# NOTICES OF FINAL RULEMAKING

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

## NOTICE OF FINAL RULEMAKING

### TITLE 4. PROFESSIONS AND OCCUPATIONS

### CHAPTER 20. BOARD OF DISPENSING OPTICIANS

[R07-92]

### PREAMBLE

**1. Sections Affected** **Rulemaking Action**
R4-20-117 Amend

**2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rule are implementing (specific):**
Authorizing statute: A.R.S. § 32-1673

Implementing statute: A.R.S. § 32-1671

**3. The effective date of the rule:**
May 5, 2007

**4. A list of all previous notices appearing in the *Register* addressing the final rule:**
Notice of Rulemaking Docket Opening: 12 A.A.R. 1033, March 31, 2006

Notice of Proposed Rulemaking: 12 A.A.R. 3869, October 20, 2006

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

| | |
|---|---|
| Name: | Lori D. Scott, Executive Director |
| Address: | 1400 W. Washington, Rm. 230<br>Phoenix, Arizona 85007 |
| Telephone: | (602) 542-3095 |
| Fax: | (602) 542-3093 |
| E-mail: | director@asbdo.state.az.us |

**6. An explanation of the rule, including the agency's reasons for initiating the rule:**
The rule change provides detailed licensing and regulatory information and procedural instructions. The Board is amending the rule for clarification of dispensing contact lenses.

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

**8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:**
The amendments do not diminish a previous grant of authority of a political subdivision of this state.

**9. The summary of the economic, small business, and consumer impact:**
This rulemaking will have minimal to no impact on small business. The Board anticipates this to be a minimal impact on applicants and licensees.

**10. A description of the changes between the proposed rules, including supplemental notices, and final rules:**
None

**11. A summary of comments made regarding the rule and the agency response to them:**
No written comments have been received.

**12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:**
None

**13. Incorporations by reference and their location in the rules:**
None

**14. Was this rule previously made as an emergency rule?**
No

**15. The full text of the rule follows:**

**TITLE 4. PROFESSIONS AND OCCUPATIONS**

**CHAPTER 20. BOARD OF DISPENSING OPTICIANS**

**ARTICLE 1. GENERAL**

Section
R4-20-117. Scope of Practice

**ARTICLE 1. GENERAL**

**R4-20-117. Scope of Practice**

**A.** The scope of practice of a dispensing optician means the activities described in A.R.S. § 32-1671(3).

**B.** The dispensing optician shall fill a refill of a contact lens prescription prior to its expiration date with no more than the sufficient quantity of replacement contact lenses needed through the expiration date.

# NOTICE OF FINAL RULEMAKING

**TITLE 12. NATURAL RESOURCES**

**CHAPTER 1. RADIATION REGULATORY AGENCY**

[R07-82]

**PREAMBLE**

| **1. Sections Affected** | **Rulemaking Action** |
|---|---|
| R12-1-102 | Amend |
| R12-1-103 | Amend |
| R12-1-311 | 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 |
| R12-1-708 | New Section |
| R12-1-709 | New Section |
| R12-1-710 | Repeal |
| 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 |
| 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):**

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

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

**3. The effective date of the rules:**

May 5, 2007

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

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

Notice of Proposed Rulemaking: 12 A.A.R. 2097, June 16, 2006

**5. 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

**6. An explanation of the rules, 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 regarding the storage of radioactive material.

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

R12-1-434 and R12-1-438 are rules that affect licensees 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 RAM. 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 RAM in the practice of medicine. The Agency is revising all of Article 7 to remain compatible with the Nuclear Regulatory Commission (NRC) regulations. The Agency maintains an Agreement with the NRC, as do 34 other states, which allows Arizona to regulate RAM 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.

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

None

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

Not applicable

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

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 security methods ha not been determined, because they are readily available in the market-place and are not expensive. During transport, the licensees may use a lock and chain and provided visual control mechanisms to maintain control at all times. If the licensee must leave the gauge unattended in the transport vehicle, the licensee may need to purchase a security system such as a 16 gauge box that is bolted to the interior of 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 if the gauge is stored in a motel room, or security may be achieved by installing or making available a double security system similar to that used at the licensee's office facility, at any temporary job-site or the operator's home. In all cases, procedures for security during storage and transport that are specific to the location will have to be approved by the Agency.

The second area of new regulation is in Article 7. The entire article, with the exception of training standards for nuclear cardiologists, is being replaced with the new NRC standards in 10 CFR 35. Authorized user training will follow the current standards. Cardiologist training will follow NRC accepted standards with the exception that a nuclear

cardiologist will not be permitted to practice general nuclear medicine without receiving the additional training prescribed in Article 7. Because there have always been NRC training requirements, the Agency believes that enforcement of the current training standards will not add any new costs for licensees or physicians, practicing nuclear medicine, to become qualified users on an Arizona RAM 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 burdens for medical licensees. Not all licensees are affected equally because of the different scopes of operation that exist in the nuclear medicine community.

Regulation of a relatively new diagnostic tool, positron emission tomography (PET), might lead the casual observer to think that new PET rules in Article 7 will result in an increase in cost to the affected medical licensees. However, the Agency believes the cost will be a small added expense relative to diagnostic equipment costs. Licensees are required to notify the Agency of their planned activities and explain how the licensee will provide radiation protection for personnel in accordance with the radiation exposure standards in Article 4. If the Article 4 standards cannot be easily met, the licensee will be required to retrofit the existing facility with shielding, or reconstruct the facility. Reconstruction may be more expensive than building a safe PET facility from the start by incorporating protective conditions that will limit radiation exposure and meet the regulatory standard. A local health physics consultant informed the Agency that shielding costs may be as high as $25,000, an amount 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. 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, which costs between $1,000,000 and $1,500,000, $25,000 is actually a small price to pay for radiation safety.

