NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for making, amending, or repealing any rule. (A.R.S. §§ 41-1013 and 41-1022)

NOTICE OF PROPOSED RULEMAKING

TITLE 2. ADMINISTRATION

CHAPTER 8. STATE RETIREMENT SYSTEM BOARD

[R05-404]

PREAMBLE

1. Sections Affected **Rulemaking Action**

R2-8-115 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. § 38-714(F)(5)

Implementing statute: A.R.S. §§ 38-740, 38-762, 38-773

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

Notice of Rulemaking Docket Opening: 11 A.A.R. 3580, September 23, 2005

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

Name:	Nancy O. Johnson, Rules Coordinator
Address:	Arizona State Retirement System 3300 N. Central, 14th Fl. Phoenix, AZ 85012
Telephone:	(602) 308-5172
Fax:	(602) 264-6113
E-mail:	nancyj@asrs.state.az.us
Or	
Name:	Susanne Dobel, Manager, External Operations
Address:	Arizona State Retirement System 3300 N. Central, 14th Fl. Phoenix, AZ 85012
Telephone:	(602) 240-2039
Fax:	(602) 246-6113
E-mail:	susanned@asrs.state.az.us

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

A.R.S. § 38-740 provides for the return of contributions for an ASRS member who leaves ASRS employment other than by retirement or death. In the Performance Audit and Sunset Review of the Arizona State Retirement System, published on September 15, 2005, the Auditor General recommended that the ASRS improve the timeliness of returning these contributions. In order to effectuate that recommendation, this rulemaking will amend the definition of the term "termination of employment" to remove the minimum 21-day waiting period now required before returning contributions, and provide another standard for determining if a member has terminated employment. The ASRS is also making technical and clarifying changes to the rule.

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

None

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

Not applicable

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

Annual costs/revenues changes are designated as minimal when less than $1,000, moderate when between $1,000 and $10,000, and substantial when $10,000 or greater in additional costs or revenues.

The ASRS will bear moderate to substantial costs for promulgating and enforcing the rules. Costs for promulgating the rules include staff time to write, review, and direct the rules through the rulemaking process.

The ASRS members who wish a return of their contributions will benefit by receiving their contributions sooner as the ASRS will be able to process the request immediately upon receipt, instead of waiting until the 21-day waiting period is over.

All members of the public will benefit by the amendment of this rule because the technical and clarifying changes will make the rules more understandable.

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

Name:	Nancy O. Johnson, Rules Coordinator
Address:	Arizona State Retirement System 3300 N. Central, 14th Fl. Phoenix, AZ 85012
Telephone:	(602) 308-5172
Fax:	(602) 264-6113
E-mail:	nancyj@asrs.state.az.us
Or	
Name:	Susanne Dobel, Manager, External Operations
Address:	Arizona State Retirement System 3300 N. Central, 14th Fl. Phoenix, AZ 85012
Telephone:	(602) 240-2039
Fax:	(602) 246-6113
E-mail:	susanned@asrs.state.az.us

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

The ASRS has scheduled an oral proceeding on the proposed rulemaking:

Date:	Tuesday, November 29, 2005
Location:	3300 N. Central, Board Room, 10th Floor Phoenix, AZ 85012
Time:	2:00 p.m.

The close of record is 5 p.m., Tuesday, November 29, 2005.

A person may also submit written comments on the proposed rules no later than 5 p.m., Tuesday, November 29, 2005, to the individuals listed in items #4 and 9.

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

Not applicable

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

Not applicable

13. The full text of the rules follows:

TITLE 2. ADMINISTRATION

CHAPTER 8. STATE RETIREMENT SYSTEM BOARD

ARTICLE 1. RETIREMENT SYSTEM; DEFINED BENEFIT PLAN

Section
R2-8-115. Return of Contributions Upon Termination of Membership by Separation from ~~Service~~ All ASRS Employment by Other Than Retirement or Death; Payment of Survivor Benefits Upon the Death of a Member

ARTICLE 1. RETIREMENT SYSTEM; DEFINED BENEFIT PLAN

R2-8-115. Return of Contributions Upon Termination of Membership by Separation from ~~Service~~ All ASRS Employment by Other Than Retirement or Death; Payment of Survivor Benefits Upon the Death of a Member

