

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. 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 making, amending, or repealing any rule. (A.R.S. §§ 41-1013 and 41-1022)

NOTICE OF PROPOSED RULEMAKING

TITLE 3. AGRICULTURE

CHAPTER 11. VETERINARY MEDICAL EXAMINING BOARD

[R06-198]

PREAMBLE

1. Sections Affected

R3-11-101
R3-11-108
R3-11-401
R3-11-502
R3-11-807
R3-11-901

Rulemaking Action

Amend
Amend
Amend
Amend
Amend
Amend

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

Authorizing statute: A.R.S. § 32-2207(8)

Implementing statutes: A.R.S. §§ 32-2201, 32-2207(2), 32-2207(8), 32-2218, 32-2234, 32-2237, 32-2281, 41-1072 through 41-1079

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

Notice of Rulemaking Docket Opening: 12 A.A.R. 1786, May 26, 2006

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

Name: Jenna Jones, Executive Director
Address: 1400 W. Washington, Suite 240
Phoenix, AZ 85007
Telephone: (602) 364-1739
Fax: (602) 364-1039
E-mail: jenna.jones@vetbd.state.az.us

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

The Board is making technical corrections to its rules by correcting rule or statutory citations, and correcting the reference in the time-frame rule in R3-11-108 (E)(2) from the national, or clinical competency veterinary examination, to the North American Veterinary Licensing Examination, a national veterinary technician examination, or the Arizona Veterinary Technician Examination. The Board is also adding a provision in R3-11-401 for continuing education for licensees who graduate within 11 months preceding initial licensure. The Board is correcting references to route of administration for medications in R3-11-502.

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

The Board did not review or rely on any study.

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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:

Annual cost/revenue changes are designated as minimal when less than \$1,000, moderate when between \$1,000 and \$10,000, and substantial when greater than \$10,000.

The rulemaking affects the Board, applicants, licensees, certificate holders, and consumers seeking veterinary medical services.

The Board bears minimal costs for writing the rule and related economic, small business, and consumer impact statement and mailing the new rules to interested persons.

The Board does not believe that the technical changes in the rules impose additional costs on a licensee, applicant for a veterinary medical license or certificate, or a certificate holder. The rules benefit a licensee by allowing the licensee who graduated from a veterinary medical college within 11 months before the license application date to apply 10 credit hours of college course work toward the continuing education requirement in R3-11-401. A provider of continuing education may lose minimal revenue because of the new provision in R3-11-401 that allows a licensee who graduated from a veterinary medical college within 11 months before the license application date to apply 10 credit hours of college course work toward the continuing education requirement. A veterinary medical premise that chooses to pay for continuing education for its licensee's may benefit because it will not have to pay for continuing education for these licensees.

The corrections to route of administration for medications in R3-11-502 should minimally affect a business.

The rules should not increase costs to consumers of veterinary medical services but should benefit the consumer by providing clear, concise, and understandable standards.

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: Jenna Jones, Executive Director

Address: 1400 W. Washington, Suite 240
Phoenix, AZ 85007

Telephone: (602) 364-1739

Fax: (602) 364-1039

E-mail: jenna.jones@vetbd.state.az.us

10. The time, place, and nature of the proceedings for the making, 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 will be conducted by the Board at the following location in the state for the purpose of taking oral and written testimony on the proposed rules from members of the public:

Date: July 19, 2006

Time: 9:00 a.m.

Location: 1400 W. Washington, Basement Room B1
Phoenix, AZ 85007

The public record on the proposed rulemaking will close at 5:00 p.m. on July 19, 2006.

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. The full text of the rules follows:

TITLE 3. AGRICULTURE

CHAPTER 11. VETERINARY MEDICAL EXAMINING BOARD

ARTICLE 1. GENERAL PROVISIONS

Section

R3-11-101. Definitions

R3-11-108. Time-frames for Licensure, Certification, and Permit Approvals

ARTICLE 4. CONTINUING EDUCATION REQUIREMENTS

Section

R3-11-401. Continuing Education

ARTICLE 5. STANDARDS OF PRACTICE

Section

R3-11-502. Standards of Practice

ARTICLE 8. DRUG DISPENSING

Section

R3-11-807. Dispensing a Controlled Substance or Prescription-only Drug

ARTICLE 9. INVESTIGATIONS AND HEARINGS

Section

R3-11-901. Investigations of Alleged Violations

ARTICLE 1. GENERAL PROVISIONS

R3-11-101. Definitions

1. No change
2. No change
3. No change
 - a. No change
 - b. No change
4. No change
5. No change
6. No change
7. No change
8. No change
9. No change
10. No change
11. No change
12. No change
13. No change
14. No change
15. No change
16. No change
17. No change
18. No change
19. No change
20. No change

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- 21. No change
- 22. No change
- 23. "Veterinary medical services" means the acts listed in A.R.S. § ~~32-2201(16)~~ 32-2201(21).

R3-11-108. Time-frames for Licensure, Certification, and Permit Approvals

- A. In addition to the definitions in R3-11-101, the following definitions apply to this Chapter unless otherwise specified:
 - 1. "Administrative completeness review" means the Board's process for determining that an individual has provided all of the information and documents required by A.R.S. §§ 32-2201 through ~~32-2282~~ 32-2296 and this Chapter for an application.
 - 2. No change
 - 3. No change
 - 4. No change
- B. No change
- C. No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - 2. No change
 - 3. No change
 - 4. No change
- D. No change
 - 1. No change
 - 2. No change
 - 3. No change
- E. No change
 - 1. No change
 - 2. Take the state, ~~national, or clinical competency~~ veterinary examination, ~~or~~ the North American Veterinary Licensing Examination, a national veterinary technician examination, or the Arizona Veterinary Technician Examination.
- F. No change
- G. No change

ARTICLE 4. CONTINUING EDUCATION REQUIREMENTS

R3-11-401. Continuing Education

- A. No change
 - 1. No change
 - 2. No change
- B. A licensee receiving an initial license in an even-numbered year is required to complete 10 credit hours of continuing education before the licensee's initial renewal date.
 - 1. If the licensee graduated from a veterinary college within 11 months before the license application date, the licensee may apply 10 credit hours of veterinary college course work to fulfill the continuing education requirement.
 - 2. ~~Thereafter,~~ After the initial renewal the licensee shall complete 20 credit hours of continuing education ~~for the licens-~~ ing period as required in subsection (A).
- C. No change
- D. No change

ARTICLE 5. STANDARDS OF PRACTICE

R3-11-502. Standards of Practice

- A. No change
- B. No change
 - 1. No change
 - 2. No change
- C. No change
- D. No change
- E. No change

- F. No change
- G. No change
- H. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
- I. No change
- J. No change
 - 1. No change
 - 2. No change
- K. No change
 - 1. No change
 - 2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - 3. No change
 - a. No change
 - b. Strength and route of administration of the controlled substance,
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - g. No change
- L. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
 - 6. Name of each medication administered including concentration, amount, ~~and~~ frequency, and route of administration, except when the medication is only offered in one size and strength;
 - 7. No change
 - 8. No change
 - 9. No change
 - 10. No change
- M. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
- N. No change
 - 1. No change
 - 2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change

Notices of Proposed Rulemaking

- e. No change
- f. No change
- g. No change
- O. No change
 - 1. No change
 - 2. No change

ARTICLE 8. DRUG DISPENSING

R3-11-807. Dispensing a Controlled Substance or Prescription-only Drug

- A. No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - 2. No change
 - a. No change
 - b. No change
 - c. No change
 - 3. No change
- B. No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - 2. The dispensing veterinarian authorizing the dispensing shall ensure that records are maintained according to ~~R3-11-502(H) and~~ R3-11-502(K) and ~~R3-11-502(L) and~~ all state and federal laws are followed.

ARTICLE 9. INVESTIGATIONS AND HEARINGS

R3-11-901. Investigations of Alleged Violations

- A. A person may notify the Board of an alleged violation of A.R.S. §§ 32-2201 through ~~32-2282~~ 32-2296 and this Chapter. The Board also may initiate a complaint on its own motion.
- B. No change
- C. No change
- D. No change

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 33. BOARD OF EXAMINERS FOR NURSING CARE INSTITUTION ADMINISTRATORS AND ASSISTED LIVING FACILITY MANAGERS

[R06-184]

PREAMBLE

1. Sections Affected

R4-33-101
R4-33-102
R4-33-103
R4-33-104
R4-33-105
R4-33-106
R4-33-106
R4-33-107
R4-33-108

Rulemaking Action

Amend
Amend
Amend
Amend
New Section
Re-number
Amend
New Section
New Section

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Table 1	Amend
R4-33-201	Renumber
R4-33-201	Amend
R4-33-202	Renumber
R4-33-202	Amend
R4-33-203	Renumber
R4-33-203	Amend
R4-33-204	Renumber
R4-33-204	Amend
R4-33-205	Renumber
R4-33-205	Amend
R4-33-206	Amend
R4-33-207	Amend
R4-33-208	Amend
R4-33-209	Renumber
R4-33-210	Repeal
R4-33-210	New Section
R4-33-211	Amend
R4-33-212	Renumber
R4-33-213	Repeal
R4-33-214	Repeal
Article 4	Amend
R4-33-401	Renumber
R4-33-401	Amend
R4-33-402	Renumber
R4-33-402	Amend
R4-33-403	Amend
R4-33-404	Amend
R4-33-405	Renumber
R4-33-405	Amend
R4-33-406	Renumber
R4-33-406	New Section
R4-33-407	Amend
R4-33-408	Repeal
R4-33-408	New Section
R4-33-409	Repeal
R4-33-410	Renumber
R4-33-411	Repeal
R4-33-412	Repeal
Article 5	New Article
R4-33-501	New Section
R4-33-502	New Section
R4-33-503	New Section
R4-33-504	New Section

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

Authorizing statute: A.R.S. § 36-446.03(A)

Implementing statute: A.R.S. §§ 36-446.03(B) and (K), 36-446.04, 36-446.06, 36-446.07, and 36-446.12

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

Notice of Rulemaking Docket Opening: 12 A.A.R. 1342, April 21, 2006

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

Name: Allen Imig, Executive Director
Address: NCIA Board
1400 W. Washington, Ste. B-8
Phoenix, AZ 85007
Telephone: (602) 542-8156
Fax: (602) 542-8316
E-mail: allen.imig@nciabd.state.az.us

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

In response to a five-year review report, the Board is updating its rules to make them consistent with state and federal law and agency practice. The Board will also make the rules conform to current rulewriting standards.

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

None

7. A showing of good cause why the 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:

None

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

The following rule changes will have a minimal economic impact on nursing care institution administrators or assisted living facility managers:

- a. Establishing a new fee for renewing an inactive manager certificate;
- b. Establishing a new charge to verify the status of a manager's certificate;
- c. Broadening the fields of study that qualify an individual to become licensed as an administrator;
- d. Allowing six months after passing the required examinations for an applicant to pay to have a license or certificate issued or the application is administratively closed;
- e. Requiring an applicant for manager certification to have a high school diploma or GED;
- f. Increasing the passing score that a manager applicant must obtain on the Arizona examination;
- g. Increasing the number of hours of continuing education required to renew a manager certificate;
- h. Pro-rating the number of hours of continuing education required during the biennial period following initial licensure;
- i. Adding a provision regarding audit of continuing education records; and
- j. Increasing the amount of time for the Board to conduct its administrative completeness review of certain applications.

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: Allen Imig, Executive Director
Address: NCIA Board
1400 W. Washington, Ste. B-8
Phoenix, AZ 85007
Telephone: (602) 542-8156
Fax: (602) 542-8316
E-mail: allen.imig@nciabd.state.az.us

10. The time, place, and nature of the proceedings for the making, 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 regarding the proposed rules will be held as follows:

Date: Wednesday, July 19, 2006
Time: 12:00 p.m.
Location: 1400 W. Washington, Room B-1
Phoenix, AZ 85007

The rulemaking record will close on July 19, 2006, at 5:00 p.m.

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. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 33. BOARD OF EXAMINERS FOR NURSING CARE INSTITUTION ADMINISTRATORS AND ASSISTED LIVING FACILITY MANAGERS

ARTICLE 1. GENERAL

Section

- R4-33-101. Definitions
- R4-33-102. Board Officers
- R4-33-103. Time-frames for Licenses, Certifications, and Approvals
- R4-33-104. Fees
- R4-33-105. ~~Reserved~~ Hearing Procedures
- ~~R4-33-209~~ ~~R4-33-106~~ ~~Reserved~~ Rehearing or Review of Decision
- R4-33-107. ~~Reserved~~ Change of Name or Address
- R4-33-108. ~~Reserved~~ Display of License or Certificate
- Table 1. Time-frames (in days)

ARTICLE 2. NURSING CARE INSTITUTION ADMINISTRATOR LICENSING

Section

- ~~R4-33-204~~ ~~R4-33-201~~ Qualifications Requirements for Initial License by Examination
- ~~R4-33-203~~ ~~R4-33-202~~ Licensure Requirements for Initial License by Endorsement Reciprocity
- ~~R4-33-212~~ ~~R4-33-203~~ Requirements for Temporary License
- ~~R4-33-201~~ ~~R4-33-204~~ Initial Application
- ~~R4-33-202~~ ~~R4-33-205~~ Licensure by Examination Administration of Examinations; License Issuance
- R4-33-206. Renewal Application
- R4-33-207. Inactive Status
- R4-33-208. Standards of Conduct; Disciplinary Action
- ~~R4-33-209~~ Renumbered
- R4-33-210. Restoration of Revoked License Licensure following Revocation
- R4-33-211. Display of License and Board Notification Notice of Appointment
- ~~R4-33-212~~ Renumbered
- R4-33-213. Denial of License or Renewal of License Repealed
- R4-33-214. Criteria for Continuing Education Repealed

ARTICLE 4. ASSISTED LIVING FACILITY MANAGER CERTIFICATION

Section

- ~~R4-33-402~~ ~~R4-33-401~~ Eligibility Requirements for Initial Certification by Examination
- ~~R4-33-410~~ ~~R4-33-402~~ Requirements for a Temporary Certificates-Certificate
- R4-33-403. Initial Application
- R4-33-404. Administration of Examination; Certificate Issuance
- ~~R4-33-406~~ ~~R4-33-405~~ Renewal Application
- ~~R4-33-406~~ Inactive Status
- R4-33-407. Standards of Conduct; Suspension or Revocation-Disciplinary Action
- R4-33-408. Criteria for Continuing Education-Referral Requirements
- R4-33-409. Display of Certificate Repealed
- ~~R4-33-410~~ Renumbered
- R4-33-411. Denial of Certificate Repealed
- R4-33-412. Rehearing or Review of Decision Repealed

ARTICLE 5. CONTINUING EDUCATION

Section

- R4-33-501. Continuing Education Requirement
R4-33-502. Approval of Continuing Education
R4-33-503. Audit of Compliance and Sanction for Noncompliance with Continuing Education Requirement
R4-33-504. Extension of Time to Complete the Continuing Education Requirement

ARTICLE 1. GENERAL

R4-33-101. Definitions

The definitions in A.R.S. § 36-446 apply to this Chapter. Additionally, ~~in~~ in this Article Chapter, unless otherwise specified:

1. “Accredited” means ~~authorized~~ approved by the North Central Association of Colleges and Secondary Schools, New England Association of Schools and Colleges, Middle States Association of Colleges and Secondary Schools, Northwest Association of Schools and Colleges, Southern Association of Colleges and Schools, or Western Association of Schools and Colleges.
“ACHCA certified” means written evidence of completing the Professional Certification Program administered by the American College of Health Care Administrators.
“Administrator” has the meaning prescribed at A.R.S. § 36-446 and means an individual licensed under this Chapter.
2. “Administrator in training” or “AIT” means ~~a person~~ an individual who is taking an ~~NAB-approved AIT~~ program of training to be licensed as an administrator for a nursing care institution.
3. “AIT ~~Program~~ program” means an NAB-approved training ~~program~~ lasting not less than 20 weeks nor more than 52 weeks, at 40 hours per week, conducted as an educational experience in a licensed nursing care institution.
4. “ACHCA Certified” means ~~having evidence of completing the Professional Certification Program administered by the American College of Health Care Administrators.~~
“Applicant” means an individual who applies to the Board to be licensed as an administrator of a nursing care institution, to be certified as a manager of an assisted living facility, or for approval of a continuing education.
“Application package” means the forms, documents, and fees that the Board requires an applicant to submit or have submitted on the applicant’s behalf.
“Arizona examination” means a measure of an applicant’s knowledge of Arizona statutes and rules regarding nursing care institution administration or assisted living facility management.
5. “AzACHCA” means ~~the Arizona chapter of the American College of Health Care Administrators.~~
“Biennial period” means July 1 of an even-numbered year through June 30 of the next even-numbered year for an administrator and July 1 of an odd-numbered year through June 30 of the next odd-numbered year for a manager.
6. “Contact hour” means an hour during which an administrator or manager is physically present at ~~an instructional activity that is to be used for either a continuing education credit or a manager is physically present at a required initial training credit required for adult care home managers.~~
“Continuing education” means a planned educational course or program that the Board approves under R4-33-502.
7. “Good standing” means that a nursing care institution administrator is the holder of a current and valid license, not subject to any disciplinary action or consent order, and not currently under investigation for alleged unprofessional conduct.
“Health care institution” means every place, institution, building or agency, whether organized for profit or not, which provides facilities with medical services, nursing services, health screening services, other health-related services, supervisory care services, personal care services or directed care services and includes home health agencies as defined in A.R.S. § 36-151 and hospice services agencies. A.R.S. § 36-401.
“Manager” means an assisted living facility manager, as defined at A.R.S. § 36-446, who is certified under this Chapter.
8. “NAB” means the National Association of Board of Examiners for Nursing Home Administrators.
“Party” has the same meaning as prescribed in A.R.S. § 41-1001.
9. “Preceptor” means a practicing nursing care institution administrator who ~~undertakes the role of teacher through the tutorial process;~~ has taken a board-approved preceptor training course; and helps to develop a new professional in the field of long-term care administration by tutoring the new professional.
10. “Program Advisory Committee” means the group ~~comprised~~ of practicing nursing care administrators that provides oversight to AITs and ensures the application of uniform training standards and guidelines outlined in the ~~NAB-approved AIT Program program.~~

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- 11. "Qualified instructor" means a person who meets one or more of the following criteria:
 - a. A registered nurse, licensed under A.R.S. Title 32, Chapter 15;
 - b. An instructor employed by an accredited ~~junior~~ college, ~~or~~ university ~~program~~, or health care institution to teach a health-care related ~~courses~~ course; or
 - e. A person or entity who ~~that possesses a combination of~~ has sufficient education and training ~~equivalent to the qualifications listed above~~ be qualified to teach a health-care related course.
- 12. "Training program" means an educational syllabus approved by the Board of Examiners of Nursing Care Institution Administrators and Assisted Living Facility Managers in accordance with the requirements of A.R.S. § 36-446.04(A)(2) and (B)(2).
"Work experience in a health-related field" means employment in a health care institution or in the professional fields of medicine, nursing, social work, gerontology, or other closely related field.

R4-33-102. Board Officers

- A. At its first annual meeting, the Board shall elect ~~from among its membership~~ a president, and vice-president, ~~and secretary-treasurer~~.
- B. The functions, duties, and limitations of these officers are as follows:
 - 1. President. The president shall call and preside at all Board meetings. The president shall act as chief officer of the Board, appoint committees, and delegate authority to other members of the Board as needed.
 - 2. Vice-president. The vice-president shall preside at Board meetings in the absence of the president and may exercise all the powers and duties of the president in the absence of the president.
 - 3. ~~Secretary-treasurer. The secretary-treasurer shall prepare and maintain minutes of all meetings, monitor the attendance of members and keep account of all monies that are collected and disbursed by the Board.~~
- C. Board officers ~~shall~~ serve for a term of one year. ~~No~~ A Board officer ~~may~~ shall not serve more than two consecutive ~~terms~~ years.

R4-33-103. Time-frames for Licenses, Certifications, and Approvals

- A. For each type of license, certification, or approval, ~~or renewal of license or certification~~ issued by the Board, the overall time-frame described in A.R.S. § 41-1072(2) is ~~set forth~~ listed in Table 1.
- B. For each type of license, certification, or approval, ~~or renewal of license or certification~~ issued by the Board, the administrative completeness review time-frame described in A.R.S. § 41-1072(1) is ~~set forth~~ listed in Table 1 and begins on the date the Board receives an application ~~and required documents and information package~~.
 - 1. If ~~the~~ an application ~~and documents are~~ package is not administratively complete, the Board shall send a deficiency notice to ~~an~~ the applicant ~~a deficiency notice~~.
 - a. ~~The deficiency notice shall state that specifies each deficiency and the piece of information or document needed to complete the application and documents package.~~
 - b. Within the time provided in Table 1 for response to ~~the~~ a deficiency notice, beginning on the mailing date of the deficiency notice, the applicant shall submit to the Board the missing information or document specified in the deficiency notice. The time-frame 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 or document.
 - 2. If ~~the~~ an application package is administratively complete, the Board shall send a written notice of administrative completeness to the applicant.
 - 3. If ~~the~~ an application ~~and submitted documents are~~ package is not completed within the time provided to respond to the deficiency notice, the Board shall send a written notice to the applicant informing the applicant that the application is deemed withdrawn.
- C. For each type of license, certification, or approval, ~~or renewal of license or certification~~ issued by the Board, the substantive review time-frame described in A.R.S. § 41-1072(3) is ~~set forth~~ listed in Table 1 and begins on the date the Board sends written notice of administrative completeness to the applicant.
 - 1. During the substantive review time-frame, the Board may make one comprehensive written request for additional information. Within the time provided in Table 1 for response to a comprehensive written request for additional information, beginning on the mailing date of the comprehensive written request for additional information, the applicant shall submit to the Board the requested additional information. The time-frame for the Board to finish the substantive review is suspended from the date the Board mails the comprehensive written request for additional information to the applicant until the Board receives the requested additional information.
 - 2. ~~The Board shall issue a written notice of denial of license or renewal of license if the Board determines that the applicant does not meet all of the substantive criteria required by statute and this Chapter for licensing, certification, approval, or renewal of license or certification.~~
 - 3. The Board shall issue a written notice informing the applicant that the application is deemed withdrawn if the appli-

Notices of Proposed Rulemaking

cant does not submit the requested additional information within the time-frame provided in Table 1.

4. ~~If the applicant meets all of the substantive criteria required by statute and this Chapter for license, certification, approval, or renewal of license or certification, the Board shall issue the license, certification, approval, or renewal of license or certification to the applicant.~~

D. Within the overall time-frame listed in Table 1, the Board shall:

1. Deny a license, certificate, or approval to an applicant if the Board determines that the applicant does not meet all of the substantive criteria required by statute and this Chapter; or
2. Grant a license, certificate, or approval to an applicant if the Board determines that the applicant meets all of the substantive criteria required by statute and this Chapter.

E. If the Board denies a license, certificate, or approval under subsection (D)(1), the Board shall provide a written notice of denial to the applicant that explains:

1. The reason for the denial, with citations to supporting statutes or rules;
2. The applicant's right to seek a fair hearing to challenge the denial; and
3. The time for appealing the denial.

~~**D.**~~ **F.** 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~~ is not be included. The last day of the period ~~shall be~~ is 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 Saturday, Sunday, or a state holiday. The computation ~~shall include~~ includes intermediate Saturdays, Sundays, and state holidays. The time period ~~shall begin~~ begins on the date of personal service, date shown as received on a certified mail receipt, or postmark date.

R4-33-104. Fees

A. ~~For~~ Under the authority provided at A.R.S. § 36-446.12(A), the Board establishes and shall collect the following fees for nursing care institution administrators, ~~the Board shall charge the following fees, which~~ The fees are nonrefundable unless A.R.S. § 41-1077 applies:

1. Initial application, \$100
2. ~~Examination~~ Arizona examination, \$500
3. ~~Re-administering state~~ Re-administer Arizona examination, \$150
4. Issuance of a license, \$260 or \$11 for each month remaining in the biennial period
5. Duplicate license, \$50
6. Biennial active license renewal, \$300
7. Biennial inactive license renewal, \$100
8. Late renewal penalty, \$50
9. Temporary license, \$250
10. ~~Certifying~~ Certify licensure status, \$10
11. Review ~~sponsor's sponsorship of a continuing education program~~, \$20.

B. ~~For~~ Under the authority provided by at A.R.S. § 36-446.03(B), the Board establishes and shall collect the following fees for assisted living facility managers, ~~the Board shall charge the following fees, which~~ The fees are nonrefundable unless A.R.S. § 41-1077 applies:

1. Initial application, \$100
2. ~~Examination~~ Arizona examination, \$100
3. ~~Re-administering state~~ Re-administer Arizona examination, \$100
4. Issuance of a certificate, \$100 or \$4 for each month remaining in the biennial period
5. Duplicate certificate, \$50
6. Biennial active certificate renewal, \$100
7. Biennial inactive certificate renewal, \$75
- ~~8.~~ 9. Late renewal penalty, \$50
- ~~9.~~ 10. Temporary certificate, \$50
- ~~10.~~ 11. Verify certificate status, \$10
- ~~11.~~ Review ~~sponsor's sponsorship of a continuing education program~~, \$20.

C. ~~If the Board approves an applicant for a license and issues a license to the applicant for less than the biennial license period, the applicant shall submit to the Board \$11 for each month remaining in the licensure period.~~

D. ~~If the Board approves an applicant for a certificate and issues a certificate for less than the biennial certificate period, the applicant shall submit to the Board \$4 for each month remaining in the certificate period.~~

R4-33-105. Reserved Hearing Procedures

As required under A.R.S. § 36-446.07(J), the Board shall conduct all hearings according to the procedures in A.R.S. Title 41, Chapter 6, Article 10 and rules issued by the Office of Administrative Hearings.

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~~R4-33-209~~ ~~R4-33-106~~ Reserved Rehearing or Review of Decision

- ~~A.~~ Except as provided in subsection (G), any party in a contested case before the Board who is aggrieved by a decision rendered in the case may file with the Board, not later than 30 days after service of the decision, a written motion for rehearing or review of the decision which specifies the particular grounds on which it is based. For purposes of this subsection, a decision shall be deemed to have been served when personally delivered or mailed by certified mail to the party at the party's last known residence or place of business. The Board shall provide for a rehearing and review of its decisions under A.R.S. Title 41, Chapter 6, Article 10 and the rules established by the Office of Administrative Hearings.
- ~~B.~~ Except as provided in subsection (I), a party is required to file a motion for rehearing or review of a decision of the Board to exhaust the party's administrative remedies.
- ~~C.~~ A party may amend a motion for rehearing under this rule may be amended or review at any time before it is ruled upon by the Board rules on the motion. A response may be filed within 10 days after service of the motion. The Board may require the filing of written briefs upon the issues raised in the motion and may provide for oral argument.
- ~~C.~~ D. The Board may grant a rehearing or review of the decision for any of the following causes reasons materially affecting the moving a party's rights:
 1. Irregularity in the administrative proceedings of the agency or its hearing officer or the prevailing party Board or any order or abuse of discretion that deprived the moving party of a fair hearing; ;
 2. Misconduct of the Board, its staff, or its hearing officer or the prevailing party an administrative law judge; ;
 3. Accident or surprise that could not have been prevented by ordinary prudence; ;
 4. Newly discovered material evidence that could not, with reasonable diligence, have been discovered and produced at the original hearing; ;
 5. Excessive or insufficient penalties, penalty;
 6. Error in the admission or rejection of evidence or other errors of law occurring at the administrative hearing or during the progress of the proceedings; ; and
 7. ~~That the~~ The findings of fact or decision is not justified by the evidence or is contrary to law.
- ~~D.~~ E. The Board may affirm or modify the a decision or grant a rehearing or review to all or any some of the parties; on all or part some of the issues; for any of the reasons listed in subsection ~~(C)~~ (D). An order modifying a decision or granting a rehearing or review shall specify with particularity the ground or grounds on which the rehearing is granted, and for the order. If a rehearing or review is granted, the rehearing or review shall cover only the specified matters specified in the order.
- ~~E.~~ F. Not later than 30 days after the date of a decision is rendered and after giving the parties notice and an opportunity to be heard, the Board may, on its own initiative, order a rehearing or review of its decision for any reason for which it might have granted a rehearing or review on motion of a party. After giving the parties or their counsel notice and an opportunity to be heard on the matter, the The Board may grant a motion for rehearing or review, timely served, for a reason not stated in the motion. In either case the An order granting a rehearing or review shall specify with particularity the grounds on which it the rehearing or review is granted.
- ~~F.~~ G. When a motion for rehearing is based upon affidavits, they shall be served with the motion. An opposing party may, within 15 days after service, serve opposing affidavits. This period may be extended by the Board for a maximum of 20 days by the Board for good cause shown as described in subsection (H) or by written stipulation of the parties. Reply affidavits may be permitted.
- ~~H.~~ I. The Board may extend all time limits listed in this Section upon a showing of good cause. A party demonstrates good cause by showing that the grounds for the party's motion or other action could not have been known in time, using reasonable diligence, and a ruling on the motion will:
 1. Further administrative convenience, expedition, or economy; or
 2. Avoid undue prejudice to any party.
- ~~G.~~ H. Except as provided in subsection (H), a decision shall be final when rendered if further review is unavailable, upon expiration of the time for filing a request for rehearing, or upon denial of a request for rehearing, whichever is later. If a rehearing is granted, the decision shall be stayed until affirmed, amended, or reversed.
- ~~H.~~ I. If, in a particular decision, the Board makes a specific findings finding that the immediate effectiveness of the decision is necessary for the immediate preservation of the public peace, health, or safety, or welfare and that a rehearing or review of the decision is impracticable, unnecessary, or contrary to the public interest, the decision may be issued as a final decision without an opportunity for a rehearing or review. If a decision is issued as a final decision without an opportunity for rehearing, the decision shall be effective when issued. Any If an application for judicial review of the decision shall be made, within the time limits permitted for applications for judicial review of the Board's final decisions it shall be made under A.R.S. § 12-901 et seq.
- ~~I.~~ J. For purposes of this Section, the terms "contested case" and "party" have the meanings provided in A.R.S. § 41-1001.

~~R4-33-107.~~ Reserved Change of Name or Address

- ~~A.~~ A. The Board shall communicate with an administrator or manager using the name and address in the Board's records. To ensure timely communication from the Board, an administrator or manager shall inform the Board in writing of any

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change in name or address.