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

Until the publication of the Supplemental Notice in the *Register*, the changes to this rule package came from two sources: the Nuclear Regulatory Commission (NRC) and the Chairman of the Radiation Regulatory Hearing Board.

The NRC-requested changes are as follows:

1. A reference to 10 CFR 35.500 was incorrectly made in R12-1-728. The reference should have been 10 CFR 35.590. It is believed this was a typing mistake because the listed NRC regulation had nothing to do with the material in which it was referenced. R12-1-728 is corrected to include dentists and podiatrists, which is consistent with 10 CFR 35.590. As noted, 10 CFR 35.590 would have been listed in Exhibit A of the rule package if the typing mistake had not been made. The intent of the rule was to include all authorized users and their training. It is believed this is not a substantive change for two reasons:
   a. The simple typing mistake of typing a zero instead of the number "9."
   b. The intent of the changes was to include all of the NRC requirements in 10 CFR 35, as stated in the introduction to the proposed rulemaking project published in the *Register*.
2. Group 500 activities in Exhibit A to Article 7 should not include research. The research activities have been removed from Group 500.

The Radiation Regulatory Hearing Board changes are as follows:

1. There was confusion created by the use of "human subject" in the following rules: R12-1-722, R12-1-724, R12-1-725, R12-1-731, and R12-1-732, and that single definition be applied as suggested by the Chairman of the Agency Board. The suggested definition was added and "human subject" was deleted as suggested.
2. The word "basic" should be removed from R12-1-704(B)(1) because the referenced research must be reviewed by an Institutional Review Board. The change was made as requested.
3. A reference to the Board of Medical Examiners should now be Arizona Medical Board in R12-1-706(B).
4. There are grammatical construction problems in R12-1-710, R12-1-711, and R12-1-712. The corrections have been made, incorporating the language from the equivalent NRC regulation.

Other minor spelling and grammatical changes were made as a result of comments from the Agency staff, the Radiation Regulatory Hearing Board, and the Governor's Regulatory Review Council (G.R.R.C.) staff.

The November 24th Supplemental Notice was published because Package RMP-0057 was created from outdated base text. The notice contains the needed changes to the text and does not introduce any substantive changes.

Some minor final changes are noted that resulted from a review by G.R.R.C. staff. None of the changes were substantive in nature and greatly improved the readability of the rule package. Most of the changes were grammatical in nature. One change involves the use of a wrong term in Group 400 and Group 600 at the end of Article 7. The two groups refer to the use of sealed sources in therapy. If research is being conducted the sources and their planned use must be described to the Agency in an investigational device exemption (IDE) application rather than the incorrectly stated investigational new device (IND) application listed in the proposed Group descriptions.

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

No written comments were received from the public. Likewise, during the public hearing no comments were received from the public participants. However, the NRC, Agency Board Chairman, G.R.R.C. staff, and the editor at the Secretary of State's office have offered a number of suggestions concerning content, punctuation, format, and grammatical corrections. The content changes are described in item 10.

Contrary to NRC authorization, nuclear cardiologists in Arizona will be limited to nuclear cardiology. Their training with radioactive material is typically much less than the training received by radiology and nuclear medicine physicians.

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

None

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

| Rule | Incorporation |
|---|---|
| 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, 32.103 |
| R12-1-311(J) | 10 CFR 32.72 |
| R12-1-311(L) | 10 CFR 32.74 |
| R12-1-702 | |
| "Radioactive Drug Research Committee" | 21 CFR 361.1 |
| "Radioactive Drug" | 21 CFR 310.3(c) and 600.3 |
| R12-1-704(B) | Policy for Protection of Human Research Subjects, 45 CFR 46 |
| R12-1-716(C)(2) | AAPM Task Group 108: PET and PET/CT Shielding Requirements |
| 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 35.590 |
| R12-1-744(A) | 10 CFR 35.690 |

**14. Were these rules previously made as emergency rules?**

No

**15. The full text of the rules follows:**

## TITLE 12. NATURAL RESOURCES

## CHAPTER 1. RADIATION REGULATORY AGENCY

### ARTICLE 1. GENERAL PROVISIONS

Section
R12-1-102. 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 that Contain Radioactive Material

**ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION**

Section
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. MEDICAL USES OF RADIOACTIVE MATERIAL**

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 and Determination of Dosages~~ Determination of Prescribed Dosages, and Possession, Use, and Calibration of Instruments
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 and Removal; Accountability
R12-1-725. Safety Instructions and Precautions for Brachytherapy Patients that Cannot be Released Under R12-1-717
R12-1-726. Calibration Measurements of Brachytherapy Sources, Decay of Sources Used for Ophthalmic Treatments, and Computerized Treatment Planning Systems
R12-1-727. Training for Use of Manual Brachytherapy Sources and Training for the Use of Strontium-90 Sources for Treatment of Ophthalmic Disease
R12-1-728. Training for Use of Sealed Sources for Diagnosis
R12-1-729. Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit
R12-1-730. Installation, Maintenance, Adjustment, and Repair of an Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit
R12-1-731. Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units
R12-1-732. Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units
R12-1-733. Dosimetry Equipment
R12-1-734. Full Calibration Measurements on Teletherapy Units
R12-1-735. Full Calibration Measurements on Remote Afterloader Units
R12-1-736. Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units
R12-1-737. Periodic Spot-checks for Teletherapy Units
R12-1-738. Periodic Spot-checks for Remote Afterloader Units
R12-1-739. Periodic Spot-checks for Gamma Stereotactic Radiosurgery Units