A. The following definitions apply to this Section unless otherwise specified:

1. "ASRS" means the same as in A.R.S. § 38-711.
2. "ASRS employer" has the same meaning as "employer" in A.R.S. § 38-711.
3. "Authorized employer representative" means an individual specified by the ASRS employer to provide the ASRS with information about a member who previously worked for the ASRS employer.
4. "Beneficiary" means the individual specified by a member to receive the balance of the member's account or, if applicable, selected benefits upon the death of the member.
5. "Contribution" means:
   a. Amounts required by A.R.S. Title 38, Chapter 5, Article 2 to be paid to ASRS by a member or an employer on behalf of a member other than amounts attributed to the long-term disability ~~insurance~~ program;
   b. Any voluntary amounts paid by a System member to ASRS to be placed in the System member's account; and
   c. Any amount credited to a non-retired System member's employer account or to a retired System member's non-guaranteed benefit as determined by Section 24(B) of Arizona Session Laws 1995, Chapter 32, Section 24, as amended by Arizona Session Laws 1999, Chapter 66, Section 1.
6. "Court" means a superior, appellate, or the Supreme court of this state, a corresponding court of another state of the United States, or a federal court of the United States.
7. "Designated beneficiary" has the same meaning as in A.R.S. § 38-762(H).
8. ~~"Direct rollover" has the same meaning as in A.R.S. § 38-770.~~
9 ~~8~~. "Domestic relations order" has the same meaning as in A.R.S. § 38-773(G).
9. "Eligible retirement plan" has the same meaning as in A.R.S. § 38-770(C)(3).
10. "Employer number" means a unique identifier the ASRS assigns to a member employer.
11. "Employer plan" means the same as eligible retirement plan in A.R.S. § 38-770(C)(3)(c), (d), (e), and (f).
~~10~~ 12."Fiscal year" means July 1 of one year to June 30 of the next year.
13. "Individual retirement account" means the same as eligible retirement plan in A.R.S. § 38-770(C)(3)(a) and (b).
~~11~~ 14."Lump-sum payment" means a member receives the total amount in the member's ASRS account to which the member is entitled by law.
~~12~~ 15."Member" has the same meaning as in A.R.S. § 38-711.
~~13~~ 16."Personal representative" means a person who is authorized by law to represent the estate of a deceased individual.
17. "Process date" means the calendar day the ASRS generates the contribution withdrawal documents to be sent to the member.
~~14. "Separate from service" means to terminate employment with an ASRS employer during a service year.~~
~~15~~ 18."Service year" has the same meaning as in A.R.S. § 38-711.
~~16~~ 19."System" means the same as "defined contribution plan" as defined in A.R.S. § 38-769, and which is administered by the ASRS.
~~17~~ 20."Terminate employment" means~~:~~
   ~~a.~~ ~~To~~ to end the employment relationship between a member and an ASRS employer with the intent that the member not return to employment~~, and~~
   ~~b. There is an interval of not less than 21 calendar days between the last date of employment in any position subject to participation in the ASRS and the first date of employment or of reemployment in the same or in any other position subject to participation in the ASRS~~ with that ASRS employer.

~~18~~ 21. "Trustee" means an individual who holds monetary assets in an eligible retirement plan under the Internal Revenue Code ~~or IRA~~ for the benefit of the member.

~~19~~ 22. "United States" means the same as in A.R.S. § 1-215.

~~20~~ 23. "Warrant" means a voucher authorizing payment of funds due to a member.

B. A member who ~~separates~~ terminates from ~~service~~ all ASRS employment by other than retirement or death and desires a return of the member's contributions, including amounts received for the purchase of service, any employer contributions authorized under A.R.S. § 38-740, and interest on the contributions, shall ~~complete an~~ request from the ASRS, in writing or verbally, the documents necessary to apply for the withdrawal of the member's contributions.

C. Upon receipt of the request, the ASRS shall provide the member with:

1. An Application for ~~Return or Transfer~~ Withdrawal of Contributions and Termination of Membership form,
2. An Ending Payroll Verification – Withdrawal of Contribution and Termination of Membership form, and
3. The process date.

D. The member shall complete and return to the ASRS the Application for Withdrawal of Contributions and Termination of Membership form that includes the following information:

1. The member's full name;
2. The member's Social Security number;
3. The member's current mailing address;
4. The member's daytime telephone number, if applicable;
5. The member's birth date;
6. The date of termination;

~~6 Whether the member wants a lump-sum payment or direct rollover;~~

7. Dated ~~and notarized~~ signature of the member certifying that the member:
   a . Is no longer employed by ~~an~~ any ASRS employer~~, and has provided the last date of employment~~;
   b. ~~Understands that if a payroll transaction occurred in the six months before the date of application, the member's former ASRS employer must complete Section 4 of the application, providing the following:~~
      ~~i. The last date the member worked;~~
      ~~ii. Final pay period ending date with final contribution adjustment or correction amount, if applicable;~~
      ~~iii. Amount of final contribution to the ASRS or payroll adjustment that does not include long-term disability contributions;~~
      ~~iv. Printed name, title, and signature of the authorized representative;~~
      ~~v. The authorized representative's phone~~ telephone~~ number;~~
      ~~vi. The authorized representative's fax number, if applicable;~~
      ~~vii. The name of the ASRS employer; and~~
      ~~viii. The date Section 4 was completed~~ Is neither under contract nor has any verbal or written agreement for employment in the future with an ASRS employer;
   c. Is not currently in a leave of absence status with an ASRS employer;
   d. Understands that all of the member's former ASRS employers' payroll departments will complete a payroll verification form if payroll transactions occurred with the ASRS employer within the last 6 months prior to the process date;
   ~~e~~ e. Has read and understands the Special Tax Notice Regarding Plan Payments the member received with the application;
   ~~d. Has read and understands the statements of information in the instructions the member received with the application;~~
   ~~e~~ f. Understands that the member is forfeiting all future retirement rights and privileges of membership with the ASRS;
   ~~f~~ g. Understands that long-term disability benefits will be canceled if the member elects to withdraw contributions while receiving or electing to receive long-term disability benefits;
   ~~g. Has provided the member's correct Social Security number on the form; and~~
   h. ~~Is or is not a resident of the United States~~ Understands that if the member elects to roll over all or any portion of the member's distribution to another employer plan, it is the member's responsibility to verify that the receiving employer plan will accept the rollover and, if applicable, agree to separately account for the pre-tax and post-tax amounts rolled over and the related subsequent earnings on the amounts;
   i. Understands that if the member elects to roll over all or any portion of the member's distribution to an individual retirement account, it is the member's responsibility to separately account for pre-tax and post-tax amounts; and
   j. Understands that if the member elects a rollover to another employer plan or individual retirement account, any portion of the distribution not designated for rollover will be paid directly to the member and any taxable amounts will be subject to 20% federal income tax withholding and 5% state tax withholding; and