B. An administrator or manager shall include in a notice of change in name or address either the new and former name or new and former address.

C. An administrator or manager shall attach to a notice of change in name a copy of the legal document changing the name.

R4-33-108. Reserved Display of License or Certificate

A. An administrator shall display the administrator’s original license and current renewal receipt in a conspicuous place in the nursing care institution at which the administrator is appointed.

B. A manager shall display the manager’s original certificate and current renewal receipt in a conspicuous place in the assisted care facility at which the manager is employed.

Table 1. Time-frames (in days)

Type of License	Overall Time-Frame	Administrative Review Time-Frame	Time to Respond to Deficiency Notice	Substantive Review Time-Frame	Time to Respond to Request for Additional Information
Initial License R4-33-201 and R4-33-202 A.R.S. §§ 36-446.04(A) and 36-446.05	120 135	15 30	90	105	60
Renewal of License R4-33-206 A.R.S. § 36-446.07(E)	75	30	15	45	15
Temporary License R4-33-212 R4-33-203 A.R.S. § 36-446.06	120 135	15 30	90	105	60
Continuing Education Program Approval R4-33-214 R4-33-502 A.R.S. § 36-446.07(E) and (F)	60	15	30	45	15
Administrator-in-Training Program Approval R4-33-301 A.R.S. § 36-446.04	60	15	30	45	15
Initial Certification R4-33-403 R4-33-401 A.R.S. § 36-446.04(B)	120 135	15 30	90	105	60
Renewal of Certification R4-33-406 R4-33-405 A.R.S. § 36-446.07(F)	75	30	15	45	15
Approval of Continuing Education Program R4-33-408 A.R.S. § 36-446.07(F)	60	15	30	45	15
Temporary Certification R4-33-410 R4-33-402 A.R.S. § 36-446.06	120 135	15 30	90	105	60

ARTICLE 2. NURSING CARE INSTITUTION ADMINISTRATOR LICENSING

~~R4-33-204~~R4-33-201. Qualifications Requirements for Initial License by Examination

An applicant for licensing ~~To be eligible to receive an initial license by examination as a nursing care institution administrator, who completes the requirement of R4-33-201 and meets either of the following requirements shall be eligible to take the licensure examination an individual shall:~~

1. Education and training.
 - a. ~~Has successfully completed a Board approved AIT program and holds~~ Hold a minimum of a baccalaureate degree from an accredited college or university and successfully complete an AIT program; or
 2. ~~b. Holds~~ Hold a minimum of a masters degree in health care administration or long term care administration a health-related field from an accredited college or university; or
 - c. Hold a minimum of an associate of arts degree in nursing from an accredited college or university and:
 - i. Be currently licensed as a registered nurse under A.R.S. § 32-1632.
 - ii. Have worked as a registered nurse for five of the last seven years, and
 - iii. Successfully complete an AIT program.
2. Examination.
 - a. Obtain the scaled passing score on the NAB examination, and
 - b. Obtain a score of at least 80 percent on the Arizona examination; and
3. Application. Submit all applicable information required under R4-33-204.

~~R4-33-203~~R4-33-202. Licensure Requirements for Initial License by Endorsement-Reciprocity

The Board, in its discretion and otherwise subject to the law pertaining to the licensing of nursing care institution administrators, shall issue ~~To be eligible for an initial license by reciprocity as a nursing care institution administrator, license upon application and payment of the prescribed fee and submission of evidence satisfactory to the Board that an applicant an individual shall:~~

1. ~~Has met the requirements specified in R4-33-201. Instead of meeting the requirements of R4-33-201(F), the applicant may submit evidence of ACHCA certification~~ Substantially equivalent educational requirement.
 - a. Hold a minimum of a master's degree from an accredited college or university, or
 - b. Hold ACHCA certification;
2. Substantially equivalent examination requirement.
 - a. ~~Holds~~ Hold a valid and current license as a nursing care institution administrator for issued by a state or territory, which was obtained by passing the NAB examination; and required by R4-33-202(A)(1). If the applicant took the national examination before January 1990, a passing score shall be a raw score of 105 or better. After January 1990, a passing score shall be 70%. The applicant shall arrange to have the licensing agency of the state in which the applicant is licensed complete and directly return to the Board a certification on a form provided by the Board which provides the name of the secretary of the state board providing the certification, the full name of the applicant, the applicant's license number, date of licensing, expiration date of the license, the national examination taken by the applicant and the applicant's score, a statement that the applicant is fit and proper for licensing, the signature of the secretary, and the agency name and address.
 - 3-b. ~~Has met or exceeded~~ Obtain a score of at least 80% percent on the written the Arizona examination administered by the Board in accordance with R4-33-202(A)(2); and
3. Application.
 - a. Submit all applicable information required under R4-33-204.
 - b. Have submitted directly to the Board a certified copy of the valid and current license issued by a state or territory; and
 - c. Have submitted directly to the Board the score that the applicant obtained on the NAB examination.

~~R4-33-212~~R4-33-203. Requirements for Temporary License

- A. ~~To qualify be eligible for a temporary license to fill as a nursing care institution administrator position, an applicant individual shall submit the application required in R4-33-201 and provide evidence of the following:~~
1. ~~That the applicant meets~~ Meet or exceeds the requirements specified in R4-33-201 and R4-33-203, or R4-33-204. or R4-33-202 except for the requirement at R4-33-201(2) or R4-33-202(2)(b);
 2. ~~That an administrator's position is available and that the applicant will be engaged in the capacity of administrator if the applicant is successful in obtaining a temporary license~~ Have the owner of an a nursing care institution that intends to employ the applicant as administrator if the applicant is successful in obtaining a temporary license submit to the Board a Letter of Intent to Employ on a form that is available from the Board. The owner of the nursing care institution shall include the following in the Letter of Intent to Employ:
 - a. Name of the owner of the nursing care institution;
 - b. Name and address of the nursing care institution;
 - c. Name of the applicant;
 - d. An affirmation of intent to employ the applicant;

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- e. Reason for requesting a temporary license for the applicant;
 - f. License number of the nursing care institution; and
 - g. Notarized signature of the owner of the nursing care institution;
3. ~~That the applicant has not~~ Not have held an Arizona temporary license as a nursing care institution administrator within the past three years; and
 4. ~~That the applicant has not~~ Not have failed a state the Arizona or national NAB examination ~~within one year~~ before applying for a temporary license.
- B.** At the Board's request, an applicant for a temporary license shall appear or be available by telephone for an interview with the Board.
- C.** A temporary license is valid for 150 days and is not renewable. Before expiration of the temporary license, the temporary licensee shall become licensed under ~~the terms of~~ A.R.S. § 36-446.04 and this Article or discontinue as administrator of the nursing care institution.
- D.** If a temporary licensee fails the Arizona or NAB examination during the term of the temporary license, the temporary license is automatically revoked and the former licensee shall discontinue as administrator of the nursing care institution.

~~R4-33-201~~ **R4-33-204, Initial Application**

- A.** ~~A person~~ An individual who desires to be licensed as a nursing care institution administrator shall submit the following information to the Board on an application on a form, which is available from ~~provided by the Board which provides the following information:~~
1. Full name of the applicant;
 2. Type of license for which application is being submitted; and
 3. Sworn statement that applicant has answered all questions on all forms related to the application truthfully and has authorized educational and other institutions, employers, and governmental agencies to provide to the Board any information requested by the Board.
- B.** ~~The applicant shall arrange to have two persons who are unrelated to the applicant and not in the applicant's employment complete "Moral Character Certification" forms and return them directly to the Board. The certification shall contain the applicant's full name; type of examination for which the applicant is applying to sit; a certification that person is personally acquainted with the applicant; the number of years of acquaintance; the belief that the applicant is of appropriate moral character and suitability; and a recommendation of the applicant to the Board.~~
- C.** ~~The applicant shall have a licensed physician complete a "Medical Certification" form and return it directly to the Board. The certification shall contain the applicant's full name; type of examination for which the applicant is applying to sit; a certification by the physician that the applicant is in good health, free from contagious diseases, and absent any physical or mental impairments that would interfere with the performance of administrator duties; the number of years the physician has provided care to the applicant; the date the applicant was examined; other remarks; and the signature, full name, address and license number of the physician.~~
- D.** ~~An applicant who has been convicted of a felony shall submit, with the application, evidence that the applicant is in compliance with all court imposed requirements. The evidence shall be issued by an appropriate court, Board of Parole, or equivalent agency. The evidence shall provide information on the specific type of felony offense and the related circumstances.~~
- E.** ~~The applicant shall complete and submit a sworn, notarized, and completed personal data sheet form prescribed by the Board which provides the following information:~~
1. The name as the applicant wants it to appear on the certificate;
 2. The full name of the applicant Other names that the applicant has used;
 3. The home Mailing address of the applicant;
 4. The home Home, work, and mobile telephone number numbers of the applicant;
 5. The applicant's Applicant's date and place of birth;
 6. The applicant's social security Applicant's Social Security number;
 7. The sex of the applicant Whether the applicant is a U.S. citizen and if not, evidence of authorization to work in the United States;
 8. The work telephone number of the applicant Address of every residence at which the applicant has lived in the last five years;
 9. Whether the applicant is presently serving as an administrator, and if so, the address of the institution Name and address of every accredited college or university attended, dates of attendance, date of graduation, and degree or certificate received;
 10. Information regarding professional licenses or certifications currently or previously held by the applicant, including:
 - a. Name of issuing agency;
 - b. License or certificate number;
 - c. Issuing jurisdiction;
 - d. Date on which the license or certificate was first issued;
 - e. Whether the license or certificate is current; and

- f. Whether the license or certificate is in good standing and if not, an explanation;
11. Information regarding the applicant's employment record for the last five years, including:
 - a. Name, address, and telephone number of each employer;
 - b. Title of position held by the applicant;
 - c. Name of applicant's supervisor;
 - d. Dates of employment; and
 - e. Reason for employment termination;
12. Whether the applicant was ever denied a professional license or certificate and if so, the kind of license or certificate denied, licensing authority making the denial, and date;
13. Whether the applicant ever voluntarily surrendered a professional license or certificate and if so, the kind of license or certificate surrendered, licensing authority, date, and reason for the surrender;
14. Whether the applicant ever allowed a professional license or certificate to lapse and if so, the kind of license or certificate that lapsed, licensing authority, date, reason for lapse, and whether the license or certificate was reinstated;
15. Whether the applicant ever had a limitation imposed on a professional license or certificate and if so, the kind of license or certificate limited, licensing authority, date, nature of limitation, reason for limitation, and whether the limitation was removed;
- ~~10-~~16. Whether the applicant has ever had an administrator a professional license or certificate suspended or revoked and if so, the kind of license or certificate suspended or revoked, licensing authority, date, and reason for the suspension or revocation;
17. Whether the applicant ever was subject to disciplinary action with regard to a professional license or certificate and if so, the kind of license or certificate involved, licensing authority, date, and reason for and nature of the disciplinary action;
18. Whether the applicant was ever restricted in or terminated from employment as a nursing care institution administrator and if so, name of employer, date, circumstances of restriction or termination, and nature of restriction;
19. Whether the applicant ever resigned from employment to avoid being terminated or disciplined and if so, name of employer, date, and circumstances of the resignation;
20. Whether any unresolved complaint against the applicant is pending with a licensing authority, professional association, health care facility, or nursing care institution and if so, the nature of and where the complaint is pending;
21. Whether the applicant ever was charged with or convicted of a felony or a misdemeanor, other than a minor traffic violation, in any court and if so, the nature of the offense, jurisdiction, and date of discharge; and
22. Whether the applicant ever was pardoned from or had the record expunged of a felony conviction and if so, the nature of the offense, jurisdiction, and date of pardon or expunging.
- ~~11-~~ Whether the applicant has ever had a nursing care institution administrator license denied;
- ~~12-~~ Whether the applicant is currently licensed as an administrator in any other state, including name of state, license number, and expiration date;
- ~~13-~~ Whether the applicant's administrator license has ever been suspended or revoked;
- ~~14-~~ The names of the two persons to whom moral character certificates were sent;
- ~~15-~~ The name and address of the physician to whom the medical certificate was sent;
- ~~16-~~ Whether the applicant has been convicted for a violation of any law other than a minor traffic violation, and, if so, the date, place, and nature of the conviction;
- ~~17-~~ The state of current licensure, date license received, and the license number, if the applicant wishes to apply for licensure by reciprocity;
- ~~18-~~ The educational record of the applicant, including:
 - a. Name of the high school attended by applicant, its location, highest grade completed, whether the applicant received a diploma and year, and if not, GED certificate number and date issued and where the GED exam was taken;
 - b. Undergraduate education, including name and location of college or university, course of study, years attended, and degree and date received;
 - c. Post-graduate education, including name and location of college or university, course of study, years attended, and degree and date received;
 - d. Field training or short courses, including name and location of institution or agency, dates attended, course pursued, and date completed;
 - e. Memberships in professional or honorary societies and dates of membership;
 - f. Any special honors received and dates;
 - g. Professional licenses or certificates held, including type, license number, licensing authority, state, and dates;
 - h. Articles or books published, including name of publication, publisher, and copyright year or date of publication;
- ~~19-~~ The applicant's employment record for the last 10 years, including name and address of each employer, position held, immediate supervisor, and description of duties;
- ~~20-~~ A description of applicant's participation in health care institution association offices and activities;

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- 21. A description of the applicant's involvement in health-related community service activities; and,
- 22. A finished, unmounted color photograph of the applicant's head and shoulders, not less than 2 1/2 inches nor more than 3 inches square and taken within six months before the date of application.
- ~~F.~~ The applicant shall provide to the Board transcripts, a certificate of AIT program completion, or both, which demonstrate that the requirements of R4-33-204 have been met.
- ~~G.~~ An applicant shall submit the completed application forms and prescribed fees to the Board at least 45 days before the date of the next regularly scheduled examination.
- ~~H.~~ An applicant shall appear before the Board upon its request.
- B. In addition to the application form required under subsection (A), an applicant shall submit or have submitted on the applicant's behalf:
 - 1. Official transcript submitted directly to the Board by each accredited college or university attended by the applicant;
 - 2. Verification of license that is signed, authenticated by seal or notarization, and submitted directly to the Board by each agency that ever issued a professional license to the applicant;
 - 3. "Moral Character Certification" form submitted directly to the Board by two individuals who have known the applicant for at least three years and are not related to, employed by, or employing the applicant;
 - 4. If the applicant is certified by ACHCA, verification of certification submitted directly to the Board by ACHCA;
 - 5. If the applicant completed an AIT program, a photocopy of the certificate issued upon completion;
 - 6. For every felony or misdemeanor charge listed under subsection (A)(21), a copy of documents from the appropriate court showing the disposition of each charge;
 - 7. For every felony or misdemeanor conviction listed under subsection (A)(21), a copy of documents from the appropriate court showing whether the applicant met all judicially imposed sentencing terms;
 - 8. Passport-size, color, full-face photograph of the applicant taken within the last 180 days and signed on the back by the applicant;
 - 9. Signed and notarized affidavit affirming that the information provided in the application is true and complete and authorizing others to release information regarding the applicant to the Board; and
 - 10. Fees required under R4-33-104(A)(1) and (A)(2).
- C. If required by the Board under A.R.S. § 36-446.03(D), an applicant shall appear before the Board.
- D. When the information required under subsections (A) and (B) is received and following an appearance before the Board required under subsection (C), the Board shall provide notice regarding whether the applicant may take the licensing examinations required under R4-33-201 or R4-33-202.
- E. Because of the time required for the Board to perform an administrative completeness review under R4-33-103, an applicant shall submit the information required under subsections (A) and (B) at least 30 days before the applicant expects to take the Arizona examination.

~~R4-33-202, R4-33-205, Licensure by Examination Administration of Examinations; License Issuance~~

- ~~A.~~ To be eligible for licensure as a nursing care institution administrator, an applicant shall obtain the following:
 - 1. A score of 70% on a written national examination of NAB;
 - 2. A score of 80% on a written examination based on Arizona statutes and rules.
- ~~B.~~ An applicant who passes one of the examinations in subsection (A) but fails the other shall be required to retake only the examination failed to be eligible for licensure.
- ~~C.~~ The Board shall administer the Arizona examinations not less than examination at least twice each year at times and places specified by the Board.
- ~~D.~~ An applicant who fails either part of the examination two times shall not be eligible to take another examination for 11 months from the date of the last examination. An applicant who fails the examination three times may not take another examination until the applicant successfully completes an AIT program.
- B. An applicant shall make arrangements directly with NAB to take the NAB examination.
- C. The Board shall provide written notice to an applicant regarding whether the applicant passed a required examination.
- D. An applicant for licensure under R4-33-201 is not required to take or pass both examinations at the same time. An applicant who passes one of the examinations listed in R4-33-201(2) but fails the other is required to retake only the examination failed.
- E. When an applicant passes the examinations required under R4-33-201 or R4-33-202, the Board shall send the applicant a written notice that the Board will issue a license to the applicant when the applicant submits to the Board the fee required under R4-33-104(A)(4). If the applicant fails to submit the fee within six months of the Board's notice, the Board shall administratively close the applicant's file. An individual whose file is administratively closed may receive further consideration only by submitting a new application under R4-33-201 or R4-33-202.

R4-33-206. Renewal Application

- A. A license year begins July 1 and ends June 30. The Board shall provide a licensee with notice of the need for license renewal. Failure to receive notice of the need for license renewal does not excuse a licensee's failure to renew timely.
- B. All licenses, except temporary, expire. An administrator license expires at midnight on June 30 of each even-numbered year. Temporary licenses expire at midnight on the date designated on the license.

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- C. A licensee shall submit an application for renewal of license, accompanied by the prescribed fee and evidence of completion of 50 hours of continuing education credit under R4-33-214, not later than June 1. A licensee who received an original license on or after January 1 and before June 30 of the renewal year shall submit evidence of completion of 10 hours of continuing education credit under R4-33-214. To renew an administrator license, the licensee shall submit the following information to the Board, on or before June 30, on a renewal application, which is available from the Board:
1. Current address;
 2. Current home and business telephone numbers;
 3. Whether within the last 24 months the licensee was convicted of or pled guilty or no contest to a criminal offense, other than a minor traffic violation, in any court and if so, attach a copy of the original arrest record and final court judgment;
 4. Whether within the last 24 months the licensee was denied a professional license or had a professional license revoked, suspended, placed on probation, limited, or restricted in any way by a state or federal regulatory authority and if so, the kind of license, license number, issuing authority, nature of the regulatory action, and date;
 5. An affirmation that the number of hours of continuing education required under R4-33-501 has been completed; and
 6. The licensee's dated and notarized signature affirming that the information provided is true and complete.
- D. In addition to the renewal application required under subsection (C), a licensee shall submit the license renewal fee required under R4-33-104.
- ~~D.E.~~ A person An individual whose license has expired expires because of failure to renew in accordance with subsection (C) timely may apply for renewal by complying with subsections (C) and (D) if:
1. The person's license was not revoked under A.R.S. § 36-446.07;
 2. No more than 30 days have lapsed since expiration of the license The individual complies with subsections (C) and (D) on or before July 31;
 - ~~3.2.~~ The person individual pays the prescribed fees penalty prescribed under R4-33-104; and
 - ~~4.3.~~ The person meets the applicable continuing education requirements individual affirms that the individual has not acted as a nursing care institution administrator since the license expired.
- F. An individual whose license expires because of failure to renew timely and who does not comply with subsection (E) may become licensed as a nursing care institution administrator only by complying with R4-33-201 or R4-33-202.

R4-33-207. Inactive Status

- A. The Board shall place ~~a person's an administrator's~~ license on inactive status if the licensee administrator:
1. Is currently licensed in good standing in Arizona; ,
 2. Notifies Submits a written request to the Board in writing of the wish to be placed on inactive status; , and
 3. Meets the Submits evidence that complies with R4-33-501(D) showing that the administrator completed two hours of continuing education requirements for each month in the current biennial period before the request to be placed on inactive status. These continuing education requirements may be prorated, based upon the commencement of the renewal period.
- B. The Within seven days after receiving a request to be placed on inactive status, the Board shall provide the licensee administrator written confirmation of inactive status.
- C. An administrator whose license is on inactive status is not required to comply with R4-33-501.
- D. An inactive license expires under R4-33-206 unless the administrator timely submits a renewal application and the fee required under R4-33-104(A)(7).
- ~~C.E.~~ To resume active licensure status, the licensee an administrator shall:
1. complete the Submit evidence that complies with R4-33-501(D) showing that the administrator completed 25 hours of continuing education credits required in A.R.S. § 36-446.07(H) continuing education within the six months before making written request to the Board for resumption of requesting to resume active licensure status-, and
 2. Submit a written request to the Board to resume active licensure status.
- ~~D.F.~~ The Board shall grant the a request to resume active licensure status if the requirements of subsection (C) (E) are met. The Within seven days after receiving the written request to resume active licensure status, the Board shall send written notice to the licensee administrator granting or denying active status. If denied, the licensee shall have 15 days from the date of receipt of the notice to file a request for hearing with the Board, appealing the denial. Hearings shall be conducted in accordance with A.R.S. Title 41, Chapter 6, Article 6 and Article 10.

R4-33-208. Standards of Conduct; Disciplinary Action

- A. The following standards of conduct apply to an An administrator licensed under this Article shall know and comply with all federal and state laws and regulations applicable to operation of a nursing care institution.
- B. An administrator shall not:
1. An administrator shall not engage Engage in unprofessional conduct: as defined at A.R.S. § 36-446;
 2. An administrator:
 - a. Shall be familiar with the federal and state laws and regulations applicable to operation of a nursing care institution.

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- ~~b. Shall not be Be~~ addicted to or dependent upon on the use of narcotics or other drugs, including alcohol, which interferes with the performance of the duties as a nursing care institution administrator. ;
 - ~~e-3. Shall not wilfully~~ Directly or indirectly permit an owner, officer, or employee of a nursing care institution or its owners, officers, or employees to solicit, offer, or receive any premium, rebate, or other valuable consideration in connection with the furnishing of items goods or services to patients of the institution or for referral of patients to another person or place if unless the resulting economic benefit is not directly passed on to the patients. ;
 - 4. Directly or indirectly permit an owner, officer, or employee of a nursing care institution to solicit, offer, or receive any premium, rebate, or other valuable consideration for referring a patient to another person or place unless the resulting economic benefit is directly passed to the patient. ;
 - ~~d-5. Shall not wilfully~~ Willfully permit the unauthorized disclosure of information relating to a patient or a patient's records. ;
 - ~~e-6. Shall not discriminate~~ Discriminate against patients a patient or employees employee, on the basis of race, sex, age, religion, disability, or national origin. ;
 - ~~f-7. Shall not misrepresent~~ Misrepresent the administrator's qualifications, education, or experience or affiliations. ;
 - ~~g-8. Shall not aid~~ Aid or abet anyone in misrepresenting another person to misrepresent that person's qualifications, education, or experience, or affiliations. ;
 - ~~h-9. Shall not defend~~ Defend, support, or ignore unethical conduct perpetrated by employees, owners, or peers of an employee, owner, or other administrator. ;
 - ~~i-10. Shall not engage~~ Engage in any conduct or practice contrary to recognized community standards or ethics of a nursing care institution administrator. ; or
 - 11. Engage in any conduct or practice which does that is or might constitute incompetence, gross negligence, repeated negligence, or negligence that might constitute a danger to the health, welfare, or safety of the a patient or the public. ;
 - ~~j-12. Shall not procure~~ Procure or attempt by fraud or misrepresentation to procure a license or renewal of a license to practice as a nursing care institution administrator. ;
 - ~~k-13. Shall not violate~~ Violate a formal order, condition of probation, or stipulation issued by the Board. ;
 - ~~l-14. Shall not commit~~ Commit an act of sexual abuse, misconduct, harassment, or exploitation. ; or
 - ~~m-15. Shall not retaliate~~ Retaliate against any person who reports in good faith to the Board alleged incompetence, or illegal, or unethical conduct of any practitioner administrator.
- ~~B.C.~~ The Board shall consider a Final final judgment or conviction for a felony, or any an offense involving moral turpitude, or direct or indirect elder abuse shall be as grounds for disciplinary action under A.R.S. § 36-446.07 et seq., or denial of a license application or license renewal.
- ~~C.D.~~ An administrator who has violated violates any provision of A.R.S. Title 36, Chapter 4, Article 6 or this Article Chapter shall be is subject to discipline in accordance with under A.R.S. § 36-446.07.

R4-33-209. Renumbered

R4-33-210. Restoration of Revoked License Licensure Following Revocation

- A. No earlier than 12 months from the date of revocation, a former licensee may file a request for license restoration. The former licensee shall submit evidence satisfactory to the Board that the basis for revocation has been removed. The former licensee shall meet all of the requirements of R4 33 201, R4 33 202 and R4 33 204. The requirements of R4 33 201(D) shall be applicable to a former licensee who was convicted of a felony.
- B. Following receipt of a request for license restoration, the Board shall require the former licensee to appear before the Board and provide evidence that all the requirements of R4 33 210(A) have been met. If a request for license restoration is denied, the former licensee may request a hearing under A.R.S. § 41-1065.
An individual who wishes to be licensed after the individual's license as a nursing care institution administrator is revoked shall:
 - 1. Not apply for licensure until at least 12 months have passed since the revocation; and
 - 2. Apply for licensure under R4-33-201 or R4-33-202.

R4-33-211. Display of License and Board Notification Notice of Appointment

- A. A licensee shall display the licensee's certificate of licensure and current renewal certificate in a conspicuous place in the licensee's office or place of business or employment.
- ~~B.~~ A licensee shall notify the Board, within 30 days, of any change of name or mailing address, providing both former and new name or address.
- ~~C.~~ An administrator shall notify provide written notice to the Board, within 30 days, each time that the licensee is of being appointed administrator of a nursing care institution and each time or terminating an appointment terminates. Each notification shall include the name and address of the facility or facilities involved and the dates of appointment or termination.
- ~~B.~~ An administrator shall include the following in a notice regarding the administrator's appointment:

1. Administrator's name.
2. Administrator's license number.
3. Name and address of the nursing care institution to which the administrator is appointed.
4. Date of appointment.
5. Name and address of the nursing care institution at which the administrator's appointment is terminated, and
6. Date of termination.

R4-33-212. Renumbered

R4-33-213. Denial of License or Renewal of License Repealed

- ~~A. A person who is denied the right to take an examination may file a request for an informal interview before the Board within 15 days after receipt of the notice of denial.~~
- ~~B. A person who is denied a license or renewal of license shall be notified in writing and may file a request for a hearing before the Board under A.R.S. § 41-1092.03.~~

R4-33-214. Criteria for Continuing Education Repealed

- ~~A. A licensee shall obtain 50 hours of continuing education credit per renewal period for renewal of license except that, if an administrator is initially licensed on or after January 1 and before June 30 of the renewal year, only 10 hours shall be required for that first renewal period.~~
- ~~B. No later than June 1, a licensee shall submit evidence of attendance at continuing education programs with the application for renewal of license required under R4-33-206. Evidence of attendance includes a certificate, letter of attendance, or grade report from the provider of the continuing education program.~~
- ~~C. Licensees shall complete continuing education programs between June 1 and May 31, during the renewal period.~~
- ~~D. To be eligible for credit, a continuing education program shall be approved by the Board and shall be in at least one of the following subject areas:
 1. Statutes and regulations on environmental health and safety (OSHA);
 2. Principles of management;
 3. Psychology and principles of patient care;
 4. Personal and social care;
 5. Therapeutic and supportive care and services in long term care; and
 6. Community health and social resources.~~
- ~~E. Continuing education credits shall be awarded as follows:
 1. Seminars or workshops: one hour of credit for each contact hour.
 2. College accredited courses: 15 credit hours for each semester hour.
 3. Annual meetings of national health care organizations and annual state association meetings affiliated with national health care organizations: 1/2 hour credit for each business meeting.
 4. Two continuing education credits for each month that an AIT preceptor trains an AIT. A preceptor shall receive a maximum of 50% of required continuing education hours during a renewal period from serving as a preceptor.~~
- ~~F. A licensee who participates as an instructor in an approved continuing education program shall receive the same credit as a student. The licensee may receive continuing education credit for instructing the same approved program only once during a renewal period.~~
- ~~G. A licensee shall receive credit for no more than 20 hours of required continuing education during a renewal period from correspondence courses.~~
- ~~H. Requests for approval of a continuing education program shall be submitted by individuals or sponsors in writing and shall contain the following information:
 1. Title of program;
 2. Sponsor: name, address and contact person;
 3. Date, time and place of program;
 4. Content and applicability to nursing home administration;
 5. Qualification of instructors;
 6. Number of contact hours; include a time schedule of events and an agenda with specific times for instruction, breaks and meals; and
 7. If an accredited college course, the number of semester credits available.~~

ARTICLE 4. ~~ADULT CARE HOME~~ ASSISTED LIVING FACILITY MANAGER CERTIFICATION

~~R4-33-402~~ R4-33-401. Eligibility Requirements for Initial Certification by Examination

- ~~A. A person may apply for To be eligible to receive an initial adult care home manager certificate by examination pursuant to A.R.S. § 36-446.04(B) if one of the following requirements is met as an assisted living facility manager, an individual shall:
 1. Education:~~

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- a. Earn a high school diploma or G.E.D., and
- 1- ~~b. The applicant has successfully completed a Board-approved adult care home manager~~ Complete a Department-approved training program in personal, supervisory, and directed care and management of an assisted living facility; or
- 2- ~~c. In lieu of a Board-approved training program, the applicant may provide a certified transcript from~~ Complete at least 34 contact hours of instruction at an accredited university or college or provide other evidence of a combination of education and training which verifies a total of at least 34 hours of instruction, including a minimum of the indicated hours in the following areas: resident rights (two hours); hands on care of elderly, disabled or physically handicapped adults (ten hours); nutrition and food preparation (four hours); caring for confused individuals (four hours); pharmacology of medications commonly prescribed for adults (four hours); care plan development (four hours); environment and fire safety (two hours); business practices and recordkeeping (four hours); the following hours in the following subject areas:
 - i. Residents' rights, two contact hours;
 - ii. Care of elderly or disabled adults, 10 contact hours;
 - iii. Nutrition and food preparation, four contact hours;
 - iv. Care of confused individuals, four contact hours;
 - v. Pharmacology of commonly prescribed medications, four contact hours;
 - vi. Care plan development, four contact hours;
 - vii. Environmental and fire safety, four contact hours; and
 - viii. Business practices and recordkeeping, four contact hours;
2. Work experience. Complete at least 2,080 hours of paid work experience in a health-related field within the five years before application;
3. Examination. Obtain a score of at least 75 percent on the Arizona examination;
- ~~B.4. Training. Complete~~ The applicant shall also provide evidence of successful completion of an adult cardiopulmonary resuscitation program and a basic first-aid training program; and
5. Submit all applicable information required under R4-33-403.

