subsection (A), if the additional dose equivalent to the embryo or fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.
- E. A declaration of pregnancy shall remain in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

Arizona Administrative Register
Notices of Proposed Rulemaking

R12-1-416. Dose Limits for Individual Members of the Public

- A. Each licensee or registrant shall conduct operations so that:
1. The total effective dose equivalent to any individual ~~member~~ members of the public from the licensed or registered operation does not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose contribution from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with R12-1-436; and
 2. ~~Registrants shall not be required to retrofit locations within facilities where only radiation machines exist prior to the effective date of these rules and met the previous requirement of (0.5 rem) in a year; and~~
- 2.3. The dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any 1 hour.
- B. A licensee, registrant, or an applicant for a license or registration may apply for ~~prior~~ Agency authorization to operate with an up to an annual dose limit of 5 mSv (0.5 rem) for an individual member of the public ~~of 5 mSv (0.5 rem)~~. The This application shall include the following information:
1. An explanation ~~Demonstration~~ of the need for and the expected duration of operations in excess of the limit in subsection (A) above, and.
 2. No change.
 3. No change.
- C. A ~~In addition to the requirements of Article 4, a licensee or registrant shall comply with subject to the provisions of the U.S. Environmental Protection Agency's applicable environmental radiation standards in 40 CFR 190 1999 Edition, published July 1, 1999, by the Office of Federal Register National Archives and Records Administration, incorporated by reference and on file with the Agency and the Office of the Secretary of State, containing no future editions or amendments. U.S. Environmental Protection Agency's generally applicable environmental radiation standards in Title 40, Code of Federal Regulations, Part 190, 1992 Edition, published July 1, 1992, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Office of Secretary of State, shall comply with those standards.~~
- D. No change.
- E. Each licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted areas and radioactive materials contained in effluents released to unrestricted areas to demonstrate compliance with the dose limits for ~~individual~~ members of the public ~~listed above~~.
- F. Each licensee or registrant shall ~~show compliance with the annual dose limit listed above by:~~
1. Demonstrate by measurement ~~Demonstrating by measurement~~ or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or
 2. Demonstrate ~~Demonstrating~~ that:
 - a. The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Appendix B, Table II ~~of Appendix B~~; and
 - b. No change.
- G. No change.
- H. ~~Records.~~ Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public; and shall retain the records for 3 ~~three~~ years after the Agency terminates each pertinent license or registration requiring the record.

R12-1-417. Testing for Leakage or Contamination of Sealed Sources

- A. A ~~The~~ licensee in possession of any sealed source shall assure that:
1. Each sealed source, except as specified in subsection (B) below, is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within 6 months before transfer to the licensee or registrant.
 2. Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 6 months or at alternative intervals approved by the Agency, after evaluation of information specified by R12-1-311 (D)(2) and (3) of these rules ~~regulations~~, or equivalent information specified by an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.
 3. Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 3 months or at alternative intervals approved by the Agency, after evaluation of information specified by R12-1-311 (D)(2) and (3). of these rules ~~regulations~~, or equivalent information specified by an Agreement State, a Licensing State, or the Nuclear Regulatory Commission.
 4. Each ~~For each~~ sealed source suspected of damage or leakage shall ~~that is required to~~ be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee or registrant shall assure that the sealed source is tested for leakage or contamination before further use.
 5. Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, are ~~shall be~~ capable of detecting the presence of 185 Bq (0.005 μ Ci) of radioactive material on a test sample. The person conduct-

Arizona Administrative Register
Notices of Proposed Rulemaking

~~ing the test shall take test~~ Test samples ~~shall be taken~~ from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which ~~one might expect~~ contamination ~~could~~ to accumulate. For a sealed source contained in a device, the person conducting the test shall obtain test samples ~~are obtained~~ when the source of radiation is in the "off" position.

6. The test for leakage ~~from~~ for brachytherapy sources containing radium ~~manufactured to contain Radium is~~ shall be capable of detecting an absolute leakage rate of 37 Bq (0.001 μ Ci) of Radon-222 in a 24 hour period when the collection efficiency for Radon-222 and its daughters has been determined with respect to collection method, volume, and time.
 7. Tests for contamination from radium ~~Radium~~ daughters ~~are~~ shall be taken on the interior surface of brachytherapy source storage containers and ~~are~~ shall be capable of detecting the presence of 185 Bq (0.005 μ Ci) of a radium ~~Radium~~ daughter which has a half-life greater than 4 days.
- B.** A licensee ~~or registrant~~ need not required to perform tests ~~perform test~~ for leakage or contamination on the following sealed sources:
1. No change.
 2. No change.
 3. No change.
 4. No change.
 5. No change.
 6. Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used, and identified as in storage. The licensee or registrant shall, ~~however~~, test each ~~such~~ sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within 6 months before the date of use or transfer.
- C.** Persons specifically authorized by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission shall perform tests for leakage or contamination of sealed sources. ~~Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.~~
- D.** A licensee shall maintain test ~~Test results shall be kept~~ in units of becquerel or microcurie and ~~maintained~~ for inspection by the Agency.
- E.** The following ~~is~~ shall be considered evidence that a sealed source is leaking:
1. No change.
 2. No change.
 3. The presence of removable contamination resulting from the decay of 185 Bq (0.005 μ Ci) or more of radium. ~~Radium.~~
- F.** ~~A~~ ~~The licensee or registrant~~ shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this Article 4. ~~Article 4.~~
- G.** ~~Reports.~~ A ~~The licensee~~ shall file a report with the Agency within 5 days with the Agency if the test for leakage or contamination indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results and the corrective action taken.
- H.** A licensee shall maintain records ~~Records. Records~~ of tests for leakage or contamination of sealed sources ~~shall be kept~~ in units of becquerel or microcurie and ~~maintained for inspection by the Agency~~ for 3 years after the records are made.

R12-1-418. Surveys and Monitoring

- A.** No change.
1. No change.
 2. No change.
 - a. No change.
 - b. No change.
 - c. No change.
- B.** No change.
1. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology, according pursuant to NVLAP procedures ~~Procedures published August 1994 as NIST Handbook 150 November 1990 as Edition NISTIR 4493~~ by the U.S. Department of Commerce, incorporated ~~herein~~ by reference and on file with the Agency and the Office of the Secretary of State, containing no future editions or amendments; and
 2. No change.
- C.** No change.
- D.** No change.
1. No change.

Arizona Administrative Register
Notices of Proposed Rulemaking

2. The licensee or registrant shall retain each of the following records for 3 years after the Agency terminates ~~the each~~ ~~pertinent~~ license or registration ~~requiring the record~~:
 - a. Records of the survey results used ~~results of surveys~~ to determine the dose from external sources of radiation ~~used~~, in the absence of or in combination with individual monitoring data, and provide an ~~in the~~ assessment of individual dose equivalents;
 - b. Records of the measurement and calculation results ~~results of measurements and calculations~~ used to determine individual intakes of radioactive material and used in the assessment of internal dose;
 - c. Records showing the results of air sampling, surveys, and bioassays required according ~~pursuant~~ to R12-1-425(A)(3)(a) and (b); and
 - d. Records of the measurement and calculation results ~~results of measurements and calculations~~ used to evaluate the release of radioactive effluents to the environment.

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

- A. No change.
- B. No change.
 1. No change.
 2. No change.
 3. No change.
 4. No change.
 - a. No change.
 - b. An individual monitoring device used for lens ~~eye~~ dose equivalent shall be located at the neck, or an unshielded location closer to the eye, outside the protective apron.
 - c. No change.
- C. No change.
 1. Adults likely to receive, in 1 year, an intake in excess of 10% of the applicable ALI in Table I, Columns 1 and 2, of Appendix B; and
 2. No change.
- D. No change.
 1. No change.
 - a. The deep dose equivalent to the whole body, lens ~~eye~~ dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;
 - b. No change.
 - c. No change.
 - d. No change.
 - e. No change.
 - f. No change.
 2. No change.
 3. No change.
 4. No change.
 5. No change.

R12-1-420. Control of Access to High Radiation Areas

- A. ~~The~~ licensee or registrant shall ensure that each entrance or access point to a high radiation area has 1 or more of the following features:
 1. A control device that, upon entry into the area, causes the level of radiation to be reduced below the ~~that~~ level at which an individual might receive a deep-dose equivalent of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates;
 2. No change.
 3. No change.
- B. No change.
- C. No change.
- D. The licensee or registrant shall establish the controls required by subsection (A) and (C) ~~above~~ in a way that does not prevent individuals from leaving a high radiation area.
- E. No change.
 1. No change.
 2. No change.
- F. The licensee or registrant is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the estab-

Arizona Administrative Register
Notices of Proposed Rulemaking

lished limits in Article 4 and to operate in accordance with R12-1-407(B) and the provisions of the licensee's or registrant's radiation protection program.

- G.** The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in this Section if the registrant has met all the specific requirements for access and control specified in other applicable Articles of these rules regulations, such as, Article 5 for industrial radiography, Article 6 for x-rays in the healing arts, and Article ~~9~~ 8 for particle accelerators.

R12-1-421. Control of Access to Very-high Radiation Areas

- A.** In addition to the requirements in R12-1-420, ~~a~~ the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 5 Gy (500 rad) or more in 1 hour at 1 meter from a source of radiation or from any surface ~~that through which~~ the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation; or ~~to~~ non-self-shielded irradiators.
- B.** The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area, ~~as~~ described in subsection (A) ~~above~~, if the registrant has met all ~~the specific~~ requirements for access and control specified in other applicable Articles of these rules regulations, such as, Article 5 for industrial radiography, Article 6 for x rays in the healing arts, and Article ~~9~~ 8 for particle accelerators.
- C.** Each licensee or registrant shall maintain records of tests made according pursuant to R12-1-422(B)(9) on entry control devices for very high radiation areas. These records shall include the date, time, and results of each ~~such~~ test of function.
- D.** No change.

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

- A.** This Section applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. This Section does not apply to sources of radiation that are used in teletherapy, ~~in~~ industrial radiography, or ~~in~~ completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.
- B.** ~~A licensee or a registrant shall ensure that each~~ Each area in which there may exist radiation levels in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation that is used to irradiate materials meets ~~shall meet~~ the following requirements:
1. Each entrance or access point ~~is shall be~~ equipped with entry control devices that ~~which~~:
 - a. No change.
 - b. No change.
 - c. No change.
 2. Additional control devices ~~is shall be~~ provided so that, upon failure of the entry control devices to function as required by subsection (B)(1) ~~above~~:
 - a. No change.
 - b. Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least 1 other authorized individual, who is physically present, familiar with the process activity and equipment prepared to render or summon assistance, aware of the failure of the entry control devices.
 3.
 - a. No change.
 - b. Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or registrant or at least 1 ~~one~~ other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barriers ~~barrier~~.
 4. No change.
 5. Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of subsections (B)(3) paragraphs (A)(3) and (4) ~~above~~.
 6. ~~The licensee or registrant shall equip each~~ Each area ~~shall be equipped~~ with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, ~~which shall be~~ installed in the area, and which can prevent the source of radiation from being put into operation.
 7. ~~The licensee or registrant shall control each~~ Each area ~~shall be controlled~~ by use of such administrative procedures and ~~such~~ devices ~~as are~~ necessary to ensure that the area is cleared of personnel before prior to each use of the source of radiation.
 8. ~~The licensee or registrant shall check~~ Each area ~~shall be checked~~ by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of

Arizona Administrative Register
Notices of Proposed Rulemaking

radiation in the area is below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour.

9. The licensee or registrant shall test the entry control devices required in subsection paragraph (B)(1) above shall be tested for proper functioning and keep records according to ~~Record keeping shall be in accordance with~~ R12-1-421.
 - a. Testing shall be conducted before prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day;
 - b. Testing shall be conducted before prior to resumption of operation of the source of radiation after any unintentional interruption: and
 - c. No change.
 10. The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in a safe condition or to effect repairs on controls, unless control devices are functioning properly.
 11. The licensee or registrant shall control entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such with devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and automatically to prevent loose radioactive material from being carried out of the area.
- C. A licensee, registrant, or applicant seeking a license or registration for a source of radiation ~~Licensees, registrants, or applicants for licenses or registrations for sources of radiation~~ within the purview of subsection (B) that above which will be used in a variety of positions or in locations, such as open fields or forests, that make it impractical impracticable to comply with certain requirements of subsection (B) above, such as those for the automatic control of radiation levels, may apply to the Agency for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to that those specified in subsection (B) above. At least 1 of the alternative measures shall be include an entry-preventing interlock control, based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where the such sources of radiation are used.
- D. A licensee or registrant shall provide the The entry control devices required by subsections (B) and (C) above shall be established in such a way that no individual will be prevented from leaving the area.
- E. No change.
1. Each licensee or registrant shall maintain records of tests made according pursuant to subsection paragraph (B)(9) above on entry control devices for very high radiation areas. These records shall include the date, time, and results of each such test of function.
 2. The licensee or registrant shall retain the records for 3 years from the date after the record is made.