~~8. If a payroll transaction for the member has occurred with an ASRS employer within the six months before the date of application, the member shall ensure that the ASRS employer completes Section 4 of the application as specified in~~

~~subsection (B)(7) (b); and~~

~~9~~ 8. ~~If the member requests a direct rollover, the member shall:~~

~~a.~~ Specify ~~either~~ that:

a. The entire amount of the distribution be paid directly to the member, or

~~i~~ b. The entire amount of the distribution be transferred to an eligible retirement plan ~~or individual retirement account~~, or

~~ii~~ c. ~~A specific dollar~~ An identified amount of the distribution be transferred to an eligible retirement plan ~~or individual retirement account~~ and the remaining amount be paid directly to the member;

9. If the member selects all or a portion of the withdrawal be paid to an eligible retirement plan specify;

a. The type of eligible retirement plan;

b. ~~Provide the individual retirement~~ The eligible retirement plan account number, if applicable; and

c. ~~Provide the~~ The name and mailing address of the ~~individual retirement account trustee or the name of the eligible retirement plan~~ eligible retirement plan.~~; and~~

~~d. Obtain from the eligible retirement plan, if applicable, the authorized representative's:~~

~~i. Signature, date, and title,~~

~~ii. Business telephone number; and~~

~~iii. E-mail address, if applicable.~~

E. If a payroll transaction for the member occurred with any ASRS employer within six months prior to the process date the member shall complete and return to the ASRS an Ending Payroll Verification – Withdrawal of Contributions and Termination of Membership form for each ASRS employer that includes the following information:

1. Filled out by the member:
   a. The member's full name; and
   b. The member's social security number; and
2. Filled out by each ASRS employer:
   a. The member's termination date,
   b. The member's final pay period ending date;
   c. The final amount of contributions, including any adjustments or corrections, but not including any long term disability contributions,
   d. The ASRS employer name and telephone number;
   e. The name and title of the authorized employer representative; and
   f. Certification by the authorized employer representative that:
      i. The member terminated employment and is neither under contract nor bound by any verbal or written agreement for employment with the employer;
      ii. There is no agreement to re-employ the member;
      iii. The authorized employer representative has the legal power to bind the employer in transactions with the ASRS.
   g. The signature of the authorized employer representative and date of signature.

~~C~~ F. If the member requests a return of contributions and a warrant is distributed during the fiscal year that the member began membership in the ASRS, no interest is paid to the account of the member.

G. If the member requests a return of contributions after the first fiscal year of membership, ASRS shall credit interest at the rate specified in Column 3 of the table in R2-8-118(B) to the account of the member as of June 30 of each year, on the basis of the balance in the account of the member as of the previous June 30. The ASRS shall credit interest for ~~an incomplete~~ a partial fiscal year of ~~participation~~ membership in the ASRS on the previous June 30 balance ~~at the rate of 1/12th of the annual rate for each month of participation following the previous June 30~~ based on the number of days up to and including the day the ASRS issues the warrant divided by the total number days in the fiscal year. Contributions made after the previous June 30 are returned without interest.

~~D~~ H. Upon submitting ~~a request for a return of contributions~~ to the ASRS the completed and accurate Application for Withdrawal of Contributions and Termination of Membership form and, if applicable, any Ending Payroll Verification – Withdrawal of Contributions and Termination of Membership forms, a member is entitled to payment of the amount due to the member as specified in subsection ~~(C)~~ (F) or (G) unless a present or former spouse submits to the ASRS a domestic relations order that specifies entitlement to all or part of the return of contributions under A.R.S. § 38-773 before the ASRS returns the contributions ~~to~~ as specified by the member.

~~E~~ I. Upon death of a member, the ASRS shall provide survivor benefits based on the deceased member's last dated written designation of beneficiary that is on file with the ASRS prior to the date of the member's death.