**ARTICLE 9. PARTICLE ACCELERATORS**



**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
"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
"Certified cabinet x-ray system" No change
"CFR" No change
"Chelating agent" No change
"Civil penalty" No change
"Collective dose" No change
"Committed dose equivalent" No change
"Committed effective dose equivalent" No change
"Curie" No change

"Current license or registration" No change
"Deep-dose equivalent" No change
"Depleted uranium" No change
"Dose" No change
"Dose equivalent" No change
"Dose limits" No change
"Dosimeter" No change
"Effective dose equivalent" No change
"Effluent release" No change
"Embryo/fetus" No change
"Enclosed beam x-ray system" No change
"Enclosed radiography" No change
    "Cabinet radiography" No change
    "Shielded room radiography" No change
"Entrance or access point" No change
"Exhibit" No change
"Explosive material" No change
"Exposure" No change
"Exposure rate" No change
"External dose" No change
"Extremity" No change
"Fail-safe characteristics" No change
"Field radiography" No change
"Field station" No change
"Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities" No change
"Generally applicable environmental radiation standards" No change
"Gray" No change
"Hazardous waste" No change
"Healing arts" No change
"Health care institution" No change
"High radiation area" No change
"Human use" No change
"Impound" No change
"Individual" No change
"Individual monitoring" No change
"Individual monitoring device" No change
"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
"Natural radioactivity" No change
"NRC" No change
"Nuclear waste" No change
"Occupational dose" No change
"Open beam system" No change
"Package" No change
"Particle accelerator" No change
"Permanent radiographic installation" No change
"Personnel dosimeter" No change
"Personnel monitoring equipment" No change
"Personal supervision" No change
"Pharmacist" No change
"Physician" No change
"Primary beam" No change
"Public dose" No change
"Pyrophoric liquid" No change
"Pyrophoric solid" No change
"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~~ that 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 always an authorized medical physicist; however, an authorized medical physicist is included within the definition 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
"Shallow-dose equivalent" No change
"Shielded position" No change
"Sievert" No change
"Site boundary" No change
"Source changer" No change
"Source holder" No change
"Source material" No change
"Source material milling" No change
"Source of radiation" or "source" No change
"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
"Very high radiation area" No change

"Waste" No change
"Waste handling licensees" No change
"Week" No change
"Well-bore" No change
"Well-logging" No change
"Whole body" No change
"Wireline" No change
"Wireline service operation" No change
"Worker" No change
"WL" No change
"WLM" No change
"Workload" No change
"Year" No change

**R12-1-103. Exemptions**

**A.** Common and contract carriers, freight forwarders, and warehousemen who are subject to 49 CFR 107.109, 107.111, 107.113, 171.2, 171.3, 172.200, 173.1, 173.3, 173.4, 173.401, 175.3, 175.5, 175.10, 176.3, 176.5, 176.11, 176.24, 176.27, and 177.801, 2000 Edition, published October 1, 2000, 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, store 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 that 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
i. No change
j. No change
k. No change
l. No change
m. No change
n. No change
3. No change

**B.** No change
1. No change
a. No change
b. No change
c. No change
2. No change
a. No change
b. No change
c. No change
i. No change
ii. No change
d. No change
i. No change
ii. No change
iii. No change
3. No change

**C.** The Agency shall grant a specific license to incorporate 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 applicant satisfies requirements contained in 10 CFR 32.26, January 1, ~~2005~~ 2006, which is incorporated by reference, published by the Office of Federal Register, National Archives and Records Administration, Washington, ~~D.C.~~ DC 20408, and on file with the Agency, and contains no future editions or references, and provided:
1. No change
2. The licensee files annual reports required by 10 CFR 32.29, January 1, ~~2005~~ 2006, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington ~~D.C.~~ DC 20408, and on file with the Agency. The material incorporated 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. A licensee authorized under subsection (D) to distribute a device to a generally licensed person shall provide, if a device that contains radioactive material is to be transferred for use under the general license granted in R12-1-306(B), the name of each person that is licensed under R12-1-311(D) and the information specified in this subsection for each person to whom a device will be transferred. The licensee shall provide this information before the device may be transferred. In the case of transfer through another person, the licensee shall provide the listed information to the intended user before initial transfer to the other person.
   a. The licensee shall provide:
   ~~a.~~ i. A copy of the general license, issued under R12-1-306(B);
   ~~b.~~ ii. A copy of R12-1-443 and R12-1-445;
   ~~c.~~ iii. A list of the services that can only be performed by a specific licensee;
   ~~d.~~ iv. Information on authorized disposal options, including estimated costs of disposal; and
   ~~e.~~ v. A list of civil penalties for improper disposal.
   b. 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, DC 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 subsection (D)(4)(b).
      iii. Maintain records required by subsection (D)(4)(b) for a period of three years following the date of the recorded event.
5. No change
   a. No change
   b. No change
   c. No change
   d. No change
6. No change
7. No change
8. No change
   a. 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, 32.59, 32.102, and 70.39, January 1, ~~2005~~ 2006, which are incorporated by reference, published by the Office of Federal Register, National Archives and Records Administration, Washington

~~D.C.~~ DC 20408, and on file with the Agency. The material incorporated by reference contains 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 32.103, January 1, ~~2005~~ 2006, which are incorporated by reference, published by the Office of Federal Register, National Archives and Records Administration, Washington ~~D.C.~~ DC 20408, and on file with the Agency. The material incorporated by reference contains no future editions or amendments.