~~R4-33-410-R4-33-402.~~ **Requirements for a Temporary Certificate**

- A. ~~To qualify be eligible for a temporary certificate to fill an adult care home as an assisted living facility manager position, the applicant an individual shall have completed one of the following:~~
 1. Meet the requirements under R4-33-401 except for the requirement at R4-33-401(A)(3); 27 hours of instruction in an approved adult care home manager training program; or
 2. Be registered as a Nurse's Aide in Arizona; or
 3. Have current licensure with the State Board of Nursing;
 2. Have the owner of an assisted living facility that intends to employ the applicant as manager if the applicant is successful in obtaining a temporary certificate submit to the Board a Letter of Intent to Employ on a form that is available from the Board. The owner of the assisted living facility shall include the following in the Letter of Intent to Employ:
 - a. Name of the owner of the assisted living facility;
 - b. Name and address of the assisted living facility;
 - c. Name of the applicant;
 - d. An affirmation of intent to employ the applicant;
 - e. Reason for requesting a temporary certificate for the applicant;
 - f. License number of the assisted living facility; and
 - g. Notarized signature of the owner of the assisted living facility;
 3. Not have held an Arizona temporary certificate as an assisted living facility manager within the past three years; and
 4. Not have failed the Arizona examination before applying for the temporary certificate.
- B. ~~The requirements specified in R4-33-303 and R4-33-305 shall also be met~~ At the Board's request, an applicant for a temporary certificate shall appear or be available by telephone for an interview with the Board.
- C. ~~The owner or governing authority of the adult care home shall submit a letter indicating the manager position is available and that the applicant shall be engaged in the capacity of manager if the applicant is successful in obtaining a temporary certificate~~ A temporary certificate is valid for 150 days and is not renewable. Before expiration of the temporary certificate, the temporary certificate holder shall obtain a certificate under A.R.S. § 36-446.04 and this Article or discontinue as manager of the assisted living facility.
- D. ~~Prior to the expiration of the 150-day period, the~~ If a temporary certificate holder shall become certified under the terms of A.R.S. § 36-446.04(B) or fails the Arizona examination during the term of the temporary certificate, the temporary certificate is automatically revoked and the former temporary certificate holder shall discontinue as the manager of the adult care home assisted living facility.

R4-33-403. Initial Application

- A. ~~All applicants for adult care home manager shall submit a sworn, notarized application form supplied by the Board releasing information to the Board and identifying both the type of certificate requested and the statute under which they are applying.~~ An individual who desires to be certified as a manager of an assisted living facility shall submit the following information to the Board on an application form, which is available from the Board:
1. Full name of the applicant;
 2. Other names that the applicant has used;
 3. Mailing address of the applicant;
 4. Home, work, and mobile telephone numbers of the applicant;
 5. Applicant's date and place of birth;
 6. Applicant's Social Security number;
 7. Whether the applicant is a U.S. citizen and if not, evidence of authorization to work in the United States;
 8. Address of every residence at which the applicant has lived in the last five years;
 9. Education information regarding the applicant, including:
 - a. Name and location of last high school attended;
 - b. Date of high school graduation or date on which a G.E.D. was earned; and
 - c. Name and address of every accredited college or university attended, dates of attendance, date of graduation, and degree or certificate earned;
 10. Information regarding professional licenses or certifications currently or previously held by the applicant, including:
 - a. Name of issuing agency;
 - b. License or certificate number;
 - c. Issuing jurisdiction;
 - d. Date on which the license or certificate was first issued;
 - e. Whether the license or certificate is current; and
 - f. Whether the license or certificate is in good standing and if not, an explanation;
 11. Information regarding the applicant's employment record for the last five years, including:
 - a. Name, address, and telephone number of each employer;
 - b. Title of position held by the applicant;
 - c. Name of applicant's supervisor;
 - d. Dates of employment;
 - e. Number of hours worked each week;
 - f. Whether the employment was full or part time; and
 - g. Reason for termination;
 12. Whether the applicant has ever been certified as an assisted living facility manager and if so, the licensing authority and the name on the certificate;
 13. Whether the applicant was ever denied a professional license or certificate and if so, the kind of license or certificate denied; licensing authority making the denial, and date;
 14. Whether the applicant ever voluntarily surrendered a professional license or certificate and if so, the kind of license or certificate surrendered, licensing authority, date, and reason for the surrender;
 15. Whether the applicant ever allowed a professional license or certificate to lapse and if so, the kind of license or certificate that lapsed, licensing authority, date, reason for lapse, and whether the license or certificate was reinstated;
 16. Whether the applicant ever had a limitation imposed on a professional license or certificate and if so, the kind of license or certificate limited, licensing authority, date, nature of limitation, reason for limitation, and whether the limitation was removed;
 17. Whether the applicant ever had a professional license or certificate suspended or revoked and if so, the kind of license or certificate suspended or revoked, licensing authority, date, and reason for suspension or revocation;
 18. Whether the applicant ever was subject to disciplinary action with regard to a professional license or certificate and if so, the kind of license or certificate involved, licensing authority, date, and reason for and nature of the disciplinary action;
 19. Whether the applicant was ever restricted in or terminated from employment as an assisted living facility manager and if so, name of employer, date, circumstances of restriction or termination, and nature of restriction;
 20. Whether the applicant ever resigned from employment to avoid being terminated or disciplined and if so, name of employer, date, and circumstances of the resignation;
 21. Whether any unresolved complaint against the applicant is pending with a licensing authority, professional association, health care facility, or assisted living facility and if so, the nature of and where the complaint is pending;
 22. Whether the applicant ever was charged with or convicted of a felony or a misdemeanor, other than a minor traffic violation, in any court and if so, the nature of the offense, jurisdiction, and date of discharge; and
 23. Whether the applicant ever was pardoned from or had the record expunged of a felony conviction and if so, the nature of the offense, jurisdiction, and date of pardon or expunging.

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- B. ~~The applicant shall submit a "Character Certification" form from at least two persons who are not related to or in the employment of the applicant who attest to the good character of the applicant. In addition to the application form required under subsection (A), an applicant shall submit or have submitted on the applicant's behalf:~~
1. Education:
 - a. Copy of the applicant's high school diploma or G.E.D., and
 - b. Official transcript submitted directly to the Board by each accredited college or university attended by the applicant; or
 - c. Certificate of completion from the Department-approved training course;
 2. Documentation of 2,080 hours of paid work experience in a health-related field;
 3. Copy of current certification in adult cardiopulmonary resuscitation and first aid;
 4. Verification of license that is signed, authenticated by seal or notarization, and submitted directly to the Board by each agency that ever issued a professional license to the applicant;
 5. "Character Certification" form submitted directly to the Board by two individuals who have known the applicant for at least three years and are not related to, employed by, or employing the applicant;
 6. For every felony or misdemeanor charge listed under subsection (A)(22), a copy of documents from the appropriate court showing the disposition of each charge;
 7. For every felony or misdemeanor conviction listed under subsection (A)(22), a copy of documents from the appropriate court showing whether the applicant met all judicially imposed sentencing terms;
 8. Passport-size, color, full-face photograph of the applicant taken within the last 180 days and signed on the back by the applicant;
 9. Signed and notarized affidavit affirming that the information provided in the application is true and complete and authorizing others to release information regarding the applicant to the Board; and
 10. Fees required under R4-33-104(B)(1) and (B)(2).
- C. ~~An applicant shall submit a "Medical Certification" form completed by a licensed physician attesting to the applicant's physical and mental fitness to perform the duties of manager. If required by the Board under A.R.S. § 36-446.03(D), an applicant shall appear before the Board.~~
- D. ~~Each applicant shall certify in writing that he or she has not committed any of the acts listed in A.R.S. § 36-446.07(B) or 36-448.02(B). When the information required under subsections (A) and (B) is received and following an appearance before the Board required under subsection (C), the Board shall provide notice regarding whether the applicant may take the Arizona examination required under R4-33-401(3).~~
- E. ~~An applicant shall complete and submit a properly sworn and notarized personal data sheet form prescribed by the Board which provides general information about the applicant, including name and address, telephone number, social security number (optional), date of birth, sex, history of any conviction of a violation of federal, state or local statutes other than for minor traffic violations, educational background, employment background, and an affidavit that the application is complete and accurate. A color photograph showing head and shoulders of the applicant shall be attached to the personal data sheet. The photograph shall not be less than 2 1/2 inches nor more than 3 inches square and shall have been taken within six months prior to the date of application. Because of the time required for the Board to perform an administrative completeness review under R4-33-103, an applicant shall submit the information required under subsections (A) and (B) at least 30 days before the applicant expects to take the Arizona examination.~~
- F. ~~An applicant shall submit to the Board the following documents indicating the requirements of R4-33-301(A), as applicable, have been met: certified transcripts; evidence of completion of a training program; or other evidence of education and training.~~
- G. ~~The completed application forms and the prescribed fees shall be received by the Board at least 45 days before the date of the next regularly scheduled examination.~~

R4-33-404. Administration of Examination; Certificate Issuance

- A. ~~The adult care home manager's examination shall test the applicant's knowledge of adult care home residents' needs, the laws and rules governing operation of adult care homes, and elements of good health facilities management. The minimum passing score shall be 70%. Board shall administer the Arizona examination at least twice each year at times and places specified by the Board.~~
- B. ~~Examinations shall be administered not less than twice each year at such times and places in Arizona as may be specified by the Board. The Board shall provide written notice to an applicant regarding whether the applicant passed the Arizona examination.~~
- C. ~~The score sheets and record of the examination shall be filed and retained by the Board for at least four years. When an applicant passes the Arizona examination, the Board shall send the applicant a written notice that the Board will issue a certificate to the applicant when the applicant submits to the Board the fee required under R4-33-104(B)(4). If the applicant fails to submit the fee within six months of the Board's notice, the Board shall administratively close the applicant's file. An individual whose file is administratively closed may receive further consideration only by submitting a new application under R4-33-401.~~

R4-33-406-R4-33-405, Renewal Application

- A. All certificates, except temporary certificates, expire at midnight on June 30 of each odd-numbered year. Temporary certificates expire at midnight on the date designated on the certificate. The Board shall provide a certificate holder with notice of the need for certificate renewal. Failure to receive notice of the need for certificate renewal does not excuse a certificate holder's failure to renew timely.
- B. A certified adult care home manager seeking renewal shall submit an application for biennial renewal of certificate, accompanied by the prescribed fee, showing address and current employment, and shall submit evidence of completion of six hours of continuing education credit per year, pursuant to R4-33-308, by not later than June 1 of the renewal year. A certificate holder who received an original certificate on or after January 1 of the same year that renewal is required need only submit evidence of completion of three hours of continuing education credit. A manager certificate expires at midnight on June 30 of each odd-numbered year.
- C. An individual whose Arizona certificate has expired may apply for late renewal provided the following requirements are met:
1. The certificate was not revoked pursuant to A.R.S. § 36-446.07;
 2. No more than 30 days have elapsed since the expiration of the certificate;
 3. The prescribed fees have been paid; and
 4. The applicable continuing education requirements have been met.
- To renew a manager certificate, the certificate holder shall submit the following information to the Board, on or before June 30, on a renewal application, which is available from the Board:
1. Current address;
 2. Current home and business telephone numbers;
 3. Whether within the last 24 months the certificate holder was convicted of or pled guilty or no contest to a criminal offense, other than a minor traffic violation, in any court and if so, attach a copy of the original arrest record and final court judgment;
 4. Whether within the last 24 months the certificate holder was denied a professional license or had a professional license revoked, suspended, placed on probation, limited, or restricted in any way by a state or federal regulatory authority and if so, the kind of license, license number, issuing authority, nature of the regulatory action, and date;
 5. An affirmation that the number of hours of continuing education required under R4-33-501 has been completed;
 6. An affirmation that the certificate holder complies with the disclosure requirements under R4-33-408; and
 7. The certificate holder's dated and notarized signature affirming that the information provided is true and complete.
- D. In addition to the renewal application required under subsection (C), a certificate holder shall submit the renewal fee required under R4-33-104.
- E. An individual whose certificate expires because of failure to renew timely may apply for renewal by complying with subsections (C) and (D) if:
1. The individual complies with subsections (C) and (D) on or before July 31;
 2. The individual pays the penalty prescribed under R4-33-104; and
 3. The individual affirms that the individual has not acted as an assisted living facility manager since the certificate expired.
- F. An individual whose certificate expires because of failure to renew timely and who does not comply with subsection (E) may obtain a manager certificate only by complying with R4-33-401.

R4-33-406. Inactive Status

- A. The Board shall place a manager's certificate on inactive status if the manager:
1. Is in good standing in Arizona.
 2. Submits a written request to the Board to be placed on inactive status, and
 3. Submits evidence that complies with R4-33-501(D) showing that the manager completed one hour of continuing education for each month in the current biennial period before the request to be placed on inactive status.
- B. Within seven days after receiving a request to be placed on inactive status, the Board shall provide the manager written confirmation of inactive status.
- C. A manager whose certificate is on inactive status is not required to comply with R4-33-501.
- D. An inactive certificate expires under R4-33-405 unless the manager timely submits a renewal application and the fee required under R4-33-104(B)(7).
- E. To resume active certificate status, a manager shall:
1. Complete 12 hours of continuing education within the six months before requesting to resume active certificate status.
 2. Submit a written request to the Board to resume active certificate status, and
 3. Submit the fee required under R4-33-104(B)(4).
- F. The Board shall grant a request to resume active certificate status if the requirements of subsection (E) are met. Within seven days after receiving the written request to resume active certificate status, the Board shall send written notice to the

manager granting or denying active status.

R4-33-407. Standards of Conduct; ~~Suspension or Revocation~~ Disciplinary Action

- A.** ~~A certified manager is responsible for the operation of any adult care home which he manages, as well as for his or her own conduct. In addition to the requirements of A.R.S. § 36-446.07(B), a manager shall adhere to the following standards. A manager shall know and comply with all federal and state laws and regulations applicable to the operation of an assisted living facility.~~
- B.** A manager shall not:
1. The certified adult care home manager must be knowledgeable about federal and state laws and rules applicable to the operation of adult care homes. Engage in unprofessional conduct as defined at A.R.S. § 36-446;
 2. The certified adult care home manager is prohibited from working in a home that solicits, offers, or receives any premium, rebate, or other valuable consideration to or from any person or entity, except that the certified adult care home manager may be employed in adult care homes that pay referral fees only when those adult care homes have a contract on file with private referral agencies and keep on file names of residents who were referred by such referral agencies. Be addicted to or dependent on the use of narcotics or other drugs, including alcohol;
 3. Directly or indirectly permit an owner, officer, or employee of an assisted living facility to solicit, offer, or receive any premium, rebate, or other valuable consideration in connection with furnishing goods or services to residents unless the resulting economic benefit is directly passed to the residents;
 4. Directly or indirectly permit an owner, officer, or employee of an assisted living facility to solicit, offer, or receive any premium, rebate, or other valuable consideration for referring a resident to another person or place unless the resulting economic benefit is directly passed to the resident;
 5. Willfully permit the unauthorized disclosure of information relating to a resident or a resident's records;
 6. Discriminate against a resident or employee on the basis of race, sex, age, religion, disability, or national origin;
 7. Misrepresent the manager's qualifications, education, or experience;
 8. Aid or abet another person to misrepresent that person's qualifications, education, or experience;
 9. Defend, support, or ignore unethical conduct of an employee, owner, or other manager;
 10. Engage in any conduct or practice contrary to recognized community standards or ethics of an assisted living facility manager;
 11. Engage in any conduct or practice that is or might constitute incompetence, gross negligence, repeated negligence, or negligence that might constitute a danger to the health, welfare, or safety of a resident or the public;
 12. Procure or attempt by fraud or misrepresentation to procure a certificate or renewal of a certificate as an assisted living facility manager;
 13. Violate a formal order, condition of probation, or stipulation issued by the Board;
 14. Commit an act of sexual abuse, misconduct, harassment, or exploitation; or
 15. Retaliate against any person who reports in good faith to the Board alleged incompetence or illegal or unethical conduct of any manager.
 - a. When a referral fee is paid, the certified adult care manager shall keep on file a disclosure statement signed by the competent resident, resident's representative, or resident's legal guardian upon admission indicating knowledge that the adult care home will pay a fee to the referral agency for the resident's placement into the home, and indicating that the competent resident, resident's representative, or resident's legal guardian was informed of the fee payment prior to or upon admission into the adult care home. If a referral is made to a home that has an ownership interest in the referral agency, or by a referral agency that has an ownership interest in the adult care home, the certified adult care home manager shall keep on file a disclosure statement signed by the competent resident, resident's representative, or resident's legal guardian indicating knowledge of the relationship between the referral agency and the home prior to, or upon admission to the home.
 - b. Upon renewal of certification, the certified adult care home manager who is employed by an adult care home that pays referral fees shall provide to the Board an affidavit avowing that the above disclosure requirements have been met.
- B.** A manager who has violated the provisions of this Article as an applicant for a certificate, renewal of certificate, or late renewal of certificate or in a capacity as a manager is subject to the provisions of A.R.S. § 36-446.07 relating to suspension, revocation, or denial of a certificate.
- C.** The Board shall consider a final judgment or conviction for a felony, an offense involving moral turpitude, or direct or indirect elder abuse as grounds for disciplinary action under A.R.S. § 36-446.07 or denial of a certificate or certificate renewal.
- D.** A manager who violates any provision of A.R.S. Title 36, Chapter 4, Article 6 or this Chapter is subject to discipline under A.R.S. § 36-446.07.

R4-33-408. Criteria for Continuing Education Referral Requirements

- A.** ~~Evidence of attendance at Board approved continuing education programs shall be submitted with the application for~~

renewal of certificate. Continuing education credits shall be acquired during the period of the certificate but completed by May 31 prior to the renewal period.

- ~~B.~~ All continuing education programs require Board approval and shall be in at least one of the following subject areas:
 - ~~1. Statutes and rules on environmental health and safety (OSHA);-~~
 - ~~2. Principles of management, including human resources, financial accounting, marketing, development;~~
 - ~~3. Principles of patient care, patient rights, psychology;-~~
 - ~~4. Therapeutic and supportive care services, nutrition, pharmacology, disease process, caring for confused residents;~~
 - ~~5. Community health and social resources, case management, ombudsman program;~~
 - ~~6. Rules governing adult care homes, Medicare, Arizona Health Care Cost Containment System.~~
- ~~C.~~ Continuing education credits shall be awarded as follows:-
 - ~~1. Programs of study— shall contain at least 25 contact hours and shall receive 25 credit hours.~~
 - ~~2. Seminars or workshops— one hour of credit for each contact hour.~~
 - ~~3. College accredited courses— 13 credit hours for each semester hour.~~
 - ~~4. Annual meeting of national health care organizations— three credit hours for each annual meeting attended up to a maximum of six hours per year.~~
 - ~~5. State association meetings affiliated with national health care organizations— one half hour credit for each meeting up to a maximum of three hours per year.~~
- ~~D.~~ A certificate holder who participates as an instructor in an approved program shall receive the same credit as a student.
- ~~E.~~ The Board may disapprove requests for approval which have not been submitted at least 45 days prior to the commencement of a program.
- ~~F.~~ Requests for approval may be submitted by individuals or sponsors in writing and shall contain at least the following information:
 - ~~1. Title of program;~~
 - ~~2. Sponsor: name, address and contact person;~~
 - ~~3. Date, time and place of program;~~
 - ~~4. Content and applicability to adult care home management;~~
 - ~~5. Credentials of qualified instructors;~~
 - ~~6. Number of contact hours, including a time schedule of events where possible;~~
 - ~~7. If an accredited college course, the number of semester hours granted;~~
- ~~G.~~ Sponsored educational program requests for approval shall be accompanied by the prescribed fee for Board review.
- ~~H.~~ Sponsored programs shall be submitted to the Board for reapproval prior to changes in content, instructor or hours.
- ~~I.~~ Continuing education programs shall be taught by qualified instructors as defined in R4-33-112(B)(9).
- A. A manager who is employed by an assisted living facility that pays a fee to an individual or entity for referral of a resident to the assisted living facility shall ensure that the assisted living facility:
 - 1. Has on file a contract with the individual or entity making the referral;
 - 2. Maintains a file of the names of the residents referred by the individual or entity; and
 - 3. Obtains at the time of admission and maintains a statement, signed by the resident or the resident's representative or legal guardian, which discloses that:
 - a. A fee was paid for referring the resident to the assisted living facility;
 - b. The resident or the resident's representative or legal guardian was informed of the fee arrangement; and
 - c. The resident or the resident's representative or legal guardian was informed of any ownership interest between the assisted living facility and the individual or entity making the referral.
- B. A manager shall maintain the records required under subsection (A)(1) for five years and shall maintain the records required under subsections (A)(2) and (A)(3) for five years after the resident ceases to reside in the assisted living facility.
- C. A manager shall make the records required under this Section available for review upon request by the Board.

R4-33-409. Display of Certificate Repealed

~~Every person certified and employed as an adult care home manager shall display the original certificate and the current renewal certificate in a conspicuous place in the adult care home.~~

R4-33-410. Renumbered

R4-33-411. Denial of Certificate Repealed

~~Any person who has been denied a certificate or denied the right to take an examination shall be notified as provided in A.R.S. § 41-1061.~~

R4-33-412. Rehearing or Review of Decision Repealed

~~A. Except as provided in subsection (G), any party in a contested case before the Board who is aggrieved by a decision rendered in such case may file with the Board, not later than ten days after service of the decision, a written request for rehearing or review of the decision which specifies the particular grounds therefor. For purposes of this rule, a decision~~

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shall be deemed to have been served when mailed by certified mail to the party at his last known residence or place of business.

- ~~B.~~ A request for rehearing under this rule may be amended at any time before it is ruled upon by the Board. Any party may file a response to the request within ten days after service of the request on that party. The Board may require the filing of written argument upon the issues raised in the request and may provide for oral argument.
- ~~C.~~ A rehearing or review of the decision may be granted for any of the following causes materially affecting the requesting party's rights:
 - ~~1.~~ Irregularity in the administrative proceedings of the Board or its hearing officer or the prevailing party, or any order or abuse of discretion, whereby the requesting party was deprived of a fair hearing.
 - ~~2.~~ Misconduct of the Board or its hearing officer or the prevailing party.
 - ~~3.~~ Accident or surprise which could not have been prevented by ordinary prudence.
 - ~~4.~~ Newly discovered material evidence which could not with reasonable diligence have been discovered and produced at the original hearing.
 - ~~5.~~ Excessive or insufficient penalties.
 - ~~6.~~ Error in the admission or rejection of evidence or other errors of law occurring at the administrative hearing.
 - ~~7.~~ That the decision is not justified by the evidence or is contrary to law.
- ~~D.~~ The Board may affirm or modify the decision or grant a rehearing to all or any of the parties and on all or part of the issues for any of the reasons set forth in subsection (C). An order granting a rehearing shall specify with particularity the ground or grounds on which the rehearing is granted, and the rehearing shall cover only those matters so specified.
- ~~E.~~ Not later than ten days after a decision is rendered, the Board may, on its own initiative, order a rehearing or review of its decision for any reason for which it might have granted a rehearing on request of a party. After giving the parties or their counsel notice and an opportunity to be heard on the matter, the Board may grant a request for rehearing for a reason not stated in the motion. In either case the order granting such a rehearing shall specify the grounds therefor.
- ~~F.~~ When a request for rehearing is based upon affidavits, they shall be served with the request. An opposing party may, within ten days after such service, serve opposing affidavits, which period may be extended for an additional period not exceeding 20 days by the Board for good cause shown or by written stipulation of the parties. Reply affidavits may be permitted.
- ~~G.~~ If in a particular decision the Board makes specific findings that the immediate effectiveness of such decision is necessary for the immediate preservation of the public peace, health and safety and that a rehearing or review of the decision is impracticable, unnecessary or contrary to the public interest, the decision may be issued as a final decision without an opportunity for a rehearing or review. If a decision is issued as a final decision without an opportunity for rehearing, any application for judicial review of the decision shall be made within the time limits permitted for applications for judicial review of the Board's final decisions.
- ~~H.~~ For purposes of this rule, the terms "contested case" and "party" shall be defined as provided in A.R.S. § 41-1001.

ARTICLE 5. CONTINUING EDUCATION

R4-33-501. Continuing Education Requirement

- A. Continuing education is a prerequisite of license or certificate renewal.
 - 1. A licensed administrator shall obtain 50 hours of Board-approved continuing education during each biennial period. During the biennial period in which an administrator is initially licensed, the administrator shall obtain two hours of Board-approved continuing education for each month or part of a month remaining in the biennial period.
 - 2. A certified manager shall obtain 24 hours of Board-approved continuing education during each biennial period. During the biennial period in which a manager is initially certified, the manager shall obtain one hour of Board-approved continuing education for each month or part of a month remaining in the biennial period.
- B. The Board shall award hours in an approved continuing education as follows:
 - 1. Seminar or workshop. One hour of continuing education for each contact hour.
 - 2. Course at an accredited educational institution. Fifteen hours of continuing education for each seminar hour.
 - 3. Attendance at a business meeting of a national health care organization or of a state association affiliated with a national health care organization. One-half hour of continuing education for each business meeting attended.
 - 4. Self-study, online, or correspondence course. Hours of continuing education determined by the course provider.
 - 5. Serving as a preceptor. Two hours of continuing education for each month that an administrator serves as an AIT preceptor; and
 - 6. Teaching a Board-approved continuing education. One hour of continuing education for each hour taught.
- C. The Board shall limit the number of hours of Board-approved continuing education awarded as follows:
 - 1. No more than 40 percent of the required hours may be obtained using self-study, online, or correspondence courses.
 - 2. No more than 50 percent of the required hours may be obtained from serving as an AIT preceptor.
 - 3. Hours may be obtained for teaching a particular continuing education only once during each biennial period; and

4. Hours that exceed the minimum required for a biennial period may not be carried over to a subsequent biennial period.
- D.** An administrator or manager shall obtain a certificate or other evidence of attendance from the provider of each continuing education attended that includes the following:
 1. Name of the administrator or manager;
 2. Name of the continuing education;
 3. Name of the continuing education provider;
 4. Date, time, and location of the continuing education; and
 5. Number of hours in the continuing education.
- E.** An administrator or manager shall maintain the evidence of attendance described in subsection (D) for three years and make the evidence available to the Board under R4-33-503 and as otherwise required under this Chapter.

R4-33-502. Approval of Continuing Education

- A.** The Board shall approve any continuing education approved by NAB or the ACHCA.
- B.** The Board shall approve a continuing education only if it is taught by a qualified instructor and addresses at least one of the following subject areas:
 1. Laws regarding environmental health and safety.
 2. Principles of management.
 3. Psychology and principles of patient or resident care.
 4. Personal and social care.
 5. Therapeutic and supportive care and services in long-term or assisted care.
 6. Community health and social resources.
 7. Quality assurance.
 8. Ethics, and
 9. Recordkeeping.
- C.** To obtain the Board's approval of a continuing education, an administrator, manager, or continuing education provider shall:
 1. Submit a form, which is available from the Board, containing the following information:
 - a. Title of the continuing education;
 - b. Name and address of the continuing education provider;
 - c. Name, telephone and fax numbers, and e-mail address of a contact person for the continuing education provider;
 - d. Date, time, and place at which the continuing education will be taught;
 - e. Whether the continuing education is intended for administrators or managers;
 - f. Subject matter of the continuing education;
 - g. Teaching methods and learning activities that will be used;
 - h. Learning objectives;
 - i. Description of how learning objectives will be evaluated;
 - j. Whether an examination will be given;
 - k. Number of continuing education hours requested; and
 - l. Signature of the person requesting approval of the continuing education.
 2. Submit the following documents:
 - a. Copy of any examination that will be given to those who attend the continuing education;
 - b. Curriculum vitae of each instructor;
 - c. Agenda of the continuing education showing the hours of instruction;
 - d. Certificate of attendance that meets the requirements in R4-33-501(D);
 - e. Copy of any brochure prepared regarding the continuing education; and
 - f. Fee required under R4-33-104.
- D.** The Board's approval of a continuing education is valid for one year unless there is a change in subject matter, instructor, or hours of instruction. At the end of one year or when there is a change in subject matter, instructor, or hours of instruction, the continuing education provider shall apply again for approval.

R4-33-503. Audit of Compliance and Sanction for Noncompliance with Continuing Education Requirement

When notice of the need to renew a license or certificate is provided, the Board shall also provide notice of an audit of continuing education records to a random sample of administrators or managers. An administrator or manager subject to a continuing education audit shall submit the documentation required under R4-33-501(D) at the same time that the administrator or manager submits the renewal application required under R4-33-206 or R4-33-405. If an administrator or manager fails to submit the required documentation with the renewal application on or before June 30, the license or certificate expires unless the administrator or manager obtains an extension of time in which to complete the continuing education requirement under R4-33-504.

R4-33-504. Extension of Time to Complete the Continuing Education Requirement

- A.** To obtain an extension of time under A.R.S. § 36-446.07(G) to complete the continuing education requirement, an administrator or manager shall submit to the Board a written request that includes the following:
1. Ending date of the requested extension.
 2. Continuing education completed during the current biennial period and the documentation required under R4-33-501(D).
 3. Proof of registration for additional continuing education that is sufficient to enable the administrator or manager to fulfill the continuing education requirement before the end of the requested extension, and
 4. Administrator's or manager's attestation that the continuing education obtained under the extension will be reported only to fulfill the current renewal requirement and will not be reported on a subsequent renewal application.
- B.** The Board shall grant an extension of time within seven days after receiving a request for an extension of time if the request:
1. Specifies an ending date no later than October 31.
 2. Includes the required documentation and attestation.
 3. Is submitted no sooner than April 30, and
 4. Will facilitate the safe and professional regulation of nursing care institutions or assisted living facilities in this state.