R12-1-423. Use of Process or Other Engineering Controls

~~A~~ The licensee or registrant shall use process or other engineering controls, such as; containment or ventilation, to control the concentrations of radioactive material in the air and comply with ~~as may be required to meet the requirements of~~ R12-1-407.

R12-1-424. Use of Other Controls

When it is not practical practicable to apply process or other engineering controls to control the concentrations of radioactive material in the air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent according to in accordance with R12-1-407(B), increase monitoring and limit intakes by ~~1~~ one or more of the following means:

1. Control of access, or
2. Limit Limitation of exposure times;
3. Use of respiratory protection equipment, or
4. Use other Other controls.

R12-1-425. Use of Individual Respiratory Protection Equipment

- A. If a the licensee uses respiratory protection equipment to limit intakes according pursuant to R12-1-424:
1. Except as provided in subsection (A)(2) paragraph (A)(2 b) below, the licensee shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration (NIOSH/MSHA), using standards in 30 CFR Part 11, 1993 Edition, published July 1, 1993, by the Office of the Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Office of Secretary of State.
 2. If the licensee wishes to use equipment that has not been tested or certified by NIOSH/MSHA the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration has not had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of the that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information,

Arizona Administrative Register
Notices of Proposed Rulemaking

that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use, ~~as required in 30 CFR, Part 11, referenced in paragraph (A)(1) above.~~

3. No change.
 - a. No change.
 - b. No change.
 - c. Testing of respirators for operability immediately before ~~prior to~~ each use;
 - d. No change.
 - e. No change.
 4. No change.
 - a. No change.
 - b. No change.
 - c. No change.
 5. The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require ~~such~~ relief from respirator use.
 6. No change.
- B.** When estimating exposure of individuals to airborne radioactive materials, the licensee may take credit for respiratory protection equipment used to limit intakes as allowed in ~~pursuant to~~ R12-1-424, provided that the following conditions, in addition to those in subsection (A) ~~above~~, are satisfied:
1. The licensee selects respiratory protection equipment from Appendix A, that provides a protection factor that will afford the user protection from the peak concentration of airborne radioactive material and requires its use when that provides a protection factor, specified in Appendix A, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B, Table I, Column 3. However, if the selection of respiratory protection equipment, with a protection factor greater than the peak concentration, is inconsistent with the goal of maintaining the total effective dose equivalent ALARA as specified in R12-1-407(B), a specified in R12-1-424 of keeping the total effective dose equivalent as required in R12-1-407(B), the licensee may select respiratory protection equipment with a lower protection factor, provided the equipment selection and other controls authorized in R12-1-424 result that such a selection would result in a total effective dose equivalent that is ALARA as specified in that meets the requirements in R12-1-407(B). The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in the air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.
 2. No change.
 - a. No change.
 - b. No change.
- C.** In an emergency, the licensee shall use as emergency equipment only respiratory protection equipment that has been specifically certified or ~~has had~~ certification ~~extended~~ for emergency use by NIOSH/MSHA ~~the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration~~.
- D. Reports.** ~~The licensee shall notify the Agency in writing at least 30 days before the date that respiratory protection equipment is first used according to subsections (A) or (B), pursuant to either R12-1-425 (A) or (B).~~

R12-1-426. Security of Stored Sources of Radiation

A ~~The~~ licensee or registrant shall secure from unauthorized removal or access licensed or registered sources of radiation that are stored in unrestricted areas.

R12-1-427. Control of Sources of Radiation Not in Storage

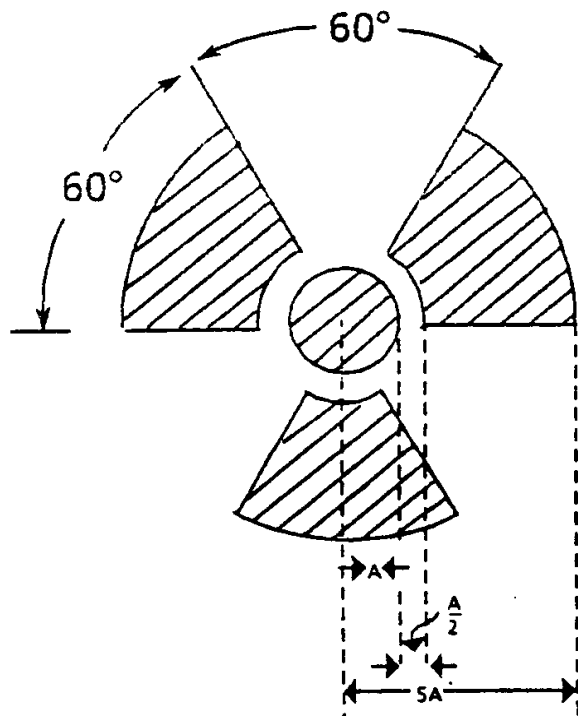
- A.** A ~~The~~ licensee shall control and maintain constant surveillance of licensed ~~or registered~~ radioactive material that is in an unrestricted area and ~~that is~~ not in storage or in a patient.
- B.** A ~~The~~ registrant shall maintain control of radiation machines that are in an unrestricted area and ~~that are~~ not in storage.

R12-1-428. Caution Signs

- A.** ~~Standard radiation symbol.~~ Unless otherwise authorized by the Agency, a licensee or registrant shall use the symbol prescribed by this Section with shall use the colors magenta, or purple, or black on yellow background as the standard radiation symbol. The symbol prescribed is the three-bladed design as follows:

RADIATION SYMBOL

1. Cross-hatched area is to be magenta, or purple, or black, and
2. The background is to be yellow.



- ~~B. Exception to color requirements for standard radiation symbol.~~ Notwithstanding the requirements of subsection (A) above, licensees or registrants are authorized to label sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols that lack the ~~and without~~ a color scheme required in subsection (A) requirement.
- ~~C. Additional information on signs and labels.~~ In addition to the contents of signs and labels prescribed in this Article 4, the licensee or registrant shall provide, on or near the required signs and labels, additional information, ~~as appropriate,~~ to make individuals aware of potential radiation exposures and to minimize the exposures.

R12-1-429. Postings Posting Requirements

- ~~A. Posting of radiation areas.~~ The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."
- ~~B. Posting of high radiation areas.~~ The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."
- ~~C. Posting of very high radiation areas.~~ The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."
- ~~D. Posting of airborne radioactivity areas.~~ The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."
- ~~E. Posting of areas or rooms in which licensed material is used or stored.~~ The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of licensed ~~such~~ material specified in Appendix C with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

R12-1-430. Posting Exceptions to Posting Requirements

- A. No change.
 1. The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this Article 4; and
 2. No change.

Arizona Administrative Register
Notices of Proposed Rulemaking

- B. ~~A licensee or registrant is not required to post caution signs in rooms~~ Rooms or other areas in hospitals that are occupied by patients ~~that have been administered radioactive material are not required to be posted under~~ with caution signs pursuant to R12-1-429, provided that confinement of the patient is not required ~~by pursuant to~~ a condition of ~~on~~ the radioactive material license.
- C. ~~A licensee or registrant is not required to post a caution sign in a~~ A room or area is not required to be posted with a caution sign because of the presence of a sealed source, provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.
- D. ~~A licensee or registrant is not required to post a caution sign in a~~ A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

R12-1-431. Labeling Containers and Radiation Machines

- A. ~~The licensee shall ensure that each container of licensed material is labeled with~~ bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL". The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the radioactivity activity is estimated, radiation level levels, kind of material kinds of materials, and mass enrichment, to permit an individual individuals handling or using a container the containers, or working in the vicinity of a container the containers, to take precautions to avoid or minimize exposure exposures.
- B. Each licensee shall, ~~before~~ prior to removal or disposal of ~~an~~ empty, uncontaminated container containers to ~~an~~ unrestricted area areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.
- C. Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner to caution an individual which cautions individuals that radiation is produced when it is energized.
- D. A licensee shall label each syringe and each vial, that contains a radiopharmaceutical, used in the practice of medicine, to identify its radiopharmaceutical content. Each syringe shield and vial shield shall also be labeled, unless the label on the syringe or vial is visible when shielded. Color-coding syringe shields and vial shields does not meet the labeling requirement.

R12-1-432. Labeling Exemptions to Labeling Requirements

A licensee is not required to label:

1. No change.
2. No change.
3. Containers attended by an individual who takes ~~the~~ the precautions necessary to prevent ~~the~~ the exposure of individuals to radiation in excess of the limits established in this by Article 4;
4. Containers holding which contain radioactive material that does not exceed the limits for excepted quantity or article as defined and limited in 49 CFR by the U.S. Department of Transportation (USDOT) regulations 49 CFR §§ 173.403(m) and (w), and 173.421 through 173.424 424, and that are transported, packaged, and labeled in transport and packaged and labeled in accordance with 49 CFR §§-172.403 and 172.436 through 172.440 440, 1999 Edition, published October 1, 1999 by the Office of Federal Register National Archives and Records Administration, incorporated by reference and on file with the Agency and Office of Secretary of State. This incorporation by reference contains no future editions or amendments of the U.S. Department of Transportation, 1992 Edition, published October 1, 1992 by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Office of Secretary of State;
5. Containers that are accessible only to individuals authorized to handle, ~~or use them,~~ or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. A licensee shall retain the The record shall be retained as long as the containers are in use for the purpose indicated on the record; or
6. No change.

R12-1-433. Procedures for Receiving and Opening Packages

- A. Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in 10 CFR 71.4, 1999 Edition, published January 1, 1999 by the Office of the Federal Register National Archives and Records Administration, incorporated by reference and on file with the Agency and Office of the Secretary of State, and containing no future editions or amendments 10 CFR § 71.4, 1993 Edition, published January 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Office of Secretary of State, shall make arrangements to receive:
 1. No change.
 2. No change.
- B. No change.
 1. Monitor the external surfaces of a package, labeled with a Radioactive White I, Yellow II, or Yellow III as specified in 49 CFR 172.403 and 172.436 through 172.440, 1999 Edition, published October 1, 1999 by the Office of Federal

Arizona Administrative Register
Notices of Proposed Rulemaking

~~Register National Archives and Records Administration, incorporated by reference and on file with the Agency and the Office of the Secretary of State, containing no future editions or amendments 49 CFR §§ 172.403 and 172.436 through 440, 1992 Edition, published October 1, 1992 by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file at the Office of Secretary of State, for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in R12-1-102 of these rules; and~~

2. Monitor the external surfaces of a package, labeled with a Radioactive White I, Yellow II, or Yellow III as specified ~~in 49 CFR §§ 172.403 and 172.436 through 440, reference in subsection (B)(1) paragraph (B)(1) above,~~ for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, ~~as defined in 10 CFR, Part 71, and referenced in subsection (A) above;~~ and
 3. No change.
- C. The licensee shall perform the monitoring required by subsection (B) ~~above~~ as soon as practical practicable after receipt of the package, but not later than 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.
- D. No change.
1. No change.
 2. No change.
- E. No change.:
1. Establish, maintain, and retain written procedures for safely opening packages that contain in which radioactive material ~~is received,~~ and
 2. No change.
- F. Licensees transferring special form sources in vehicles owned or operated by the licensee ~~or registrant~~ to and from a work site are exempt from the contamination monitoring requirements of subsection (B) ~~above~~ but are not exempt from the monitoring requirement in subsection (B) ~~above~~ for measuring radiation levels that ensures that the source of radiation is still properly lodged in its shield.

R12-1-434. General Requirements for Waste Disposal

- A. No change.
1. By transfer to an authorized recipient as provided in R12-1-439 or in Article 3 of these ~~rules~~ regulations, or to the U.S. Department of Energy;
 2. No change.
 3. No change.
 4. As authorized according pursuant to R12-1-435, R12-1-436, R12-1-437, or R12-1-438.
- B. No change.
1. No change.
 2. No change.
 3. No change.
 4. Disposal at a land disposal facility licensed according pursuant to Article 3 of these ~~rules~~ regulations; or
 5. No change.

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

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

1. A description of the waste containing licensed material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation; ~~and the proposed manner and conditions of waste disposal;~~
2. The proposed manner and conditions of waste disposal;
- ~~3.2.~~ An analysis and evaluation of pertinent information on the nature of the environment;
- ~~4.3.~~ The nature and location of other potentially affected facilities; and
- ~~5.4.~~ An analysis ~~Analyses and procedure procedures~~ to ensure that doses comply ~~are maintained in accordance~~ with R12-1-407(B), and are within the dose limits in this Article 4.

R12-1-436. Disposal by Release into Sanitary Sewerage System

- A. No change.
1. No change.
 2. No change.
 3. If more than 1 radionuclide is released, the following conditions shall also be satisfied:
 - a. No change.

Arizona Administrative Register
Notices of Proposed Rulemaking

- b. The sum of the fractions for each radionuclide required by subsection (A)(3)(a) subparagraph (A)(3)(a) above, does not exceed unity; and
- c. No change.