**J.** The Agency shall grant a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs that contain radioactive material for use by a person authorized in accordance with Article 7 of this Chapter, if the applicant meets all of the requirements in 10 CFR 32.72, January 1, ~~2005~~ 2006, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, ~~D.C.~~ DC 20408, and on file with the Agency. The material incorporated by reference contains no future editions or amendments.

**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.** The Agency shall grant a specific license to manufacture and distribute sources and devices that contain radioactive material to a person licensed in accordance with Article 7 of this Chapter for use as a calibration or reference source or for medical purposes, if the applicant meets all of the requirements in 10 CFR 32.74, January 1, ~~2004~~ 2006, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, ~~D.C.~~ DC 20408, and on file with the Agency. The material incorporated by reference contains no future editions or amendments.

**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

**R12-1-434. 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 µCi), or less, of Hydrogen-3 or Carbon-14 per gram of medium used for liquid scintillation counting; and
2. 1.85 kBq (0. 05 µCi), 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 µCi), 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.** A licensee shall employ controls approved by the Agency.

## ARTICLE 7. MEDICAL USES OF RADIOACTIVE MATERIAL

**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
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 is a "qualified expert" as defined in Article 1.

"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, dentist, or podiatrist 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 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, in research overseen by the RDRC, or a patient.

"Institutional review board" (IRB) is defined 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, 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, DC 20408, and on file with the Agency. These incorporated materials 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 21 CFR 361.1, April 1, 2006, which is incorporated by reference, published by the office of Federal Register, National Archives and Records Administration, Washington, DC 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.

"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 radioactive material if:
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 research 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 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
   d. The applicant has a radiation safety committee, if the criteria in R12-1-705 are applicable 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 through 600, in Exhibit A of this Article, for all of the materials within ~~the group or groups~~ each group requested in the application if:
   a. The applicant satisfies the requirements of subsections ~~(A), (B), and (D)~~ (A) and (B);
   ~~b. Each authorized user listed on the application meets the qualifications in R12-1-704;~~
   ~~c.~~b. ~~All other personnel who will be involved in the preparation and use of the radioactive material are qualified for their activities involving radioactive material in accordance with the statutes and rules of~~ 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 authorized uses ~~included in the group or groups~~ selected from Group 100 through Group 600; and
   ~~e.~~d. The applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the authorized uses ~~included in the group or groups~~ selected from Group 100 through Group 600.

~~2. Any licensee or registrant who is authorized to use radioactive material according to 1 or more groups in subsection (C)(1), and Exhibit A of this Article is subject to the following conditions:~~
~~a. For Groups I, II, IV and V, a licensee or registrant shall not receive, possess, or use radioactive material as a radiopharmaceutical unless manufactured in the form to be administered to the patient, labeled, packaged, and distributed according to a specific license issued by the Agency under R12-1-311(J), a specific license issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.72, 2003 edition, published January 1, 2003, by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, incorporated by reference and on file with the Agency (This incorporation by reference contains no future editions or amendments), or a specific license issued by an Agreement State or a Licensing State under equivalent rules.~~
~~b. For Group III, a licensee or registrant shall not receive, possess, or use generators or reagent kits that contain radioactive material to prepare radiopharmaceuticals containing radioactive material, except:~~
~~i. Reagent kits that do not contain radioactive material, approved by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State or Licensing State for use by persons licensed under subsection (C) and Exhibit A of this Article or equivalent regulations; or~~
~~ii. Generators or reagent kits that contain radioactive material which are manufactured, labeled, packaged, and distributed according to a specific license issued by the Agency under R12-1-311(K).~~
~~c. For Group III, any licensee who uses generators or reagent kits shall:~~
~~i. Elute the generator according to instructions furnished by the manufacturer or located on the generator label, leaflet, or brochure which accompanies the generator or reagent kit;~~
~~ii. Before administration to patients, or distribution to authorized recipients for administration to patients, cause each elution or extraction of technetium-99m from a molybdenum-99/technetium-99m generator to be tested to determine either the total molybdenum-99 activity or the concentration of molybdenum-99, according to written procedures and by personnel who have been specifically trained to perform the test;~~
~~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.~~

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);
3. Any licensee who is licensed according to subsection (C)(1), for one 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 in R12-1-309, the Agency shall issue a specific license for medical use of sealed sources only if the applicant's proposed authorized users have the qualifications listed in R12-1-704.~~ In addition to the other license application requirements in this Section, each applicant shall include in the radiation safety program required under subsection (A)(1) 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 who has the training and experience listed in 10 CFR 35, 2003 edition, published January 1, 2003, by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, which is incorporated by reference and on file with the Agency, or a physician under the supervision of a physician who has 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.~~

~~**F.** Only a physician listed on a valid radioactive material license is authorized to:~~

~~1. Supervise the use of radioactive material in the practice of medicine, and~~

~~2. Sign a preceptor statement verifying the training and experience of a physician who wants to be listed as an authorized user.~~

**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 Protection of Human Research 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, DC 20408, on file with the Agency, and contains no future editions or amendments), the licensee shall:

1. Obtain review and approval of the 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 any review and approval required by this Section, and
2. Obtain informed consent from the human research 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 health care institution is unable to meet the requirements.