J. If there is no designation of beneficiary or if the designated beneficiary predeceases the member, the survivor benefit is paid as specified in A.R.S. § 38-762(F). The designated beneficiary or other person specified in A.R.S. § 38-762(F) shall:

1. Provide a certified copy of a death certificate or a certified copy of a court order that establishes the member's death;
2. Provide a certified copy of the court order of appointment as administrator, if applicable; and
3. Except if the deceased member was retired and elected the joint and survivor option, complete and have notarized an

application for survivor benefits, provided by the ASRS, that includes:
a. The deceased member's full name,
b. The deceased member's Social Security number,
c. The following, as it pertains to the designated beneficiary or other person specified in A.R.S. § 38-762(F):
   i. Full Name,
   ii. Mailing address,
   iii. Contact telephone number,
   iv. Date of birth, if applicable; and
   v. Social Security number or Tax ID number, if applicable.

NOTICE OF PROPOSED RULEMAKING

TITLE 2. ADMINISTRATION

CHAPTER 12. OFFICE OF THE SECRETARY OF STATE

[R05-403]

PREAMBLE

1. Sections Affected — **Rulemaking Action**

Article 8	New Article
R2-12-801	New Section
R2-12-802	New Section
R2-12-803	New Section
R2-12-804	New Section
R2-12-805	New Section
R2-12-806	New Section
R2-12-807	New Section
R2-12-808	New Section
R2-12-809	New Section
R2-12-810	New Section

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

Authorizing statute: A.R.S. Title 23, Chapter 3, Article 4

Implementing statute: A.R.S. §§ 23-564(D), 23-568(A), and 23-575(E)(4)(F)

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

Notice of Rulemaking Docket Opening: 11 A.A.R. 2743, July 22, 2005

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

Name: Kevin Tyne

Address: Arizona Secretary of State
1700 W. Washington
Phoenix, AZ 85007

Telephone: (602) 542-4919

Fax: (602) 542-1575

E-mail: ktyne@azsos.gov

Or

Name: Gene Palma

Address: Arizona Secretary of State
1700 W. Washington
Phoenix, AZ 85007

Telephone: (602) 542-3060

Fax: (602) 542-7386

E-mail: gpalma@azsos.gov

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

In accordance with A.R.S. §§ 23-564(D), 23-568(A), and 23-575(E)(4) and (F), the Secretary of State shall adopt rules to implement A.R.S. Title 23, Chapter 3, Article 4 and pursuant to Title 41, Chapter 6.

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

None

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

Not applicable

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

There will be a positive impact on small business and consumers. The proposed registration of Professional Employer Organizations will give businesses and consumers more confidence in Professional Employer Organizations. Additionally, the Secretary of State's ability to regulate the PEO industry will enhance protection of businesses and workers in Arizona and prevent the unregistered operation of a PEO.

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

Name: Kevin Tyne

Address: Arizona Secretary of State
1700 W. Washington
Phoenix, AZ 85007

Telephone: (602) 542-4919

Fax: (602) 542-1575

E-mail: ktyne@azsos.gov

Or

Name: Gene Palma

Address: Arizona Secretary of State
1700 W. Washington
Phoenix, AZ 85007

Telephone: (602) 542-3060

Fax: (602) 542-7386

E-mail: gpalma@azsos.gov

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

The Secretary of State does not plan to conduct an oral proceeding on the proposed rules unless a written request for an oral proceeding is submitted one of the individuals named in item #4 within 30 days after this notice is published. The Secretary of State will accept written comments on the proposed rules for 30 days after the date of this publication. All written comments must be submitted to one of the individuals named in item #4.

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

None

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

None

13. The full text of the rules follows:

TITLE 2. ADMINISTRATION

CHAPTER 12. OFFICE OF THE SECRETARY OF STATE

ARTICLE 8. ~~RESERVED~~ PROFESSIONAL EMPLOYER ORGANIZATIONS

Section

ARTICLE 8. ~~RESERVED~~ PROFESSIONAL EMPLOYER ORGANIZATIONS

R2-12-801. Definitions

Unless the context otherwise requires, the definitions of terms contained in A.R.S. § 23-561 are applicable. Additionally, the following definitions apply in this Article, unless otherwise specified:

1. "Application" means such forms, materials, fees, and information required to enable the Secretary of State to ascertain if an applicant meets the requirements of registration.
2. "PEO" means professional employer organization.

R2-12-802. Registration

A. Each applicant shall apply to the Secretary of State in writing upon forms available from the Secretary of State. Each completed application shall contain documentation of the particular qualifications required of the applicant, shall be verified by the applicant, and shall be accompanied by the appropriate fees.

B. A certificate shall be issued to an applicant who submits a complete application if the Secretary of State determines that the applicant meets the requirements of registration.

C. A written notice of denial of registration shall be provided to an applicant who submits a complete application if the Secretary of State determines that the applicant does not meet the requirements of registration.

D. A written notice of incomplete application and conditional denial of registration shall be provided to an applicant who submits an incomplete application. This notice shall advise the applicant that the application is incomplete and that the application is denied, unless the applicant corrects the deficiencies within the time period specified in the notice and otherwise meets all requirements for registration.

E. An applicant shall respond promptly to all requests of the Secretary of State for further information on an application. Failure to provide requested information within 30 days of a request of the Secretary of State shall be grounds for the denial of an application.