B. No change.

R12-1-437. Treatment or Disposal by Incineration

A licensee ~~shall may~~ treat or dispose of licensed material by incineration only in the amounts and forms specified in R12-1-438 or as specifically approved by the Agency ~~according pursuant~~ to R12-1-435.

R12-1-438. Disposal of Specific Wastes

A. No change.

- 1. No change.
- 2. No change.
- 3. 1.85 kBq (0.05 μ Ci), or less, of Iodine-125 per gram of medium used in analyzing in vitro laboratory samples and associated sample holders contaminated during the laboratory procedure.

B. A licensee shall not dispose of tissue, contaminated with radioactive material, according pursuant to subsection (A)(2) ~~above~~ in a manner that would permit its use either as food for humans or as animal feed.

C. A licensee is authorized to hold radioactive material with a physical half-life of 120 days or less for decay in storage before disposal in ordinary trash and is exempt from the requirements of R12-1-434, provided:

- 1. Radioactive material held for disposal is permitted to decay for a minimum period of 10 half-lives;
- 2. The container of radioactive material is surveyed at its surface with no interposed shielding, before disposal as ordinary trash with a radiation detection survey meter set on its most sensitive scale and appropriate for the type of radiation being detected.
- 3. The radioactivity of the container, determined by survey, is less than 2 times background; and
- 4. All radiation labels are removed or obliterated.

~~D.C. Records.~~ The licensee shall maintain records in accordance with R12-1-441.

R12-1-439. Transfer For Disposal and Manifests

~~A.~~ The requirements of this Section are designed to control transfers of low-level radioactive waste intended for disposal at a licensed low-level radioactive waste disposal facility, establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes.

~~A.B.~~ Each shipment of radioactive waste designated for disposal at a licensed low-level radioactive waste disposal facility shall be accompanied by a shipment manifest as specified in subsection (D)(1) paragraph (E)(1) below.

~~B.C.~~ Each shipment manifest shall include a certification by the waste generator as specified in subsection (D)(2) paragraph (E)(2) below.

~~C.D.~~ Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in subsection (D)(3) paragraph (E)(3) below.

~~D.E.~~ Requirements for manifests and transfer of low-level radioactive waste ~~to for disposal at land disposal facilities and manifests:~~

1. **Manifest**

The shipment manifest shall contain the name, address, and telephone number of the person generating the waste. The manifest shall also include the name, address, and telephone number or the name and U.S. Environmental Protection Agency hazardous waste identification number of the person transporting the waste to the land disposal facility. The manifest shall also indicate: a physical description of the waste, the volume, radionuclide identity and quantity, the total radioactivity, and the principal chemical form. The solidification agent shall be specified. Waste containing more than 0.1% chelating agents by weight shall be identified and the weight percentage of the chelating agent estimated. Wastes classified as Class A, Class B, or Class C in Appendix D, Section I of Appendix D shall be clearly identified by class ~~as such~~ in the manifest. The total quantity of the radionuclides hydrogen-3, carbon-14, technetium-99, and iodine-129 shall be shown. The manifest required by this paragraph may be shipping papers used to meet U.S. Department of Transportation or U.S. Environmental Protection Agency regulations or requirements of the receiver, provided all the required information is included. Copies of manifests required by this Section may be legible carbon copies or legible photocopies.

2. **Certification**

The waste generator shall include in the shipment manifest a certification that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the U.S. Department of Transportation and the Agency. An authorized representative of the waste generator shall sign and date the manifest.

3. **Control and Tracking**

- a. Any radioactive waste generator who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in subsections (E)(3)(a)(i) through (viii) subdivision (a)(1) through

Arizona Administrative Register
Notices of Proposed Rulemaking

- (viii). Any radioactive waste generator who transfers radioactive waste to a licensed waste processor who treats or repackages waste shall comply with the requirements of subsections (E)(3)(a)(iv) through (vii) subdivision (a)(iv) through (vii). A licensee shall:
- i. Prepare all wastes so that the waste is classified according to Appendix D, Section I of Appendix D and is characterized as required in ~~meets the waste characteristics requirements in~~ Appendix D, Section II of Appendix D;
 - ii. Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with Appendix D, Section III ~~Section I of Appendix D~~;
 - iii. Conduct a quality control program, including management evaluation of audits, to ensure compliance with Appendix D, Section I and II of Appendix D; ~~the program shall include management evaluation of audits~~;
 - iv. Prepare shipping manifests to meet the requirements of subsections (E)(1) and (2) ~~Section I and II~~;
 - v. Forward a copy of the manifest to the intended recipient, at the time of shipment, or deliver the manifest to a collector at the time the waste is collected, obtaining acknowledgment of receipt in the form of a signed copy of the manifest or equivalent documentation from the collector;
 - vi. No change.
 - vii. No change.
 - viii. For any shipment shipments or any portion of a shipment for which acknowledgment of receipt is has not been received within the times ~~set forth~~ in this Section section, conduct an investigation in accordance with subsection (E)(3)(e) ~~Section III-(e)~~.
- b. No change.
- i. Acknowledge receipt of the waste from the generator within 1 week of receipt, by returning a signed copy of the manifest or equivalent documentation to the generator;
 - ii. Prepare a new manifest to reflect consolidated shipments; the new manifest shall serve as a listing or index for the detailed generator manifests. Copies of the generator manifests shall be a part of the new manifest. The waste collector may prepare a new manifest without attaching the generator manifests, provided the new manifest contains for each package the information specified in subsection (E)(1) ~~Section I~~. The collector licensee shall certify that nothing has been done to the waste that would invalidate the generator's certification;
 - iii. No change.
 - iv. No change.
 - v. No change.
 - vi. For any shipments or any portion of a shipment for which acknowledgment of receipt is not received within the times set forth in this Section section, conduct an investigation in accordance with subsection (E)(3)(e) ~~Section III-(e)~~.
- c. No change.
- i. No change.
 - ii. Prepare a new manifest that meets the requirements in subsections (E)(1) and (2) of Section I and II. Preparation of the new manifest reflects that the processor is responsible for the waste;
 - iii. Prepare all wastes so that the waste is classified according to Appendix D Section I of Appendix D and meets the waste characteristics requirements in Appendix D Section II of Appendix D;
 - iv. Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with Appendix D, Section III ~~Section I and III of Appendix D~~;
 - v. Conduct a quality control program, including management evaluation of audits, to ensure compliance with Appendix D, Sections ~~Section I and II of Appendix D~~; ~~the program shall include management evaluation of audits~~;
 - vi. Forward a copy of the new manifest to the disposal site generator or waste collector at the time of shipment, or deliver the manifest to a collector at the time the waste is collected, obtaining acknowledgment of receipt in the form of a signed copy of the manifest or equivalent documentation by the collector;
 - vii. No change.
 - viii. No change.
 - ix. For any shipment or portion of a shipment for which acknowledgment of receipt is not received within the times set forth in this Section, conduct an investigation in accordance with subsection (E)(3)(e) ~~Section III-(e)~~.
- d. No change.
- i. No change.
 - ii. No change.
 - iii. Notify the shipper, that is, the generator, the collector, or processor, and the Agency when any shipment or portion of a shipment has not arrived within 60 days after the date that the advance manifest was received.

Arizona Administrative Register
Notices of Proposed Rulemaking

- e. Any shipment or portion of a shipment for which acknowledgment is not received within the times set forth in this ~~Section~~ section shall be:
- i. ~~Investigated~~ ~~Be investigated~~ by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and
 - ii. ~~Traced~~ ~~Be traced~~ and reported to the shipper. The investigation shall include tracing the shipment and filing a report with the Agency. Each licensee who conducts a trace investigation shall file a written report with the Agency within 2 weeks of completion of the investigation.

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

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

R12-1-441. Records of Waste Disposal

- A. Each licensee ~~or registrant~~ shall maintain records of the disposal of licensed ~~or registered~~ materials made ~~according pursuant~~ to R12-1-435, R12-1-436, R12-1-437, R12-1-438, and disposal by burial in soil, including burials authorized before February 25, 1985.
- B. ~~The~~ ~~The~~ licensee ~~or registrant~~ shall retain the records required by subsection (A) ~~shall be maintained for 3~~ ~~above for three~~ years after the Agency terminates ~~the applicable~~ ~~each pertinent~~ license or registration ~~requiring the record~~.

Editor's Note: Regarding R12-1-441, the Radiation Regulatory Agency noted that a previous R12-1-419 permitted burial of small quantities of licensed materials in soil before February 25, 1985, without specific Agency authorization.

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

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

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

- A. ~~Telephone reports~~. Each licensee or registrant shall report to the Agency by telephone as follows:
1. Immediately after it becomes known to the licensee that licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C is stolen, lost, or missing under circumstances that ~~indicate it appears~~ to the licensee that an exposure could result to individuals in unrestricted areas;
 2. Within 30 days after it becomes known to the licensee that licensed radioactive material in an aggregate quantity greater than 10 times the quantity ~~specified~~ ~~identified~~ in Appendix C is stolen, lost, or missing, and is still missing.
 3. No Change.
- B. ~~Written reports~~. Each licensee or registrant required to make a report ~~according pursuant~~ to subsection (A) ~~above~~ shall, within 30 days after making the telephone report, make a written report to the Agency ~~that contains~~ ~~setting forth~~ the following information:
1. A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model, ~~and~~ serial number, type, and maximum energy of radiation emitted;
 2. No change.
 3. A statement of disposition, or probable disposition, of the licensed or registered source of radiation ~~involved~~;
 4. No change.
 5. No change.
 6. No change.
- C. ~~After~~ ~~Subsequent~~ to filling the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of ~~the~~ ~~such~~ information.
- D. ~~The~~ licensee or registrant shall provide the names of individuals who may have received an exposure to radiation as a result of an incident as required in subsection (B). ~~The~~ licensee or registrant shall prepare any report filed with the Agency pursuant to this Section so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

R12-1-444. Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits

- A. ~~Reportable events~~. In addition to the notification required by R12-1-445, each licensee or registrant shall submit a written report within 30 days after learning of any of the following ~~occurrences~~:
1. No change.
 2. No change.
 - a. No change.

Arizona Administrative Register
Notices of Proposed Rulemaking

- b. No change.
 - c. The limits for an embryo or fetus ~~embryo/fetus~~ of a declared pregnant woman in R12-1-415;
 - d. No change.
 - e. Any applicable limit in the license or registration; ~~or~~
3. No change.
- a. No change.
 - b. An unrestricted area in excess of 10 times the applicable limit ~~set forth in this~~ Article 4 or in the license or registration, whether or not ~~this involves an involving~~ exposure of any individual ~~to a dose~~ in excess of the limits in R12-1-416; ~~or~~
4. Radiation levels or concentrations of radioactive material in excess of the standards in ~~For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, 1999 Edition, published July 1, 1999, by the Office of the Federal Register, National Archives and Records Administration, incorporated by reference and on file with the Agency and the Office of Secretary of State, if the licensee is subject to these federal standards, or there is a license condition referencing the 40 CFR 190 standards. This incorporation contains no future editions or amendments. 1992 Edition, published July 1, 1992, by the Office of the Federal Register, National Archives and Records Administration, incorporated herein by reference and on file with the Office of Secretary of State, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.~~
- B.** No change.
1. Each report ~~required by this Section~~ shall contain a description of each individual's exposure ~~describe the extent of exposure of individuals~~ to radiation and radioactive material, including, as applicable ~~appropriate~~:
 - a. No change.
 - b. No change.
 - c. No change.
 - d. No change. 2. Each report filed according pursuant to subsection (A) ~~above~~ shall include for each individual exposed: the name, Social Security Number ~~account number~~, and date of birth. With respect to the limit for the embryo or fetus ~~embryo/fetus~~ in R12-1-415, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.
- C.** All licensees or registrants who make reports according pursuant to subsection (A) ~~above~~ shall submit the report in writing to the Agency.

R12-1-445. Notification of Incidents

- A.** ~~Immediate notification.~~ Notwithstanding other requirements for notification, each licensee or registrant shall immediately report to the Agency each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:
1. No change.
 - a. No change.
 - b. A lens ~~An eye~~ dose equivalent of 0.75 Sv (75 rem) or more; or
 - c. No change.
 2. No change.
- B.** ~~3.~~ If the Agency's telephone ~~phone~~ does not answer within three minutes, the Duty Officer of the Arizona Department of Public Safety is to be called and advised of:
1. The existing radiation emergency.
 2. The need to notify the Radiation Regulatory Agency's Duty Officer.
 3. The caller's identity and the name of the affected licensee or registrant.
 4. The location of the incident, and
 5. A telephone number where the caller can be reached. ~~,"this is a radiation emergency notification" and ask to contact the Radiation Regulatory Agency's Duty Officer. The caller shall identify him or herself and the licensee or registrant, state the location of the incident, and give a phone number at which the caller can be reached.~~
- C.** ~~Twenty four hour notification.~~ Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Agency each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:
1. No change.
 - a. No change.
 - b. A lens ~~An eye~~ dose equivalent exceeding 0.15 Sv (15 ~~15~~ rem); or
 - c. No change.
 2. No change.