NOTICE OF PROPOSED RULEMAKING

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

[R06-200]

PREAMBLE

<u>1. Sections Affected</u>	<u>Rulemaking Action</u>
R12-1-102	Amend
R12-1-103	Amend
R12-1-311	Amend
R12-1-415	Amend
R12-1-434	Amend
R12-1-438	Amend
R12-1-455	New Section
R12-1-701	Repeal
R12-1-701	New Section
R12-1-702	Amend
R12-1-703	Amend
R12-1-704	Repeal
R12-1-704	New Section
R12-1-705	Repeal
R12-1-705	New Section
R12-1-706	Repeal
R12-1-706	New Section
R12-1-707	Repeal
R12-1-707	New Section
R12-1-708	Repeal
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R12-1-710	New Section
R12-1-711	Repeal
R12-1-711	New Section
R12-1-712	Repeal
R12-1-712	New Section
R12-1-713	Repeal
R12-1-713	New Section
R12-1-714	Repeal
R12-1-714	New Section
R12-1-715	New Section

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R12-1-716	Repeal
R12-1-716	New Section
R12-1-717	Repeal
R12-1-717	New Section
R12-1-718	Repeal
R12-1-718	New Section
R12-1-719	Repeal
R12-1-719	New Section
R12-1-720	Repeal
R12-1-720	New Section
R12-1-721	New Section
R12-1-722	New Section
R12-1-723	New Section
R12-1-724	New Section
R12-1-725	New Section
R12-1-726	New Section
R12-1-727	New Section
R12-1-728	New Section
R12-1-729	New Section
R12-1-730	New Section
R12-1-731	New Section
R12-1-732	New Section
R12-1-733	New Section
R12-1-734	New Section
R12-1-735	New Section
R12-1-736	New Section
R12-1-737	New Section
R12-1-738	New Section
R12-1-739	New Section
R12-1-740	New Section
R12-1-741	New Section
R12-1-742	New Section
R12-1-743	New Section
R12-1-744	New Section
R12-1-745	New Section
R12-1-746	New Section
Exhibit A.	Repeal
Exhibit A.	New Section
R12-1-901	Amend
R12-1-913	Amend

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

General:

A.R.S. § 30-654(B)

Specific:

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

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

Notice of Rulemaking Docket Opening: 12 A.A.R. 2158, June 16, 2006

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

Name: Daniel H. Kuhl
Address: Arizona Radiation Regulatory Agency
4814 S. 40th St.
Phoenix, AZ 85040
Telephone: (602) 255-4845, ext. 233
Fax: (602) 437-0705
E-mail: dkuhl@azrra.gov

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

R12-1-102 contains general definitions that will assist the reader in understanding the requirements for use of ionizing radiation sources regulated in Chapter 1. The term "qualified expert" is amended in R12-1-102 to better distinguish it from the new term "authorized medical physicist" being added to Article 7. R12-1-103 is undergoing a revision to clarify an existing requirement.

Article 3, which deals with manufacturers and distributors of sources of radiation that contain radioactive material, is amended to incorporate new federal standards for sealed sources and radiopharmaceuticals used in nuclear medicine activities regulated under Article 7.

R12-1-415 is amended to correct a rule reference discrepancy. R12-1-434 and R12-1-438 are rules that affect licenses that accumulate radioactive waste. The NRC no longer allows licensees to hold radioactive waste for 10 half-lives before disposal. The only acceptable criteria will be a survey of the waste to demonstrate that its radiation is undistinguishable from background. The Agency is required through its Agreement with the NRC to adopt this disposal standard.

R12-1-455 is a new rule added to establish a higher level of security for portable gauging devices that contain sealed sources of radioactive material. The new standard includes two levels of security during the time when a gauge is in storage at the licensee's facility, in transit to a job-site, and stored at temporary locations, including motels and job-site work trailers.

Article 7 contains the standards for use of radioactive material in the practice of medicine. The Agency is revising the all of Article 7 to remain compatible with the Nuclear Regulatory Commission (NRC). The Agency maintains an Agreement with the NRC, as does thirty two other states, which allows Arizona to regulate radioactive material users under the guidance of the NRC. In many cases, the NRC will require the Agreement States to adopt certain standards. This rule revision is the first time, in the history of the Agency, that the majority of the rules contained in Article 7 will follow the standards of the NRC contained in 10 CFR 35. To better understand the new requirements, the reader should review NRC--NUREG-1556, Vol. 9, *Program-Specific Guidance About Medical Use Licenses*. The changes proposed for R12-1-901 and R12-1-913 are needed to clarify existing regulatory requirements.

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

None

7. A showing of good cause why the 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 first area of new regulation may result in some cost to the regulated community. The portable gauge user regulated under the new rule R12-455 may have to expend some resources to strengthen the security measures used to prevent loss or theft of the gauges while they are stored and transported. Depending on the licensee's situation, the licensee may need to put in a security system, add locks to doors, put in a fence, or hire a security service. The cost of these systems has not been determined. The cost is readily available from service providers. During transport, the licensees may use a lock and chain, provided visual control is maintained at all times. If the licensee must leave the gauge unattended in the transport vehicle, the licensee may be required to purchase a security system similar to a 16 gauge box that is bolted in the transport vehicle. One of these special use boxes, manufactured here in the valley, costs about \$400. Security away from the home office may be achieved through personnel supervision while stored in a motel room, or security may be achieved by installing or making available a double security system similar to what is used at the licensee's home office, at the temporary job-site or operator's home. In all cases, the specific procedures used for security during storage and transport will have to be approved by the Agency.

The second area of new regulation is in Article 7 as previously stated. The entire Article, with the exception of training standards for authorized physicians, is being replaced with the new NRC standards. With the exception of nuclear cardiologists, authorized user training will follow the standards in 10 CFR 35 prior to October 2002. The training standards can be found in the current NRC regulations under Subpart J of 10 CFR 35. Contrary to the above, the Cardiologist training will follow the standard established by the Agency that will be prescribed in Article 7. Because there is no significant change in training requirements from the old NRC standards, it is believed that enforcement of the training standards will not add any new costs for physicians to become qualified to use radioactive material on an Arizona license. The other changes in Article 7 will not result in any new costs for medical licensees. In fact, there are many changes that should result in decreased financial and administrative burden for medical licensees, if affected by the new rules. Not all licensees are affected equally.

In a similar vane, regulation of a relatively new diagnostic tool, Positron Emission Tomography (PET), would lead the casual observer to think that the new PET rules proposed in Article 7 might result in a significant increase in cost to the affected medical licensees. However, the Agency believes it may in fact, be just the opposite, or at the least, a minimum expense when compared to diagnostic equipment costs. Licensees that have already started to perform PET

without notifying the Agency under the old rules, will be required to notify the Agency as to their planned activities and how the licensee will provide radiation protection for personnel in accordance with the radiation exposure standards in Article 4. If the Article 4 standards are not currently met, the licensee will be required to retrofit the existing facility with shielding, or even worse, reconstruction of the facility. It may be more expensive than building a safe PET facility from the beginning by incorporating conditions that will limit radiation exposure that meets the regulatory standard. It was determined from a local health physics consultant that shielding costs may be as high as \$25,000, which will provide shielding in all affected walls, and the floor and ceiling, if the areas above and below the PET facility are occupied by personnel. In itself, the \$25,000 spent for shielding may seem like a large sum of money, but compared to the cost of a PET/CT (computerized tomography) gamma camera that costs between \$1,000,000 and \$1,500,000, this is actually a small price to pay for radiation safety.

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

Name: Daniel H. Kuhl, State Health Physicist II
Address: Arizona Radiation Regulatory Agency
4814 S. 40th St.
Phoenix, AZ 85040
Telephone: (602) 255-4845, ext. 233
Fax: (602) 437-0705
E-mail: dkuhl@azrra.gov

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the 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 University of Arizona Medical Center in Tucson is scheduled for Wednesday, July 19, 2006, at 10:00 a.m. The directions to the meeting site can be obtained by contacting the agency at (602) 255-4845. A person may submit written comments concerning the proposed rules by submitting them no later than 5 p.m. on July 19, 2006, to the following person:

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

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

None

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

<u>Rule</u>	<u>Incorporation</u>
R12-1-311(C)	10 CFR 32.26
R12-1-311(C)(2)	10 CFR 32.29
R12-1-311(D)(4)(f)(i)	10 CFR 32.52
R12-1-311(F)(2)	10 CFR 32.57, 32.58, 32.102, 70.39
R12-1-311(I)(2)	10 CFR 32.61, 32.62, 32.101
R12-1-311(J)	10 CFR 32.72(b)(1), (b)(2)(i), and (b)(2)(ii)
R12-1-311(L)	10 CFR 32.74
R12-1-702	21 CFR 361.1
R12-1-702	21 CFR 310.3(c) and 600.3
R12-1-704(B)	Federal Policy for the Protection of Human Subjects
R12-1-716(C)(2)	AAPM Task Group on PET and PET/CT Shielding
R12-1-719(A)	10 CFR 35.190
R12-1-721(A)	10 CFR 35.290
R12-1-723(A)	10 CFR 35.390
R12-1-723(B)	10 CFR 35.392
R12-1-723(C)	10 CFR 35.394
R12-1-727(A)	10 CFR 35.490
R12-1-727(B)	10 CFR 35.491
R12-1-728(A)	10 CFR 35.500
R12-1-744(A)	10 CFR 35.690

13. The full text of the rules follows:

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

ARTICLE 1. GENERAL PROVISIONS

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

ARTICLE 3. RADIOACTIVE MATERIAL LICENSING

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

ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

Section
R12-1-415. Dose Limits for an Embryo or Fetus
R12-1-434. General Requirements for Waste Disposal
R12-1-438. Disposal of Specific Wastes
R12-1-455. Security Requirements for Portable Gauges

ARTICLE 7. USE OF RADIONUCLIDES IN THE HEALING ARTS

Section
R12-1-701. ~~Scope~~ License Required
R12-1-702. Definitions
R12-1-703. License for Medical Use of Radioactive Material
R12-1-704. ~~Supervision~~ Provisions for the Protection of Human Research Subjects
R12-1-705. ~~Radiation Safety Officer~~ Authority and Responsibilities for the Radiation Protection Program
R12-1-706. ~~Radiation Safety Committee~~ Supervision
R12-1-707. ~~Quality Management Program~~ Written Directives
R12-1-708. ~~Misadministration Reports and Records~~ Procedures for Administrations Requiring a Written Directive
R12-1-709. ~~Reserved~~ Sealed Sources or Devices for Medical Use
R12-1-710. ~~Visiting Authorized User~~ Radiation Safety Officer Training
R12-1-711. ~~Calibration and Reference Sources~~ Authorized Medical Physicist Training
R12-1-712. ~~Sealed Sources~~ Authorized Nuclear Pharmacist Training
R12-1-713. ~~Dose Calibrators~~ Determination of Prescribed Dosages, and Possession, Use, and Calibration of Instrumentation
R12-1-714. ~~Brachytherapy~~ Authorization for Calibration, Transmission, and Reference Sources
R12-1-715. ~~Reserved~~ Requirements for Possession of Sealed Sources and Brachytherapy Sources
R12-1-716. ~~Teletherapy~~ Surveys of Ambient Radiation Exposure Rate, Surveys for Contamination, and PET Radiation Exposure Concerns
R12-1-717. ~~High Dose Rate Remote After-loading Brachytherapy Devices~~ Release of Individuals Containing Radioactive Material
R12-1-718. ~~Gamma Stereotactic Radiosurgery~~ Mobile Medical Service
R12-1-719. ~~Release of Individuals Containing Radiopharmaceuticals or Radioactive Sealed Sources from Restricted Areas~~ Training for Uptake, Dilution, and Excretion Studies
R12-1-720. ~~Decay in Storage~~ Permissible Molybdenum-99 Concentrations
R12-1-721. Training for Imaging and Localization Studies Not Requiring a Written Directive
R12-1-722. Safety Instruction and Precautions for Use of Unsealed Radioactive Material Requiring a Written Directive
R12-1-723. Training for Use of Unsealed Radioactive Material Requiring a Written Directive, Including Treatment of Hyperthyroidism, and Treatment of Thyroid Carcinoma
R12-1-724. Surveys after Brachytherapy Source Implant, Removal, and Accountability

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<u>R12-1-725.</u>	<u>Safety Instructions and Precautions for Brachytherapy Patients that Cannot be Released Under R12-1-717</u>
<u>R12-1-726.</u>	<u>Calibration Measurements of Brachytherapy Sources, Decay of Sources Used for Ophthalmic Treatments, and Computerized Treatment Planning Systems</u>
<u>R12-1-727.</u>	<u>Training for Use of Manual Brachytherapy Sources and Training for the Use of Strontium-90 Sources for Treatment of Ophthalmic Disease</u>
<u>R12-1-728.</u>	<u>Training for Use of Sealed Sources for Diagnosis</u>
<u>R12-1-729.</u>	<u>Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit</u>
<u>R12-1-730.</u>	<u>Installation, Maintenance, Adjustment, and Repair of an Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit</u>
<u>R12-1-731.</u>	<u>Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units</u>
<u>R12-1-732.</u>	<u>Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units</u>
<u>R12-1-733.</u>	<u>Dosimetry Equipment</u>
<u>R12-1-734.</u>	<u>Full Calibration Procedures on Teletherapy Units</u>
<u>R12-1-735.</u>	<u>Full Calibration Measurements on Remote Afterloader Units</u>
<u>R12-1-736.</u>	<u>Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units</u>
<u>R12-1-737.</u>	<u>Periodic Spot-checks for Teletherapy Units</u>
<u>R12-1-738.</u>	<u>Periodic Spot-checks for Remote Afterloader Units</u>
<u>R12-1-739.</u>	<u>Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units</u>
<u>R12-1-740.</u>	<u>Additional Requirements for Mobile Remote Afterloader Units</u>
<u>R12-1-741.</u>	<u>Additional Radiation Survey of Sealed Sources Used in Radiation Therapy</u>
<u>R12-1-742.</u>	<u>Five-year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units</u>
<u>R12-1-743.</u>	<u>Therapy Related Computer Systems</u>
<u>R12-1-744.</u>	<u>Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units</u>
<u>R12-1-745.</u>	<u>Report and Notification of a Medical Event</u>
<u>R12-1-746.</u>	<u>Report and Notification of a Dose to an Embryo, Fetus or a Nursing Child</u>
Exhibit A.	<u>Groups of Medical Uses of Radioactive Material Medical Use Groups</u>

ARTICLE 9. PARTICLE ACCELERATORS

Section

R12-1-901.	Purpose and Scope
R12-1-913.	Misadministration

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 below. Additional subject specific definitions are used in other Articles.

“A ₁ ”	No change
“A ₂ ”	No change
“Absorbed dose”	No change
“Accelerator”	No change
“Accelerator produced material”	No change
“Act”	No change
“Activity”	No change
“Adult”	No change
“Agency” or “ARRA”	No change
“Agreement State”	No change
“Airborne radioactive material”	No change
“Airborne radioactivity area”	No change
“ALARA”	No change
“Analytical x-ray equipment”	No change

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“Analytical x-ray system”	No change
“Annual”	No change
“Background radiation”	No change
“Becquerel”	No change
“Bioassay”	No change
“Brachytherapy”	No change
“By-product material”	No change
“Calendar quarter”	No change
“Calibration”	No change
“Certifiable cabinet x-ray system”	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 or registration”	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
“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

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“Hazardous waste”	No change
“Healing arts”	No change
“Health care institution”	No change
“High radiation area”	No change
“Human use”	No change
“Impound”	No change
“Individual”	No change
“Individual monitoring”	No change
“Individual monitoring device” or “individual monitoring equipment”	No change
“Industrial radiography”	No change
“Injection tool”	No change
“Inspection”	No change
“Interlock”	No change
“Internal dose”	No change
“Irradiate”	No change
“Laser”	No change
“Lens dose equivalent”	No change
“License”	No change
“Licensed material”	No change
“Licensed practitioner”	No change
“Licensee”	No change
“Licensing State”	No change
“Limits”	No change
“Local components”	No change
“Logging supervisor”	No change
“Logging tool”	No change
“Lost or missing licensed or registered source of radiation”	No change
“Low-level waste”	No change
“Major processor”	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
<u>“Natural radioactivity”</u>	<u>No change</u>
<u>“Normal operating procedures”</u>	<u>No change</u>
“Natural radioactivity”	No change
“NRC”	No change
“Nuclear waste”	No change
“Occupational dose”	No change

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“Open beam system”	No change
“Package”	No change
“Particle accelerator”	No change
“Permanent radiographic installation”	No change
<u>“Personal supervision”</u>	<u>No change</u>
“Personnel dosimeter”	No change
“Personnel monitoring equipment”	No change
“Personal supervision”	No change
“Pharmacist”	No change
“Physician”	No change
“Primary beam”	No change
“Public dose”	No change
“Pyrophoric liquid”	No change
“Pyrophoric solid”	No change

“Qualified expert” means an individual certified in the appropriate field by the American Board of Radiology or the American Board of Health Physics, or having equivalent qualifications which provide the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs; or an individual certified in Therapeutic Radiological Physics or X-ray and Radium Physics by the American Board of Radiology, or having equivalent qualifications that provide training and experience in the clinical applications of radiation physics to radiation therapy, to calibrate radiation therapy equipment. The detailed requirements for a particular qualified expert ~~are~~ may be provided in the respective Articles of ~~these rules~~ this Chapter. For clarification purposes, a qualified expert is not an authorized medical physicist, however, an authorized medical physicist is one of the many authorities grouped together under the title of “qualified expert”.

“Quality Factor”	No change
“Quarter”	No change
“Rad”	No change
“Radiation”	No change
“Radiation area”	No change
“Radiation dose”	No change
“Radiation machine”	No change
“Radiation safety officer”	No change
“Radioactive marker”	No change
“Radioactive material”	No change
“Radioactivity”	No change
“Radiographer”	No change
“Radiographer’s assistant”	No change
“Registrant”	No change
“Registration”	No change
“Regulations of the U.S. Department of Transportation”	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
“Sealed Source and Device Registry”	No change
<u>“Shallow-dose equivalent (H_s)”</u>	No change

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“Shielded position”	No change
“Sievert”	No change
“Site boundary”	No change
“Source changer”	No change
“Source holder”	No change
“Source material”	No change
“Source material milling”	No change
“Source of radiation” or “source”	No change
“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
<u>“Very high radiation area”</u>	No change
“Waste”	No change
“Waste handling licensees”	No change
“Week”	No change
“Well-bore”	No change
“Well-logging”	No change
“Whole body”	No change
“Wireline”	No change
“Wireline service operation”	No change
“Worker”	No change
“WL”	No change
“WLM”	No change
<u>“Worker”</u>	<u>No change</u>
“Workload”	No change
“Year”	No change

R12-1-103. Exemptions

- A. Common and contract carriers, freight forwarders, and warehousemen who are subject to 49 CFR 107.109, 107.111, 107.113, 171.2, 171.3, 172.200, 173.1, 173.3, 173.4, 173.401, 175.3, 175.5, 175.10, 176.3, 176.5, 176.11, 176.24, 176.27, and 177.801, 2000 Edition, published October 1, 2000, of the U.S. Department of Transportation, or 39 CFR 111.1 of the U.S. Postal Service, 2001 Edition, published January 1, 2001, incorporated by reference and on file with the Agency and the Office of the Secretary of State, and if need be, stores radioactive material, for periods of less than 72 hours, in the regular course of their carriage for another, are exempt from this Chapter. ~~In addition, they are exempt from this Chapter to~~

~~the extent that they store radioactive material, for periods of less than 72 hours, in the regular course of their carriage for another. Private carriers who are subject to the regulations of the U.S. Department of Transportation are exempt from this Chapter to the extent that they transport radioactive material. Common, contract, and private carriers who are not subject to the regulations of the U.S. Department of Transportation or the U.S. Postal Service are subject to this Chapter. The above incorporation by reference contains no future editions or amendments.~~

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

ARTICLE 3. RADIOACTIVE MATERIAL LICENSING

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

- A.** No change
 - 1. No change
 - a. No change
 - b. No change
 - 2. No change
 - a. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - v. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - g. No change
 - h. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - v. No change
 - vi. No change
 - i. No change
 - j. No change
 - k. No change
 - l. No change
 - m. No change
 - 3. No change
- B.** No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - 2. No change
 - a. No change
 - b. No change
 - c. No change
 - i. No change

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- ii. No change
 - d. No change
 - i. No change
 - ii. No change
 - iii. No change
 - 3. No change
- C. The Agency shall approve an application for a specific license authorizing the incorporation of radioactive material, other than source or by-product material, into gas and aerosol detectors to be distributed to persons exempt under R12-1-303(B) if the application satisfies requirements equivalent to those contained in 10 CFR 32.26, ~~1998 Edition, published January 1, 1998 2006, which~~ is incorporated by reference, and published by the Office of Federal Register, National Archives and Records Administration, Washington, D.C. 20498, and on file with the Agency. And the office of Secretary of State which shall not contain any This incorporation by reference contains no future editions or references, and provided:
 - 1. No change
 - 2. The licensee files annual reports required by 10 CFR 32.29, ~~1998 Edition, published January 1, 1998 2006, which~~ is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington D.C. 20408, and on file with the Agency ~~and the office of the Secretary of State, with the Agency.~~ This incorporation by reference contains no future editions or references.
- D. No change
 - 1. No change
 - a. No change
 - b. No change
 - i. No change
 - ii. No change
 - iii. No change
 - c. No change
 - i. No change
 - ii. No change
 - iii. No change
 - d. No change
 - e. No change
 - f. No change
 - 2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - g. No change
 - h. No change
 - i. No change
 - j. No change
 - 3. No change
 - 4. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. The licensee shall:
 - i. Report on a quarterly basis to the responsible Agreement State or NRC all transfers of devices to persons for use under a general license in accordance with 10 CFR 32.52, January 1, 2006, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration Washington, D.C. 20408, and on file with the Agency. This incorporated reference contains no future editions or amendments.
 - ii. Maintain all information concerning transfers and receipts of devices that supports the reports required by this Section.

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iii. Maintain records required by this paragraph for a period of three years following the date of the recorded event.

- 5. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
- 6. No change
- 7. No change
- 8. No change
 - a. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - v. No change
 - b. No change
 - c. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - d. No change
 - e. No change
 - f. No change
 - g. No change
- 9. No change
- E. No change
 - 1. No change
 - 2. No change
- F. No change
 - 1. No change
 - 2. The requirements of 10 CFR 32.57, 32.58, 32.102, and 70.39, ~~1998 Edition, published January 1, 1998~~ 2006, which is incorporated by reference, published by the Office of Federal Register, National Archives and Records Administration, Washington D.C. 20408, and on file with the Agency ~~and the Office of the Secretary of State, or their equivalent.~~ These incorporations by reference contain no future editions or amendments.
- G. No change
 - 1. No change
 - 2. No change
 - a. No change
 - b. No change
- H. No change
 - 1. No change
 - 2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - g. No change
 - 3. No change
 - a. No change
 - b. No change
 - 4. No change
 - a. No change
 - b. No change
 - 5. No change
- I. No change

1. No change
 2. The criteria of 10 CFR 32.61, 32.62, and 32.101, ~~1998 Edition, published January 1, 1998~~ 2006, which is incorporated by reference, published by the Office of Federal Register, National Archives and Records Administration, Washington D.C. and on file with the Agency ~~and the Office of Secretary of State~~. These incorporations by reference contain no future editions or amendments.
- J.** No change
1. No change
 - a. No change
 - b. No change
 - i. No change
 - ii. No change
 - c. The applicant submits information on the radionuclide; chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by group licensees; ~~and~~
 - d. The label affixed to each package of the radiopharmaceutical contains information on the radionuclide; quantity, and date of assay; and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the Agency for distribution to persons licensed according to the requirements in 12 A.A.C. 1, Article 7 or an equivalent license of the U.S. Nuclear Regulatory Commission or an Agreement State or Licensing State. The labels, leaflets or brochures required by this subsection supplement the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, combined with the labeling required by FDA; ~~and~~
 - e. The individual preparing the radiopharmaceutical meets the requirements in 10 CFR 32.72(b)(1), (b)(2)(i), and (b)(2)(ii), January 1, 2006, which is incorporated by reference, published by the Office of Federal Register, National Archives and Records Administration, Washington D.C., and on file with the Agency. These incorporations by reference contain no future editions or amendments.
 2. No change
- K.** No change
1. No change
 2. No change
 - a. No change
 - b. No change
 3. No change
 4. No change
 5. No change
 - a. No change
 - b. No change
- L.** Manufacture and distribution of sources or devices containing radioactive material for medical use
1. The Agency shall approve an application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed under 12 A.A.C. 1, Article 7 for use as a calibration or reference source or for certain medical uses as sealed sources if:
 - a. ~~The applicant satisfies the general requirements in R12-1-309;~~
 - b. ~~The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of radiation safety, including:~~
 - i. ~~The radioactive material contained, its chemical and physical form, and amount;~~
 - ii. ~~Details of design and construction of the source or device;~~
 - iii. ~~Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;~~
 - iv. ~~For devices containing radioactive material, the radiation profile of a prototype device;~~
 - v. ~~Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;~~
 - vi. ~~Procedures and standards for calibrating sources and devices;~~
 - vii. ~~Legend and methods for labeling sources and devices as to their radioactive content;~~
 - viii. ~~Instruction for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided that instructions which are too lengthy for the label may be summarized on the label and printed in detail on a brochure which is referenced on the label;~~
 - e. ~~The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide; quantity, the date of assay, and a statement that the (name of source or device) is licensed by the Agency for distribution to persons licensed under 12 A.A.C. 1, Article 7 or equivalent license of~~

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the U.S. Nuclear Regulatory Commission or an Agreement State or a Licensing State, provided that labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source. the source or device is manufactured and distributed in accordance with 10 CFR 32.74 (a), January 1, 2006, which is incorporated by reference, published by the Office of Federal Register, National Archives and Records Administration, Washington D.C., and on file with the Agency. This incorporation by reference contain no future editions or amendments.

- 2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - g. No change
 - h. No change
 - i. No change
 - j. No change

M. No change

- 1. No change
 - a. No change
 - b. No change
 - c. No change
- 2. No change
- 3. No change
- 4. No change
 - a. No change
 - b. No change
 - i. No change
 - ii. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - v. No change
 - vi. No change

ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

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

- A.** A 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~~ E)(4) and (5).
- B.** No change
- C.** No change
 - 1. No change
 - 2. No change
- D.** No change
- E.** No change

R12-1-434. General Requirements for Waste Disposal

- A.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change

- B. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
- C. ~~A licensee is authorized to hold radioactive waste with a physical half-life of less than 120 days for decay in storage before disposal in ordinary trash provided:~~
 - 1. ~~The radioactive waste is held for decay a minimum of 10 half lives;~~
 - 2. ~~The radioactive waste is surveyed with a survey meter, appropriate for the type of radiation being detected, to determine that its emitted radiation level cannot be distinguished from the background radiation; and~~
 - 3. ~~All radiation warning labels are removed or obliterated.~~

R12-1-438. Disposal of Specific Wastes

- A. A licensee may dispose of the following licensed material as if it were not radioactive:
 - 1. 1.85 kBq (0.05 μ Ci), or less, of Hydrogen-3 or Carbon-14 per gram of medium used for liquid scintillation counting; and
 - 2. 1.85 kBq (0.05 μ Ci), or less, of Hydrogen-3 or Carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.
 - 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 to subsection (A)(2) 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 two times background; and~~
 - 4. ~~All radiation labels are removed or obliterated.~~
 - 1. The licensee monitors the container of radioactive material at the surface before disposal to determine that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
 - 2. The licensee removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.
- D. The licensee shall maintain records in accordance with R12-1-441.

R12-1-455. Security Requirements for Portable Gauges

- A. A licensee that uses a portable gauge shall use a minimum of two independent controls to maintain security while:
 - 1. Transporting a portable gauge; and
 - 2. Storing a portable gauge.
- B. Each control shall form a tangible barrier that will prevent unauthorized removal whenever a portable gauge is not under the control and constant surveillance of the licensee.
- C. All controls employed by a licensee to secure a portable gauge against unauthorized removal shall be approved by the Agency.

ARTICLE 7. USE OF RADIONUCLIDES IN THE HEALING ARTS

R12-1-701. Scope License Required

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

- A. A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer radioactive material for medical use only in accordance with a specific license issued by the Agency, the NRC, or another Agreement State, or as allowed in subsection (B)(1) or (B)(2)
- B. A specific license is not needed for an individual who:
 - 1. Receives, possesses, uses, or transfers radioactive material in accordance with the rules in this Chapter under the supervision of an authorized user as provided in R12-1-706, unless prohibited by license condition; or

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2. Prepares unsealed radioactive material for medical use in accordance with the rules in this Chapter under the supervision of an authorized nuclear pharmacist or authorized user.

R12-1-702. Definitions

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

“Authorized nuclear pharmacist” means a pharmacist who meets the requirements in R12-1-712:

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

An authorized user on an Agency, Nuclear Regulatory Commission (NRC), or Agreement State license that authorizes the specified medical use; or

A user in a medical use broad scope program, licensed by the Agency, NRC or Agreement State to select its own authorized users in accordance with the training standards contained in this Article.

“Authorized user” means a physician, who meets the requirements in R12-1-719, R12-1-721, R12-1-723, R12-1-727, R12-1-728, or R12-1-744:

“Brachytherapy” No change

“CT” means computerized tomography.

“High dose rate afterloading brachytherapy” No change

“Human research subject” means a human subject involved in research overseen by a RDRC, not including patients participating in a protocol involving an investigational new drug or device.

“Human subject” means an individual who is or becomes a participant in research overseen by an IRB, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

“Institutional review board” (IRB) means see the incorporated reference in R12-1-704(B)

“Manual brachytherapy” means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

“Medical event” means an event that meets the criteria in R12-1-745.

“Medical institution” No change

“Medical use” No change

“Misadministration” means:

The administration of a radiopharmaceutical or the radiation from a sealed source, administered for therapy purposes and involving:

The wrong radiopharmaceutical or sealed source; or

The wrong patient; or

The wrong route of administration; or

A dose to an individual that differs from the prescribed dose by 20%; or

The administration of a diagnostic dose of a radiopharmaceutical involving:

The wrong patient; or

The wrong radiopharmaceutical; or

The wrong route of administration; and

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

A therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose differing from the final, prescribed total treatment dose by more than 10 percent.