F. When a person contacts the Secretary of State to determine whether a particular PEO is registered, if the Secretary of State has denied, revoked, or restricted that PEO's registration or has placed it on probation, and if all administrative appeals are not yet exhausted when the person inquires, the Secretary of State shall inform the inquiring person of the denial, revocation, or restriction of a registrant, or the registrant's probation and the fact that the PEO has the right to appeal the Secretary of State's decision.

R2-12-803. Late Registration

If any type of renewal registration is not received by the Secretary of State 120 days after the registrant's completed fiscal year, the registrant shall:

1. Submit a renewal registration in accordance with the statutes addressing that particular type of registration; and
2. Pay the established registration renewal fee and a late fee established by this Article.

R2-12-804. Alternative Registration

A. A PEO or PEO group may apply for an alternative registration in lieu of the registration requirements under A.R.S. § 23-564, 23-565, or 23-566 by providing the Secretary of State with an affidavit or certification granted by a qualified assurance organization.

B. A qualified assurance organization shall be an independent national organization that has been approved by the Secretary of State based on a determination that the assurance organization:

1. Has an established program for the accreditation or certification of PEO's based on requirements equal to or greater than the requirements of A.R.S. § 23-564, 23-565, or 23-566;
2. Is willing to provide a level of financial assurance acceptable to the Secretary of State;
3. Has agreed to provide to the Secretary of State an affidavit confirming the certification or accreditation of each PEO and provide written notice within two business days of any termination or default of such certification or accreditation; and
4. Has agreed to provide the Secretary of State with online access or provide a copy within five business days of request any information used as a basis for certification or accreditation of a PEO that has elected to use these procedures for alternative registration.

C. If the Secretary of State withdraws approval of a qualified assurance organization because of its failure to comply with the requirements of subsection (B), a PEO or PEO group that has elected alternative registration must otherwise satisfy the requirements of A.R.S. §§ 23-564, 23-565, or 23-566 within 30 days of written notice by the Secretary of State.

R2-12-805. Registration Fees

A. A PEO registering with the Secretary of State shall pay the following fees:

1. If applying for an initial registration:
   a. The fee shall be $1,000 and
   b. The renewal registration fee shall be $1,000.
2. If applying for a group registration:
   a. The fee shall be $1,000 for the parent organization and $1,000 for each member of the group and
   b. The group registration renewal fee shall be $1,000 for the parent organization and $1,000 for each member of the group.
3. If applying for a limited registration:
   a. The fee shall be $1,000 and
   b. The limited registration renewal fee shall be $1,000.
4. If applying for an alternative registration:
   a. The fee shall be $1,000
   b. The alternative registration renewal fee shall be $1,000 and
   c. Alternative registration fees may be paid by an approved assurance organization on behalf of a PEO or PEO group.

B. A late fee of $250 will be assessed to any of the above registrations that are not renewed within 120 days of the registrant's completed fiscal year.

C. A reinstatement fee of $50 will be assessed to any applicant requesting the reinstatement of a registration that has been revoked or restricted or whose probation has expired.

D. All registration fees are nonrefundable.

R2-12-806. Investigations

A. The Secretary of State or its agent may perform an investigation, audit, or review necessary to determine whether a person has violated any provision of A.R.S. §§ 23-563 through 23-569 or 23-575 or any rule promulgated by the Secretary of State to implement this Article.

B. The Secretary of State or its agent may assess costs associated with investigation and prosecution.

C. Material compiled by the Secretary of State or its agent in an investigation, audit, or review pursuant to this Section is confidential and is not open to public inspection.

R2-12-807. Administrative Hearings

If the Secretary of State denies an application for registration, or revokes, restricts or refuses to renew a registration, or if the Secretary of State places a registrant on probation, upon notification, the registrant may appeal the decision of the Secretary of State pursuant to the procedure provided in A.R.S. Title 41, Chapter 6, Article 10.

R2-12-808. Probation

If a PEO fails to comply with the requirements of licensure pursuant to A.R.S. § 23-575(E), the Secretary of State may place the PEO on probation for a period not exceeding three years.

R2-12-809. Requirements of Reinstatement of a Revoked, Restricted, or Probationary Registration During Term of Revocation, Restriction, or Probation

A. Reinstatement of a revoked, restricted, or probationary registration during the term of limitation or probation shall be in accordance with the disciplinary order that imposed the discipline.

B. Unless otherwise specified in a disciplinary order imposing revocation, restriction, or probation of registration, the disciplined registrant may, at reasonable intervals during the term of the disciplinary order, petition for the reinstatement of its registration.

C. Petitions for registration reinstatement during the term of a disciplinary order imposing revocation, restriction, or probation shall be treated as a request to modify the terms of the disciplinary order, and not as an application for registration.