**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.** A licensee subject to this Article shall have a Radiation Safety Committee if:~~

~~1. The licensee is authorized in a radioactive material license to use radioactive material under Group IV or V in Exhibit~~

~~A for two or more medical purposes; or~~

~~2. The licensee is authorized in a radioactive material license to use sealed sources for two or more therapy modalities regulated under R12-1-714, R12-1-716, R12-1-717, and R12-1-718.~~

~~**B.** A medical institution Radiation Safety Committee shall meet the following requirements:~~

~~1. 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~~

~~c. 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 Medical Board 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 nuclear pharmacy" 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 (μCi)), 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 μCi) 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;
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 three 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 only use:
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 equivalent requirements of 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~~

~~**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.** 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 (A)(2)(a) and (A)(2)(b) 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.

**B.** Exceptions.

1. An individual identified as a radiation safety officer on an Agency, a NRC, or an Agreement State license or a permit issued by the NRC or an Agreement State broad scope licensee or 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 (A)(1) through (A)(3).
2. A physician, dentist, or podiatrist 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.

**C.** The training and experience required in this Section shall be obtained within the seven 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).~~

**A.** A licensee shall require an 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 (A)(2) and whose certification has been recognized by the Agency, NRC or an Agreement State; or
2. Training requirements.
   a. Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics and has completed one year of full-time training in therapeutic radiological physics and an additional year of full-time 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
   b. Has obtained written certification that the individual has satisfactorily completed the requirements in subsection (A)(2)(a) 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.

**B.** Exceptions. An individual identified as a teletherapy or medical physicist on an Agency, a NRC, or an Agreement State license or a permit issued by the NRC or an Agreement State broad scope licensee or 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 subsection (A).

**C.** The training and experience required in this Section shall be obtained within the seven 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.** A licensee subject to this Article shall conduct a physical inventory every six months to account for all radioactive sealed sources received and possessed. A record of the inventories shall be maintained for three years 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 subject to this Article using a radioactive sealed source for a medical purpose, shall use it in accordance with R12-1-450(A) and (B).~~

**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.

**B.** Exceptions. An individual identified as a nuclear pharmacist on an Agency, a NRC or an Agreement State license or a permit issued by the NRC or an Agreement State broad scope licensee or 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 (A)(1) through (A)(3).

**C.** The training and experience required in this Section shall be obtained within the seven 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 and Determination of Dosages~~ Determination of Prescribed Dosages, and Possession, Use, and Calibration of Instruments**

~~**A.** A licensee subject to this Article shall not administer to a person radioactive material in an unsealed form that has not had its radioactivity determined, using one of the methods described in subsections (C) or (D).~~

~~**B.** A licensee shall make and record in a patient use log the dosage determination in subsection (A) before any medical use.~~

~~**C.** For unit dosages, the licensee shall make the determination by:~~

~~1. Direct measurement of the radioactivity in a dose calibrator; or~~

~~2. Decay correction, based on the radioactivity or radioactivity concentration determined by a properly licensed:~~

~~a. Manufacturer, or~~

~~b. Nuclear pharmacy.~~

~~**D.** For other than unit dosages, the licensee shall make the determination by:~~

~~1. Direct measurement of the radioactivity in a dose calibrator;~~

~~2. A combination of subsection (D)(1) and applicable mathematical calculation; or~~

~~3. A combination of volumetric measurement and applicable mathematical calculation, based on a radioactivity measurement determined by a supplier listed in subsection (C)(2)(a) or (C)(2)(b).~~

~~**E.** The licensee shall calibrate a dose calibrator in accordance with nationally recognized standards or manufacturer's instructions.~~

**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 procedures.

1. The procedures 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 and meet the requirements of subsection (G).

**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. A licensee shall follow the radiation safety and handling instructions approved by the Agency, or furnished by the manufacturer on the label attached to the brachytherapy source, the device that contains the brachytherapy source, or the permanent container that houses the brachytherapy source, or in the leaflet or brochure that accompanies the brachytherapy source or device; and maintain the instructions in a legible and easily accessible form. If the handling instructions, label, leaflet, or brochure is no longer available and a copy cannot be obtained from the manufacturer, the licensee shall notify the Agency that the source information is no longer available.~~

~~4. An authorized user transporting a brachytherapy source or applicator that contains a brachytherapy source for 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. An authorized user 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 a brachytherapy source has been inserted, using a calibrated survey instrument. This radiation level shall be entered on the patient's chart and signs posted as required in subsection (E). If the radioactive source is inserted for intravascular brachytherapy purposes for 10 seconds or less, the survey in this subsection is not required.~~

~~2. An authorized user 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 adjacent patient rooms. The licensee shall maintain the record three years 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 standard in subsection (D)(1) or (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, a licensee shall mark the bed, cubicle, or room of a 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.~~

~~**F.** A licensee shall select a qualified expert to assist the authorized user in determining the therapeutic sealed source output.~~

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 six 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 µSv (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 µSv (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 µC/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 qualified expert 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
   c. 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 or the axis distance used in radiation therapy;
   b. The congruence between the radiation field and the field indicated by the light beam localizing device;
   c. The uniformity of the radiation field and its dependence upon the orientation of the useful beam;
   d. Timer accuracy; and
   e. The accuracy of all distance measuring devices used for treating humans.
3. The qualified expert shall correct the exposure rate or dose rate values mathematically for cobalt-60 at intervals that do not exceed one month and for cesium-137 at intervals that do not exceed six months.