“Nuclear cardiology” means the diagnosis of cardiac disease using radiopharmaceuticals

“PET” means positron emission tomography

“Physically present” means that a supervising medical professional is in proximity to the patient during a radiation therapy procedure so that immediate emergency orders can be communicated to ancillary staff, should the occasion arise.

“Prescribed dosage” means the specified activity or range of activity of unsealed radioactive material as documented.

In a written directive; or

In accordance with the directions of the authorized user for procedures performed in accordance with the uses described in Exhibit A.

“Prescribed dose” means:

For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

For teletherapy, the total dose and dose per fraction as documented in the written directive;

For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

“Radiation Safety Officer” (RSO) for purposes of this Article, and in addition to the definition in Article 1 means an individual who:

Meets the requirements in R12-1-710 (A); or

Is identified as a Radiation Safety Officer on:

A specific medical use license issued by the NRC or Agreement State; or

A medical use permit issued by a NRC master material license.

“Radioactive drug” is defined in 21 CFR 310.3(c) and includes a “radioactive biological product” as defined in 21 CFR 600.3, April 1, 2006, both of which are incorporated by reference, published by the office of Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by references contain no future editions or amendments.

“Radioactive Drug Research Committee” (RDRC) means the committee established by the licensee to review all basic research involving the administration of a radioactive drug to human research subjects, taken from 21CFR 361.1, April 1, 2006, which is incorporated by reference, published by the office of Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments. Research is considered basic research if it is done for the purpose of advancing scientific knowledge, which includes basic information regarding the metabolism (including kinetics, distributions, dosimetry, and localization) of a radioactive drug or regarding human physiology, pathophysiology, or biochemistry. Basic research is not intended for immediate therapeutic or diagnostic purposes; and is not intended to determine the safety and effectiveness of a radioactive drug in humans. A study subject should not directly benefit from basic research.

“Radiopharmaceutical” means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of any such substance. For purposes of this Article radiopharmaceutical is equivalent to radioactive drug.

“Remote afterloading brachytherapy device” No change

“Sealed Source and Device Registry” means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

“Stereotactic radiosurgery” No change

“Teletherapy” No change

“Therapeutic dosage” means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

“Therapeutic dose” means a radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.

“Treatment site” means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

“Unit dosage” means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

“Written directive” means an order in writing for a specific individual, or a diagnostic standing procedure for a group of patients written by an authorized user and on file with the licensee. The order or standing procedure shall be dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation. an authorized user’s written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in R12-1-707.

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

A. In addition to the requirements set forth in R12-1-309, the Agency shall issue a specific license for medical use of radio-

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active material in medical institutions, ~~which will be issued if provided:~~

1. The applicant has appointed a radiation safety committee, meeting the requirements in ~~R12-1-706~~ R12-1-705, that will oversee the use of licensed material throughout the ~~medical institution and review the medical institution's licensee's facility and associated~~ radiation safety program;
 2. The applicant possesses facilities for the clinical care of patients or human subjects, and
 3. ~~Any physician~~ The individual designated on the application as an authorized user has ~~substantial training and experience in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients, and met the training and experience requirements in R12-1-719, R12-1-721, R12-1-723, R12-1-727, R12-1-728, or R12-1-744~~
 4. ~~If the application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant's staff has substantial experience in the use of a variety of radioactive materials for a variety of medical purposes.~~
- B.** Specific licenses to individual ~~physicians~~ authorized users for medical use of radioactive material:
1. The Agency shall approve an application by ~~an individual physician or group of physicians~~ a prospective individual authorized user or prospective group of authorized users for a specific license governing the medical use of radioactive material if:
 - a. The applicant satisfies the general requirements in R12-1-309;
 - b. The application is for use in the applicant's practice at an office outside of a medical institution;
 - c. The applicant has access to a medical institution with adequate facilities to hospitalize and monitor the applicant's radioactive patients or human subjects whenever it is advisable; ~~and~~
 - d. The applicant ~~has substantial experience in the handling and administration of radionuclides, and where applicable, the clinical management of radioactive patients~~ meets the training and experience requirements in subsection (A)(3); and
 - e. The applicant has a radiation safety committee, if the criteria in R12-1-705 are met and a RDRC, if the use is basic research involving humans.
 2. The Agency shall not approve an application by ~~an individual physician or group of physicians~~ a prospective authorized user or group of prospective authorized users for a specific license to receive, possess, or use radioactive material on the premises of a medical institution unless:
 - a. The use of radioactive material is limited to:
 - i. The administration of radiopharmaceuticals for diagnostic or therapeutic purposes;
 - ii. The performance of diagnostic studies on patients or human research subjects to whom a radiopharmaceutical has been administered;
 - iii. The performance of in vitro diagnostic studies; or
 - iv. The calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation, or diagnostic instrumentation;
 - b. The ~~physician~~ authorized user brings the radioactive material and removes the radioactive material upon departure; and
 - c. The medical institution does not hold a radioactive materials license under subsection (A).
- C.** Specific licenses for certain groups of medical uses of radioactive material
1. ~~Subject to the provisions of subsections (C)(2), (3), and (4), the~~ The Agency shall approve an application for a specific license under subsections (A) or (B), for any medical use or uses of radioactive material specified in ~~1 or more of Groups I to V inclusive, Groups 100 to 600,~~ in Exhibit A of this Article for all of the materials within the ~~group or groups~~ group(s) requested in the application if:
 - a. The applicant satisfies the requirements of subsections ~~(A), (B), and (D)~~ (A) and (B);
 - b. ~~The applicant, or any physician designated in the application as an individual user meets the qualifications in R12-1-704;~~
 - ~~e.b.~~ All personnel who will be involved in the preparation and use of the radioactive material have adequate training and experience in the handling of radioactive material appropriate to their participation in the uses included in the group or groups Each person involved in the preparation and use of the radioactive material is an authorized user, an authorized nuclear pharmacist, or certified as a nuclear medicine technologist by the Medical Radiologic Technology Board of Examiners (MRTBE);
 - ~~d.c.~~ The applicant's radiation detection and measuring instrumentation is adequate for conducting the procedures involved in the uses included in the group or groups group(s); and
 - ~~e.d.~~ The applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the uses included in the group or groups group(s).
 2. ~~Any licensee or registrant who is authorized to use radioactive material according to 1 or more groups in subsection (C)(1), and Exhibit A of this Article is subject to the following conditions:~~
 2. Any licensee who is authorized to use radioactive material:
 - a. In unsealed form under Groups 100, 200, or 300 listed in Exhibit A of this Article, shall do so using radiopharmaceuticals prepared in accordance with R12-1-311(J); or

- b. In sealed source form under Groups 400, 500, or 600 listed in Exhibit A of this Article, shall do so using sealed sources that have been manufactured and distributed in accordance with R12-1-311(L);
- a. For Groups I, II, IV and V, a licensee or registrant shall not receive, possess, or use radioactive material as a radiopharmaceutical unless manufactured in the form to be administered to the patient, labeled, packaged, and distributed according to a specific license issued by the Agency under R12-1-311(J), a specific license issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.72, 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of Secretary of State (this incorporation by reference contains no future editions or amendments), or a specific license issued by an Agreement State or a Licensing State under equivalent rules.
- b. For Group III, a licensee or registrant shall not receive, possess, or use generators or reagent kits that contain radioactive material to prepare radiopharmaceuticals containing radioactive material, except:
- i. Reagent kits that do not contain radioactive material, approved by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State or Licensing State for use by persons licensed under subsection (C) and Exhibit A of this Article or equivalent regulations; or
- ii. Generators or reagent kits that contain radioactive material which are manufactured, labeled, packaged, and distributed according to a specific license issued by the Agency under R12-1-311(K).
- e. For Group III, any licensee who uses generators or reagent kits shall:
- i. Elute the generator according to instructions furnished by the manufacturer or located on the generator label, leaflet, or brochure which accompanies the generator or reagent kit;
- ii. Before administration to patients, or distribution to authorized recipients for administration to patients, cause each elution or extraction of technetium 99m from a molybdenum 99/technetium 99m generator to be tested to determine either the total molybdenum 99 activity or the concentration of molybdenum 99, according to written procedures and by personnel who have been specifically trained to perform the test;
- iii. Prohibit the administration or distribution for administration of technetium 99m that, at the expiration date and time shown on the container label, contains more than 5.6 kBq (0.15 microcuries) of molybdenum 99 per 37 MBq (1 millicurie) of technetium 99m. The licensee shall determine an action level for molybdenum 99/technetium 99m at elution so that the above concentration is not exceeded by radiopharmaceutical expiration. For example, the maximum concentration is 2.6 kBq (0.07 microcurie) per 37 MBq (1 millicurie) at elution for a dose that expires 6 hours later. The licensee shall ensure that the limits above are not exceeded for any single patient dose by checking the expiration time on the container label. The results of each test performed to detect and quantify molybdenum 99 contamination and records of training given to personnel performing these tests shall be maintained for 3 years for Agency inspection; and
- d. For Groups I, II, and III, any licensee using radioactive material for clinical procedures other than those specified in the product labeling or package insert shall do so according to an authorized user's directive. Any deviation from the product labeling shall be recorded. Records shall be maintained for Agency review for 3 years from the date of the administration of the radiopharmaceutical.
3. Any licensee who is licensed according to subsection (C)(1), for 1 or more of the medical use groups in Exhibit A also is authorized to use radioactive material under the general license in R12-1-306(F) for the specified in vitro uses without filing Form ARRA-9 as required by R12-1-306(F)(2); provided, that the licensee is subject to the other provisions of R12-1-306(F).
4. Any licensee who is licensed according to this Section is authorized to receive, possess, and use calibration and reference radioactive sealed sources in accordance with R12-1-711.
- D. In addition to the requirements set forth in R12-1-309, the Agency shall issue a specific license for medical use of sealed sources only if the applicant or, if the application is made by a medical institution, the individual user has the qualifications listed in R12-1-704.
- In addition to the other license application requirements in this Section, each applicant shall include in their radiation safety program a system for ensuring that each syringe and vial that contains unsealed radioactive material is labeled in accordance with R12-1-431(D).

R12-1-704. Supervision Provisions for the Protection of Human Research Subjects

- A. For purposes of this rule "supervision" means the exercise of control over or direction of the use of radioactive material in the practice of medicine by an authorized user named on a radioactive material license. Supervision does not require a supervising physician's constant physical presence if the supervising physician can be easily contacted by radio, telephone, or telecommunication.
- B. A physician may use radioactive material if he or she is licensed by the Arizona Board of Medical Examiners or Board of Osteopathic Examiners in Medicine and Surgery and is listed as an authorized user on a radioactive material license issued by the Agency, NRC, or Agreement State, authorizing the use of radioactive material for medical purposes.
- C. A physician, having the training and experience listed in 10 CFR 35, 1998 Edition, published January 1, 1998, which is incorporated by reference and on file with the Agency and the Office of Secretary of State, or a physician under the super-

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vision of a physician having the qualifications listed above, may use radioactive material for medical purposes. This incorporation by reference contains no future editions or amendments.

- ~~D.~~ An authorized user, approved to prescribe radiopharmaceuticals for therapy purposes on a radioactive materials license, shall be physically present when a radiopharmaceutical is administered to a human being for therapeutic purposes.
- ~~E.~~ A limited-service nuclear pharmacy permittee shall dispense radiopharmaceuticals only to a physician listed as an authorized user on a valid radioactive material license issued by the Agency, an Agreement State, or the NRC.
- A. A licensee may conduct basic research involving human research subjects and research involving patients receiving investigational new drugs or devices if the licensee only uses the radioactive material specified on the license for the uses authorized on the license.
- B. If research is conducted, funded, supported, or regulated by a federal agency that has implemented the Federal Policy for the Protection of Human Subjects (45 CFR 46, June 23, 2005, which is incorporated by reference, published by the office of Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments), the licensee shall:
 - 1. Obtain review and approval of the basic research from an Institutional Review Board (IRB); and
 - 2. Obtain informed consent from the human research subject.
- C. If research will not be conducted, funded, supported, or regulated by a federal agency that has implemented the Federal Policy in subsection (B), a medical licensee shall, before conducting research, apply for and receive a specific amendment to its use license. The amendment request shall include a written commitment that the licensee will, before conducting research:
 - 1. Obtain review and approval of the research from an IRB, as defined and described in the Federal Policy; and
 - 2. Obtain informed consent from the human research subject.
- D. Before conducting the research described in subsection (A) the licensee shall apply to the Agency for and receive a specific amendment to its medical use license. The amendment request shall include a written commitment that the licensee will, before conducting research:
 - 1. Obtain the review and approval required in subsections (C) and (D), and
 - 2. Obtain informed consent from the human research subject or human subject if applicable.
- E. Nothing in this Section relieves a licensee from complying with the other requirements in this Article.

R12-1-705. ~~Radiation Safety Officer~~ Authority and Responsibilities for the Radiation Protection Program

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

- A. A licensee's management shall appoint in writing a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. Each time the RSO is changed, the licensee shall provide to the Agency within 30 days an amendment request and a copy of the correspondence between the licensee's management and the candidate, accepting the position of RSO.
- B. Licensees that are authorized for two or more different types of uses of radioactive material listed in Groups 300, 400 and 600, or two or more types of units under group 600, shall establish a Radiation Safety Committee (RSC) to oversee all uses of radioactive material permitted by the license. At a minimum, the RSC shall include an authorized user of each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor a RSO.
- C. If a licensee or applicant is not a health care institution and is unable to meet the RSC membership requirements in subsection (B), the licensee or applicant may request an exemption in accordance with A.R.S. § 30-654(B)(13). The request for exemption shall be made to the Agency in writing and list the reasons why the rule cannot be met.
- D. A licensee shall ensure that the RSC meets, at a minimum, on an annual basis and maintain the RSC meeting minutes for Agency review for three years after the date of the RSC meeting.

R12-1-706. ~~Radiation Safety Committee~~ Supervision

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

- I. Administrative requirements:
 - a. Committee membership shall consist of at least three individuals and shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.
 - b. The Committee shall meet at least once each calendar quarter, unless otherwise specified by license condition.
 - c. To establish a quorum and to conduct business, half of the Committee's membership shall be present, including the Radiation Safety Officer and the management representative.
 - d. The minutes of each Radiation Safety Committee meeting shall include:

- i. The date of the meeting;
 - ii. Members present;
 - iii. Members absent;
 - iv. A summary of deliberations and discussions;
 - v. Recommended actions and the numerical results of all ballots; and
 - vi. A reference to the review required in R12-1-407.
- e. The Committee shall provide each member with a copy of the meeting minutes, and retain one copy for three years.
2. Oversight; the Committee shall:
- a. Review the radiation protection program for all sources of radiation as required in R12-1-407;
 - b. Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the Radiation Safety Officer; and
 - e. Establish the safety objectives of the quality management program required by R12-1-707.
- A.** For purposes of this rule, “supervision” means the exercise of control over or direction of the use of radioactive material in the practice of medicine by an authorized user named on a radioactive material license. Supervision does not require a supervising physician’s constant physical presence if the supervising physician can be easily contacted by radio, telephone, or telecommunication.
- B.** A physician may use radioactive material if the person is licensed by the Arizona Board of Medical Examiners or Board of Osteopathic Examiners in Medicine and Surgery and is listed as an authorized user on the Arizona radioactive material license under which the radioactive material is obtained.
- C.** A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user, shall:
- 1. Instruct the supervised individual in the licensee’s written radiation protection procedures, written directive procedures, rules, and license conditions with respect to the use of radioactive material; and
 - 2. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures established by the licensee, written directive procedures, rules, and license conditions with respect to the medical use of radioactive material.
- D.** A licensee that permits the preparation of radioactive material for medical use by an individual who is supervised by an authorized nuclear pharmacist or a physician who is an authorized user, shall:
- 1. Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual’s involvement with radioactive material; and
 - 2. Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the rules, and license conditions.
- E.** A licensee that permits supervised activities under subsections (C) and (D) is responsible for the acts and omissions of the supervised individual.
- F.** A limited-service nuclear pharmacy licensee shall dispense radiopharmaceuticals only to a physician listed as an authorized user on a valid radioactive material license issued by the Agency, an Agreement State, or the NRC. For purposes of this rule “limited service” is defined in R4-23-110.

R12-1-707. Quality Management Program Written Directives

Each licensee, using radioactive material or the radiation from radioactive material for therapeutic purposes, shall establish and maintain a written quality management program so that radioactive material or radiation from it will be administered in accordance with a written directive from an authorized user listed on a valid radioactive material license. The quality management program shall include written policies and procedures to meet the specific patient safety objectives established by the Radiation Safety Committee or Radiation Safety Officer for licensees not required to have a Radiation Safety Committee.

- A.** A licensee shall ensure that a written directive is dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 MBq (30 microcuries (μ Ci)), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material. If, because of the emergent nature of the patient’s condition, a delay in order to provide a written directive would jeopardize the patient’s health, an oral directive is acceptable. The information contained in the oral directive shall be documented as soon as possible in writing in the patient’s record. A written directive shall be prepared within 48 hours of the oral directive.
- B.** A written directive shall contain the patient or human research subject’s name and the following information:
- 1. For any administration of quantities greater than 1.11 MBq (30 μ Ci) of sodium iodide I-131: the dosage;
 - 2. For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide I-131: the radiopharmaceutical, dosage, and route of administration;
 - 3. For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;
 - 4. For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;

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5. For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
6. For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:
 - a. Before implantation: treatment site, the radionuclide, and dose; and
 - b. After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

C. The licensee shall retain a copy of the written directive for 3 years after creation of the record.

R12-1-708. Misadministration Reports and Records Procedures for Administrations Requiring a Written Directive

A. ~~Reports of therapy misadministrations:~~

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

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

C. ~~Each licensee shall maintain, for Agency inspection, records of all misadministrations of radiopharmaceuticals or radiation from teletherapy or brachytherapy sources. These records shall contain the names of all individuals involved in the event, including the physician, allied health personnel, the patient, and the patient's referring physician; the patient's social security number or other identification number if one has been assigned; a brief description of the event; the effect on the patient; and the action taken to prevent recurrence. These records shall be preserved until the Agency authorizes disposal.~~

For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

1. The patient's or human research subject's identity is verified before each administration; and
2. Each administration is in accordance with the written directive.

R12-1-709. Reserved Sealed Sources or Devices for Medical Use

A licensee may use only:

1. Sealed sources, including teletherapy sources, or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under Article 3 of this Chapter, equivalent regulations of the NRC or an Agreement State;
or
2. Sealed sources or devices noncommercially transferred from another medical licensee; or
3. Teletherapy sources manufactured and distributed in accordance with a license issued by the Agency, the NRC, or another Agreement State.

R12-1-710. Visiting Authorized User Radiation Safety Officer Training

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

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

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

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

~~A licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer described in R12-1-705, to be an individual who:~~

- ~~1. Is certified by a specialty board whose certification process includes all of the requirements in subsection (2) and whose certification has been recognized by the Agency, NRC, or an Agreement State; or~~
- ~~2. Has completed a structured educational program consisting of both:
 - ~~a. 200 hours of didactic training in the following areas:
 - ~~i. Radiation physics and instrumentation;~~
 - ~~ii. Radiation protection;~~
 - ~~iii. Mathematics pertaining to the use and measurement of radioactivity;~~
 - ~~iv. Radiation biology; and~~
 - ~~v. Radiation dosimetry; and~~~~
 - ~~b. One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on an Agency, NRC, or an Agreement State license or permit issued by a NRC master material licensee that authorizes similar type(s) of use(s) of radioactive material involving the following:
 - ~~i. Shipping, receiving, and performing related radiation surveys;~~
 - ~~ii. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;~~
 - ~~iii. Securing and controlling radioactive material;~~
 - ~~iv. Using administrative controls to avoid mistakes in the administration of radioactive material;~~
 - ~~v. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;~~
 - ~~vi. Using emergency procedures to control radioactive material; and~~
 - ~~vii. Disposing of radioactive material; and~~~~
 - ~~c. Has obtained written certification, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in subsection (2)(i) and (ii) and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; or~~~~
- ~~3. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has Radiation Safety Officer responsibilities.~~
- ~~4. Is an individual identified as a Radiation Safety Officer on an Agency, NRC, or Agreement State license or a permit issued by an Agency, NRC, or Agreement State broad scope licensee or NRC master material license permit or by a master material license permittee of broad scope before the effective date of these rules need not comply with the training requirements in subsections (1) through (3).~~
- ~~5. Is a physician identified as an authorized user for the medical use of radioactive material on a license issued by the Agency, NRC, or Agreement State, a permit issued by a NRC master material licensee, a permit issued by an Agency, NRC, or Agreement State broad scope licensee, or a permit issued by a NRC master material license broad scope permittee before the effective date of these rules need not comply with the training requirements in this Article.~~
- ~~6. Has training and experience obtained within the 7 years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.~~

R12-1-711. Calibration and Reference Sources Authorized Medical Physicist Training

Any person authorized by R12-1-703 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, and reference purposes:

- ~~1. Sealed sources manufactured and distributed by persons specifically licensed under 12 A.A.C. 1, Article 3 or equivalent provisions of the NRC, Agreement State, or Licensing State and that do not exceed 1.1 GBq (30 millicuries) each;~~
- ~~2. Any radioactive material listed in Group I, Group II, or Group III of Exhibit A of this Article with a half life not longer than 100 days, in amounts not to exceed 555 MBq (15 millicuries) total;~~
- ~~3. Any radioactive material listed in Group I, Group II, or Group III of Exhibit A of this Article with half life greater than 100 days in amounts not to exceed 7.4 MBq (200 microcuries) total; and~~
- ~~4. Technetium-99m in individual amounts not to exceed 1.85 GBq (50 millicuries).~~

The licensee shall require the authorized medical physicist to be an individual who:

- ~~1. Is certified by a specialty board whose certification process includes all of the training and experience requirements in subsection (B) and whose certification has been recognized by the Agency, NRC or an Agreement State; or~~
- ~~2. Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics and has completed 1 year of full-time training in therapeutic radiological physics and an additional year of full-time~~

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- work experience under the supervision of an authorized medical physicist at a medical institution that includes the physics tasks associated with the sealed source radiation therapy procedures regulated in this Article; and
3. Has obtained written certification that the individual has satisfactorily completed the requirements in subsection (B) and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written certification shall be signed by a preceptor authorized medical physicist who meets the requirements in this Section or equivalent NRC or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.
 4. Is identified as a teletherapy or medical physicist on an Agency, NRC, or Agreement State license or a permit issued by a Agency, NRC, or Agreement State broad scope licensee or NRC master material license permit or by a NRC master material license permittee of broad scope before the effective date of these rules need not comply with the training requirements in subsections (A) through (C).
 5. Has the training and experience obtained within the 7 years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

R12-1-712. ~~Sealed Sources~~ Authorized Nuclear Pharmacist Training

~~A.~~ Each medical and nuclear pharmacy licensee shall conduct a quarterly physical inventory to account for all radioactive sealed sources received and possessed. Records of the inventories shall be maintained for inspection by the Agency and shall include the quantities, kinds of radioactive material, location of sources, the date of the inventory, and signature of the person performing the inventory.

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

A licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

1. Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in subsection (2) and whose certification has been recognized by the Agency, NRC, or an Agreement State; or
2. Has completed 700 hours in a structured educational program consisting of both:
 - a. Didactic training in the following areas:
 - i. Radiation physics and instrumentation;
 - ii. Radiation protection;
 - iii. Mathematics pertaining to the use and measurement of radioactivity;
 - iv. Chemistry of radioactive material for medical use; and
 - v. Radiation biology; and
 - b. Supervised practical experience in a nuclear pharmacy involving:
 - i. Shipping, receiving, and performing related radiation surveys;
 - ii. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
 - iii. Calculating, assaying, and safely preparing dosages for patients or human research subjects;
 - iv. Using administrative controls to avoid medical events in the administration of radioactive material; and
 - v. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and
3. Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subsection (2) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.
4. Is an individual identified as a nuclear pharmacist on an Agency, NRC, or Agreement State license or a permit issued by a Agency, NRC, or Agreement State broad scope licensee or NRC master material license permit or by a NRC master material license permittee of broad scope before the effective date of these rules need not comply with the training requirements in subsections (1) through (3)
5. Has training and experience obtained within the 7 years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

R12-1-713. ~~Dose Calibrators~~ Determination of Prescribed Dosages, and Possession, Use, and Calibration of Instrumentation

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

~~A.~~ A licensee shall determine and record the activity of each dosage before medical use.

~~B.~~ For a unit dosage, this determination shall be made by:

1. Direct measurement of radioactivity; or
2. Decay correction, based on the activity or activity concentration determined by
 - a. A manufacturer or preparer licensed under R12-1-311 or equivalent NRC or Agreement State requirements; or
 - b. An Agency, NRC, or Agreement State licensee for use in research in accordance with a Radioactive Drug

Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA.

- C.** For other than unit dosages, this determination shall be made by:
1. Direct measurement of radioactivity;
 2. Combination of measurement of radioactivity and mathematical calculations; or
 3. Combination of volumetric measurements and mathematical calculations based on the measurement made by a manufacturer or preparer licensed under R12-1-311, or equivalent NRC or Agreement State requirements.
- D.** Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.
- E.** A licensee shall retain a record of the dosage determination required by this Section for agency inspection for three years.
- F.** For direct measurements performed in accordance with subsection (B)(1), a licensee shall possess and use instrumentation to measure the activity of the dosage before it is administered to each patient or human research subject.
- G.** A licensee shall calibrate the instrumentation required in subsection (F) in accordance with nationally recognized standards, the manufacturer's instructions, or the following procedure
1. The procedure that may be followed are:
 - a. Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use;
 - b. Test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least two sealed sources containing different radionuclides whose activity the manufacturer has determined within 5 percent of its stated activity, whose activity is at least 10 microcuries for radium-226 and 50 microcuries for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;
 - c. Test each dose calibrator for linearity upon installation and at least quarterly thereafter over a range from the highest dosage that will be administered to a patient or human research subject to 1.1 megabecquerels (30 microcuries);
 - d. Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.
 - e. Perform appropriate checks and tests required by this Section following adjustment or repair of the dose calibrator; and
 - f. Mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.
 2. A licensee shall maintain the dose calibrator in accordance with this subsection, even though the dose calibrator is only used to "verify" a dosage prepared by a supplier authorized in subsection (B)(2).
 3. A licensee shall maintain on file for Agency review nationally recognized standards or manufacturer's instructions used to maintain a dose calibrator used to meet the requirements in this subsection.
- H.** A licensee shall calibrate the survey instruments before first use, annually, and following a repair that affects the calibration. A licensee shall:
1. Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source;
 2. Calibrate two separated readings on each scale or decade that will be used to show compliance; and
 3. Conspicuously note on the instrument the date of calibration.
- I.** A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.
- J.** A licensee shall retain records of instrument calibration for three years following the calibration.

R12-1-714. Brachytherapy Authorization for Calibration, Transmission, and Reference Sources

- A.** Accountability, storage, and transit.
1. Except as otherwise specifically authorized by the Agency, each licensee shall keep a record of the issue and return of all sealed sources.
 2. When not in use, the licensee shall keep sealed sources and applicators containing sealed sources in a protective enclosure of such material and wall thickness as is necessary to assure compliance with the provisions of 12 A.A.C. 1, Article 4.
 3. Each licensee shall conduct a quarterly physical inventory to account for all brachytherapy sources and devices containing brachytherapy sources received and possessed. Records of the inventories shall be maintained for inspection by the Agency and shall include the quantities and kinds of radioactive material, location of sources and devices, and the date of the inventory.
 4. Each licensee shall follow the radiation safety and handling instructions approved by the Agency; or follow the radiation safety and handling instructions furnished by the manufacturer on the label attached to the brachytherapy source, the device containing a brachytherapy source, the permanent container containing the brachytherapy source, or in the leaflet or brochure which accompanies the brachytherapy source or device, and maintain these such instrue-

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tions in a legible and easily accessible form. If the handling instructions, leaflet, or brochure is no longer available or a copy cannot be obtained from the manufacturer, the Agency shall be notified the source information is no longer available.

5. A physician, transporting a brachytherapy source or applicator containing a brachytherapy source for his or her own use in the practice of medicine, shall transport the brachytherapy source or applicator according to the requirements in 12 A.A.C. 1, Article 15.

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

C. Radiation surveys:

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

D. A qualified expert who meets the following training and experience requirements shall perform all physics procedures necessary to prepare a patient for a therapeutic application of radiation. The qualified expert shall:

1. Be certified by the American Board of Radiology in: Therapeutic Radiological Physics, Radiological Physics, Roentgen-Ray and Gamma-Ray Physics, or X-ray and Radium Physics; or the American Board of Medical Physicists in Radiation Oncology Physics; or
2. Have the following minimum training and experience:
 - a. A Master's or Doctor's degree in physics, biophysics, radiological physics, or health physics;
 - b. One year of full-time training in therapeutic radiological physics; and
 - c. One year of full-time experience at a radiotherapy facility, including personal experience calibrating brachytherapy radiation sources and planning associated patient treatment.
3. A candidate who does not meet the standards in subsections (D)(1) and (D)(2), may request a license amendment for an exemption from these training or experience requirements in accordance with A.R.S. § 30-654(B)(13). The request shall include the name of the proposed qualified expert, a description of the individual's training and experience, including information similar to that specified in subsection (D)(2), and a written endorsement, based on personal knowledge of the individual's qualifications, by a physicist certified by the American Board of Radiology in one of the specialties listed in subsection (D)(1).

E. Signs and records:

1. In addition to the requirements in R12-1-429, the licensee shall mark the bed, cubicle or room of the hospital brachytherapy patient with a sign indicating the presence of brachytherapy sources. This sign shall incorporate the radiation symbol and specify the radionuclide, activity, date, and individual to contact for radiation safety instructions. The sign is not required if any of the exceptions in R12-1-430 apply.
2. A physician on a radioactive material license, qualified expert, or person approved by the licensee's radiation safety officer shall include the following information in the patient's records when the patient is undergoing brachytherapy:
 - a. The radionuclide administered, the number of sources, the activity in millicuries, and the time and date of administration;
 - b. The exposure or dose rate at 1 meter, the time the measurement was made, and by whom;
 - c. The radiation symbol; and
 - d. The precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted in Article 4.

Any person authorized by R12-1-703 for medical use of radioactive material may receive, possess, and use any of the following radioactive material for check, calibration, transmission, and reference use.

1. Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under Article 3 of this Chapter or equivalent NRC or Agreement State regulations.
2. Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under Article 3 of this Chapter, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.
3. Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).
4. Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 µCi) or 1000 times the quantities in Article 4, Appendix B of this Chapter.

5. Technetium-99m in amounts as needed.
6. A licensee is limited to five sources of radiation authorized under subsections (1) through (3), unless otherwise specified in the licensee's radioactive material license.

R12-1-715. ~~Reserved~~ Requirements for Possession of Sealed Sources and Brachytherapy Sources

- A.** A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.
- B.** A licensee in possession of a sealed source shall test the source for leakage in accordance with R12-1-417.
- C.** A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a physical inventory every 6 months of all sources in its possession. During the period of time between the inventories, the licensee shall add each acquired sealed source to the inventory record and remove from the inventory record each source that leaves the licensee's control.
- D.** A licensee shall document the inventories conducted under subsection (C) and maintain inventory records in accordance with R12-1-450.

R12-1-716. ~~Teletherapy~~ Surveys of Ambient Radiation Exposure Rate, Surveys for Contamination, and PET Radiation Exposure Concerns

- A.** ~~A licensee shall use equipment that meets all of the following specifications:~~
 1. ~~The teletherapy equipment housing is constructed so that, at 1 meter (40 in.) from the teletherapy source, the maximum exposure rate does not exceed 100 μ Sv (10 mrem) per hour when the beam control mechanism is in the "off" position. The average exposure rate measure at a representative number of points about the housing, each 1 meter (40 in.) from the teletherapy source, does not exceed .20 μ Sv (2 mrem) per hour 1 meter (40 in.) from the source.~~
 2. ~~For teletherapy equipment installed after May 15, 1967, the leakage radiation measured at 1 meter from the source when the beam control mechanism is in the "on" position does not exceed 260 μ C/kg (1 R) per hour or 0.1 percent of the useful beam exposure rate, whichever is less.~~
 3. ~~Adjustable or removable beam defining diaphragms allow transmission of not more than 5% of the useful beam exposure rate.~~
 4. ~~The beam control mechanism is of a design capable of acting in any orientation of the housing. The mechanism is designed so that it can be manually returned to the "off" position with a minimum risk of exposure.~~
 5. ~~The closing device is designed to return automatically to the "off" position in the event of any breakdown or interruption of power and stays in the "off" position until activated from the control panel.~~
 6. ~~When any door to the treatment room is opened, the beam control mechanism automatically and rapidly restores the unit to the "off" position and causes it to remain there until the unit is reactivated from the control panel.~~
 7. ~~There is at the housing and at the control panel a warning device that plainly indicates whether the beam is on or off and an independent radiation monitoring device which:
 - a. ~~Continuously monitors the condition of the teletherapy beam and~~
 - b. ~~Provides a continuously visible signal to the operator.~~~~
 8. ~~The equipment has a locking device to prevent unauthorized use.~~
 9. ~~The control panel has a timer that automatically terminates the exposure after a preset time.~~
 10. ~~The equipment permits continuous observation of patients during irradiation.~~
- B.** ~~The authorized user shall ensure that no individual is in the treatment room during irradiation unless that individual is the patient. Mechanical restraining or supporting devices shall be used for positioning the patient, if necessary.~~
- C.** ~~The licensee shall test the teletherapy sources for leakage and contamination as required in R12-1-417. The licensee shall also wipe accessible surfaces of the housing port or collimator while the source is in the "off" position, measuring the wipe samples for transferred contamination.~~
- D.** ~~Calibration requirements:~~
 1. ~~The licensee's expert, qualified by training and experience under subsection (G), shall perform full calibration measurements on each teletherapy unit:
 - a. ~~Prior to the first use of the unit for treating humans.~~
 - b. ~~Prior to treating humans:
 - i. ~~Whenever spot check measurements indicate that the output value differs by more than 5% from the value obtained at the last full calibration, corrected mathematically for decay;~~
 - ii. ~~Following replacement of the radiation source or following reinstallation of the teletherapy unit in a new location; or~~
 - iii. ~~Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and~~~~
 - e. ~~At intervals not exceeding one year.~~~~
 2. ~~Full calibration measurements include determination of:
 - a. ~~The exposure or dose rate, to an accuracy within +/- 3% for the range of field sizes and for the range of distances~~~~

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- or the axis distance used in radiation therapy;
 - b. The congruence between the radiation field and the field indicated by the light beam localizing device;
 - e. The uniformity of the radiation field and its dependence upon the orientation of the useful beam;
 - d. Timer accuracy; and
 - e. The accuracy of all distance measuring devices used for treating humans.
 - 3. Reserved.
 - 4. The expert shall correct the exposure rate or dose rate values mathematically for intervals not exceeding one month.
 - E.** Spot check measurements:
 - 1. The licensee's expert or other authorized agent shall perform spot check measurements on each teletherapy unit at intervals not exceeding one month.
 - 2. Spot check measurements shall include determination of:
 - a. Timer accuracy;
 - b. The congruence between the radiation field and the field indicated by the light beam localizing device;
 - e. The accuracy of all distance measuring devices used for treating humans;
 - d. The exposure rate dose or a quantity related to this rate for one typical set of operating conditions; and
 - e. The difference between the measurement made and the anticipated output, expressed as a percentage of the anticipated output (for example, the value obtained at last full calibration corrected mathematically for decay).
 - 3. The expert shall establish spot check measurement procedures. If the expert does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by the expert within 15 days.
 - F.** Dosimetry systems:
 - 1. The licensee's expert shall perform full calibration measurements using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system shall have been calibrated within the previous two years and after any servicing that may have affected system calibration.
 - 2. Spot check measurements shall be performed using a dosimetry system that has been calibrated as required in subsection (F)(1). Alternatively a dosimetry system used solely for spot check measurements may be calibrated by direct intercomparison with a system that has been calibrated according to the standards in subsection (F)(1). This alternative calibration method shall have been performed within the previous one year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.
 - G.** The licensee shall determine if a person is an expert, qualified by training and experience to calibrate a teletherapy unit, establish procedures for spot check measurements, and review the results of such measurements. The licensee shall determine that the qualified expert:
 - 1. Is certified by the American Board of Radiology in: Therapeutic Radiological Physics, Radiological Physics, Roentgen-Ray and Gamma-Ray Physics, or X-ray and Radium Physics; or the American Board of Medical Physicists in Radiation Oncology Physics; or
 - 2. Has the following minimum training and experience:
 - a. A Master's or Doctor's degree in physics, biophysics, radiological physics or health physics;
 - b. One year of full time training in therapeutic radiological physics; and
 - e. One year of full-time experience in radiotherapy facility, including personal calibration and spot check of at least one teletherapy unit.
 - 3. Licensees, that have their teletherapy units calibrated by persons who do not meet the criteria in subsections (G)(1) and (2) for minimum training experience, may request a license amendment exempting them from these training requirements. The request should include the name of the proposed qualified expert, a description of the expert's training and experience, including information similar to that specified in subsection (G)(2), reports of at least one calibration and one spot check, based on measurements personally made by the proposed expert within the last 10 years, and a written endorsement of the expert's qualifications by a physicist certified by the American Board of Radiology in one of the specialties listed in subsection (G)(1), based on personal knowledge.
 - H.** The licensee shall maintain for inspection by the Agency: records of measurements, tests, corrective actions, and instrument calibrations made under subsections (D) and (E), and records of the licensee's evaluation of the qualified expert's training and experience under subsection (G).
 - 1. The licensee shall preserve records of the following for three years after completion of each full calibration:
 - a. Full calibration measurements; and
 - b. Calibration of the instruments used to make the full calibration measurements.
 - 2. The licensee shall preserve records of the following for three years after completion of each spot check:
 - a. Spot check measurements and corrective actions; and
 - b. Calibration of instruments used to make spot check measurements.
 - 3. The licensee shall preserve records of the licensee's evaluation of the qualified expert's training and experience for three years after the qualified expert's last performance of a full calibration on the licensee's teletherapy unit.

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- A. In addition to the surveys required in Article 4 of this Chapter, a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where unsealed radioactive material, requiring a written directive, is prepared for use or is administered. In areas of routine use, that are released for unrestricted use, a licensee shall perform a survey of the area using an instrument appropriate for detecting contamination before releasing the area for unrestricted use.
- B. A licensee shall obtain the services of a person experienced in the principles of radiation protection and installation design, to design a PET facility and to perform a radiation survey when the facility is ready for patient imaging. The licensee shall provide a copy of the installation radiation survey to the Agency within 30 days of imaging the first patient.
- C. The licensee shall use engineering controls or shield each PET use area with protective barriers necessary to comply with the radiation exposure limits in R12-1-408 and R12-1-416.
 - 1. At the time of application for a new license or amendment to an existing license, and before imaging of the first patient, the licensee shall provide to the Agency a copy of the installation report signed by the contractor who installed the shielding material recommended by the consultant and a report of the survey required in subsection (B).
 - 2. The licensee shall perform shielding calculations in accordance with *AAPM Task Group on PET and PET/CT Shielding Requirements*, which is incorporated by reference, published by the American Association of Physicists in Medicine, One Physics Ellipse, College Park, MD 20740, and on file with the Agency. This incorporation by reference contains no future editions or amendments. In lieu of these procedures, the licensee may use equivalent calculations approved by the Agency.
- D. As part of the annual ALARA review required in R12-1-407, the licensee shall document a review of the PET patient workload and associated change, if any, in public exposure resulting from the installed facility shielding and other public radiation exposure controls in use at the time of the review.

R12-1-717. ~~High Dose Rate Remote After-loading Brachytherapy Devices~~ Release of Individuals Containing Radioactive Material

- ~~A. Each after loading irradiation facility shall have a system permitting continuous observation of the patient from outside the treatment room during patient irradiation.~~
- ~~B. The licensee shall post written emergency instructions at the after-loading irradiation device operator console. These instructions shall inform the device operator of the procedures to be followed if the source fails to return to the shielded position.~~
- ~~C. The licensee shall ensure that the after-loading irradiator facility has the following:~~
 - ~~1. Access to the room housing the after loading irradiation device is controlled by a door at the entrance. The doors are normally closed.~~
 - ~~2. The entrance to the treatment room is equipped with an electrical interlock system that will cause the source to return to the shielded position immediately if the entrance door is opened. The interlock system is connected in such a manner that the source cannot be exposed until the entrance door is closed and the source "on-off" control is reset at the control panel.~~
- ~~D. The licensee shall test the following for proper operation once each month. Records of test results shall be maintained for three years for inspection by the Agency:~~
 - ~~1. The electrical interlock on the entrance door to the treatment room, and~~
 - ~~2. The radiation source locking system.~~
- ~~E. In the event of malfunction of a door interlock or source locking system, the licensee shall secure from use the after-loading irradiation device and not use the after-loading, except as may be necessary to repair or replace the interlock system, until the interlock system is shown to be functioning properly.~~
- ~~F. Before initiation of a treatment program, and after each source exchange for the after-loading device:~~
 - ~~1. The licensee shall perform radiation surveys of the following locations:~~
 - ~~a. The after loading device source housing, with the source in the shielded position. The maximum radiation level at 20 centimeters from the surface of the source housing shall not exceed 3 milliroentgens per hour.~~
 - ~~b. All areas adjacent to the treatment room with the source in the exposed position. The survey shall clearly establish:~~
 - ~~i. That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in R12-1-408 and R12-1-414.~~
 - ~~ii. That radiation levels in unrestricted areas do not exceed the limits specified in R12-1-416.~~
 - ~~iii. The activity of the source, using an Agency approved procedure and a calibrated Farmer chamber, or equivalent.~~
 - ~~2. The licensee shall retain records of the radiation surveys for three years for inspection by the Agency.~~
- ~~G. A person shall not perform the following work without written authorization by the Agency:~~
 - ~~1. Installation and replacement of sources contained in an after-loading irradiation device; or~~
 - ~~2. Any maintenance or repair operation on the after-loading irradiation device involving work on the source driving unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the~~

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safety of the unit and result in increased radiation levels.

- H.** Before making any changes to treatment room shielding, treatment room location, or use of the after-loading irradiation device which could result in an increase in radiation levels in unrestricted areas outside the treatment room, the licensee shall perform a radiation survey according to subsection (F)(1). A report describing each change, and giving the results of each survey shall be sent to the Agency.
- I.** A qualified expert who meets the following training and experience requirements shall perform all physics procedures necessary to prepare a patient for a therapeutic application of radiation. The qualified expert shall:
 1. Be certified by the American Board of Radiology in: Therapeutic Radiological Physics, Radiological Physics, Roentgen Ray and Gamma Ray Physics, or X ray and Radium Physics; or the American Board of Medical Physicists in Radiation Oncology Physics; or
 2. Have the following minimum training and experience:
 - a. A Master's or Doctor's degree in physics, biophysics, radiological physics, or health physics;
 - b. One year of full-time training in therapeutic radiological physics; and
 - c. One year of full-time experience at a radiotherapy facility, including personal experience calibrating brachytherapy radiation sources and planning associated patient treatment.
 3. A candidate who does not meet the standards in subsections (I)(1) and (I)(2), may request a license amendment for an exemption from these training or experience requirements in accordance with A.R.S. § 30-654(B)(13). The request should include the name of the proposed qualified expert, a description of the individual's training and experience, including information similar to that specified in subsection (I)(2), and a written endorsement, based on personal knowledge of the individual's qualifications, by a physicist certified by the American Board of Radiology in one of the specialties listed in subsection (I)(1).
- A.** A licensee may authorize the release from its control any individual who has been administered unsealed radioactive material or implants containing radioactive material, if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).
- B.** A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include:
 1. Guidance on the interruption or discontinuation of breast-feeding; and
 2. Information on the potential consequences, if any, of failure to follow the guidance.
- C.** A licensee shall maintain a record of the basis for authorizing the release of an individual and instructions given to a breast feeding female for 3 years from the date of the administration performed under subsection (A). Nothing in this rule relieves the licensee from the personnel exposure requirements in Article 4.

R12-1-718. Gamma Stereotactic Radiosurgery Mobile Medical Service

- A.** A licensee shall provide the manufacturer's written radiological safety and operating instructions to each person responsible for operation of a stereotactic radiosurgery system.
- B.** A person licensed by the Agency shall install the stereotactic radiosurgery system and perform all service and maintenance involving exposure to persons in the treatment room beyond normal "Beam off" conditions.
- C.** In lieu of a direct source inventory, the licensee shall perform an indirect source inventory through completion of absolute calibrations of the radiation dose rate at the intersection of all beam axes of the radiosurgery radiation unit on a six-month basis. The magnitude of this dose rate shall be compared with the appropriately decayed value of the initial or acceptance date, calibrated dose rate at the intersection of all beam axes. This measured dose rate serves as verification that all sources inserted into the gamma knife are still present.
- D.** A licensee shall ensure that a stereotactic radiosurgery facility has the following safeguards:
 1. Access to the radiosurgery room is controlled by a door at each entrance. The doors are normally closed.
 2. Each entrance to the radiosurgery room is equipped with an electrical interlock system that will turn the unit's primary beam of radiation off immediately if any entrance door is opened. The interlock system is connected in such a manner that the machine's primary beam of radiation cannot be turned on until all treatment room entrance doors are closed and the beam "ON-OFF" control is reset at the control panel.
 3. In the event of malfunction of any door interlock, the radiosurgery system control is locked in the "OFF" position and not used, except as may be necessary to the repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.
 4. The radiosurgery room has a system permitting continuous observation of the patient from outside the radiosurgery room during patient irradiation.
 5. Written instructions, including the manufacturer's radiological safety and operating procedures, are available at the stereotactic radiosurgery controls. These instructions inform the operator of the procedure to be followed in the event of malfunction. These instructions caution individuals on how to avoid exposure to radiation in the treatment room

- and include specific instructions for:
 - a. Removing the patient from the treatment room;
 - b. Securing the room against unauthorized entry; and
 - e. Notifying the responsible physician or radiation safety officer.
- E.** The licensee shall test electrical interlocks on entrance doors to the radiosurgery room for proper operation at least once every three months. Records of test results shall be maintained for inspection by the Agency.
- F.** The licensee shall cease treatment of patients with the therapy unit if a safety related system of the unit is found inoperative, including couch or helmet drive mechanisms, positioning mechanisms, treatment timing systems, safety interlocks, or radiation field alarms.
- G.** Before initiation of a treatment program, and after each installation of radiosurgery sources:
 - 1. The licensee shall perform radiation surveys of the following locations:
 - a. The radiosurgery system source housing. The maximum and average radiation levels at 1 meter from the nearest source with the device's shielding door closed, shall not exceed 10 milliroentgens per hour and 2 milliroentgens per hour, respectively, for any of the device's sources, when all sources are installed.
 - b. Unrestricted areas adjacent to the treatment room, with the device's shielding door open. The survey shall be performed with a phantom in the primary beam of radiation and shall clearly establish that radiation levels in restricted and unrestricted areas do not exceed the limits specified in 12 A.A.C. 1, Article 4.
 - 2. The licensee shall test the following safety equipment:
 - a. Electrical interlocks on entrance doors to the therapy treatment room;
 - b. The therapy source "ON-OFF" indicators, both at the source housing and on the system control panel; and
 - e. The radiosurgery system treatment timing device.
- H.** After any changes made in treatment room shielding, treatment room location, or use of the stereotactic radiosurgery system which could result in an increase in radiation levels in unrestricted areas outside of the therapy treatment room, the licensee shall conduct a radiation survey according to subsection (G). A report describing the changes and giving the survey results shall be sent to the Agency no later than 30 days following completion of the changes.
- I.** A qualified expert who meets the following training and experience requirements shall perform all physics procedures necessary to prepare a patient for a therapeutic application of radiation. The qualified expert shall:
 - 1. Be certified by the American Board of Radiology in: Therapeutic Radiological Physics, Radiological Physics, Roentgen-Ray and Gamma-Ray Physics, or X-ray and Radium Physics; or the American Board of Medical Physicists in Radiation Oncology Physics; or
 - 2. Have the following minimum training and experience:
 - a. A Master's or Doctor's degree in physics, biophysics, radiological physics, or health physics;
 - b. One year of full time training in therapeutic radiological physics; and
 - e. One year of full time experience at a radiotherapy facility, including personal experience calibrating a gamma stereotactic radiosurgery system and planning associated patient treatment.
 - 3. A candidate who does not meet the standards in subsections (I)(1) and (I)(2), may request a license amendment for an exemption from these training or experience requirements in accordance with A.R.S. § 30-654(B)(13). The request should include the name of the proposed qualified expert, a description of the individual's training and experience, including information similar to that specified in subsection (I)(2), and a written endorsement, based on personal knowledge of the individual's qualifications, by a physicist certified by the American Board of Radiology in one of the specialties listed in subsection (I)(1).
- A.** A licensee providing mobile medical service shall:
 - 1. Obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client.
 - 2. Check instruments used to measure the activity of unsealed Radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph shall include a constancy check.
 - 3. Check survey instruments for proper operation with a dedicated check source before use at each client's address; and
 - 4. Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in Article 4 of this Chapter.
- B.** A mobile medical service may not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a license allowing its possession. If applicable, radioactive material delivered to the client shall be received and handled in conformance with the client's license.
- C.** A licensee providing mobile medical services shall retain the letter required in subsection (A)(1) and the record of each survey required in subsection (A)(4) for 3 years from the date of the recording.

R12-1-719. Release of Individuals Containing Radiopharmaceuticals or Radioactive Sealed Sources from Restricted Areas Training for Uptake, Dilution, and Excretion Studies

- A.** A licensee may authorize the release of any individual who has received radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem) or an amount specified in license conditions.
- B.** The licensee shall provide the released individual with oral and written instructions, on recommended actions that will make doses to other individuals as low as is reasonably achievable, if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem).
- C.** The licensee shall maintain a record of the criteria used to authorize the release of an individual containing radioactive material. The record shall be maintained for three years after the date of release if the total effective dose equivalent is calculated by using:
 - 1. The retained activity rather than the activity administered;
 - 2. An occupancy factor of less than 0.25 at 1 meter;
 - 3. The biological or effective half-life; or
 - 4. The shielding by tissue.
- A.** Except as provided in R12-1-710, each licensee shall require an authorized user of unsealed radioactive material for the uses authorized under Group 100 to be a physician who has completed the training requirements in 10 CFR 35.190, January 1, 2006, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.
- B.** The training and experience shall have been obtained within the 7 years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

R12-1-720. Decay in Storage Permissible Molybdenum-99 Concentrations

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

- A.** A licensee may not administer to humans a radiopharmaceutical that contains more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m).
- B.** A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with subsection (A).
- C.** A licensee shall maintain a record of each molybdenum-99 concentration measurement for 3 years following completion of the measurement.

R12-1-721. Training for Imaging and Localization Studies Not Requiring a Written Directive

- A.** Except as provided in R12-1-710, a licensee shall require an authorized user of unsealed radioactive material for the uses authorized under Group 200 to be a physician who has completed the training requirements in 10 CFR 35.290, January 1, 2006, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.
- B.** An authorized user candidate that is a cardiologist, is limited to nuclear cardiology if the candidate is unable to provide proof that he or she has participated in 700 hours of training and experience, required in 10 CFR 35.290(c).
- C.** The training and experience shall have been obtained within the 7 years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

R12-1-722. Safety Instruction and Precautions for Use of Unsealed Radioactive Material Requiring a Written Directive

- A.** A licensee shall provide radiation safety instruction, initially and at least annually, for all personnel caring for the patient or the human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with R12-1-717. To satisfy this requirement, the instruction shall describe the licensee's procedures for:
 - 1. Patient or human research subject control;
 - 2. Visitor control;
 - 3. Contamination control;
 - 4. Waste control; and
- B.** For each patient or human research subject who cannot be released under R12-1-717, a licensee shall:
 - 1. Quarter the patient or the human research subject in a private room with a private sanitary facility;
 - 2. Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign.
 - 3. Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and
 - 4. Monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey

instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste.

- C. A licensee shall notify the Radiation Safety Officer, or his or her designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.
- D. A licensee shall retain records of instruction and safety procedures performed under this rule for 3 years from the date of the activity.

R12-1-723. Training for Use of Unsealed Radioactive Material Requiring a Written Directive, Including Treatment of Hyperthyroidism, and Treatment of Thyroid Carcinoma

- A. Except as provided in R12-1-710, a licensee shall require an authorized user of unsealed radioactive material for the uses authorized under Group 300 to be a physician who has completed the training requirements in 10 CFR 35.390, January 1, 2006, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.
- B. Except as provided in R12-1-710, a licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician who has completed the training requirements in 10 CFR 35.392, January 1, 2006, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.
- C. Except as provided in R12-1-710, a licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician who has completed the training requirements in 10 CFR 35.394, January 1, 2006, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.
- D. The training and experience shall have been obtained within the 7 years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

R12-1-724. Surveys after Brachytherapy Source Implant, Removal, and Accountability

- A. A licensee shall make a survey to locate and account for all sources that have not been implanted immediately after implanting sources in a patient or a human research subject.
- B. A licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument immediately after removing the last temporary implant source to confirm that all sources have been removed.
- C. A licensee shall maintain accountability at all times for all sources in storage or use.
- D. A licensee shall return brachytherapy sources to a secure storage area as soon as possible after removing sources from a patient or a human research subject.
- E. A licensee shall record the procedures performed in subsections (A) through (D) and retain the records for 3 years following completion of the record.

R12-1-725. Safety Instructions and Precautions for Brachytherapy Patients that Cannot be Released Under R12-1-717

- A. In addition to the training requirements in Article 10, a licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under R12-1-717. To satisfy this requirement, the instruction shall be commensurate with the duties of the personnel and include the:
 - 1. Size and appearance of the brachytherapy sources;
 - 2. Safe handling and shielding instructions;
 - 3. Patient or human research subject control;
 - 4. Visitor control, including both:
 - a. Routine visitation of hospitalized individuals in accordance with Article 4 of this Chapter
 - b. Visitation authorized in accordance with Article 4 of this Chapter; and
 - 5. Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.
- B. For each patient or human research subject who is receiving brachytherapy and cannot be released under R12-1-717, a licensee shall:
 - 1. Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy;
 - 2. Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and
 - 3. Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

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- C. A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:
 - 1. Dislodged from the patient; and
 - 2. Lodged within the patient following removal of the source applicators.
- D. A licensee shall notify the Radiation Safety Officer, or the RSO's designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.
- E. A licensee shall record the instructions given under subsections (A) and retain the records for 3 years after recording the instruction.

R12-1-726. Calibration Measurements of Brachytherapy Sources, Decay of Sources Used for Ophthalmic Treatments, and Computerized Treatment Planning Systems

- A. Before the first medical use of a brachytherapy source after the effective date of this rule, a licensee shall have:
 - 1. Determined the source output or activity using a dosimetry system that meets the requirements of R12-1-733(A);
 - 2. Determined source positioning accuracy within applicators; and
 - 3. Used published protocols currently accepted by nationally recognized bodies to meet the requirements of subsection (A)(1) and (2).
- B. A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with subsection (A).
- C. A licensee shall mathematically correct the outputs or activities determined in subsection (A) for physical decay at intervals consistent with 1 percent physical decay.
- D. Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay shall be based on the activity determined under subsection (A).
- E. A licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of:
 - 1. The source-specific input parameters required by the dose calculation algorithm;
 - 2. The accuracy of dose, dwell time, and treatment time calculations at representative points;
 - 3. The accuracy of isodose plots and graphic displays; and
 - 4. The accuracy of the software used to determine sealed source positions from radiographic images.
- F. A licensee shall retain records of each source activity determination and ophthalmic source decay correction, and documentation of the acceptance testing protocol required under subsection (E) for 3 years after the date of the procedure required in subsections (A) and (D), and for the records created in conjunction with subsection (E) the record shall be maintained for 3 years from the last date of the protocol's use.

R12-1-727. Training for Use of Manual Brachytherapy Sources and Training for the Use of Strontium-90 Sources for Treatment of Ophthalmic Disease

- A. Except as provided in R12-1-710, a licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under Group 400 to be a physician who has completed the training requirements in 10 CFR 35.490, January 1, 2006, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.
- B. Except as provided in R12-1-710, a licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who has completed the training requirements in 10 CFR 35.491, January 1, 2006, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.
- C. The training and experience shall have been obtained within the 7 years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

R12-1-728. Training for Use of Sealed Sources for Diagnosis

- A. Except as provided in R12-1-710, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under Group 500 to be a physician who has completed the training requirements in 10 CFR 35.500, January 1, 2006, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.
- B. The training and experience shall have been obtained within the 7 years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

R12-1-729. Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit

- A. Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the

human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.

- B.** A licensee shall make records of these surveys conducted under subsection (A) and retain them for 3 years from the date of each survey.

R12-1-730. Installation, Maintenance, Adjustment, and Repair of an Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit

- A.** Only a person specifically licensed by the Agency, NRC, or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).
- B.** Except for low dose-rate remote afterloader units, only a person specifically licensed by the Agency, NRC, or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.
- C.** For a low dose-rate remote afterloader unit, only a person specifically licensed by the Agency, NRC, or an Agreement State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.
- D.** A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units for 3 years from the completion date of the activity listed in this subsection.

R12-1-731. Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

- A.** A licensee shall:
1. Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;
 2. Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);
 3. Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and
 4. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures shall include:
 - a. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
 - b. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
 - c. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.
- B.** A licensee shall post instructions at the unit console to inform the operator of:
1. The location of the procedures required by subsection (A)(4); and
 2. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.
- C.** A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:
1. The procedures identified in subsection (A)(4); and
 2. The operating procedures for the unit.
- D.** A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.
- E.** A licensee shall retain a record of individuals receiving instruction required by subsection (C) for 3 years from the date of the instruction.
- F.** A licensee shall retain a copy of the procedures required by subsection (A)(4) and (C)(2) for Agency review. The copy shall be maintained for 3 years beyond the termination date of the activities for which the procedures were written.

R12-1-732. Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

- A.** A licensee shall control access at each entrance to a treatment room.
- B.** A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:
1. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
 2. Cause the source(s) to be shielded when an entrance door is opened; and
 3. Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.
- C.** A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation

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monitors, that radiation levels have returned to ambient levels.

- D.** Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.
- E.** For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.
- F.** In addition to the requirements specified in subsections (A) through (E), a licensee shall:
 - 1.** For medium dose-rate and pulsed dose-rate remote afterloader units, require:
 - a.** An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during the initiation of all patient treatments involving the unit; and
 - b.** An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.
 - 2.** For high dose-rate remote afterloader units, require:
 - a.** An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and
 - b.** An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.
 - 3.** For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit. As used in this provision, physically present means to be within hearing distance of normal voice, and does not include the use of portable communication devices, intercoms, or other devices that could be used to amplify human voice.
 - 4.** Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.
- G.** A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:
 - 1.** Remaining in the unshielded position; or
 - 2.** Lodged within the patient following completion of the treatment.

R12-1-733. Dosimetry Equipment

- A.** Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:
 - 1.** The system shall have been calibrated using a system or source traceable to the National Institute of Science and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration shall have been performed within the previous 2 years and after any servicing that may have affected system calibration; or
 - 2.** The system shall have been calibrated within the previous 4 years. Eighteen to thirty months after that calibration, the system shall have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison shall indicate that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.
- B.** The licensee shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with subsection (A). This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in subsection (A).
- C.** The licensee shall retain, for 3 years from the date of the procedure, a record of each calibration, intercomparison, and comparison.

R12-1-734. Full Calibration Procedures on Teletherapy Units

- A.** A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:
 - 1.** Before the first medical use of the unit; and
 - 2.** Before medical use under the following conditions:
 - a.** Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output

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- obtained at the last full calibration corrected mathematically for radioactive decay;
 - b. Following replacement of the source or following reinstallation of the teletherapy unit in a new location;
 - c. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
- 3. At intervals not exceeding 1 year.
- B.** To satisfy the requirement of subsection (A), full calibration measurements shall include determination of:
 - 1. The output within +/-3 percent for the range of field sizes and for the distance or range of distances used for medical use;
 - 2. The coincidence of the radiation field and the field indicated by the light beam localizing device;
 - 3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;
 - 4. Timer accuracy and linearity over the range of use;
 - 5. On-off error; and
 - 6. The accuracy of all distance measuring and localization devices in medical use.
- C.** A licensee shall use the dosimetry system described in R12-1-733(A) to measure the output for one set of exposure conditions. The remaining radiation measurements required in subsection (B)(1) may be made using a dosimetry system that indicates relative dose rates.
- D.** A licensee shall make full calibration measurements required by subsection (A) in accordance with published protocols accepted by nationally recognized bodies.
- E.** A licensee shall mathematically correct the outputs determined in subsection (B)(1) for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.
- F.** Full calibration measurements required by subsection (A) and physical decay corrections required by subsection (E) shall be performed by the authorized medical physicist.
- G.** A licensee shall retain a record of each calibration for 3 years from the date it was completed.