Arizona Administrative Register
Notices of Proposed Rulemaking

~~D.C.~~ The licensee or registrant shall prepare each report filed with the Agency according pursuant to this Section so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

~~E.D.~~ Licensees or registrants shall make the reports required by subsections (A) and (C) ~~(B) above to the Agency~~ by telephone, telegram, mailgram, or facsimile.

~~E.E.~~ The provisions of this Section do not apply to doses that result from planned special exposures, provided the doses from the planned special exposure such doses are within the planned limits for ~~planned special exposures~~ and are reported according pursuant to R12-1-413.

R12-1-446. Notifications and Reports to Individuals

A. Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in R12-1-1004 ~~of these regulations~~.

B. Each licensee or registrant shall notify the individual exposed to radiation or radioactive material in the report to the Agency required in R12-1-445. ~~When a licensee or registrant is required pursuant to R12-1-445 to report to the Agency any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. A separate notice to the exposed individual shall be provided no later than the date the report is submitted to the Agency and shall comply with R12-1-1004(A). Such notice shall be transmitted at a time not later than the transmittal to the Agency and shall comply with the provisions of R12-1-1004(A).~~ ~~of these regulations.~~

R12-1-447. Vacating Premises

~~A. If a facility has been used for activities involving radioactive material each licensee shall notify the Agency in writing of the intent to vacate the facility no less than 45 days before relinquishing possession or control of the facility. Each specific licensee shall, no less than 45 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of his activities, notify the Agency in writing of intent to vacate. When deemed necessary by the Agency, the licensee shall decontaminate the premises in such a manner as the Agency may specify.~~

~~B. If a facility is contaminated with radioactive material, the licensee vacating the facility shall decontaminate it using Agency approved procedures.~~

~~C. The Agency shall inspect a vacated facility to determine whether it is contaminated with radioactive material.~~

R12-1-448. Additional Reporting Requirements

A. Each licensee shall notify the Agency as soon as possible, but not later than immediately, ~~not later than~~ 4 hours after the discovery of an event, and take immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed the limits specified in this Chapter or releases of licensed material that could exceed the limits specified in this Chapter. For purposes of this Section ~~section~~, event means a radiation accident involving a fire, explosion, gas release, or similar occurrence.

B. No change.

1. No change.

a. No change.

b. Involves a quantity of radioactive material greater than 5 times the lowest annual limit on intake specified in Appendix B of this Article; and

c. No change.

2. No change.

a. No change.

b. No change.

c. No change.

3. No change.

4. No change.

a. No change.

b. No change.

C. No change.

1. No change.

2. No change.

3. No change.

4. No change.

5. No change.

D. Each licensee who makes a report required by subsections (A) or (B) above shall submit a written follow-up report within 30 days of the initial report. Written reports prepared as required by ~~pursuant to~~ other rules may be submitted to fulfill this requirement if the reports contain all of the required information in this Section. The licensee shall send the written report to the Agency. The report shall include the following:

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

R12-1-449. Survey Instruments and Pocket Dosimeters

- A. No change.
- B. No change.
 1. No change.
 2. No change.
- C. No change.
- D. No change.
 1. No change.
 2. No change.
- E. No change.
- F. Each licensee or registrant shall ensure that pocket dosimeters used to show compliance with this Article:
 1. Have been evaluated for proper operation annually, and following repair, unless more frequent evaluation is required by license condition. The evaluation shall include a check for drift over a 24 hour period, and
 2. Meet the performance criteria listed in R12-1-523(B).
- G. Records of personnel dosimeter operational checks shall be maintained for 3 years.

R12-1-450. Sealed Sources Source Requirements

- A. A licensee shall only receive, possess, and use radioactive materials contained in a sealed source that has been manufactured, labeled, packaged, and distributed in accordance with a specific license for its manufacture and distribution. The license to manufacture and distribute a sealed source shall be issued by the Agency, U.S. Nuclear Regulatory Commission, a Licensing State, or another Agreement State.
- ~~B.~~ 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 sealed source, on the permanent container of the sealed sources or in the leaflet or brochure that accompanies the sealed 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 sealed source information is no longer available.
- ~~C.~~ Any licensee who possesses and uses sealed sources containing radioactive material, including calibration and reference sources, shall, unless otherwise specified, conduct a physical inventory at intervals not to exceed 6 months, unless a shorter interval is specified by license condition, 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 sealed 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.
- ~~D.~~ 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.
- E. Sealed sources, containing radioactive material, shall not be opened unless authorized by license condition.
- F. Sealed sources and machines, devices, or equipment containing sealed sources shall be used in accordance with procedures described in the manufacturer's instructions and the safety precautions described in the Nuclear Regulatory Commission Sealed Sources and Device Registry, unless the instructions or precautions conflict with these rules or license condition.

**ARTICLE 5. RADIATION SAFETY REQUIREMENTS FOR
INDUSTRIAL RADIOGRAPHIC OPERATIONS**

R12-1-501. Limits on Levels of Radiation for Radiographic Exposure Devices and Storage Containers

- A. A licensee shall ensure that a radiographic Radiographic exposure devices with measuring less than 10 centimeters (4 inches) of space ~~four inches (10 centimeters)~~ from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of 500 microsievert (50 millirem) per hour at 15 centimeters (6 inches) ~~six inches (15 centimeters)~~ from any exterior surface of the device.
- B. A licensee shall ensure that radiographic Radiographic exposure devices with measuring 10 centimeters (4 inches) of space ~~four inches (10 centimeters)~~ or more from the sealed source storage position to any exterior surface of the device,

Arizona Administrative Register
Notices of Proposed Rulemaking

and all storage containers for sealed sources or for radiographic exposure devices, ~~shall~~ have no radiation level in excess of ~~2 two~~ 2 millisievert (200 millirem) per hour at any exterior surface, and 100 microsievert (10 millirem) per hour at 1 meter (40 inches) ~~40 inches (one meter)~~ from any exterior surface. The radiation levels specified are with the sealed source in the shielded position.

R12-1-502. Radiographic Equipment Standards and Equipment Failure Notification

- A.** ~~Each registrant shall ensure that each x-ray machine has~~ Each x-ray machine shall be provided with a lock designed to prevent unauthorized use or accidental production of radiation and shall be kept locked at all times except when under the direct surveillance of a radiographer or radiography trainee ~~radiographer's assistant~~.
- B.** ~~Each radiographic exposure device, storage container and source changer shall be provided with:~~
- B.** ~~+~~ Exposure devices shall ~~Devices:~~
1. ~~a.~~ Have ~~A~~ A lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from the shielded position; and
2. ~~b.~~ Be ~~Shall be~~ kept locked when not under the direct surveillance of a radiographer or radiography trainee unless alternate safety measures, radiographer's assistant, as may be otherwise authorized in R12-1-531, are in place. In addition, during radiographic operations the sealed source assembly shall be secured in the shielded position each time the sealed source is returned to that position.
- C.** ~~2.~~ Sealed source storage containers and source changers shall: ~~Source Storage Containers and Source Changers:~~
1. ~~a.~~ Have ~~A~~ A lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position; and
2. ~~b.~~ Be ~~Shall be~~ kept locked if they contain ~~when containing~~ sealed sources, unless they are ~~except when~~ under the direct surveillance of a radiographer or a radiography trainee ~~radiographer's assistant~~.
- D.** ~~C.~~ No change.
1. Each radiographic exposure device, sealed source, and all associated equipment shall meet the requirements specified in American National Standards ~~Standard~~ Publication N43.9-1991 (previously N432-1980) "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," 1991 Edition, published October 24, 1991, by the American National Standards Institute, 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. The incorporated material may be purchased from the American National Standards Institute, Inc., 1430 Broadway, New York, New York, 10018 ~~incorporated herein by reference and on file with the Office of the Secretary of State.~~
2. In addition to the requirements specified in subsection (C)(1) paragraph (1) of this subsection, the following requirements apply to radiographic exposure devices and associated equipment.
- a. The licensee shall have available for review documented proof that each device and associated equipment meets the requirements of R12-1-502(D)(1) aforementioned standard;
- b. ~~The licensee shall ensure that each~~ Each radiographic exposure device has ~~shall have~~ attached to it by the user, a durable, legible, clearly visible label bearing the following:
- i. Chemical symbol and mass number of the radionuclide in the device;:
- ii. Activity and the date on which this activity was last measured;
- iii. Model number and serial number of the sealed source;:
- iv. Manufacturer of the sealed source; and
- v. Licensee's name, address, and telephone number.
- c. Radiographic exposure devices intended for use as Type B transport containers shall ~~must~~ meet the applicable requirements of 10 CFR 71.51, 1999 Edition, published January 1, 1999, by the Office of the Federal Register National Archives and Records Administration, 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 ~~1993 Edition, published January 1, 1993, by the Office of the Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Office of the Secretary of State.~~
- d. Modification of radiographic ~~my~~ exposure devices and associated equipment is prohibited unless the design of any replacement component, including sealed source holder, sealed source assembly, controls or guide tubes would not compromise the design safety features of the system.
3. In addition to the requirements specified in subsections (C)(1) and (2) paragraphs (1) and (2) of this subsection, the following requirements apply to radiographic exposure devices and associated equipment that allow the sealed source to be moved out of the device for routine radiographic operations ~~operation~~.
- a. The coupling between the sealed source assembly and the control cable shall ~~must~~ be designed in such a manner that the sealed source assembly will not become disconnected if cranked outside the guide tube. The coupling shall be constructed so that ~~must be such that~~ it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

Arizona Administrative Register
Notices of Proposed Rulemaking

- b. The device ~~shall~~ **must** automatically secure the sealed source assembly when it is cranked back into the fully shielded position within the device. This securing system ~~shall~~ **may** only be released by means of a deliberate operation on the exposure device.
 - c. The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device ~~shall~~ **must** be equipped with safety plugs or covers which ~~shall~~ **must** be installed during storage and transportation to protect the sealed source assembly from water, mud, sand, or other foreign matter.
 - d. Each sealed source or sealed source assembly ~~shall~~ **must** have attached to it or engraved in it, a durable, legible, visible label with the words: "DANGER - RADIOACTIVE". The label ~~shall~~ **must** not interfere with the safe operation of the exposure device or associated equipment.
 - e. The guide tube ~~shall~~ **must** have passed the crushing tests for the control tube as specified in ANSI N43.9-1991 and a kinking resistance test that closely approximates the kinking forces likely to be encountered during use.
 - f. Guide tubes ~~shall~~ **must** be used when moving the radiation source out of the device.
 - g. An exposure head or similar device designed to prevent the sealed source assembly from passing out the end of the guide tube ~~shall~~ **must** be attached to the outermost end of the guide tube during radiographic operations.
 - h. The guide tube exposure head connection ~~shall~~ **must** be able to withstand the tensile test for control units specified in ANSI N43.9-1991.
 - i. Source changers ~~shall~~ **must** provide a system of assuring that the radiation source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a sealed source assembly.
 - j. All newly manufactured radiographic exposure devices and associated equipment acquired by licensees after January 10, 1992, ~~shall~~ **must** comply with the requirements of this Section.
 - k. All radiographic exposure devices and associated equipment in use after January 10, 1996, ~~shall~~ **must** comply with the requirements of this Section.
- D.** In addition to the notification requirements in Article 4, each licensee or registrant shall submit a written report within 30 days to the Agency whenever 1 or more of the following equipment failure events occurs:
- 1. No change.
 - 2. ~~A sealed~~ The source assembly ~~is~~ **becomes** unintentionally disconnected from the drive cable;
 - 3. ~~Any component~~ ~~All components~~ critical to safe operation of the radiographic exposure device fails to properly perform its intended function;
 - 4. No change.
 - 5. Personnel overexposure submitted under R12-1-444, involving failure of safety components of radiography exposure devices, sealed source storage containers, ~~or~~ **and** source changers.
- E.** Each report required in subsection (D) ~~above~~ shall contain the following information:
- 1. No change.
 - 2. No change.
 - 3. Manufacturer and model number of equipment involved in the incident;
 - 4. No change.
 - 5. No change.
 - 6. No change.
 - 7. No change.

R12-1-504. Radiation Survey Instruments

- A.** ~~A~~ The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys ~~as~~ required by this Article and Article 4 of this Chapter. Instrumentation required by this Article shall have a range such that 20 microsievert (2 millirem) per hour through 10 millisievert (1 rem) per hour can be measured.
- B.** No change.
- 1. ~~On the scales and associated energies the meter will be used~~ ~~At energies appropriate for use~~ and at intervals not to exceed:
 - a. Three months and after each instrument servicing for instruments used in radiographic operations utilizing sealed sources containing radioactive material, or
 - b. No change.
 - 2. ~~In such a way so that~~ ~~Such that~~ accuracy within plus or minus 20% of the calibration source ~~percent~~ can be demonstrated; and
 - 3. For linear scale instruments, at 2 points located approximately 1/3 and 2/3 of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at 2 points of at least 1 decade; and for digital instruments, at 3 points between 0.02 and 10 mSv (2 and 1000 mRem) per hour. At two or more widely separated points, other than zero, on each scale.
- C.** Records of the calibrations shall be retained for 3 ~~three~~ years after the calibration date.