**E.** Spot check measurements.
1. The licensee's qualified expert or other authorized agent shall perform spot check measurements on each teletherapy unit at intervals that do not exceed one month.
2. Spot check measurements shall include determination of:
   a. Timer accuracy;
   b. The congruence between the radiation field and the field indicated by the light beam localizing device;
   c. The accuracy of all distance measuring devices used for treating humans;
   d. The exposure rate dose or a quantity related 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 qualified expert shall establish spot check measurement procedures. If the qualified expert does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by the qualified expert within 15 days.

**F.** Dosimetry systems.
1. The licensee's qualified expert shall perform full calibration measurements using a dosimetry system that is calibrated by the National Institute of Standards and Technology or by a regional calibration laboratory accredited by the American Association of Physicists in Medicine. The licensee shall ensure that the dosimetry system is calibrated every two years and after any servicing that may affect 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 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 (H).

~~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.~~

~~**H.** A licensee shall ensure that all physics procedures performed to prepare for application of radiation to a patient for therapy purposes are performed by a qualified expert who:~~
~~1. Is certified by the American Board of Radiology in Therapeutic Radiological Physics, Radiological Physics, Roentgen Ray and Gamma Ray Physics, or X ray and Radium Physics or the American Board of Medical Physicists in Radiation Oncology Physics; or~~
~~2. Has the following minimum training and experience:~~
~~a. A Master's or Doctor's degree in physics, biophysics, radiological physics, or health physics;~~
~~b. One year of full-time training in therapeutic radiological physics; and~~
~~c. One year of full-time experience at a radiotherapy facility, which included personal calibration of gamma stereotactic therapy system and associated patient treatment planning.~~
~~3. If an individual does not meet the standard in subsection (H)(1) or (H)(2), the licensee may request a license amendment that exempts the individual from these training 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 (H)(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 (H)(1).~~

**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 administered. In areas of routine use, that are to be 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 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 a person meeting the requirements in subsection (B) and a copy of the installation radiation survey required in subsection (B).
2. The licensee shall perform shielding calculations in accordance with AAPM Task Group 108: PET and PET/CT Shielding Requirements, in Medical Physics, Vol. 33, No. 1, January 2006, 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 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 of 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 provided to a breast-feeding female for three 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~~

~~c. Notifying the responsible physician or radiation safety officer.~~

~~**E.** The licensee shall test electrical interlocks on entrance doors to the radiosurgery room for proper operation at least once every 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~~

~~c. The radiosurgery system treatment timing device.~~

~~**H.** After any changes made in treatment room shielding, treatment room location, or use of the stereotactic radiosurgery system which could result in an increase in radiation levels in unrestricted areas outside of the therapy treatment room, the licensee shall conduct a radiation survey according to subsection (G). A report describing the changes and giving the survey results shall be sent to the Agency no later than 30 days following completion of the changes.~~

~~**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 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 subsection 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 three years from the date of the survey.

**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, DC 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 seven 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 three 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, DC 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

**B.** An authorized user candidate who 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 seven 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 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 three 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, DC 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 an authorized user of 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, DC 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 an authorized user of 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, DC 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 seven 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 and Removal; 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 three 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.

**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 subsection (A) and retain the records for three years after recording the instructions.

**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 subsections (A)(1) and (A)(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 three 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 three 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, DC 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 an authorized user of 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, DC 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 seven 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, dentist, or podiatrist who has completed the training requirements in 10 CFR 35.590, January 1, 2006, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

**B.** The training and experience shall have been obtained within the seven 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 each source 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 three 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 any source shielding, the source's driving unit, or other electronic or mechanical component that could expose a source, reduce the shielding around a source, or compromise the radiation safety of a unit or a source.

**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 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 three years from the completion date of the activity listed in this Section.

**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 a source;
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 a source 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 three years from the date of the instruction.

**F.** A licensee shall maintain a copy of the procedures required by subsections (A)(4) and (C)(2) for Agency review. The copy shall be maintained for three 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 each source to be shielded when an entrance door is opened; and
3. Prevent any source 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 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 each source applicator 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 the human voice.
4. Notify the radiation safety officer, or radiation safety officer's 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 two years and after any servicing that may have affected system calibration; or

2. The system shall have been calibrated within the previous four years. Eighteen to 30 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 two 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 three years from the date of the procedure, a record of each calibration, intercomparison, and comparison.

**R12-1-734. Full Calibration Measurements 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 five percent from the output 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 one 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 one month for cobalt-60, six months for cesium-137, or at intervals consistent with one 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 an authorized medical physicist.

**G.** A licensee shall retain a record of each calibration for three 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 one 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 one 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 sources to verify inventory and source arrangement at intervals not exceeding one 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 subsections (A) through (E).

**G.** A licensee shall mathematically correct the outputs determined in subsection (B)(1) for physical decay at intervals consistent with one percent physical decay.

**H.** Full calibration measurements required by subsection (A) and physical decay corrections required by subsection (G) shall be performed by an authorized medical physicist.

**I.** A licensee shall retain a record of each calibration for three 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 one 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 one 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 each source to verify inventory and source arrangement at intervals not exceeding one 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 subsections (A) through (E).