R12-1-735. Full Calibration Measurements on Remote Afterloader Units

- A.** A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:
 - 1. Before the first medical use of the unit;
 - 2. Before medical use under the following conditions:
 - a. Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
 - b. Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
 - 3. At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and
 - 4. At intervals not exceeding 1 year for low dose-rate remote afterloader units.
- B.** To satisfy the requirement of subsection (A), full calibration measurements shall include, as applicable, determination of:
 - 1. The output within ± 5 percent;
 - 2. Source positioning accuracy to within ± 1 millimeter;
 - 3. Source retraction with backup battery upon power failure;
 - 4. Length of the source transfer tubes;
 - 5. Timer accuracy and linearity over the typical range of use;
 - 6. Length of the applicators; and
 - 7. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.
- C.** A licensee shall use the dosimetry system described in R12-1-733(A) to measure the output.
- D.** A licensee shall make full calibration measurements required by subsection (A) in accordance with published protocols accepted by nationally recognized bodies.
- E.** In addition to the requirements for full calibrations for low dose-rate remote afterloader units in subsection (B), a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.
- F.** For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with subsection (A) through (E).
- G.** A licensee shall mathematically correct the outputs determined in subsection (B)(1) for physical decay at intervals consistent with 1 percent physical decay.
- H.** Full calibration measurements required by subsection (A) and physical decay corrections required by subsection (G) shall be performed by the authorized medical physicist.
- I.** A licensee shall retain a record of each calibration for 3 years from the date it was completed.

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R12-1-736. Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units

- A.** A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:
1. Before the first medical use of the unit;
 2. Before medical use under the following conditions:
 - a. Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
 - b. Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and
 - c. Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and
 3. At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.
- B.** To satisfy the requirement of subsection (A), full calibration measurements shall include determination of:
1. The output within ± 3 percent;
 2. Relative helmet factors;
 3. Isocenter coincidence;
 4. Timer accuracy and linearity over the range of use;
 5. On-off error;
 6. Trunnion centricity;
 7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
 8. Helmet microswitches;
 9. Emergency timing circuits; and
 10. Stereotactic frames and localizing devices (trunnions).
- C.** A licensee shall use the dosimetry system described in R12-1-733(A) to measure the output for one set of exposure conditions. The remaining radiation measurements required in subsection (B)(1) may be made using a dosimetry system that indicates relative dose rates.
- D.** A licensee shall make full calibration measurements required by subsection (A) in accordance with published protocols accepted by nationally recognized bodies.
- E.** A licensee shall mathematically correct the outputs determined in subsection (B)(1) at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.
- F.** Full calibration measurements required by subsection (A) and physical decay corrections required by subsection (E) shall be performed by the authorized medical physicist.
- G.** A licensee shall retain a record of each calibration for 3 years from the date of the procedure.

R12-1-737. Periodic Spot-checks for Teletherapy Units

- A.** A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:
1. Timer accuracy, and timer linearity over the range of use;
 2. On-off error;
 3. The coincidence of the radiation field and the field indicated by the light beam localizing device;
 4. The accuracy of all distance measuring and localization devices used for medical use;
 5. The output for one typical set of operating conditions measured with the dosimetry system described in R12-1-733(B); and
 6. The difference between the measurement made in subsection (A)(5) and the anticipated output, expressed as a percentage of the anticipated output.
- B.** A licensee shall perform measurements required by subsection (A) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.
- C.** A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.
- D.** A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:
1. Electrical interlocks at each teletherapy room entrance;
 2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);
 3. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
 4. Viewing and intercom systems;
 5. Treatment room doors from inside and outside the treatment room; and
 6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

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- E. If the results of the checks required in subsection (D) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
- F. A licensee shall retain a record of each spot-check required by subsections (A) and (D) for 3 years from the date of the procedure, and a copy of the procedures required by subsection (B) until licensee terminates all medical activities involving the teletherapy unit.

R12-1-738. Periodic Spot-checks for Remote Afterloader Units

- A. A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit:
 - 1. Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;
 - 2. Before each patient treatment with a low dose-rate remote afterloader unit; and
 - 3. After each source installation.
- B. A licensee shall perform the measurements required by subsection (A) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.
- C. A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.
- D. To satisfy the requirements of subsection (A), spot-checks shall, at a minimum, assure proper operation of:
 - 1. Electrical interlocks at each remote afterloader unit room entrance;
 - 2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
 - 3. Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;
 - 4. Emergency response equipment;
 - 5. Radiation monitors used to indicate the source position;
 - 6. Timer accuracy;
 - 7. Clock (date and time) in the unit's computer; and
 - 8. Decayed source(s) activity in the unit's computer.
- E. If the results of the checks required in subsection (D) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
- F. A licensee shall retain a record of each spot-check required by subsections (A) and (D) for 3 years from the date of the procedure, and a copy of the procedures required by subsection (B) until licensee terminates all medical activities involving the afterloader unit.

R12-1-739. Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units

- A. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:
 - 1. Monthly;
 - 2. Before the first use of the unit on a given day; and
 - 3. After each source installation.
- B. A licensee shall:
 - 1. Perform the measurements required by subsection (A) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.
 - 2. Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.
- C. To satisfy the requirements of subsection (A)(1), spot-checks shall, at a minimum:
 - 1. Assure proper operation of:
 - a. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
 - b. Helmet microswitches;
 - c. Emergency timing circuits; and
 - d. Stereotactic frames and localizing devices (trunnions).
 - 2. Determine:
 - a. The output for one typical set of operating conditions measured with the dosimetry system described in R12-1-733(B);
 - b. The difference between the measurement made in subsection (C)(2)(i) and the anticipated output, expressed as a percentage of the anticipated output;
 - c. Source output against computer calculation;
 - d. Timer accuracy and linearity over the range of use;
 - e. On-off error; and

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- f. Trunnion centricity.
- D.** To satisfy the requirements of subsections (A)(2) and (A)(3), spot-checks shall assure proper operation of:
1. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
 2. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
 3. Viewing and intercom systems;
 4. Timer termination;
 5. Radiation monitors used to indicate room exposures; and
 6. Emergency off buttons.
- E.** A licensee shall arrange for the repair of any system identified in subsection (C) that is not operating properly as soon as possible.
- F.** If the results of the checks required in subsection (D) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
- G.** A licensee shall retain a record of each check required by subsections (C) and (D) for 3 years from the date of the procedure, and a copy of the procedures required by subsection (B) until licensee terminates all medical activities involving the radiosurgery unit.

R12-1-740. Additional Requirements for Mobile Remote Afterloader Units

- A.** A licensee providing mobile remote afterloader service shall:
1. Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and
 2. Account for all sources before departure from a client's address of use.
- B.** In addition to the periodic spot-checks required by R12-1-738, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks shall be made to verify the operation of:
1. Electrical interlocks on treatment area access points;
 2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
 3. Viewing and intercom systems;
 4. Applicators, source transfer tubes, and transfer tube-applicator interfaces;
 5. Radiation monitors used to indicate room exposures;
 6. Source positioning (accuracy); and
 7. Radiation monitors used to indicate whether the source has returned to a safe shielded position.
- C.** In addition to the requirements for checks in subsection (B), a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.
- D.** If the results of the checks required in subsection (B) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
- E.** A licensee shall retain a record of each check required by subsection (B) for 3 years from the date of the procedure.

R12-1-741. Additional Radiation Survey of Sealed Sources Used in Radiation Therapy

- A.** In addition to the survey requirement in Article 4 of this Chapter, a person licensed to use sealed sources in the practice of radiation therapy shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.
- B.** A licensee shall make the survey required by subsection (A) at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).
- C.** A licensee shall retain a record of the radiation surveys required by subsection (A) for 3 years from the date of each survey.

R12-1-742. Five-year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units

- A.** A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.
- B.** This inspection and servicing may only be performed by persons specifically licensed to do so by the Agency, NRC or an Agreement State.
- C.** A licensee shall keep a record of each five-year inspection for 3 years from the date of the inspection, if the inspection determined that service was unnecessary, and 3 years from the date of the completed service if the inspection determined that service was needed.

R12-1-743. Therapy Related Computer Systems

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of:

1. The source-specific input parameters required by the dose calculation algorithm;
2. The accuracy of dose, dwell time, and treatment time calculations at representative points;
3. The accuracy of isodose plots and graphic displays;
4. The accuracy of the software used to determine sealed source positions from radiographic images; and
5. The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

R12-1-744. Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

- A. Except as provided in R12-1-710, the licensee shall require an authorized user of a sealed source for a use authorized under Group 600 to be a physician who has completed the training requirements in 10 CFR 35.690, January 1, 2006, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.
- B. The training and experience shall have been obtained within the 7 years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

R12-1-745. Report and Notification of a Medical Event

- A. A licensee shall report any "medical" event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material results in:
 1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and
 - a. The total dose delivered differs from the prescribed dose by 20 percent or more;
 - b. The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
 - c. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.
 2. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:
 - a. An administration of a wrong radiopharmaceutical containing radioactive material;
 - b. An administration of a radiopharmaceutical containing radioactive material by the wrong route of administration;
 - c. An administration of a dose or dosage to the wrong individual or human research subject;
 - d. An administration of a dose or dosage delivered by the wrong mode of treatment; or
 - e. A leaking sealed source.
 3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).
- B. A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.
- C. The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of the medical event.
- D. The licensee shall submit a written report to the Agency within 15 days after discovery of the medical event.
 1. The written report must include:
 - a. The licensee's name;
 - b. The name of the prescribing physician;
 - c. A brief description of the event;
 - d. Why the event occurred;
 - e. The effect, if any, on the individual(s) who received the administration;
 - f. What actions, if any, have been taken or are planned to prevent recurrence; and
 - g. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.
 2. The report may not contain the individual's name or any other information that could lead to identification of the individual.
- E. The licensee shall provide notification of the event to the referring physician and also notify the individual who is the sub-

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ject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this subsection, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

- F.** Aside from the notification requirement, nothing in this Section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.
- G.** A licensee shall:
1. Annotate a copy of the report provided to the Agency with the:
 - a. Name of the individual who is the subject of the event; and
 - b. Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and
 2. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

R12-1-746. Report and Notification of a Dose to an Embryo, Fetus or a Nursing Child

- A.** A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.
- B.** A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breastfeeding individual that:
1. Is greater than 50 mSv (5 rem) total effective dose equivalent; or
 2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.
- C.** The licensee shall notify the Agency by telephone no later than the next calendar day after discovery of a dose to the embryo, fetus, or nursing child that requires a report in subsections (A) or (B).
- D.** The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo, fetus, or nursing child that requires a report in subsections (A) or (B). The written report shall include
1. The licensee's name;
 2. The name of the prescribing physician;
 3. A brief description of the event;
 4. Why the event occurred;
 5. The effect, if any, on the embryo/fetus or the nursing child;
 6. What actions, if any, have been taken or are planned to prevent recurrence; and
 7. Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.
- E.** The report, required in subsection (D), shall not contain the individual's or child's name or any other information that could lead to identification of the individual or child.
- F.** The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under subsections (A) or (B), unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee shall not delay any appropriate medical care for the embryo, fetus, or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this subsection, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide the written description upon request.
- G.** A licensee shall:
1. Make a copy of the report provided to the Agency and include with it the:
 - a. Name of the pregnant individual or the nursing child who is the subject of the event; and

- b. Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and
2. Provide the copy of the information required in subsection (G)(1) to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

Exhibit A. ~~Groups of Medical Uses of Radioactive Material~~ Medical Use Groups

~~Group I.~~

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

~~Group II.~~

- ~~C.~~** A use of prepared radiopharmaceuticals for diagnostic study, imaging, and tumor localization.
1. ~~Iodine-123~~
 2. ~~Iodine-125~~
 3. ~~Iodine-131~~
 4. ~~Selenium-75~~
 5. ~~Technetium-99m~~
 6. ~~Ytterbium-169~~
 7. ~~Indium-111~~
 8. ~~Indium-113m~~
 9. ~~Chromium-51~~
 10. ~~Fluorine-18~~
 11. ~~Gallium-67~~
 12. ~~Gold-198~~
 13. ~~Thallium-201~~
 14. ~~Rubidium-82~~
 15. ~~Carbon-11~~
- ~~D.~~** A licensee shall use a radioactive material listed in subsection (C) in the form of a radiopharmaceutical prepared for medical purposes that is:
1. ~~Obtained from a manufacturer or preparer according to subsection (B)(1); or~~
 2. ~~Prepared by a nuclear pharmacist or a physician who is authorized according to subsection (B)(2)~~

~~Group III.~~

- ~~E.~~** Use of generators and reagent kits for the preparation and use of radiopharmaceuticals containing radioactive material for certain diagnostic uses.
1. ~~Molybdenum-99/Technetium-99m generators~~
 2. ~~Tin-113/Indium-113m generators~~
 3. ~~Technetium-99m (in bulk)~~
 4. ~~Rubidium-81/Krypton-81m~~
- ~~F.~~** A licensee shall acquire and use a radioactive material listed in subsection (E) in the form of a radiopharmaceutical pre-

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pared for medical purposes that is:

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

Group IV:

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

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

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

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

Group V:

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

1. Iodine-131
2. Gold-198

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

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

Group 100

Included is the use of any unsealed radioactive material for use in uptake, dilution, or excretion studies and not requiring a written directive: The radioactive material in this group shall be:

1. Obtained from a manufacturer or preparer licensed under R12-1-703(C)(2)(a) of this Chapter; or
2. Prepared by an authorized nuclear pharmacist who meets the requirements in R12-1-712, a physician who is an authorized user and who meets the requirements specified in R12-1-721 and R12-1-723, or an individual under the supervision of either as specified in R12-1-706;
3. And if a research protocol:
 - a. Obtained from and prepared by an Agreement State or NRC licensee for use in basic research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or
 - b. Prepared by the licensee for use in basic research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

Group 200

Included is the use of any unsealed radioactive material for use in imaging and localization not requiring a written directive. PET radiopharmaceuticals may be used if the licensee meets the requirements in R12-1-716. The radioactive material in this group shall be:

1. Obtained from a manufacturer or preparer licensed under R12-1-703(C)(2)(a) of this Chapter, or equivalent NRC or Agreement State requirements; or
2. Prepared by an authorized nuclear pharmacist who meets the requirements in R12-1-712, a physician who is an authorized user and who meets the requirements specified in R12-1-721 and R12-1-723, or an individual under the supervision of either as specified in R12-1-706;
3. And if a research protocol:
 - a. Obtained from and prepared by an Agreement State or NRC licensee for use in basic research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA; or
 - b. Prepared by the licensee for use in basic research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

Group 300

Included is the use of any unsealed radioactive material for medical use (radiopharmaceutical) for which a written directive is required. The radioactive material in this group shall be:

1. Obtained from a manufacturer or preparer licensed under R12-1-703(C)(2)(a); or
2. Prepared by an authorized nuclear pharmacist who meets the requirements in R12-1-712, a physician who is an authorized user and who meets the requirements specified in R12-1-721 and R12-1-723, or an individual under the supervision of either as specified in R12-1-706; or
3. And if a research protocol:

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- a. Obtained from and prepared by an Agreement State or NRC licensee for use in basic research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA; or
- b. Prepared by the licensee for use in basic research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

Group 400

Included is the use of any brachytherapy source for therapeutic medical use that is manufactured in accordance with R12-1-703(C)(2)(b) and is:

1. Approved for therapeutic use in the Sealed Source and Device Registry; or
2. Part of a research protocol that is approved for therapeutic use under an active Investigational New Device (IND) application accepted by the FDA, and meets the requirements of R12-1-709.

Group 500

Included is the use of any sealed source that is manufactured in accordance with R12-1-703(C)(2)(b), and is:

1. Approved for diagnostic use in the Sealed Source and Device Registry; or
2. Part of a research protocol that is approved for diagnostic use under an active Investigational New Device (IND) application accepted by the FDA, and meets the requirements of R12-1-709.

Group 600

Included is the use of sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units that are manufactured in accordance with R12-1-703(C)(2)(b) and is:

1. Approved for therapeutic use in the Sealed Source and Device Registry; or
2. Part of a research protocol that is approved for therapeutic use under an active Investigational New Device (IND) application accepted by the FDA and provided the requirements of R12-1-709 are met.

ARTICLE 9. PARTICLE ACCELERATORS

R12-1-901. Purpose and Scope

- A. No change
- B. In addition to the requirements of this Article, all registrants are subject to the requirements of Articles 1, 2, 4 and 10. Registrants engaged in industrial radiographic operations are subject to the requirements of ~~Article 5~~ **Article 11**, and registrants engaged in the healing arts are subject to the requirements of Article 6 of this Chapter. Registrants using a particle accelerator for the production of radioactive material are subject to the requirements of Article 3, and if the radioactive material is used for medical purposes, Article 7.

R12-1-913. Misadministration

- A. No change
 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 2. No change
- B. No change
 1. Within 24 hours after discovery of 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 one 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. No change
 3. No change

Arizona Administrative Register / Secretary of State

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R20-5-829	Amend
R20-5-830	New Section
R20-5-831	Renumber
R20-5-831	Amend
R20-5-832	Renumber
R20-5-832	Amend

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

Authorizing Statute: A.R.S. § 23-405(4)

Implementing Statutes: A.R.S. §§ 23-420(F)

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

Notice of Rulemaking Docket Opening: 12 A.A.R. 2045, June 9, 2006

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

Name: Andrew F. Wade, Esq.

Address: Industrial Commission of Arizona
800 W. Washington, Suite 303
Phoenix, AZ 85007

Telephone: (602) 542-5781

Fax: (602) 542-6783

E-mail: awade@ica.state.az.us

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

The original Occupational Safety and Health Rules of Procedure were adopted in 1975. Since then, practices and procedures have changed and the Industrial Commission initiated this rulemaking to update the language and to improve the clarity of the rules. In response to concerns and comments received from attorneys who represent employers and practice before the Commission, amendments are also proposed that encourage disclosure of information. The intent of these amendments is to provide a framework that will allow sufficient discovery of facts and information and to make the process more expeditious and less expensive.

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

None

7. A showing of good cause why the 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:

The proposed amendments do not diminish a previous grant of authority of a political subdivision of this state.

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

The proposed amendments concern rules of procedure governing resolution of disputes between the Arizona Division of Occupational Safety and Health and employers before the Administrative Law Judge Division of the Industrial Commission of Arizona. Individuals using the rules will benefit from the rules to the extent that the proposed amendments are intended to make the rules easier to read and understand. Rules that provide for disclosure of facts and information should reduce the cost of litigation and with greater disclosure by all parties, encourage resolution of disputes. The Industrial Commission does not anticipate or foresee any measurable negative economic impact on small businesses or consumers as a result of amendments to this Article. Other than costs associated with printing the rules in a booklet for distribution to the public, the Industrial Commission does not anticipate that the proposed rule changes will have any measurable negative economic impact on this agency.

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: Andrew F. Wade, Esq.

Address: Industrial Commission of Arizona
800 W. Washington, Suite 303
Phoenix, AZ 85007

Telephone: (602) 542-5781

Fax: (602) 542-6783

E-mail: awade@ica.state.az.us

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10. The time, place, and nature of the proceedings for the making, 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: August 8, 2006
Time: 1:30 p.m.
Location: Industrial Commission of Arizona
800 W. Washington St.
Third Floor Conference Room
Phoenix, AZ 85007
Nature: Oral and written comments will be accepted on or before the date set forth in this item.

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. The full text of the rules follows:

TITLE 20. COMMERCE, FINANCIAL INSTITUTIONS, AND INSURANCE

CHAPTER 5. INDUSTRIAL COMMISSION OF ARIZONA

ARTICLE 8. OCCUPATIONAL SAFETY AND HEALTH ~~RULES OF PRACTICE AND PROCEDURE BEFORE THE INDUSTRIAL COMMISSION OF ARIZONA~~

Section

R20-5-801. ~~Notice~~ Scope of Rules
R20-5-802. ~~Location of Office~~ Offices and Office Hours
R20-5-803. Definitions
R20-5-804. Computation of Time
R20-5-805. Record Address
R20-5-806. General Service and Filing Requirements; and Notice to Affected Employees
R20-5-807. ~~Consolidation~~ Notice of Appearance filed by Affected Employees or Authorized Employee Representative
R20-5-808. ~~Severance~~ Notice of Appearance
R20-5-809. ~~Election to Appear~~ Consolidation
R20-5-810. ~~Employee Representatives~~ Severance
R20-5-811. Form of Pleadings Documents
R20-5-812. ~~Caption; Titles of Cases~~ Caption
R20-5-813. ~~Requests for Hearing~~ Production of Division Inspection File
R20-5-814. Prohibition of Ex Parte Communication
R20-5-815. Mandatory Disclosure
~~R20-5-814-R20-5-816.~~ Pre-hearing Conference
~~R20-5-815-R20-5-817.~~ Payment of Non-party Witness Fees and Mileage
~~R20-5-816.~~ Notice of Hearing Repealed
~~R20-5-818.~~ Continuance of Hearing
~~R20-5-817-R20-5-819.~~ Failure to Appear -- at Hearing; Withdrawal of Request for Hearing or Notice of Contest
~~R20-5-818-R20-5-820.~~ Duties and Powers of Hearing Officers the ALJ
~~R20-5-821.~~ Sanctions
R20-5-822. Refusal to Answer; Refusal to Attend Affidavit of Good Faith Effort to Resolve Discovery Disputes
~~R20-5-819-R20-5-823.~~ Witnesses' Oral Deposition; In State Depositions
R20-5-820. Witnesses' Oral Depositions; Out of State Repealed
~~R20-8-821-R20-5-824.~~ Parties Disposition upon Interrogatories
R20-5-825. ~~Legal Memoranda~~ Subpoena Requests
R20-5-826. Submission of Documents and Reports into Evidence
~~R20-5-823-R20-5-827.~~ Burden of Proof
~~R20-5-824-R20-5-828.~~ Intermediary Interlocutory Rulings or Orders by the Hearing Officer an ALJ
~~R20-5-826-R20-5-829.~~ Decisions of Hearing Officers the ALJ

~~R20-5-830. Transcription of the Record~~
~~R20-5-827-R20-5-831, Settlement~~
~~R20-5-828-R20-5-832, Special Circumstances; Waiver of Rules~~
~~R20-5-829. Variances Repealed~~

**ARTICLE 8. OCCUPATIONAL SAFETY AND HEALTH ~~RULES OF PRACTICE AND PROCEDURE BEFORE~~
~~THE INDUSTRIAL COMMISSION OF ARIZONA~~**

R20-5-801. ~~Notice~~ Scope of Rules

~~Sections R20-5-801 et seq. apply~~ Except as otherwise provided, this Article applies to all actions and proceedings of or before the Commission and Review Board pertaining to those issues arising out of A.R.S. Title 23, Chapter 2, Article 10.

R20-5-802. ~~Location of Office~~ Offices and Office Hours

~~The main office~~ offices of the Industrial Commission of Arizona is are located in Phoenix and Tucson, Arizona. ~~An office is also located in Tucson, Arizona.~~ The offices are open for the transaction of business from 8 a.m. until 5 p.m. every day except Saturdays, Sundays, and legal holidays.

R20-5-803. Definitions

~~In these Rules of Procedures, In addition to the definitions set forth in A.R.S. § 23-401, in this Article unless the context otherwise requires, specified:~~ the following words and terms shall have the following meanings:

1. "Commission" means the Industrial Commission of Arizona.
2. "Affected employee" means an employee of a cited employer who is exposed to the alleged hazard described in the citation, as a result of his assigned duties.
3. "Authorized employee representative" means a labor organization which has a collective bargaining relationship with the cited employer and which represents affected employees.
4. "Representative" means any person, including an authorized employee representative, authorized by a party to represent him in a proceeding.
5. "Citation" means a written communication issued by the Division of Occupational Safety and Health of the Industrial Commission of Arizona pursuant to A.R.S. § 23-415.
6. "Notification of proposed penalty" means a written communication issued by the Industrial Commission of Arizona pursuant to A.R.S. § 23-418.
7. "Party" means the Occupational Safety and Health Division of the Commission, the affected employer and affected employees.

"Act" means the Arizona Occupational Safety and Health Act that is set forth in A.R.S. § 23-401 et seq.

"Affected employee" means an employee who is exposed to a hazard described in a citation as a result of the employee's assigned duties.

"ALJ" means an administrative law judge presiding over an occupational safety and health proceeding.

"ALJ Division" means the Administrative Law Judge Division of the Commission.

"Authorized employee representative" means a labor organization that has a collective bargaining relationship with a cited employer and that represents affected employees.

"Citation" means a written notice of a violation issued by the Division pursuant to A.R.S. § 23-415.

"Cited employer" means an employer issued a citation or notification of penalty by the Division.

"Inspection number" means the number assigned by the Division relating to one or more citations issued by the Division as a result of an inspection.

"Notification of penalty" means a written notice issued by the Division pursuant to A.R.S. § 23-418.

"Representative" means any person, including an authorized employee representative, authorized by an interested party to represent that party in an occupational safety and health hearing.

R20-5-804. Computation of Time

~~In computing any period of time prescribed or allowed in these rules, in this Article, the day from which the designated specified period begins to run shall is not be included. The last day of the specified period so computed shall be is included unless it is a Saturday, Sunday, or legal holiday. holiday, in which event the period runs until the end of the next day that is not a Saturday, Sunday, or legal holiday. When the specified period of time prescribed or allowed is less than seven 11 days, intermediate Saturdays, Sundays, and legal holidays shall be are excluded in the computation.~~

R20-5-805. Record Address

~~The initial pleading filed by any person~~ A party who files a document with the Division or ALJ Division shall contain place

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that his party's correct name, address and telephone number on the document. Any change in such information must be communicated promptly. A party whose name, address, or telephone number changes shall communicate the changed information in writing to the Commission Division or ALJ Division and to all other parties within 5 days of the change. A The Division or ALJ Division shall deem any party who fails to furnish such correct and current information shall be deemed to comply with this Section to have waived his the right to object to the validity of any notice, document, and/or or service which has been made that is sent to the last known address of the party as shown by contained in the records of the Commission. Division or ALJ Division.

R20-5-806. General Service and Filing Requirements; and Notice to Affected Employees

- ~~A.~~ At the time of filing pleadings or other documents a copy thereof shall be served by the filing party on every other party.
- ~~B.~~ ~~A.~~ Service upon a party who has appeared through a representative shall be made only upon such the representative.
- ~~C.~~ ~~B.~~ Unless otherwise herein indicated, service of any document may be accomplished by postage prepaid first class mail or by personal delivery. Service is deemed effected completed at the time of mailing (if by mail) or at the time of personal delivery (if by personal delivery); except that all papers or documents required to be filed with the ALJ Division must be received by the ALJ Division within the time fixed for filing.
- ~~D.~~ ~~C.~~ Proof of service is shall be accomplished by a written statement of the same which that sets forth the date and manner of service. Such statement shall be filed with the pleading or document. A party who serves a document upon another party as required by this Article shall ensure that the statement described in this subsection accompanies the document served.
- ~~E.~~ ~~D.~~ Service Except as provided in subsection (E), service upon employees represented by an authorized employee representative shall be deemed accomplished by serving the representative in the manner prescribed in subsection (C); described in subsection (B) of this Section.
- ~~F.~~ ~~E.~~ In the event that there are any affected employees who are not represented by an authorized employee representative, the employer shall, immediately upon receipt of Notice of the Date of Hearing, post, where the citation is required to be posted, a copy of the Notice and Date of Hearing and a notice; informing such affected employees of their right to appear at the hearing and state their position and of the availability of all pleadings for inspection and copying at reasonable times. A notice in the following form shall be deemed to comply with this subsection:
Upon receipt of a Notice of Hearing, the employer shall immediately serve a copy of the Notice of Hearing and Notice of Rights of Affected Employees upon affected employees as follows:
 1. If affected employees are not represented by an authorized employee representative, the employer shall post, where the citation is required to be posted, a copy of the Notice of Hearing and the notice in Exhibit A:

Exhibit A. Notice to Affected Employees of (Name of employer)

Your employer has been cited by the Industrial Commission of Arizona for violation of the Arizona Occupational Safety and Health Act of 1972. The citation has been contested and will be the subject of a hearing before the Industrial Commission. Affected The rules of procedure adopted by the Industrial Commission permit affected employees are entitled to appear in at this hearing under the terms and conditions established by the Industrial Commission in its Rules of Procedure: to state their position. Notice of Intent an affected employee's intent to Participate participate should be sent to: to the Division of Occupational Safety and Health at the address listed on the Notice of Hearing.

THE INDUSTRIAL COMMISSION OF ARIZONA
1601 West Jefferson Street,
Phoenix, Arizona 85007.

All papers documents relevant to this matter may be inspected at:
(Place reasonably convenient to employees, preferably at or near workplace.)

Note: Where appropriate, the following sentence shall replace the second sentence of the above Notice will be deleted and the following sentence will be substituted:-

The reasonableness of the period prescribed by the Industrial Commission for abatement of the violation has been contested and will be the subject of a hearing before the Industrial Commission.

2. If the employees are represented by an authorized employee representative, the employer shall serve the authorized representative as provided in subsection (B) or provide to the authorized employee representative proof of posting under subsection (E)(1) no later than the first day after the posting.
 3. An employer serving affected employees by posting, as provided in subsection (E)(1), shall file a copy of the written statement under subsection (C) with the Division no later than the first business day following the posting.
- ~~G.~~ Where service is accomplished by posting, proof of such posting shall be filed not later than the first working day following the posting.
 - ~~H.~~ The authorized employee representative, if any, shall be served with the notice set forth in subsection (G) and with a copy of the Notice of the Date of Hearing.
 - ~~I.~~ A copy of the Notice of the Date of Hearing shall be served by the employer on affected employees who are not repre-

sented by an authorized employee representative by posting a copy of the Notice of such hearing at or near the place where the citation is required to be posted.