Arizona Administrative Register
Notices of Proposed Rulemaking

R12-1-505. Leak Testing, Repair, Tagging, Opening, Modification, and Replacement of Sealed Sources

- A. ~~A licensee shall ensure that the~~ The replacement of any sealed source ~~fastened to or contained in permanently mounted in~~ a radiographic exposure device and the leak testing, repair, tagging, opening, or ~~any~~ modification of any sealed source ~~is~~ shall be performed ~~only~~ by persons specifically licensed to do so by the Agency, the U. S. Nuclear Regulatory Commission, or an Agreement or Licensing State.
- B. Each sealed source shall be tested for leakage at intervals not to exceed 6 months. In the absence of a certificate from a transferor that a test has been made within the 6 months ~~before~~ ~~prior~~ to the transfer, the sealed source shall not be ~~used~~ ~~put~~ ~~into use~~ until ~~it is~~ tested.
- C. The leak test shall be capable of detecting the presence of 185 becquerel (0.005 microcurie) of removable contamination. The leak test for a sealed source in a radiographic exposure device or ~~sealed~~ source changer shall consist of swab testing the exit port using a procedure submitted in detail as part of the license application. Records of leak test results shall be kept in units of microcuries or becquerel and ~~maintained~~ ~~retained~~ for ~~3~~ ~~three~~ years after the ~~next required~~ leak test is performed.
- D. Any leak test ~~that which~~ reveals the presence of removable ~~contamination~~ ~~radioactive material~~ in excess of the amount specified in subsection (C) ~~above~~ shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and ~~decontaminate, repair, or dispose~~ ~~shall cause it to be decontaminated and repaired or to be disposed of it~~ in accordance with this Chapter. ~~The licensee shall file a~~ ~~A~~ report shall be filed with the Agency within ~~5~~ ~~five~~ days ~~after~~ ~~of~~ receiving the results of the test, describing the equipment involved, the test results, and the corrective action taken.
- E. Each radiographic exposure device using depleted uranium (DU) shielding and an "S" tube configuration shall be tested for DU contamination at intervals not to exceed 12 months. The analysis shall be performed in accordance with subsections (A) and (C). Should leak testing reveal the presence of 185 Bq (0.005 microcuries) or more of removable DU contamination, the exposure device shall be removed from service until an evaluation of the wear on the S-tube has been conducted. The exposure device shall not be used if the evaluation reveals that the S-tube is worn through. DU shielded exposure devices do not have to be tested for DU contamination while in storage. However, before using or transferring a radiographic exposure device, the device shall be tested for DU contamination if it has been stored for more than 12 months. Records of the DU leak test shall be maintained in accordance with subsection (C). Licensees will have 3 months from the effective date of this rule to comply with the DU leak testing requirements in this subsection.
- ~~F.~~ A sealed source ~~that which~~ is not fastened to or contained in a radiographic exposure device or ~~sealed~~ source changer shall have permanently attached to it a durable tag at least ~~2.5 centimeters (1 inch)~~ ~~one inch (2.5 centimeters)~~ square bearing the prescribed radiation caution symbol in conventional colors, magenta or purple on a yellow background, and at least the instructions: "DANGER - RADIOACTIVE MATERIAL - DO NOT HANDLE -NOTIFY CIVIL AUTHORITIES IF FOUND".

R12-1-507. Utilization Logs logs

Each licensee or registrant shall maintain current logs, which shall be retained for ~~3~~ ~~three~~ years from the date of the recorded event and which ~~show~~ ~~shows~~ the following information for each source of radiation:

1. A description, including make, model, and serial number (or make and model number) of each radiographic exposure device source of radiation or storage container in which a source of radiation ~~the sealed source~~ is located;
2. The identity of the radiographer to whom the source of radiation is assigned;
3. Locations where the source of radiation was used and dates of use; and
4. No change.

R12-1-508. Inspection and Maintenance of Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments

- A. ~~Each~~ ~~The~~ licensee shall perform visual and operability checks on radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments ~~check for defects in or damage to radiographic exposure devices, storage containers, and source changers~~ ~~before~~ ~~prior~~ to use each day the equipment is used. Survey instrument operability must be performed using a check source or other means acceptable to the Agency
- B. ~~Each~~ ~~The~~ licensee shall perform inspection and maintenance on radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments ~~conduct a program for inspection and maintenance of radiographic exposure devices, storage containers and source changers~~ at intervals not to exceed ~~3~~ ~~three~~ months and before their initial use to ensure ~~or prior to the first use thereafter to assure~~ proper functioning of components important to safety. All parts shall be maintained in accordance with the licensee's written procedures and manufacturer's specifications. Records of inspection and maintenance shall be retained for ~~3~~ ~~three~~ years from the date the record is made.
- C. If any inspection reveals defects or damage to components critical to radiation safety, the radiographic exposure devices, transport and storage containers, associated equipment, source changers, or survey instruments ~~device~~ shall be removed from service until repairs have been made.

Arizona Administrative Register
Notices of Proposed Rulemaking

R12-1-509. Permanent Sealed Source Radiographic Installations

~~A licensee or registrant shall ensure that a permanent radiographic installation~~ ~~Permanent radiographic installations with having~~ high radiation area entrance controls of the types described in R12-1-420(A) ~~shall also~~ meet the following requirements:

1. Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation shall have both visible and audible warning signals to warn persons of the presence of radiation. The visible signal shall be activated by radiation whenever the radiation source is exposed. The audible signal shall be activated by when an attempt is made to enter the installation while the radiation source is exposed; and
2. The control device or alarm system shall be tested for proper operation at the beginning of each workday the installation is used ~~at the beginning of each use~~. Records of the such tests shall be retained for 3 three years from the date the record is made.

R12-1-510. Operating Personnel Requirements

Each licensee and registrant shall provide, at least as a minimum, 2 radiographic personnel for each radiographic exposure device in use for any industrial radiography conducted at a location other than at a permanent radiographic installation facility (shielded room, bay, or bunker) meeting the requirements of R12-1-509(1). If one of the personnel is a radiography trainee radiographer's assistant, the other shall be a certified radiographer authorized by the license.

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

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

1. The applicant has a program to provide the instruction specified in R12-1-521 for radiographers and trainees, or if applicable, a program to provide instruction to enclosed radiography x-ray machine operators. The applicant shall submit 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 trainee's 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 an internal inspection program adequate to assure that Agency rules, Agency license and registration provisions, and the applicant's operating and emergency procedures are followed by radiographers, trainees and radiographer's assistants, and enclosed radiography x-ray machine operators. The inspection program shall include the internal inspections at intervals not to exceed 3 months and inspection record retention for 2 years;
4. No change.
5. The sealed source radiographer applicant who desires to conduct leak tests has established procedures to be followed in leak testing sealed sources for possible leakage and contamination and submits to the Agency a description of the such procedures including:
 - a. No change.
 - b. No change.
 - c. No change.
6. No change.

R12-1-512. Radiation Safety Officer

A. Each licensed or registered industrial radiography operation shall have a radiation safety officer. The Radiation Safety Officer (RSO) shall oversee radiation safety activities to ensure they are being performed in accordance with state statutes and rules.

B. The minimum qualifications, training, and experience for an industrial radiography RSO are as follows:

1. Completion of the training and testing requirements in R12-1-521;
2. Completion of 1 year (2000 hours) of practical experience as a qualified radiographer in industrial radiographic operations; and
3. Completion of formal training in the establishment and maintenance of a radiation safety program acceptable to the Agency.

C. The Agency shall consider a candidate if the candidate has training and experience in the field of ionizing radiation, and in addition, has formal training with respect to the establishment and maintenance of a radiation safety program.

D. An RSO shall:

1. Establish, oversee, and review all operating, emergency, and ALARA procedures as required by R12-1-407.
2. Oversee and approve all phases of the training program for radiography personnel, ensuring that appropriate and effective radiation protection practices are taught;

Arizona Administrative Register
Notices of Proposed Rulemaking

3. Ensure that required radiation surveys and leak tests are performed and documented in accordance with these rules and take corrective measures when levels of radiation exceed established limits;
4. Ensure that personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by R12-1-444, and
5. Ensure that operations are conducted safely and institute corrective actions, including cessation of operations when necessary.

E. Licensees and registrants have 6 months from July 1, 2000, to meet the requirements of subsections (B) and (C).

R12-1-521. Radiographer and Radiography Trainee Qualifications, Radiographer Certification, and Audits Requirements for Radiographers and Radiographer's Assistants

A. A ~~The~~ licensee or registrant shall not permit any individual to act as a radiographer until ~~the such~~ individual:

1. No change.
 - a. No change.
 - i. No change.
 - ii. No change.
 - iii. Significance of radiation dose, radiation protection standards, and biological effects of radiation
 - (1) ~~Radiation protection standards~~
 - (2) ~~Biological effects of radiation~~
 - iv. No change.
 - v. Methods of controlling radiation dose by minimizing working time, maximizing working distance, and use of shielding
 - (1) ~~Working time~~
 - (2) ~~Working distance~~
 - (3) ~~Shielding~~
 - b. No change.
 - i. Use of radiation survey instruments, including their operation, calibration, and limitations
 - (1) ~~Operation~~
 - (2) ~~Calibration~~
 - (3) ~~Limitations~~
 - ii. No change.
 - iii. Use of personnel monitoring equipment, including film badges, thermoluminescent dosimeters, alarm rate-meters, and direct reading dosimeters
 - (1) ~~Film badges~~
 - (2) ~~Thermoluminescent dosimeters~~
 - (3) ~~Alarming and direct reading dosimeters~~
 - c. No change.
 - i. No change.
 - ii. No change.
 - iii. No change.
 - iv. No change.
 - d. No change.
 - e. No change.
 - f. No change.
2. No change.
3. No change.
4. No change.

B. The licensee or registrant shall not permit any individual to act as a radiography trainee ~~radiographer's assistant~~ until the individual:

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

C. A licensee or registrant shall not permit an individual to act as an industrial radiographer until the individual is certified by passing the certification examination provided by the Conference of Radiation Control Program Directors (CRCPD), or any other radiographer certification examination the Agency deems equivalent. The licensee or registrant shall provide the Agency with proof of a candidate's passing score on the certification examination when requesting to have the candidate added as an authorized user, and maintained at the job site where a radiographer is performing field radiography. An uncertified individual may act as a radiographer for 3 months after the effective date of this rule. Once the 3 months has expired, the individual is no longer authorized to use radioactive material unless the individual is certified under this subsection.

Arizona Administrative Register
Notices of Proposed Rulemaking

~~D.C.~~ Each licensee or registrant shall retain records of training and testing which demonstrate that the requirements of this rule are met for each radiographer and ~~trainee radiographer's assistant~~.

~~E.D.~~ Each licensee or registrant shall conduct an internal audit program to ensure that the rules of this Chapter, the conditions of the license, and the licensee's operating and emergency procedures are followed by each radiographer and ~~radiography trainee radiographer's assistant~~. The audit program shall include:

1. The observation of the performance of each radiographer and ~~radiography trainee radiographer's assistant~~ during an actual radiographic operation at intervals not to exceed 3 months;
2. A provision that, if a radiographer or a ~~radiography trainee radiographer's assistant~~ has not participated in a radiographic operation for more than 3 months since the last audit, that individual's performance must be observed and recorded the next time the individual participates in a radiographic operation; and
3. The retention of inspection records on the performance of ~~each radiographer radiographers~~ or ~~radiography trainee radiographers' assistants~~ for 3 years.

~~E.~~ A trainee shall use industrial radiography devices and related equipment only under the direct supervision of a radiographer. A trainee shall remain a trainee for 1 year from the starting date of the training, at which time the trainee shall become a radiographer or be removed from all radiography activities.

R12-1-522. Operating and ~~Emergency Procedures~~ ~~emergency procedures~~

~~A~~ the licensee's or registrant's operating and emergency procedures shall include instructions regarding all of the following subjects for at least the following:

1. The handling and use of sources of radiation to be employed ~~so that an individual to be employed such that no individual is likely to be~~ exposed to radiation doses in excess of the limits established in Article 4, "Standards for Protection Against Radiation";
2. No change.
3. No change.
4. Methods and occasions for locking and securing ~~radiographic exposure devices~~ ~~sources of radiation~~ and storage containers;
5. No change.
6. Transportation to field locations, including packing of sources of radiation and storage containers in the vehicles, posting and placarding of vehicles, and control of sources of radiation during transportation;
7. No change.
8. The procedure for notifying ~~the Agency~~ ~~proper persons~~ in the event of an accident;
9. No change.
10. No change.