R2-12-810. Requirements of Reinstatement of a Revoked, Restricted, or Probationary Registration After the Specified Term of Revocation or Restriction of the License or After the Expiration of Probationary Status

Unless otherwise provided by a disciplinary order, an applicant who applies for reinstatement of a registration after the specified term of revocation or restriction of the registration, or after the expiration of probationary status shall:

1. Submit an application for registration complete with all supporting documents as is required when making an initial application for registration demonstrating the applicant meets all current qualifications for registration and compliance with requirements and conditions of registration reinstatement;
2. Pay the established registration renewal fee and the reinstatement fee;
3. Provide information requested by the Secretary of State to clearly demonstrate the applicant is currently competent to be reinstated to engage in offering PEO services; and
4. Pay any fines or citations owed to the Secretary of State prior to the disciplinary action.

NOTICE OF PROPOSED RULEMAKING

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

[R05-379]

PREAMBLE

1. Sections Affected	Rulemaking Action
R12-1-102	Amend
R12-1-311	Amend
R12-1-455	New Section
R12-1-701	Repeal
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

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
Exhibit A.	Repeal
Exhibit A.	New Section

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

General:

A.R.S. § 30-654(B)

Specific:

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

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

Notice of Rulemaking Docket Opening: 11 A.A.R. 3184, August 19, 2005

Notice of Rulemaking Docket Opening: 11 A.A.R. 4309, October 28, 2005

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

Name: Daniel H. Kuhl

Address: Arizona Radiation Regulatory Agency
4814 S. 40th St.
Phoenix, AZ 85040

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

Fax: (602) 437-0705

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

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

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

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

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

Article 7 contain the standards for use of radioactive material in the practice of medicine. The Agency is revising the all of Article 7 to remain compatible with the Nuclear Regulatory Commission (NRC). The Agency maintains an Agreement with the NRC, as do 32 other states, which allows Arizona to regulate radioactive material users under the guidance of the NRC. In many cases the NRC will require the Agreement States to adopt certain standards. This rule revision is the first time, in the history of the Agency, that the majority of the rules contained in Article 7 will follows 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.*

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

None

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

Not applicable

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

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

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

In a similar vane, regulation of a relatively new diagnostic tool, Positron Emission Tomography (PET), would lead the casual observer to think that the new PET rules proposed in Article 7 might result in a significant increase in cost to the affected medical licensees. However, the Agency believes it may in fact, be just the opposite, or at the least, a minimum expense when compared to diagnostic equipment costs. Licensees that have already started to perform PET without notifying the Agency under the old rules, will be required to notify the Agency as to their planned activities and how the licensee will provide radiation protection for personnel in accordance with the radiation exposure standards in Article 4. If the Article 4 standards are not currently met, the licensee will be required to retrofit the existing facility with shielding, or even worse reconstruction the facility. It may be more expensive than building a safe PET facility from the beginning by incorporating conditions that will limit radiation exposure that meets the regulatory standard. It was determined from a local health physics consultant that shielding costs may be as high as $25,000, which will provide shielding in all affected walls, and the floor and ceiling, if the areas above and below the PET facility are occupied by personnel. In itself the $25,000 spent for shielding may seem like a large sum of money, but

compared to the cost of a PET/CT (computerized tomography) gamma camera that costs between $750,000 an $1,000,000, this is actually a small price to pay for radiation safety.

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

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

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

An oral proceeding at the Agency is scheduled for Monday, December 5, 2005, at 10:00 a.m. A person may submit written comments concerning the proposed rules by submitting them no later than 5 p.m., on December 5, 2005, to the following person:

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

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

None

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

Rule	Incorporation
R12-1-311(C)	10CFR 32.26
R12-1-311(C)(2)	10CFR 32.29
R12-1-311(D)(4)(e)	10CFR 32.52
R12-1-311(F)	10CFR 32.56, 32.101
R12-1-311(F)(2)	10CFR 32.57, 32.58, 32.102, 70.39
R12-1-311(I)	10CFR 32.61, 32.62, 32.101
R12-1-311(J)	10CFR 32.72
R12-1-311(L)	10CFR 32.74
R12-1-702	21CFR 361.1
R12-1-716(C)(2)	AAPM Task Group on PET and PET/CT Shielding
R12-1-719(A)	10CFR 35.910
R12-1-721(A)	10CFR 35.920
R12-1-723(A)	10CFR 35.930
R12-1-723(B)	10CFR 35,932
R12-1-723(C)	10CFR 35.934
R12-1-727(A)	10CFR 35.940
R12-1-727(B)	10CFR 35.941
R12-1-728	10CFR 35.950
R12-1-744	10CFR 35.960

13. The full text of the rules follows:

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

ARTICLE 1. GENERAL PROVISIONS

Section
R12-1-102. Definitions

ARTICLE 3. RADIOACTIVE MATERIAL LICENSING

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

ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

Section
R12-1-455. Security Requirements for Portable Gauges

ARTICLE 7. USE OF RADIONUCLIDES IN THE HEALING ARTS

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

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
"CFR"	No change
"Chelating agent"	No change
"Civil penalty"	No change