- ~~J.~~ A copy of the Notice of the Date of Hearing shall be served by the employer on the authorized employee representative of affected employees in the manner prescribed in subsection (C) of this Section, if the employer has not been informed that the authorized employee representative has entered an appearance as of the date such Notice is received by the employer.
- ~~K.~~ F. Where a petition request for hearing is filed by an affected employee who is not represented by an authorized employee representative and there are other affected employees who are represented by an authorized employee representative, the unrepresented employee shall, upon receipt of the Notice of the Date of Hearing, serve a copy of the Notice of Hearing thereof on such the authorized employee representative in the manner prescribed described in subsection (C) (B) of this Section and shall file proof of such service: service with the Division.
- ~~L.~~ G. Where a Petition request for Hearing hearing is filed by an affected employee or an authorized employee representative, a copy of the Petition request for Hearing hearing shall be provided to the employer for posting by the employer at the place the citation is required to be posted.
- ~~M.~~ H. An authorized employee representative who files a Notice of Contest request for hearing shall be responsible for serving any other authorized employee representative whose members are affected employees.
- ~~N.~~ I. Where posting is required by Any party or person serving a notice or other paper required to be posted under this Section, such posting Section shall be maintained keep the notice or other paper properly posted until the commencement of the hearing or until earlier disposition.

R20-5-807. Consolidation Notice of Appearance filed by Affected Employees or Authorized Employee Representative

Cases may be consolidated on the motion of any party, or on the hearing officer's own motion, where there exist common parties, common questions of law or fact, or both, or in such other circumstances as justice and the administration of the Act require.

- A. Except as provided in subsection (B), an affected employee or authorized employee representative may elect to appear at a hearing to testify or state its position by filing a written notice of appearance at least 15 days before the hearing. The notice of appearance shall be in writing and served upon the ALJ Division with a copy served upon all parties.
- B. An affected employee has no rights as a party under this Article until the employee or authorized employee representative files the notice of appearance described in subsection (A) of this Section.
- C. If a notice of appearance is filed by an authorized employee representative, then affected employees who are represented by that employee representative may not represent themselves or file a separate notice of appearance. An authorized employee representative shall be deemed to control all matters respecting the interest of such employees in the proceeding.
- D. Any representative may withdraw from the representation by filing a written notice of withdrawal and by serving a copy of the notice on all other parties.

R20-5-808. Severance Notice of Appearance

Upon its own motion, or upon motion of any party, the hearing officer may, for good cause, order any proceeding severed with respect to some or all issues or parties.

An interested party or the representative of that party who wishes to appear and participate in proceedings before the Commission under this Article shall file a written notice of appearance with the ALJ Division. A copy of the notice of appearance shall be served on all other parties.

R20-5-809. Election to Appear Consolidation

- A. Affected employees may elect to appear at a hearing for the purpose of testifying or stating their position concerning the subject matter of the hearing.
- B. If affected employees desire to appear at the hearing they must so notify in writing the Commission or the hearing officer, if the case has been assigned.

On the motion of any party, or on the ALJ's own motion, an ALJ may consolidate cases if there are common parties, common questions of law or fact, or both, or in such other circumstances as justice and the administration of the Act require.

R20-5-810. Employee Representatives Severance

- A. Employees may appear in person or through a representative.
- B. An authorized employee representative shall be deemed to control all matters respecting the interest of such employees in the proceeding.
- C. Affected employees who are represented by an authorized employee representative may appear only through such authorized employee representative.
- D. Withdrawal of appearance of any representative may be effected by filing a written Notice of Withdrawal and by serving a copy thereof on all parties.

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On the motion of any party, or on the ALJ's own motion, an ALJ may, for good cause, order any proceeding severed with respect to some or all issues or parties.

R20-5-811. Form of Pleadings Documents

- A. ~~Except as provided herein, there are no specific requirements as to the form of any pleading. A pleading is simply required to contain a caption sufficient to identify the parties in accordance with R20-5-812, which shall include the Commission's citation number, and a clear and plain statement of the relief that is sought, together with the grounds therefor. A person who files a document (other than exhibits) with the Division or ALJ Division shall ensure that the document is legible and contains a caption that identifies the parties and the Division's inspection number.~~
- B. Pleadings and other documents (other than exhibits and petitions for hearing) shall be typewritten and double spaced, on letter size opaque paper (approximately 8 1/2 inches by 11 inches). The left margin shall be 1 1/2 inches and the right margin 1 inch. Pleadings and other documents shall be fastened at the upper left corner.
- C. Pleadings shall be signed by the party filing or by his representative. A party or representative who files a pleading or other document with the Division or ALJ Division shall sign the document. Signing the document constitutes a representation by the signer party or representative that he the party or representative has read the document or pleading, and that to the best of the party's or representative's his knowledge, information, and belief the statements made therein contained in the document are true, and that it is not interposed for delay. The ALJ may impose sanctions upon the signing party or representative under R20-5-821 for violations of this subsection.
- D. ~~The Commission Division or ALJ Division may refuse for filing to accept any pleading or document which that does not comply with the requirements of paragraphs (A), (B), and (C) of this Section.~~

R20-5-812. Caption; Titles of Cases Caption

- A. ~~Cases initiated by the a cited employer filing a Petition for Hearing contesting a the violations cited citation shall be titled: "Arizona Division of Occupational Safety and Health of the Industrial Commission of Arizona, Complainant, vs. (name of employer), Respondent."~~
- B. ~~Cases initiated by the a cited employer filing a Petition of Hearing for requesting a modification of the an abatement period shall be titled: "(name of cited employer), Petitioner vs. Arizona Division of Occupational Safety and Health of the Industrial Commission of Arizona, Health, Respondent."~~
- C. ~~Cases initiated by an affected employee or authorized employee representative requesting a filing a Petition for Hearing for modification of the an abatement period shall be titled: "(name of affected employee or authorized employee representative), Petitioner Petition vs. Arizona Division of Occupational Safety and Health of the Industrial Commission of Arizona, Respondent, and (employer), Respondent. (name of employer), Respondent."~~
- D. ~~The Titles applicable caption listed in subsections (A) and (B) of this Section shall appear at the left upper portion of on the initial first page of any pleading or document filed with the Division or ALJ (other than exhibits and Petitions for Hearing filed). Division.~~
- E. The initial page of any pleading or document (other than exhibits and requests for hearing) shall show the citation number at the upper right of the page, opposite the title.

R20-5-813. Requests for Hearing Production of Division Inspection File

- ~~A. Requests for hearing shall be filed with the Commission.~~
- ~~B. Requests for hearing shall be in writing and contain a clear and plain statement of the relief that is sought, together with the grounds thereof.~~
- ~~C. The Commission shall, after receipt of a request for hearing, refer the file to the Hearing Officer Division for determination.~~

Not later than 30 days after receipt of a written request by a party, the Division shall provide a copy of its inspection file, including, if requested, copies of photographs taken by the compliance officer. Reproduction expenses shall be paid, in advance, by the requesting party.

R20-5-814. Prohibition of Ex Parte Communication

- A. Parties to a proceeding before the Administrative Law Judge Division shall not communicate with an ALJ with respect to the merits of the proceeding without the consent of the other parties.
- B. A person filing a pleading or submitting correspondence, including subpoena requests, to an administrative law judge concerning a matter pending before the administrative law judge, shall contemporaneously serve a copy of the matter upon all other parties, or if represented, the parties' authorized representatives.

R20-5-815. Mandatory Disclosure

- A. A party may request mandatory disclosure under this Section if a written request is filed no later than 10 days after the party files its request for hearing or notice of contest.
- B. If requested under this Section, the parties shall exchange written disclosure statements that contain the following information:
 - 1. The factual basis of each and every citation, claim, or defense;

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2. The legal theory upon which each and every citation, claim, or defense is based, including where necessary for a reasonable understanding of the citation, claim, or defense, legal or case authorities;
 3. The name, address, and telephone number of any witness whom the disclosing party expects to call at the hearing with a description of the substance of the witness' expected testimony;
 4. The name, address, and telephone number of any person whom the party believes may have knowledge or information relevant to the events, transactions, or occurrences at issue, and the nature of the knowledge or information each such individual is believed to possess;
 5. The name, address, and telephone number of any person who has given a statement, whether written or recorded, signed or unsigned, and the custodian of the copy of the statement;
 6. The name and address of each person whom the disclosing party expects to call as an expert witness at the hearing, the subject matter on which the expert is expected to testify, a summary of the grounds for each opinion, the qualifications of the witness and the name and address of the custodian of copies of any reports prepared by the expert;
 7. The existence, location, custodian, and general description of tangible evidence or relevant documents that the disclosing party plans to introduce at the hearing;
 8. A list of the documents or, in the case of voluminous documentary information, a list of the categories of documents, known by a party to exist whether or not in the party's possession, custody, or control and which the party believes may be relevant to the subject matter of the action, and those which appear reasonably calculated to lead to the discovery of admissible evidence, and the date(s) upon which those document will be made or have been made, available for inspection and copying. Unless good cause is stated for not doing so, a copy of each document listed shall be served with the disclosure. If production is not made, the name and address of the custodian of the document shall be indicated. A party who produces documents for inspection shall produce them as they are kept in the usual course of business.
- C.** Mandatory disclosure statements shall be exchanged within 30 days after the later of when:
1. A party files a request under subsection (A), or
 2. A party receives a copy of the Division file under R20-5-813, provided the party requested the Division file not later than the time of filing the request under subsection (A).
- D.** For good cause, an ALJ may shorten or extend the time to provide disclosure statements under this Section.
- E.** A party shall have a continuing duty to disclose information under this Section. Within 30 days of the discovery or revelation of new, additional, or different information, a party shall disclose the information to the other party. A party may introduce into evidence, new information disclosed within 30 days before hearing only with the approval of the ALJ and after the other party has had an opportunity to respond to the request to admit the information into evidence. The ALJ may admit the information for good cause and in the absence of prejudice.
- F.** An ALJ may impose sanctions under R20-5-821 for failure of a party to comply with this Section.

R20-5-814, R20-5-816, Pre-hearing Conference

- A.** At any time before a hearing, the hearing officer, on his own motion or on motion of a party, may direct the parties, or their representatives, to exchange information or to participate in a pre-hearing conference for the purpose of considering matters which will tend to simplify the issues or expedite the proceedings. upon request of a party or on its own order, an ALJ may direct the parties to participate in a pre-hearing conference for the purpose of, but not limited to:
1. Expediting the proceeding;
 2. Simplifying the issues;
 3. Resolving a discovery dispute;
 4. Facilitating settlement of the case;
 5. Discouraging wasteful or excessive prehearing activities;
 6. Identifying witnesses and evidence to be presented at the hearing;
 7. Establishing a schedule regarding discovery deadlines;
 8. Establishing whether memoranda will be filed before or after the hearing; and
 9. Determining whether it is appropriate to issue a confidentiality order under A.R.S. § 23-426.
- B.** The hearing officer may If a pre-hearing conference is held, the ALJ may issue a pre-hearing order written post-conference statement which includes the outcome of the conference, orders of the ALJ, or agreements reached by the parties. Such order shall be served The ALJ shall serve the statement on all parties before the scheduled hearing and the statement shall be part of the record.

R20-5-815, R20-5-817, Payment of Non-party Witness Fees and Mileage

Witnesses summoned before the hearing officer shall be paid the same fees and mileage that are paid witnesses in the courts If a non-party witness requests a witness fee, the party requesting the subpoena for that witness shall pay the witness fees and mileage provided for witnesses in civil actions in the Superior Court of Arizona. Witness fees and mileage shall be paid by the party at whose instance the witness appears. If more than one party subpoenas the same witness, the parties shall divide the fee equally.

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R20-5-816. Notice of Hearing Repealed

Notice of the time, place and nature of a hearing shall be given to the parties at least five days in advance of such hearing.

R20-5-818. Continuance of Hearing

An ALJ may continue a hearing to allow the parties to meet the time-frames of this Article or to provide the parties additional time to prepare for hearing.

~~R20-5-817.~~ R20-5-819. Failure to Appear – at Hearing; Withdrawal of Request for Hearing or Notice of Contest

- A. The Except as provided in subsection (D) of this Section, an ALJ shall deem the failure of a party who has requested a hearing to appear at such scheduled a hearing shall be deemed scheduled in response to that party's request for hearing or notice of contest an admission of the validity of any citation, abatement period, or penalty issued or proposed, and additionally a waiver of all rights except the right to be served with a copy of the decision of the hearing officer and to request review: penalty. If a party who requests a hearing or files a notice of contest fails to appear at the hearing, then the ALJ shall dismiss the request for hearing or notice of contest, and the contested citation, abatement period, or penalty shall be deemed final without further evidentiary proceedings.
- B. Except as provided in subsection (D) of this Section, an ALJ shall deem the failure of a party to appear at hearing to be a waiver of all claims and defenses with regard to the citation, abatement period or penalty.
- ~~B. C. Withdrawal~~ An ALJ shall consider a withdrawal of a request for hearing shall be construed as to be an admission of the validity of any citation, abatement period, or penalty issued or proposed. No decision need be issued in this case as the subject instrument is deemed to be admitted: penalty.
- D. A party's failure to appear at a hearing may be excused by an ALJ upon clear and convincing evidence of the following:
1. The party complied with R20-5-805 but did not receive notice of the scheduled hearing; or
 2. The party was unable to attend the scheduled hearing due to unexpected or unavoidable circumstances.

~~R20-5-818.~~ R20-5-820. Duties and Powers of Hearing Officers the ALJ

~~It shall be the duty of the hearing officer to conduct a fair and impartial hearing, to assure that the facts are fully elicited, to adjudicate all issues and avoid delay. The hearing officer shall have authority with respect to cases assigned to him, between the time he is designated and the time he issued his decision, subject to the rules and regulations of the Commission, to:~~

- A. An ALJ shall perform the following duties:
1. Conduct a fair and impartial hearing; and
 2. Hear and determine all issues presented.
- B. In addition to the powers set forth in A.R.S. § 23-420(G), the ALJ shall exercise the following powers:
1. Administer oaths and affirmations;
 2. Rule upon admissibility of exhibits; evidence;
 3. Rule upon applications for depositions; discovery requests and motions;
 4. Regulate the course of the hearing and, if appropriate or necessary, exclude persons or counsel from the a hearing for uncivil, disrespectful, or contemptuous conduct and strike all related testimony of witnesses refusing to answer any proper questions; conduct;
 5. Strike the related testimony of a witness who refuses to answer questions ordered to be answered by the ALJ;
 6. When requested by a party, exclude non-party witnesses from the hearing until called to testify;
 - ~~7. Call and examine~~ Examine witnesses;
 - ~~8. Request the parties at any time during the hearing to state their respective positions concerning any issue in the case or theory in support thereof; in the case;~~
 9. Adjourn the hearing as the needs of justice and good administration require;
 10. Issue appropriate orders for protection of trade secrets;
 9. Take any other action necessary under the foregoing and authorized by the rules and regulations of the Commission.
 11. Request the filing of pre-hearing or post-hearing memoranda to discuss any issue or theory in the case;
 12. Determine whether the case may be submitted on stipulated facts and memoranda in lieu of a hearing;
 13. Impose sanctions under R20-5-821 against any party who violates the rules in this Article without good cause;
 14. Take official notice of rules, regulations, official reports, decisions, and orders of the Commission or any Arizona regulatory agency; and
 15. Take official notice of matters of common knowledge and established technical or scientific facts.

R20-5-821. Sanctions

An ALJ may impose any or all of the following sanctions for violations of the rules in this Article:

1. Dismiss the party's request for hearing; and
2. Prohibit or limit the party's evidence on any claim or defense.

R20-5-822. Refusal to Answer; Refusal to Attend Affidavit of Good Faith Effort to Resolve Discovery Disputes

A. If a party or other deponent refuses to answer any question propounded upon oral examination pursuant to R20-5-819 and R20-5-820, the examination shall be completed in other matters or adjourned, as the proponent of the question may prefer.

Thereafter on reasonable notice to all persons affected thereby the proponent of the question may apply to the hearing officer for an order compelling an answer. Upon the refusal of a deponent to answer any interrogatory submitted under R20-5-821, the proponent of the question may on like notice make like application for such an order. If the motion is granted and if the hearing officer finds that the refusal was without substantial justification, the hearing officer shall require the refusing party, or deponent and the party, or representative advising the refusal or either of them to pay to the examining party the amount of the reasonable attorney's fees incurred in obtaining the order and the reasonable expenses which will be incurred to obtain the requested answers. If the motion is denied and if the hearing officer finds that the motion was made without substantial justification, the hearing officer shall require the examining party or the representative advising the motion, or both of them, to pay to the refusing party or witness the amount of the reasonable attorney's fees incurred in opposing the motion.

- B.** If a party or an officer or managing agent of a party willfully fails to appear before an officer who is to take his deposition after being served with the proper notice, or fails to serve answers to interrogatories after proper service of such interrogatories, the hearing officer, on motion and notice, may strike out all or any part of any pleading of that party, dismiss the action or proceeding or any part thereof, or preclude the introduction of evidence.

All requests or motions from a party requesting the ALJ to rule on a discovery dispute shall be accompanied by an affidavit from each party to the dispute that the parties have made a good faith effort to resolve the dispute informally. The ALJ is not required to rule on any discovery dispute that does not include the affidavit described in this Section.

R20-5-819. R20-5-823. Witnesses' Oral Deposition; In-State Depositions

- A.** After a request for hearing ~~has been~~ is filed with the Commission, ~~any~~ a party desiring to take the oral deposition of ~~any other another~~ party or witness residing within the state of Arizona shall file with the hearing officer, in duplicate, ~~shall serve the notice setting the of taking deposition by oral examination. Copies of such Notice shall be served at least five days prior to the date of the deposition upon the deponent and upon every party by the party desiring to take the oral deposition. at least 10 days before the deposition.~~ shall serve the notice setting the of taking deposition by oral examination. Copies of such Notice shall be served at least five days prior to the date of the deposition upon the deponent and upon every party by the party desiring to take the oral deposition. at least 10 days before the deposition.
- B.** The party setting the deposition shall include the following information in the notice of deposition:
1. Name and address of the person being deposed. If the name of the deponent is unknown, then a general description sufficient to identify the person or the group or class to which the persons belongs;
 2. Date and time of deposition;
 3. Place of deposition; and
 4. Name of person taking the deposition.
- C.** A notice of deposition may include a request for the deponent to produce documents or tangible things in the possession or control of the deponent. The deponent shall produce the requested documents or tangible items as they are kept in the usual course of business or shall organize and label them to correspond with the categories listed in the notice of deposition.
- D.** Unless otherwise permitted by an ALJ under R20-5-816, a notice of deposition shall be served at least 30 days before the first scheduled hearing.
- B. E.** If any a party or the deponent has any an objection to the taking of the oral deposition of the party or witness, he a deposition, that person shall file with the presiding hearing officer and serve on all parties written objections thereto ALJ written notice of the objection setting forth the basis of for the opposition to the deposition: objection. Such Notice of the objection shall be filed with the hearing officer ALJ within two 5 days after the notice of taking deposition by oral examination is served. is served upon the party making the objection. Except as provided in R20-5-822, the ALJ shall rule on the objection no later than 3 days after the objection is filed. The deposition that is the subject of the objection shall be held in abeyance pending a ruling by the ALJ.
- C.** If objections to the taking of the oral deposition are filed with the hearing officer as provided in subsection (B) hereof, the hearing officer shall rule on the objections within five days after the filing of the objections. The taking of the oral deposition shall be held in abeyance pending the ruling of the hearing officer. The hearing officer shall either order the deposition to proceed, order that the deposition not be taken, or enter such other protective order as may be appropriate.
- D.** The party taking the deposition shall comply with the Arizona Rules of Civil Procedure governing the taking of depositions.
- E.** The parties may agree that the deposition be taken by telephone.
- G.** A deposition shall not exceed 4 hours except by stipulation of the parties or consent of the ALJ upon a showing of good cause.
- H.** The parties and deponent participating in a deposition shall not engage in unreasonable, groundless, abusive or obstructive conduct or take any action to annoy, embarrass, harass, or oppress the deponent or any party during the taking of the deposition.
- I.** If a deponent refuses to answer a question asked during the taking of a deposition, the deposition shall be completed in all other respects or adjourned at the option of the examiner. Within 3 days of the date the deposition was completed or suspended, the examiner may file a motion with the ALJ for an order compelling the answer. If the motion is granted, the ALJ shall require the party or deponent to pay attorney fees incurred by the examiner to obtain the order. If the motion is

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denied, the ALJ shall require the examiner to pay attorney fees incurred by the refusing party or deponent to respond to the motion. In addition to granting the relief requested, the ALJ may impose sanctions under R20-5-821 against any party, attorney, or witness for violations of this subsection.

- ~~E. J.~~ The expense of any deposition shall be borne by the party taking the deposition but shall not include the expense of any other party. The party taking a deposition shall pay the expense of the deposition, which shall not include the expenses of any other party.
- ~~F. K.~~ No Absent a showing of good cause, an ALJ shall not cancel or continue a scheduled hearing shall be canceled or continued for failure to take or complete a deposition taken pursuant to the provisions of this rule: deposition.
- ~~G. L.~~ Depositions taken pursuant to the provisions of this rule shall only be used The party taking a deposition may use the deposition at the time of a hearing for impeachment of to impeach a witness, unless the deponent is deceased at the time of the scheduled hearing, in which event it may be admitted into evidence: except that for good cause and with the consent of the ALJ, the deposition may be admitted into evidence.

R20-5-820: Witnesses' Oral Depositions; Out-of-State Repealed

- ~~A.~~ After a request for hearing is filed with the Commission, any party desiring to take the oral deposition of any other party or witness residing without the state of Arizona shall file with the hearing officer, in duplicate, a request for permission to take the deposition of such witness or witnesses. Such request shall show the name and address of such witness or witnesses and set forth the reason why said witness or witnesses' testimony is necessary for an adjudication of the issue. Copies of such request shall be served upon each party by the party requesting permission to take the deposition. If no objection to the request for permission to take the deposition is filed as provided in subsection (B) hereof, the hearing officer may, within ten days, in his discretion, grant or deny the permission to take the deposition. If the hearing officer permits the taking of the deposition, the party may proceed in the manner provided by and subject to the limitations of subsections (A), (D), (E), and (F).
- ~~B.~~ If any party has any objections to the taking of the oral deposition of the party or witness, he shall file with the hearing officer and serve on all other parties written objections thereto setting forth the basis for the opposition to the deposition. Such objection shall be filed with the hearing officer within five days after the request to take the deposition is served.
- ~~C.~~ If objections to the taking of the oral deposition are filed with the hearing officer as provided in subsection (B) hereof, the hearing officer shall rule on the objections within five days after the filing of the objections. The taking of the oral deposition shall be held in abeyance pending the ruling of the hearing officer. The hearing officer shall either order the deposition to proceed, order that the deposition not be taken, or enter such other protective order as may be appropriate. If the hearing officer orders that the deposition proceed, the party may proceed to take the deposition in the manner provided by and subject to the limitation of R20-5-819, subsections (A), (D), (E), and (F).
- ~~D.~~ Any deposition taken pursuant to the provisions of this rule shall be filed with the Commission at least five days prior to the hearing date or any scheduled hearing and may be admitted into evidence. If the deposition is not filed within the time prescribed herein, it shall not be considered for any purpose except by stipulation of all interested parties, and then only with the concurrence of the hearing officer.

R20-8-821. R20-5-824. Parties' Disposition upon Interrogatories

- ~~A.~~ After a request for hearing is filed with the Commission, any party desiring to take the deposition of another party upon may serve written interrogatories shall file with the hearing officer, in duplicate, copies of the interrogatories sought to be submitted to the party: upon another party by serving an original and 1 copy of the written interrogatories upon the party to whom the written interrogatories are directed. The written interrogatories submitted pursuant to this rule shall be limited to 25 questions in number with no subsections. Copies of such interrogatories shall be filed at least 5 days prior to any scheduled hearing.
- ~~B.~~ Unless permitted by an ALJ under R20-5-816, interrogatories shall be served at least 30 days before the first scheduled hearing.
- ~~B. C.~~ Answers The party answering the written interrogatories shall serve answers to the interrogatories shall be served on all parties by the party answering the interrogatories within 10 days after service of the written interrogatories, or within 10 days after a ruling by the hearing officer that the interrogatories be answered: as mutually agreed to by the parties or as directed by the ALJ if a ruling has been requested.
- ~~C. D.~~ No Absent a showing of good cause, the ALJ shall not cancel or continue a scheduled hearing shall be canceled or continued for failure to take or complete the taking of a deposition taken pursuant to the provisions of this rule: serve written interrogatories.
- ~~E.~~ If a party refuses to answer any or all of the written interrogatories, the party serving the written interrogatories may file a motion with the ALJ for an order compelling the answers. If the motion is granted, the ALJ shall require the party who refused to answer to pay attorney fees incurred by the party serving the interrogatories to obtain the order. If the motion is denied, the ALJ shall require the party serving the interrogatories to pay attorney fees incurred by the refusing party to respond to the motion. In addition to granting the relief requested, the ALJ may impose sanctions under R20-5-821 against any party who fails to comply with this subsection.

~~D. E. Depositions taken pursuant to the provisions of this rule shall~~ The party serving the written interrogatories may use the interrogatory answers only be used at the time of hearing for impeachment of to impeach a witness unless the deponent is deceased at the time of the scheduled hearing in which event they may be admitted into evidence. witness, except that for good cause and with the consent of the ALJ, the interrogatory answers may be admitted into evidence.

R20-5-825. ~~Legal Memoranda~~ Subpoena Requests

~~Legal memoranda may be filed if request is granted by the hearing officer. If such request is granted the hearing officer shall establish a reasonable time for such filing and response or simultaneous filing-~~

- A. A party may request an ALJ to issue a subpoena to compel the appearance of a witness by filing a subpoena request with the ALJ 15 days before the scheduled hearing.
- B. An ALJ shall subpoena the witness requested by a party if the testimony of the witness is deemed material and necessary to the case. Service of the subpoena may be made by mail unless the person requesting the subpoena requests personal service. If a party requests personal service of the subpoena, then the ALJ shall issue the subpoena to the party requesting the personal service. The party requesting personal service of the subpoena is responsible for personally serving the subpoena and the expense of the personal service.
- C. A party does not have the right to request that a hearing be canceled or continued because a witness failed to appear at a scheduled hearing unless the party timely requested a subpoena for the witness who failed to appear. If the testimony of a subpoenaed witness who failed to appear at hearing is material and necessary, an ALJ may continue the hearing to take the testimony of that subpoenaed witness.

R20-5-826. ~~Submission of Documents and Reports into Evidence~~

- A. An ALJ shall deem documents and reports contained in the Division file at the time the Division file is referred to the ALJ Division in evidence unless a party objects to the documents and reports at least 60 days before the first scheduled hearing.
- B. A party may submit documents and reports not contained in the Division file into evidence by filing the documents and reports with the ALJ no later than 25 days before the first scheduled hearing.
- C. The party submitting documents and reports into evidence shall serve a copy of the documents and reports upon all other parties at the time the documents and reports are filed with the ALJ.
- D. The party submitting documents and reports into evidence shall file with the documents and reports, a cover letter stating the party's name, listing the documents and reports filed, and proof of service of copies upon other parties.
- E. A party may object to the filing of documents and reports into evidence by another party and request that the party submitting the document produce the author for cross-examination either at a deposition and/or at a hearing.
- F. Absent prejudice to a party and for good cause, an ALJ may receive documents and reports into evidence that were not timely submitted.

~~R20-5-823. R20-5-827. Burden of Proof~~

- A. ~~The Division shall have the burden of proof in all proceedings other than those stated in subsection (B) commenced by the filing of a request for hearing, the burden of proof shall rest with the Commission, and (C) of this Section.~~
- B. ~~In proceedings commenced by a request for hearing requesting modification of the abatement period, The party requesting a modification to an abatement period shall have the burden of establishing the necessity for such the modification shall rest with the petitioner. modification.~~
- C. The party raising an affirmative defense shall have the burden of proof to establish the affirmative defense.

~~R20-5-824. R20-5-828. Intermediary Interlocutory Rulings or Orders by the Hearing Officer an ALJ~~

~~No intermediary A party may not appeal an interlocutory ruling or order rulings or orders by the hearing officer may be appealed to the Review Board an ALJ. An interlocutory ruling or order but shall become a part of the record.~~

~~R20-5-826. R20-5-829. Decisions of Hearing Officers the ALJ~~

- A. ~~The decision of the hearing officer~~ An ALJ shall include findings and conclusions of fact and law, fact, conclusions of law, and an order. order in each decision.
- B. ~~The hearing officer shall sign the decision. Upon issuance of the decision, jurisdiction shall rest solely in the Commission, and if a request for review is filed it shall be addressed to the Commission.~~

R20-5-830. ~~Transcription of the Record~~

- A. ~~Within 10 days of receiving a request for review under A.R.S. § 23-421(C), an ALJ shall notify the requesting party of the fee required to transcribe the record of the proceedings before the ALJ.~~
- B. ~~Absent good cause, an ALJ may deem the request for review withdrawn if a party fails to pay the required transcription fee within 10 days of being notified of the amount due.~~

~~R20-5-827. R20-5-831. Settlement~~

- A. ~~Settlement is encouraged at any stage of the proceedings where such settlement is consistent with the provisions and objectives of the Act.~~

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- ~~B. A.~~ Settlement agreement submitted by the parties shall be Parties that reach a settlement shall submit an agreement signed by an authorized representative of each party accompanied by an appropriate proposed order that, if approved which shall be signed by the assigned hearing officer or chief hearing officer, an ALJ.
- ~~C. B.~~ Where parties to the settlement agree upon a proposal, it When parties reach a settlement, the settlement agreement shall be served upon represented and unrepresented affected employees in the manner set forth in R20-5-806, who have filed a notice of appearance. The parties shall submit proof of this Proof of such service shall accompany at the same time that the proposed settlement when submitted to the Commission or the hearing officer, is submitted to the ALJ.

R20-5-828. R20-5-832, Special Circumstances; Waiver of Rules

In special circumstances, or for good cause shown, ~~the hearing officer~~ an ALJ may, upon application by any party, or on ~~his~~ the ALJ's own motion, waive any rule or make such orders as justice or the administration of the Act requires.

R20-5-829. ~~Variancees~~ Repealed

- ~~A.~~ Any hearing concerning variancees shall be filed before the Commissioners at a time set by the Commission.
- ~~B.~~ Such proceeding shall be informal but shall be transcribed at the expense of the person seeking the variancee if a written record of the proceeding is desired.