**G.** A licensee shall mathematically correct the outputs determined in subsection (B)(1) for physical decay at intervals consistent with one percent physical decay.

**H.** Full calibration measurements required by subsection (A) and physical decay corrections required by subsection (G) shall be performed by an authorized medical physicist.

**I.** A licensee shall retain a record of each calibration for three years from the date it was completed.

**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 five 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 one 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 one month for cobalt-60 and at intervals consistent with one 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 an authorized medical physicist.

**G.** A licensee shall retain a record of each calibration for three 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 an authorized medical physicist. That individual need not actually perform the spot-check measurements.

**C.** A licensee shall have an 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.

**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 three 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 an authorized medical physicist. That individual need not actually perform the spot-check measurements.

**C.** A licensee shall have an 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 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 three 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 an 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)(a) 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
   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 three 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 three years from the date of the procedure.

**R12-1-741. Additional Radiation Surveys 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 each source 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 any source shielding, a source's driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around a source, or compromise the radiation safety of the unit or the source.

**C.** A licensee shall retain a record of the radiation surveys required by subsection (A) for three 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 five 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 three years from the date of the inspection, if the inspection determined that service was unnecessary, and three 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 treat-

ment 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, a 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, DC 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 seven 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 shall 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 each individual 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 each individual (or the individual's responsible relative or guardian), and if not, why not.
2. The report may not contain an 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 subject 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 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, 2003 edition, published January 1, 2003, by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, or equivalent Agreement State requirements. This incorporation by reference is on file with the Agency 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(Subpart J), or an individual under the supervision of an authorized user that meets the training and experience requirements in 10 CFR 35(Subpart J), 2003 edition, published January 1, 2003, by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, which is incorporated by reference and on file with the Agency. This incorporation contains 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 prepared for medical purposes that is:~~

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

**~~Group IV.~~**

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

1. ~~Iodine-131, in quantities less than 33 millicuries~~
2. ~~Phosphorus-32~~

~~3. Strontium-89~~
~~4. Samarium-153~~
~~5. Yttrium-90~~

~~**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), 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 or 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), 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 or 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 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 or R12-1-723, or an individual under the supervision of either as specified in R12-1-706; or
3. And if a research protocol:
   a. Obtained from and prepared by an Agreement State or NRC licensee for use in an Investigational New Drug (IND) protocol accepted by FDA; or
   b. Prepared by the licensee for use in basic research in accordance with 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:

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 Device Exemption (IDE) 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 approved for diagnostic use in the Sealed Source and Device Registry.

**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:

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 Device Exemption (IDE) application accepted by the FDA and meets the requirements of R12-1- 709.

### 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

## NOTICE OF FINAL RULEMAKING

### TITLE 17. TRANSPORTATION

### CHAPTER 5. DEPARTMENT OF TRANSPORTATION COMMERCIAL PROGRAMS

[R07-74]

### PREAMBLE

**1. Sections Affected:** **Rulemaking Action:**

R17-5-209 Amend

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

Authorizing statute: A.R.S. § 28-366

Implementing statutes: A.R.S. §§ 28-5204 and 28-5235

**3. The effective date of the rule:**

May 5, 2007

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

Notice of Rulemaking Docket Opening: 12 A.A.R. 3245, September 8, 2006

Notice of Proposed Rulemaking: 12 A.A.R. 3872, October 20, 2006

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

| | |
|---|---|
| Name: | Celeste M. Cook, Administrative Rules Analyst |
| Address: | Department of Transportation, Motor Vehicle Division<br>1801 W. Jefferson St., Mail Drop 530M<br>Phoenix, AZ 85007 |
| Telephone: | (602) 712-7624 |
| Fax: | (602) 712-3081 |
| E-mail: | ccook@azdot.gov |

Please visit the ADOT web site to track progress of this rule and any other agency rulemaking matters at http://mvd.azdot.gov/mvd/MVDRules/rules.asp.

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

The Motor Vehicle Division (MVD) engages in this rulemaking to incorporate sections of the 2005 edition of Hazardous Materials Regulations published in 49 CFR, Transportation, Subtitle B - Other Regulations Relating to Transportation, Chapter I - Research and Special Programs Administration, Department of Transportation by reference into Arizona Motor Carrier Safety administrative rules. This rulemaking does not arise from a Five-Year Review Report but is an annual update. Changes are also made to ensure conformity to Arizona Administrative Procedure Act, the Secretary of State, and the Governor's Regulatory Review Council rulemaking format and style requirements.

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

Not applicable

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

Not applicable

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

The Division experiences neither cost nor benefit under the provisions of this rule.

The primary cost bearers of this rule's provisions are the Arizona Department of Public Safety (DPS) in the public arena and business entities engaged in transporting hazardous materials in the private sector. DPS incurs substantial costs of $20,000 annually for program administration as well as approximately 47 officer salaries averaging $40,000 each whose duties include hazardous materials transportation program enforcement. Business entities bear minimal to moderate costs (under $10,000) in possible federal registration fees, inspection fees, insurance, and equipment maintenance to remain in compliance to rule provisions.

The rule will bring Federal Motor Carrier Safety Assistance Program (MCSAP) grant funds of approximately $2 million to state law enforcement of motor carrier safety and hazmat programs. MCSAP funds are distributed chiefly to DPS but may also be sub-allocated to county and municipal enforcement agencies upon application to underwrite local enforcement costs. Hazardous material transport businesses benefit from rule compliance in decreased insurance premium costs, an increased margin of transportation safety, and better service to their customers resulting from expedited enforcement processing.