R12-1-523. Personnel Monitoring Control

A. ~~A~~ The licensee or registrant shall not permit any individual to act as a radiographer or as a ~~radiography trainee radiographer's assistant~~ unless, at all times during radiographic operations, each individual wears on the trunk of the body a direct-reading pocket dosimeter, ~~either~~ a film badge or a thermoluminescent dosimeter (TLD), and an alarm ~~alarming~~ ratemeter at all times during radiographic operations. For permanent radiographic installations where other appropriate alarming warning devices are in routine use, the wearing of an alarming ratemeter is not required.

B. No change.

1. Pocket dosimeters shall meet the criteria in American National Standards Publication N13.5-1972, "Performance Specifications For Direct Reading and Indirect Reading Pocket Dosimeters for X- and Gamma Radiation," 1972 Edition, published December 9, 1971, by the American National Standards Institute, incorporated by reference and on file with the Agency and the Office of the Secretary of State; and shall have a range of 0 to millisieverts ~~51.6 micro-coulomb/kg~~ (200 mRem ~~milliroentgen~~). This incorporation by reference contains no future editions or amendments. The incorporated material may be purchased from the American National Standards Institute, Inc. 1430 Broadway, New York, New York, 10018.
2. No change.
3. ~~At~~ ~~As~~ a minimum, pocket dosimeters shall be recharged and initial use readings recorded:
 - a. No Change.
 - b. Before beginning radiographic operations on any subsequent calendar day (if the source of radiation has not been checked back into an authorized storage location ~~site~~).
4. ~~If~~ ~~Whenever~~ radiographic operations are concluded for the day, final use readings on pocket dosimeters shall be recorded and the accumulated occupational doses for that day determined and recorded.
5. If an individual's pocket dosimeter is discharged beyond its range (for example, goes "off scale"), industrial radiography operations by that individual shall be discontinued until the individual's film badge or TLD has been processed. The individual shall not return to work with sources of radiation until a determination of the individual's radiation exposure ~~to the individual~~ has been made.

Arizona Administrative Register
Notices of Proposed Rulemaking

6. Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed 1 year. Acceptable dosimeters shall read within plus or minus ~~20%~~ 30% of the true radiation exposure. Records of pocket dosimeter response shall be maintained for ~~3~~ 2 years after the record is made, ~~by the licensee or registrant for Agency inspection.~~
 7. Records of pocket dosimeter readings of personnel exposure shall be maintained for 2 years after the record is made ~~by the licensee or registrant for Agency inspection.~~ If the dosimeter readings were used to determine external radiation dose (for example, no film badge or TLD exposure records exist), the records shall be maintained according to R12-1-419 ~~until the Agency authorizes disposal.~~
- C. No change.
1. No change.
 2. No change.
 3. If a film badge or TLD is ~~A~~ lost or damaged ~~film badge, or TLD,~~ shall result in the worker affected shall cease ~~discontinuing~~ work immediately until a replacement film badge or TLD is provided and the exposure is calculated for the time period from issuance to loss or damage.
 4. No change.
- D. ~~Alarm~~ Alarming ratemeters:
1. Each ~~alarm~~ alarming ratemeter shall be tested ~~have a function test~~ to ensure that the audible alarm functions is ~~functioning~~ properly prior to use at the start of each work shift.
 2. Each ~~alarm~~ alarming ratemeter shall be set to give an alarm at a preset dose rate of 5 millisieverts ~~129 microcoulomb/kg/hr (500 mRem milliroentgen/ hr).~~
 3. Each ~~alarm~~ alarming ratemeter shall require special means to change the preset alarm function.
 4. Each ~~alarm~~ alarming ratemeter shall be calibrated at periods ~~intervals~~ not to exceed 1 year for correct response to radiation. Acceptable ratemeters shall give an alarm within plus or minus 20% of the true radiation dose rate.
 5. Records of ~~alarm~~ alarming ratemeter calibration shall be maintained for 2 years for Agency inspection from the date the record is made, ~~by the licensee or registrant for Agency inspection.~~

R12-1-524. Supervision of Radiography Trainees ~~radiographers' assistants~~

Whenever a radiography trainee ~~radiographers assistant~~ uses radiographic exposure devices, associated equipment, or sealed sources ~~or related source handling tools~~, or conducts radiation surveys required by R12-1-533 to determine that the sealed source has returned to the shielded position after an exposure, the radiographer's assistant shall be under the personal supervision of a radiographer.

R12-1-531. Security

During each radiographic operation, the radiographer or radiography trainee ~~radiographer's assistant~~ shall maintain continuous ~~a~~ direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area ~~areas~~, as defined in Article 1, unless ~~except~~:

1. ~~The~~ Where the high radiation area is equipped with a control device or an alarm system as prescribed ~~described~~ in R12-1- 420(A), or
2. ~~The~~ Where the high radiation area is locked to protect against unauthorized or accidental entry.

R12-1-533. Radiation Surveys ~~surveys and Survey Records~~ survey records

- A. A licensee or registrant shall provide and use at ~~At~~ least 1 calibrated and operable radiation survey instrument, as described in R12-1-504, ~~shall be available and used~~ at each site where radiographic exposures are made and at each storage area when an exposure device, storage container or sealed source is placed in storage.
- B. A radiographer or radiographer trainee shall conduct a survey with a radiation survey instrument ~~shall be made~~ after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall include the guide tube.
- C. A radiographer or radiographer trainee shall conduct a ~~physical~~ radiation survey ~~shall be made~~ to determine the exposure levels from a sealed source that has been ~~that the sealed source has been~~ returned to its shielded position and the ~~at any time~~ a radiographic exposure device is placed in a storage area. The entire circumference of the radiographic exposure device shall be surveyed.
- D. Records of all ~~physical~~ radiation surveys performed with a survey meter, required in this Article, shall be retained for 3 ~~three~~ years after completion of the survey, except that records of a survey to determine an individual's dose shall be retained for the period of time specified in R12-1-418(D)(2) ~~permanently~~.

R12-1-534. Records Required at Temporary Job Sites ~~required at temporary job sites~~

Each licensee or registrant conducting industrial radiography at a temporary job site shall maintain ~~have~~ the following records available at that site:

1. A copy of the ~~Copy of~~ appropriate license or registration certificate;

Arizona Administrative Register
Notices of Proposed Rulemaking

2. No change.
3. No change.
4. Survey records required ~~under pursuant to~~ R12-1-533 for the period of operation at the site;
5. Daily dosimeter records for the period of operation at the site; ~~and~~
6. The latest instrument calibration and leak test record for specific devices in use at the site; ~~and~~;
7. A radiographer certification card, or other proof of certification, for each radiographer working at the temporary job site.

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

- A. No change.
1. The registrant shall make, or cause to be made, an evaluation of each certified and certifiable cabinet x-ray system, at intervals not to exceed 12 months, to determine conformance with the standards for certified and certifiable cabinet x-ray systems defined in Article 1. Records of ~~the such~~ evaluations shall be retained for 3 years from the date of their creation; and
 2. Physical radiation surveys shall be performed with a survey instrument appropriate for the energy range and levels of radiation to be assessed and calibrated within the preceding 12 months
- B. The registrant shall ensure that Cabinet x-ray systems not exempted in subsection (A) ~~above~~ shall comply with the record-keeping requirements of this Article and the following special requirements:
1. Radiation levels measured at 5 centimeters (2 inches) ~~two inches (five centimeters)~~ from any accessible exterior surface of the enclosure shall not exceed 50 microsievert (0.5 milliroentgen) in 1 one hour for any combination of technical factors (i.e., mA, kVp);
 2. Access to the interior of the enclosure shall be possible only through interlocked doors or panels ~~that which~~ allow production of radiation only when all ~~interlocked such~~ doors or panels are securely closed. Opening any point of access shall result in immediate termination of radiation production, and subsequent reactivation of the x-ray tube shall only be possible at the control panel;
 3. Visible warning signals ~~that which~~ are activated only during production of radiation shall be provided at the control panel and at each point of access to the interior of the enclosure;
 4. The registrant shall make, or cause to be made, evaluations of each x-ray system to determine conformance with this Article, before placing the x-ray ~~prior to such~~ systems into use and thereafter at intervals not to exceed 3 months. Records of ~~the such~~ evaluations shall be retained for 2 two years, and
 5. Physical radiation surveys to satisfy the requirements of subsection (4) shall be performed only with instrumentation meeting the requirements of R12-1-504.
- C. The registrant shall ensure that shielded room x-ray systems shall comply with the recordkeeping requirements of this Article and the following special requirements;
1. No change.
 2. Access to the interior of a shielded x-ray room shall only be possible through doors or panels ~~which are so~~ interlocked so that radiation production is only possible when all ~~interlocked such~~ doors and panels are securely closed. Opening of any interlocked access points shall result in immediate termination of radiation production, and subsequent reactivation of the x-ray tube shall only be possible at the control panel;
 3. Each access point shall be provided with 2 interlocks, each on a separate circuit so that failure of 1 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 before ~~prior to~~ placing the system into use and thereafter at intervals not to exceed 3 months to determine conformation with this Article. Records of ~~the such~~ evaluations shall be retained for 2 years.
 6. Radiation ~~Physical radiation~~ surveys performed to determine exposure shall be performed ~~only~~ with instrumentation meeting the requirements of R12-1-504;
 7. Electrical interlocks and warning devices shall be inspected for proper operation at the beginning of each period of use, and records results of ~~the these~~ inspections shall be prepared documented and retained for 2 years;
 8. The registrant shall not permit any individual to operate an x-ray machine for shielded room radiography unless that individual has received a copy of, and instruction in, the operating procedures and has demonstrated competence in the safe use of ~~the such~~ equipment;
 9. No Change.
 10. No change.
 11. No change
 - a. No change.
 - b. No change.
 12. No change.

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

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

A. Equipment-

1. Leakage radiation
 - a. X-ray leakage radiation from the source housing assembly shall not exceed 0.1% of the maximum dose equivalent rate of the unattenuated useful beam.
 - b. Neutron leakage radiation from the source housing assembly shall not exceed 0.5% of the maximum dose equivalent rate of the unattenuated useful beam.
 - c. 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.
2. Beam-limiting devices. Adjustable or interchangeable beam limiting devices shall be provided and shall transmit no more than 2% of the useful beam for the portion of the useful beam which is to be attenuated by the beam limiting device. The neutron component of the useful beam shall not be included in this requirement. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters (15.5 square inches) at the normal treatment distance.
3. Filters. The following requirements shall apply to systems which utilize a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters:
 - a. Irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;
 - b. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
 - c. An indication of the wedge filter orientation with respect to the treatment field shall be provided at the control panel, by direct observation or by electronic means, when wedge filters are used;
 - d. A display shall be provided at the treatment control panel showing the filter or filters in use;
 - e. Each filter which is removable from the system shall be clearly identified as to that filter's material of construction, thickness, and the wedge angle for wedge filters; and
 - f. An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.
4. Beam monitor. Equipment installed after the effective date of this Section shall be provided with at least one radiation detector in the radiation head. This detector shall be incorporated into a primary system in such a manner that all of the following criteria are met:
 - a. Each primary system shall have a detector which is a transmission detector and a full beam detector and which is placed on the patient side of any fixed added filters other than a wedge filter;
 - b. The detectors shall be removable only with tools and shall be interlocked to prevent incorrect positioning;
 - c. Each detector shall be capable of independently monitoring and controlling the useful beam;
 - d. Each detector shall form part of a dose monitoring system from which the absorbed dose can be calculated at a reference point in the treatment volume;
 - e. Each dose monitoring system shall have a legible display at the treatment control panel that:
 - i. Maintains a reading until intentionally reset to 0;
 - ii. Has only 1 scale and no scale multiplying factors in replacement equipment; and
 - iii. Utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined under all nominal conditions of use or foreseeable failures;
 - f. In the event of power failure, the dose monitoring information required in subsection (A)(4) displayed at the control panel at the time of failure shall be retrievable in at least 1 system; and
 - g. Selection and display of dose monitor units
 - i. Irradiation shall not be possible until a selection of dose monitor units has been made at the treatment control panel.
 - ii. Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.
 - iii. Each secondary system shall terminate irradiation when 102% of the preselected number of dose monitor units has been detected by the system.
 - iv. 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

Arizona Administrative Register
Notices of Proposed Rulemaking

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. 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. **Timer.** A timer shall be provided and shall meet all of the following requirements:
 - a. The timer shall have a display at the treatment control panel, and shall have a preset time selector and elapsed time indicator.
 - b. The timer shall be a cumulative timer which switches on and off with the radiation and retains its reading after irradiation is interrupted or terminated. It shall be necessary to zero and subsequently reset the elapsed time indicator and the preset time selector after irradiation is terminated before further irradiation is possible.
 - c. The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems fail to do so.
6. **Treatment beam mode selection.** In equipment capable of both x-ray and electron therapy:
 - a. Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.
 - b. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
 - c. An interlock system shall be provided to prevent irradiation with x-rays when electron applicators are fitted and irradiation with electrons when accessories specific for x-ray therapy are fitted.
 - d. The radiation type selected shall be displayed at the treatment control panel before and during irradiation.
7. **Treatment beam energy selection.** Equipment capable of generating radiation beams of different energies shall meet all of the following requirements:
 - a. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;
 - b. An interlock system shall be provided to insure that the equipment can emit only the energy of radiation which has been selected;
 - c. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel; and
 - d. The energy selected shall be displayed at the treatment control panel before and during irradiation.
8. **Selection of stationary or moving beam therapy.** Equipment capable of both stationary and moving beam therapy modes shall meet all of the following requirements:
 - a. Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel;
 - b. An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected;
 - c. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel;
 - d. An interlock system shall be provided to terminate irradiation if the movement stops during moving beam therapy;
 - e. Moving beam therapy shall be so controlled that the required relationship between the number of dose monitor units and movement is obtained; and
 - f. The mode of operation shall be displayed at the treatment control panel.
9. **Focal spot location and beam orientation.** The registrant shall determine, or obtain from the manufacturer, the location in reference to an accessible point on the radiation head of all of the following:
 - a. The x-ray target or the virtual source of x-rays;
 - b. The electron window or the scattering foil; and
 - c. All possible orientations of the useful beam.
10. **System checking facilities.** Capabilities shall be provided for checking of all safety interlock systems.