"Collective dose"	No change
"Committed dose equivalent"	No change
"Committed effective dose equivalent"	No change
"Curie"	No change
"Current license or registration"	No change
"Deep-dose equivalent"	No change
"Depleted uranium"	No change
"Dose"	No change
"Dose equivalent (H_T)"	No change
"Dose limits"	No change
"Dosimeter"	No change
"Effective dose equivalent (H_E)"	No change
"Effluent release"	No change
"Embryo/fetus"	No change
"Enclosed beam x-ray system"	No change
"Enclosed radiography"	No change
"Cabinet radiography"	No change
"Shielded room radiography"	No change
"Entrance or access point"	No change
"Exhibit"	No change
"Explosive material"	No change
"Exposure"	No change
"Exposure rate"	No change
"External dose"	No change
"Extremity"	No change
"Fail-safe characteristics"	No change
"Field radiography"	No change
"Field station"	No change
"Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities"	No change
"Generally applicable environmental radiation standards"	No change
"Gray"	No change
"Hazardous waste"	No change
"Healing arts"	No change
"Health care institution"	No change
"High radiation area"	No change
"Human use"	No change
"Impound"	No change
"Individual"	No change
"Individual monitoring"	No change
"Individual monitoring device" or "individual monitoring equipment"	No change
"Industrial radiography"	No change
"Injection tool"	No change
"Inspection"	No change
"Interlock"	No change
"Internal dose"	No change
"Irradiate"	No change
"Laser"	No change
"Lens dose equivalent"	No change
"License"	No change
"Licensed material"	No change
"Licensed practitioner"	No change
"Licensee"	No change
"Licensing State"	No change
"Limits"	No change
"Local components"	No change

"Logging supervisor"	No change
"Logging tool"	No change
"Lost or missing licensed or registered source of radiation"	No change
"Low-level waste"	No change
"Major processor"	No change
"Medical dose"	No change
"Member of the public"	No change
"MeV"	No change
"Mineral logging"	No change
"Minor"	No change
"Monitoring"	No change
"Multiplier"	No change
"NARM"	No change
"Normal operating procedures"	No change
"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 provide the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs; or an individual certified in Therapeutic Radiological Physics or X-ray and Radium Physics by the American Board of Radiology, or having equivalent qualifications that provide training and experience in the clinical applications of radiation physics to radiation therapy, to calibrate radiation therapy equipment. The detailed requirements for a particular qualified expert ~~are~~ may be provided in the respective Articles of ~~these rules~~ this Chapter. For clarification purposes a qualified expert is not an authorized medical physicist, however, an authorized medical physicist is one of the many authorities grouped together under the title of qualified expert.

"Quality Factor"	No change
"Quarter"	No change
"Rad"	No change
"Radiation"	No change
"Radiation area"	No change
"Radiation dose"	No change
"Radiation machine"	No change
"Radiation safety officer"	No change
"Radioactive marker"	No change
"Radioactive material"	No change
"Radioactivity"	No change
"Radiographer"	No change
"Radiographer's assistant"	No change
"Registrant"	No change
"Registration"	No change
"Regulations of the U.S. Department of Transportation"	No change
"Rem"	No change

"Research and Development"	No change
"Restricted area"	No change
"Roentgen"	No change
"Safety system"	No change
"Sealed source"	No change
"Sealed Source and Device Registry"	No change
"Shallow-dose equivalent (H_s)"	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

ARTICLE 3. RADIOACTIVE MATERIAL LICENSING

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

A. No change
1. No change
   a. No change
   b. No change
2. No change
   a. No change
      i. No change

ii. No change
iii. No change
iv. No change
v. No change
b. No change
c. No change
d. No change
e. No change
f. No change
g. No change
h. No change
i. No change
ii. No change
iii. No change
iv. No change
v. No change
vi. No change
i. No change
j. No change
k. No change
l. No change
m. No change
3. No change

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

C. The Agency shall approve an application for a specific license authorizing the incorporation of radioactive material, other than source or by-product material, into gas and aerosol detectors to be distributed to persons exempt under A.A.C. R12-1-303(B) if the application satisfies requirements equivalent to those contained in 10 CFR 32.26, ~~1998 Edition, published~~ January 1, ~~1998~~2005, which is incorporated by reference, ~~and~~ published by the office of Federal Register, National Archives and Records Administration, Washington, D.C. 20498, and on file with the Agency~~, and the Office of the Secretary of State which shall not contain any~~ This incorporation by reference contains no future editions or references, and provided:
1. No change
2. The licensee files annual reports required by 10 CFR 32.29, ~~1998 Edition, published~~ January 1, ~~1998~~2005, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency~~ and the Office of the Secretary of State, with the Agency~~. This incorporation by reference contains no future editions or references.