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

Minor formatting changes were made to Section (C)(1)(b), (C)(2)(a), and (C)(2)(b).

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

None

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

Not applicable

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

In R17-5-209(A):

49 CFR, Transportation, Hazardous Materials Regulations, Subtitle B - Other Regulations Relating to Transportation, Chapter I - Research and Special Programs Administration, Department of Transportation published October 1, 2005

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

No

**15. The full text of the rules follows:**

**TITLE 17. TRANSPORTATION**

**CHAPTER 5. DEPARTMENT OF TRANSPORTATION COMMERCIAL PROGRAMS**

**ARTICLE 2. MOTOR CARRIERS**

Section
R17-5-209. Hazardous Materials Transportation

**ARTICLE 2. MOTOR CARRIERS**

**R17-5-209. Hazardous Materials Transportation**

**A.** Incorporation of federal regulations.

1. The Motor Vehicle Division incorporates the following portions of the Federal Hazardous Materials Regulations by reference. Materials incorporated by reference are on file in the Secretary of State's Office. The incorporated Hazardous Materials Regulations are published in 49 CFR, Transportation, Subtitle B - Other Regulations Relating to Transportation, Chapter I - Research and Special Programs Administration, Department of Transportation:
   a. Subchapter A - Hazardous Materials and Oil Transportation; Part 107 - Hazardous materials program procedures; and
   b. Subchapter C - Hazardous Materials Regulations; Parts:
      i. 171 - General information, regulations, and definitions;
      ii. 172 - Hazardous materials table, special provisions, hazardous materials communications, emergency response information, and training requirements;
      iii. 173 - Shippers - general requirements for shipments and packagings;
      iv. 177 - Carriage by public highway;
      v. 178 - Specifications for packagings; and
      vi. 180 - Continuing qualification and maintenance of packagings.
2. These parts are incorporated as printed in the October 1, ~~2002~~ 2005 edition, and those sections of the October 1, 1991 edition authorized for use under the transitional provisions of Section 171.14 of the October 1, ~~2002~~ 2005 edition and no later amendments or editions. The incorporated material is available from the U.S. Government Printing Office, Superintendent of Documents, Mail Stop: SSOP, Washington, DC 20402-0001, and is on file with the Division.

**B.** Application and exceptions.

1. Application.
   a. Regulations incorporated in subsection (A) apply as amended by subsection (C) to motor carriers, shippers, and manufacturers as defined ~~in~~ under A.R.S. § 28-5201.
   b. Regulations incorporated in subsection (A) also apply to any vehicle owned or operated by the state, a political subdivision, or a state public authority, used to transport a hazardous material, including hazardous substances and hazardous waste.
2. Exceptions. An authorized emergency vehicle, as defined ~~in~~ under A.R.S. § 28-101, is excepted from the provisions of this Section.

**C.** Amendments. The following sections of the Federal Hazardous Materials Regulations, incorporated under subsection (A), are amended as follows:

1. Part 171. General information, regulations, and definitions.
   a. Section 171.1 Purpose and scope.
      Paragraph (a) is amended to read:
      "The transportation of hazardous materials by and their offering to: (1) interstate, intrastate, and foreign motor carriers; and (2) vehicles owned or operated by the state, a political subdivision or a state public authority, ~~which~~ that are used to transport hazardous material."
   b. Section 171.8 Definitions and abbreviations. Section 171.8 is amended by revising the definitions for "Carrier,"

"Hazmat employer," and "Person," and adding a definition for "Highway" as follows:

"'Carrier' means a person engaged in the transportation of passengers or property by highway as a common, contract, or private carrier and also includes the state, a political subdivision, and a state public authority engaged in the transportation of hazardous material."

"'Hazmat employer' means a person who uses one or more ~~of its~~ employees in connection with: transporting hazardous material; causing hazardous material to be transported or shipped; or representing, marking, certifying, selling, offering, reconditioning, testing, repairing, or modifying containers, drums, or packagings as qualified for use in the transportation of hazardous material. This term includes motor carriers, shippers, and manufacturers defined ~~in~~ under A.R.S. § 28-5201 and includes the state, political subdivisions, and state public authorities."

"'Highway' means a public highway defined ~~in~~ under A.R.S. § 28-5201."

"'Person' has the same meaning as defined ~~in~~ under A.R.S. § 28-5201."

2. Part 172 - Hazardous materials table, special provisions, hazardous materials communications, emergency response information, and training requirements. Section 172.3 Applicability. Paragraph (a)(2) is amended to read~~:~~ "Each motor carrier that transports hazardous materials, and each state agency, political subdivision, and state public authority that transports hazardous material by highway."
3. Part 177. Carriage by public highway.
   a. Section 177.800 Purpose and scope of this part and responsibility for compliance and training. In paragraph (a), the phrase "by private, common, or contract carriers by motor vehicle" is amended to read, "by a motor carrier operating in Arizona, a state agency, a political subdivision, or a state public authority that transports hazardous material by highway."
   b. Section 177.802 Inspection. Section 177.802 is amended to read: "Records, equipment, packagings, and containers under the control of a motor carrier or other persons subject to this part, affecting safety in transportation of hazardous material by motor vehicle, must be made available for examination and inspection by an authorized representative of the Department as prescribed ~~in~~ under A.R.S. §§ 28-5204 and 28-5231."