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. Except for entrance doors or beam interceptors, all the required barriers shall be fixed barriers;
 - b. The treatment control panel shall be located outside the treatment room;
 - 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.
 - d. Provision shall be made for two-way oral communication between the patient and the operator at the treatment control panel;
 - e. Each point of entry into the treatment room shall be provided with warning lights which will indicate when the useful beam is "on" in a readily observable position outside of the room; and

Arizona Administrative Register
Notices of Proposed Rulemaking

- f. Interlocks shall be provided and shall result in all entrance doors being closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall be possible to restore the machine to operation only by closing the door and reinitiating exposure by manual action at the control panel.
- 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.
- 3. Calibrations:
 - a. Calibration of the therapy system, including radiation output calibration, shall be performed prior to placing new installations into operation for the purpose of irradiation of patients. Subsequent calibrations shall be made at intervals not to exceed 6 months, and after any change which may cause the calibration of the therapy system to change.
 - b. Calibration of the radiation output of the therapy beam shall be performed with an instrument which has been calibrated directly traceable to a national standard within the preceding 24 months.
 - 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), and a copy of the calibration report shall be maintained by the registrant for inspection by the Agency.
 - d. Calibration of the therapy beam shall include, but not necessarily be limited to, all of the following determinations:
 - i. Verification that the equipment is operating within the design specifications concerning the light localizer, the side light and back pointer alignment with the isocenter, when applicable, variation in the axis of rotation for the table, gantry and jaw system, and beam flatness and symmetry at specific depths;
 - ii. The exposure rate or dose rate in air and at various depths of water for the range of field sizes used for each effective energy, and for each treatment distance used for radiation therapy;
 - iii. The congruence between the radiation field and the field defined by the localizing device;
 - iv. The uniformity of the radiation field and its dependency upon the direction of the useful beam; and
 - v. The calibration determinations above shall be provided in sufficient detail, to allow the absorbed dose to tissue in the useful beam to be calculated to within $\pm 5\%$.
 - e. Records of calibrations shall be maintained for 2 years following the date the calibration was performed.
 - f. A copy of the current calibration report shall be available in the therapy facility 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. Spot checks:**
 - 1. The spot check procedures shall be in writing and shall have been developed by a person trained and experienced in performing calibrations.
 - 2. The measurements taken during spot checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the system or the radiation dose delivered to a patient during a therapy procedure.
 - 3. The written spot check procedure shall indicate the frequency at which tests or measurements are to be performed, not to exceed monthly.
 - 4. The spot check procedure shall note conditions which shall require, recalibration of the therapy system prior to further human irradiation.
 - 5. Records of spot checks shall be maintained available for inspection by the Agency for 2 years following the spot check measurements.
- D. Operating procedures**
 - 1. Only the patient shall be in the treatment room during irradiation.
 - 2. If a patient must be held in position during treatment only, mechanical supporting or restraining devices shall be used for this purpose.
 - 3. The therapy system shall not be used for human irradiation unless the requirements of R12-1-611(B)(2) and (3) are met.

R12-1-612. Computerized Tomographic Systems

A. Definitions:

"CT" means computerized tomography.

Arizona Administrative Register
Notices of Proposed Rulemaking

“CT conditions of operation” means all selectable parameters governing the operation of a CT including, but not limited to, nominal tomographic section thickness, filtration, and technique factors.

“CTDI” means computed tomography dose index, the integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic thickness and the number of tomograms produced in a single scan.

“CTN” means CT number, the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

“Dose profile” means the dose as a function of position along a line.

“Elemental area” means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted.

“Noise” means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water.

“Nominal tomographic section thickness” means the full width at half-maximum of the sensitivity profile taken at the center of the cross-section volume over which x-ray transmission data are collected.

“Reference plane” means a plane that is displaced from and parallel to the tomographic plane.

“Scan” means the complete process of collecting x-ray transmission data for the production of a tomogram.

B. Facility:

A registrant shall ensure that a CT facility has:

1. An operable two-way communication system between the patient and the operator in each CT room.
2. A viewing system that will allow the operator to continuously view the patient from the control panel during each examination. If the primary viewing system is by electronic, each CT room shall have a secondary viewing system.

C. Equipment:

A registrant shall ensure that:

1. There is a means to terminate x-ray exposure automatically in the event of equipment failure by:
 - a. De-energizing the x-ray source; or
 - b. Shuttering the x-ray beam.
2. The operator is able to terminate the x-ray exposure at any time during the examination, provided the scan or series of scans is greater than 1/2 second duration.
 - a. If an operator terminates x-ray exposure, the operator shall reset the CT conditions of operation before the initiation of another scan.
 - b. A visible signal shall indicate when an x-ray exposure has been terminated because of equipment failure.
3. A means is provided to permit visual determination of the tomographic plane for a single tomogram system, or the location of a reference plane offset from a single tomograph or multiple tomogram system.
 - a. If a light source is used to satisfy this requirement, it shall provide illumination of the tomographic plane or reference plane under ambient light conditions.
 - b. The total error in the indicated location of a tomographic plane or reference plane shall not exceed 5 millimeters.
 - c. The deviation of indicated scan increment versus actual increment shall not exceed plus or minus 1 millimeter with any mass from 0 to 100 kilograms resting on the patient support device.
4. The control panel and gantry provides a visual indication, if x-rays are produced.
5. Emergency buttons and switches are marked by function.
6. Conditions of CT operation used during a patient examination are visible to the operator upon initiation of the scan. If a particular condition is fixed, this subsection may be met by a permanent marking.
7. If the CT is not in use, the radiation 1 meter in any direction from the tube port does not exceed 100 mR in 1 hour.
8. The angular position where the maximum surface CTDI occurs is identified to allow for reproducible positioning of a CT dosimetry phantom.

D. Operating Procedures:

A registrant shall ensure that:

1. Operating procedures are available at the control panel regarding the operation and calibration of the system.
2. The operating procedures contain the following information:
 - a. A copy of the latest calibration;
 - b. Instructions on the use of the CT dosimetry phantom, a schedule of spot checks with the results of the most recent spot check, and the allowable variations for the indicated parameters;
 - c. The distance in millimeters between the tomographic plane and the reference plane if a reference plane is used; and
 - d. A current technique chart containing the CT’s operating parameters, if applicable, and a procedure for determining the number of scans per patient examination.
3. If the calibration or spot check identifies a parameter exceeding the tolerance established by a qualified expert, the use of a CT for patient examination is limited to those uses established in written instructions from the qualified expert.

Arizona Administrative Register
Notices of Proposed Rulemaking

E. Surveys:

A registrant shall ensure that:

1. A CT x-ray system is surveyed by, or under the direction of a qualified expert, before any patient is examined.
2. Any change in the facility or equipment results in the survey being repeated.
3. A copy of the survey report is maintained for Agency inspection.

F. Spot checks:

A registrant shall have a written spot check procedure, developed by a qualified expert, and ensure that the spot check procedure:

1. Incorporate the use of a CT dosimetry phantom that indicates:
 - a. Contrast scale;
 - b. Noise;
 - c. Nominal tomographic section thickness;
 - d. Resolution capability of the system for low and high contrast objects; and
 - e. The mean CTN for water or other reference materials;
2. Is included in the CT calibration and that the interval and system conditions are specified by the registrant's qualified expert.
3. Includes obtaining spot check images with the CT dosimetry phantom using the same processing mode and CT conditions of operation that are used to perform the CT calibration.
4. Requires that images obtained under subsection (F)(3) be retained until a new CT calibration is performed in the following 2 forms:
 - a. Photographic copies obtained from the image display device; and
 - b. A digital form on a storage medium compatible with the CT x-ray system.
5. Requires the spot check procedure and written records of spot checks performed be maintained for Agency inspection.

G. Calibration of radiation output:

A registrant shall ensure that:

1. The calibration of a CT is performed by, or under the direct supervision of, a qualified expert who is physically present at the facility during the CT calibration.
2. The calibration of a CT:
 - a. Is performed annually and after any change or replacement of components that could, in the opinion of the qualified expert, cause a change in radiation output;
 - b. Is performed so that radiation output for each type of head, body, or whole body scan performed is evaluated; and
 - c. Includes:
 - i. A dose profile that is performed with a CT dosimetry phantom placed on the patient couch or support device without additional materials present;
 - ii. A dose profile measured along the center axis of the CT dosimetry phantom for each nominal tomographic section thickness used by the registrant; and
 - iii. Measurement of the CTDI along the 2 axes specified in subsection (G)(4)(b).
3. The calibration of a CT x-ray system is performed with a calibrated dosimetry system that:
 - a. Is traceable to a national standard, and
 - b. Has been calibrated within the preceding 2 years.
4. CT dosimetry phantoms used in determining radiation output meet the requirements specified by the CT manufacturer or a qualified expert who is responsible for maintaining proper operation and:
 - a. Are constructed in such a way that the parameters used to image the most commonly imaged parts of the human body are evaluated; and
 - b. At a minimum, provide means for placement of a dosimeter along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom.
5. Any effects on the measured dose due to the removal of phantom material to accommodate the dosimeter are accounted for in the reported data or included in the statement of maximum deviation for the measured values.

ARTICLE 7. USE OF RADIONUCLIDES IN THE HEALING ARTS

R12-1-702. Definitions

"Authorized user"	No change.
"Brachytherapy"	No change.
"High dose rate after loading brachytherapy"	No change.
"Medical institution"	No change.
"Medical use"	No change.
"Misadministration" means:	

No change.

No change.

No change.

No change.

No change.

The administration of a diagnostic dose of a radiopharmaceutical involving:

The wrong patient, or

The wrong radiopharmaceutical, or

The wrong route of administration; ~~and~~ ~~or~~

A dose to an individual that exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ; or

No change.

“Radiopharmaceutical”

No change.

“Remote after loading brachytherapy device”

No change.

“Stereotactic radiosurgery”

No change.

“Teletherapy”

No change.

“Written directive”

No change.

R12-1-720. Decay in Storage

Radioactive waste shall be held for decay in storage according to R12-1-438(C).

ARTICLE 9. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

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

A. No change.

B. No change.

C. No change.

1. No change.

a. No change.

b. No change.

c. No change.

d. No change.

2. No change.

a. No change.

i. No change.

ii. No change.

iii. No change.

iv. No change.

b. No change.

i. No change.

ii. No change.

iii. No change.

iv. No change.

v. No change.

c. No change.

i. No change.

ii. No change.

iii. No change.

iv. No change.

D. No change.

E. No change.

F. No change.

G. ~~The Agency shall inspect a particle accelerator before it is used to treat a human.~~

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

A. Equipment

1. Leakage radiation

a. X-ray leakage radiation from the source housing assembly shall not exceed 0.1% of the maximum dose equivalent rate of the unattenuated useful beam.

Arizona Administrative Register
Notices of Proposed Rulemaking

- b. Neutron leakage radiation from the source housing assembly shall not exceed 0.5% of the maximum dose equivalent rate of the unattenuated useful beam.
 - c. 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.
2. Beam limiting devices. Adjustable or interchangeable beam limiting devices shall be provided and shall transmit no more than 2% of the useful beam for the portion of the useful beam which is to be attenuated by the beam limiting device. The neutron component of the useful beam shall not be included in this requirement. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters (15.5 square inches) at the normal treatment distance.
3. Filters. The following requirements shall apply to systems which utilize a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters:
- a. Irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;
 - b. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
 - c. An indication of the wedge filter orientation with respect to the treatment field shall be provided at the control panel, by direct observation or by electronic means, when wedge filters are used;
 - d. A display shall be provided at the treatment control panel showing the filter or filters in use;
 - e. Each filter which is removable from the system shall be clearly identified as to that filter's material of construction, thickness, and the wedge angle for wedge filters; and
 - f. An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.
4. Beam monitor. Equipment installed after the effective date of this Section shall be provided with at least one radiation detector in the radiation head. This detector shall be incorporated into a primary system in such a manner that all of the following criteria are met:
- a. Each primary system shall have a detector which is a transmission detector and a full beam detector and which is placed on the patient side of any fixed added filters other than a wedge filter;
 - b. The detectors shall be removable only with tools and shall be interlocked to prevent incorrect positioning;
 - c. Each detector shall be capable of independently monitoring and controlling the useful beam;
 - d. Each detector shall form part of a dose-monitoring system from which the absorbed dose can be calculated at a reference point in the treatment volume;
 - e. Each dose monitoring system shall have a legible display at the treatment control panel that:
 - i. Maintains a reading until intentionally reset to 0;
 - ii. Has only 1 scale and no scale multiplying factors in replacement equipment; and
 - iii. Utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined under all nominal conditions of use or foreseeable failures;
 - f. In the event of power failure, the dose monitoring information required in subsection (A)(4) displayed at the control panel at the time of failure shall be retrievable in at least 1 system; and
 - g. Selection and display of dose monitor units
 - i. Irradiation shall not be possible until a selection of dose monitor units has been made at the treatment control panel.
 - ii. Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.
 - iii. Each secondary system shall terminate irradiation when 102% of the preselected number of dose monitor units has been detected by the system.
 - iv. 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. 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. Timer. A timer shall be provided and shall meet all of the following requirements:
- a. The timer shall have a display at the treatment control panel, and shall have a preset time selector and elapsed time indicator.

Arizona Administrative Register
Notices of Proposed Rulemaking

- b. The timer shall be a cumulative timer which switches on and off with the radiation and retains its reading after irradiation is interrupted or terminated. It shall be necessary to zero and subsequently reset the elapsed time indicator and the preset time selector after irradiation is terminated before further irradiation is possible.
 - c. The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems fail to do so.
 - 6. Treatment beam mode selection. In equipment capable of both x-ray and electron therapy:
 - a. Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.
 - b. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
 - c. An interlock system shall be provided to prevent irradiation with x-rays when electron applicators are fitted and irradiation with electrons when accessories specific for x-ray therapy are fitted.
 - d. The radiation type selected shall be displayed at the treatment control panel before and during irradiation.
 - 7. Treatment beam energy selection. Equipment capable of generating radiation beams of different energies shall meet all of the following requirements:
 - a. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;
 - b. An interlock system shall be provided to ensure that the equipment can emit only the energy of radiation which has been selected;
 - c. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel; and
 - d. The energy selected shall be displayed at the treatment control panel before and during irradiation.
 - 8. Selection of stationary or moving beam therapy. Equipment capable of both stationary and moving beam therapy modes shall meet all of the following requirements:
 - a. Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel;
 - b. An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected;
 - c. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel;
 - d. An interlock system shall be provided to terminate irradiation if the movement stops during moving beam therapy;
 - e. Moving beam therapy shall be so controlled that the required relationship between the number of dose monitor units and movement is obtained; and
 - f. The mode of operation shall be displayed at the treatment control panel.
 - 9. Focal spot location and beam orientation. The registrant shall determine, or obtain from the manufacturer, the location in reference to an accessible point on the radiation head of all of the following:
 - a. The x-ray target or the virtual source of x-rays;
 - b. The electron window or the scattering foil; and
 - c. All possible orientations of the useful beam.
 - 10. System checking facilities. Capabilities shall be provided for checking of all safety interlock systems.
- B. Facility and shielding requirements.**
- 1. In addition to protective barriers sufficient to ensure compliance with R12-1-907, all of the following design requirements shall apply:
 - a. Except for entrance doors or beam interceptors, all the required barriers shall be fixed barriers;
 - b. The treatment control panel shall be located outside the treatment room;
 - 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.
 - d. Provision shall be made for two-way oral communication between the patient and the operator at the treatment control panel;
 - e. Each point of entry into the treatment room shall be provided with warning lights which will indicate when the useful beam is "on" in a readily observable position outside of the room; and
 - f. Interlocks shall be provided and shall result in all entrance doors being closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall be possible to restore the machine to operation only by closing the door and reinitiating exposure by manual action at the control panel.
 - 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.
 - 3. Calibrations.

Arizona Administrative Register
Notices of Proposed Rulemaking

- a. Calibration of the therapy system, including radiation output calibration, shall be performed prior to placing new installations into operation for the purpose of irradiation of patients. Subsequent calibrations shall be made at intervals not to exceed 6 months, and after any change which may cause the calibration of the therapy system to change.
- b. Calibration of the radiation output of the therapy beam shall be performed with an instrument which has been calibrated directly traceable to a national standard within the preceding 24 months.
- 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), and a copy of the calibration report shall be maintained by the registrant for inspection by the Agency.
- d. Calibration of the therapy beam shall include, but not necessarily be limited to, all of the following determinations:
 - i. Verification that the equipment is operating within the design specifications concerning the light localizer, the side light and back pointer alignment with the isocenter, when applicable, variation in the axis of rotation for the table, gantry and jaw system, and beam flatness and symmetry at specific depths;
 - ii. The exposure rate or dose rate in air and at various depths of water for the range of field sizes used for each effective energy, and for each treatment distance used for radiation therapy;
 - iii. The congruence between the radiation field and the field defined by the localizing device;
 - iv. The uniformity of the radiation field and its dependency upon the direction of the useful beam; and
 - v. The calibration determinations above shall be provided in sufficient detail, to allow the absorbed dose to tissue in the useful beam to be calculated to within +/-5%.
- e. Records of calibrations shall be maintained for 2 years following the date the calibration was performed.
- f. A copy of the current calibration report shall be available in the therapy facility 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. Spot checks.

1. The spot check procedures shall be in writing and shall have been developed by a person trained and experienced in performing calibrations.
2. The measurements taken during spot checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the system or the radiation dose delivered to a patient during a therapy procedure.
3. The written spot check procedure shall indicate the frequency at which tests or measurements are to be performed, not to exceed monthly.
4. The spot check procedure shall note conditions which shall require, recalibration of the therapy system prior to further human irradiation.
5. Records of spot checks shall be maintained available for inspection by the Agency for 2 years following the spot check measurements.

D. Operating procedures

1. Only the patient shall be in the treatment room during irradiation.
2. If a patient must be held in position during treatment only, mechanical supporting or restraining devices shall be used for this purpose.
3. The therapy system shall not be used for human irradiation unless the requirements of R12-1- 611(B)(2) and (3) are met.

R12-1-911. Radiation Survey Requirements

- A. No change.
- B. No change.
- C. The registrant shall retain the following records:
 1. Records of the ~~facility 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.

Arizona Administrative Register
Notices of Proposed Rulemaking

R12-1-912. Ventilation systems

- A.** Means shall be provided to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in Article 4, Appendix A, Table I of this Chapter.
- B.** A registrant or licensee as required by R12-1-407 shall not vent, release or otherwise discharge airborne radioactive material to an uncontrolled area which exceed the limits specified in Article 4, Appendix A -- Table II of this Chapter, except as authorized pursuant to Section R12-1-417 or subsection R12-1-407(B) of this Chapter. For purposes of this Section, concentrations may be averaged over a period not greater than one year. Every reasonable effort should be made to maintain releases of radioactive material to uncontrolled areas as far below these limits as practicable.

R12-1-913. Misadministrations

A. For purposes of this rule "misadministration" means:

1. The administration of radiation from a machine, for therapy purposes involving:
 - a. The wrong energy;
 - b. The wrong modality;
 - c. The wrong patient; or
 - d. A dose to an individual from a single application that differs from the prescribed dose by 20%; or
2. A therapeutic radiation dose from a machine such that errors in the calibration, time of exposure, or treatment geometry result in a calculated total treatment dose differing from the final, prescribed total treatment dose by more than 10%.

B. Reports of therapy misadministrations

1. Within 24 hours after a misadministration, a registrant shall notify the Agency by telephone. The registrant 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 registrant 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. If the referring physician or the patient's responsible relative or guardian cannot be reached within 24 hours, the registrant shall notify them as soon as practicable. The registrant shall not delay medical care for the patient because of notification problems.
2. Within 15 days following the verbal notification to the Agency, the registrant shall report, in writing, to the Agency and individuals notified under subsection (A)(1). The written report shall include the registrant'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 registrant 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.
3. Records of misadministrations shall be maintained according to R12-1-708(C).

R12-1-914. Initial Inspections of Particle Accelerators Used in the Practice of Medicine

The Agency shall inspect a particle accelerator, used in the practice of medicine, before its initial use to treat human disease.

ARTICLE 12. ADMINISTRATIVE PROVISIONS

R12-1-1209. Notice of Violation

- A.** No change.
- B.** The notice shall specify:
1. The severity level and circumstances of the alleged violation;
 2. The particular statute, rule or license condition violated; and
 3. The division of the registration or license.
- The notice shall specify the severity level and circumstances of the alleged violation, and the particular statute, rule or license condition violated. The notice shall also specify the category of the registration or license.
- C.** The notice will specify a civil penalty if one is to be imposed by the Agency. 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 waived authorized in R12-1-1216(C).

NOTICE OF PROPOSED RULEMAKING

TITLE 15. REVENUE

CHAPTER 12. DEPARTMENT OF REVENUE
PROPERTY TAX OVERSIGHT COMMISSION

PREAMBLE

- 1. Sections Affected**

R15-12-101	Amend
R15-12-103	Amend
- 2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**

Authorizing statutes: A.R.S. §§ 42-1005 and 42-17002

Implementing statutes: A.R.S. §§ 42-17001 through 42-17003, and 42-17051
- 3. List of all previous notices appearing in the Register addressing the proposed rules:**

Notice of Rulemaking Docket Opening: 6 A.A.R. 1809, May 19, 2000
- 4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:**

Name:	Ernest Powell, Supervisor
Address:	Tax Research and Analysis Section Arizona Department of Revenue 1600 W. Monroe Phoenix, AZ 85007
Telephone:	(602) 542-4672
Fax:	(602) 542-4680
E-mail:	powelle@revenue.state.az.us
- 5. An explanation of the rule, including the agency's reasons for initiating the rule:**

These rules deal with the general provisions of the Property Tax Oversight Commission. As a result of the 5-year review of Title 15, Chapter 12, the recodification of A.R.S. Title 42, and other legislative changes the Department is proposing to amend the rules to update statutory references, remove obsolete language and conform to current rule-making guidelines.
- 6. Reference to any study that the agency proposes to rely on and 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
- 7. 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
- 8. The preliminary summary of the economic, small business, and consumer impact:**

It is expected that the benefits of the rules will be greater than the costs. The amendment of these rules will benefit the political subdivisions that deal with the Property Tax Oversight Commission and the public by making the rules more accurate as well as clearer and easier to understand. The Department will incur the costs associated with the rulemaking process. The political subdivisions and the public are not expected to incur any expense in the amendment of these rules other than the cost of obtaining copies.
- 9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:**

Name:	Ernest Powell, Supervisor
Address:	Tax Research and Analysis Section Arizona Department of Revenue 1600 W. Monroe

Arizona Administrative Register
Notices of Proposed Rulemaking

Phoenix, AZ 85007
Telephone: (602) 542-4672
Fax: (602) 542-4680
E-mail: powelle@revenue.state.az.us

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

The Department has not scheduled any oral proceedings. Written comments on the proposed rules or preliminary economic, small business, and consumer impact statements may be submitted to the person listed above. Pursuant to A.R.S. § 41-1023(C), the Department will schedule oral proceedings if 1 or more individuals file written requests for oral proceedings within 30 days after the publication of this Notice.

A person may submit written comments regarding the proposed rules by submitting the comments no later than 5:00 p.m., July 24, 2000, to the person above.

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

Not applicable

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

None

13. The full text of the rules follows:

TITLE 15. REVENUE

**CHAPTER 12. DEPARTMENT OF REVENUE
PROPERTY TAX OVERSIGHT COMMISSION**

ARTICLE 1. GENERAL PROVISIONS

Section
R15-12-101. Definitions
R15-12-103. Quorum

ARTICLE 1. GENERAL PROVISIONS

R15-12-101. Definitions

Unless the context requires otherwise, the following definitions shall apply:

1. "Commission" means the Property Tax Oversight Commission as established by ~~A.R.S. § 42-306~~ A.R.S. § 42-17002.
2. "Excess collections" means ~~sums the amount~~ collected during the previous fiscal year in excess of the ~~sum of the~~ previous fiscal year's maximum allowable primary property tax levy ~~and the amount which could have been collected for escaped property for taxes levied in the previous fiscal year.~~
3. "Excess expenditures" means the amount certified by the Auditor General's office.
4. "Political subdivision" means counties, cities including charter cities, towns, and community college districts.
5. "Quorum" means a majority of the members of the Commission.

R15-12-103. Quorum

~~A quorum~~ The Commission shall be required have a quorum for making orders and decisions or transacting other official business, as delineated in ~~A.R.S. § 42-306~~ A.R.S. § 42-17003.