D. No change
1. No change
a. No change
b. No change
i. No change
ii. No change
iii. No change
c. No change

i. No change
ii. No change
iii. No change
d. No change
e. No change
f. No change
2. No change
a. No change
b. No change
c. No change
d. No change
e. No change
f. No change
g. No change
h. No change
i. No change
j. No change
3. No change
4. No change
a. No change
b. No change
c. No change
d. No change
e. No change
f. The licensee shall;
i. Report on a quarterly basis to the responsible Agreement State or NRC all transfers of devices to persons for use under a general license in accordance with 10 CFR 32.52, January 1, 2005, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration Washington, D.C. 20408, and on file with the Agency. This incorporated reference contains no future editions or amendments.
ii. Maintain all information concerning transfers and receipts of devices that supports the reports required by this Section.
iii. Maintain records required by this subsection 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. The requirements of 10 CFR 32.53 through 32.56 and 32.101, ~~1998~~ 2005 ~~Edition, published~~ January 1, ~~1998~~ 2005, which is incorporated by reference, published by the Office of the Federal Register, National; Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency ~~and the Office of the Secretary of State, or their equivalent~~. These incorporations by reference contain no future editions or amendments.

F. No change
1. No change
2. The requirements of 10 CFR 32.57, 32.58, 32.102, and 70.39, ~~1998 Edition, published~~ January 1, ~~1998~~ 2005, which is incorporated by reference, published by the Office of Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency ~~and the Office of the Secretary of State, or their equivalent~~. These incorporations by reference contain no future editions or amendments.

G. No change
1. No change
2. No change
   a. No change
   b. No change

H. No change
1. No change
2. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
   f. No change
   g. No change
3. No change
   a. No change
   b. No change
4. No change
   a. No change
   b. No change
5. No change

I. No change
1. No change
2. The criteria of 10 CFR 32.61, 32.62, and 32.101, ~~1998 Edition, published~~ January 1, ~~1998~~ 2005, which is incorporated by reference, published by the office of Federal Register, National Archives and Records Administration, Washington, D.C. and on file with the Agency ~~and the Office of the Secretary of State~~. These incorporations by reference contain no future editions or amendments.

J. No change

K. No change
1. No change
2. No change
   a. No change
   b. No change
3. No change
4. No change
5. No change
   a. No change
   b. No change

L. No change

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

R12-1-455. Security Requirements for Portable Gauges

A. A licensee that uses a portable gauge shall use a minimum of two independent controls to maintain security while:
   1. Transporting a portable gauge; and
   2. Storing a portable gauge.

B. Each control shall form a tangible barrier that will prevent unauthorized removal, whenever a portable gauge is not under the control and constant surveillance of the licensee.

C. All controls employed by a licensee to secure a portable gauge against unauthorized removal shall be approved by the Agency.

ARTICLE 7. USE OF RADIONUCLIDES IN THE HEALING ARTS

R12-1-701. ~~Scope~~ Repealed

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

R12-1-702. Definitions

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

"Authorized nuclear pharmacist" means a pharmacist who meets the requirements in A.A.C. R12-1-712:

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

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

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

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

"Brachytherapy" No change

"CT" means computerized tomography.

"High dose rate afterloading brachytherapy" No change

"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 physician is in proximity to the patient during a radiation therapy procedure so that the physician is able to communicate immediate emergency orders 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" for purposes of this Article, and in addition to the definition in Article 1 means an individual who:

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

Is identified as a Radiation Safety Officer on:

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

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

"Radioactive Drug Research Committee" or RDRC means the committee established by the licensee to review all protocols involving the administration of radioactive material to human research subjects, which is further defined in 21CFR 361.1, April 1, 2005, which is incorporated by reference, published by the office of Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments

"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.

"Written directive" No change

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

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

1. The applicant has appointed a radiation safety committee, meeting the requirements in ~~R12-1-706~~ R12-1-705, that will oversee the use of licensed material throughout the medical institution ~~and review the medical institution's~~ 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 who has ~~substantial training and experience in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients, and~~ met the training and experience requirements in R12-1-719, R12-1-721, R12-1-723, R12-1-727, R12-1-728, or R12-1-744
4. ~~If the application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant's staff has substantial experience in the use of a variety of radioactive materials for a variety of medical purposes.~~

B. Specific licenses to individual ~~physicians~~ authorized users for medical use of radioactive material:

1. The Agency shall approve an application by ~~an individual physician or group of physicians~~ a prospective individual authorized user or prospective group of authorized users for a specific license governing the medical use of radioactive material if:
   a. The applicant satisfies the general requirements in R12-1-309;
   b. The application is for use in the applicant's practice at an office outside of a medical institution;
   c. The applicant has access to a medical institution with adequate facilities to hospitalize and monitor the applicant's radioactive patients or human research subjects whenever it is advisable; ~~and~~
   d. The applicant ~~has substantial experience in the handling and administration of radionuclides, and where applicable, the clinical management of radioactive patients~~ meets the training and experience requirements in subsection (A)(3); and
   e. The applicant has a radiation safety committee, if the criteria in R12-1-705 are met and a RDRC if the use involves human research.
2. The Agency shall not approve an application by ~~an individual physician or group of physicians~~ a prospective authorized user or group of prospective authorized users for a specific license to receive, possess, or use radioactive material on the premises of a medical institution unless:
   a. The use of radioactive material is limited to:
      i. The administration of radiopharmaceuticals for diagnostic or therapeutic purposes;
      ii. The performance of diagnostic studies on patients or human research subjects to whom a radiopharmaceutical has been administered;
      iii. The performance of in vitro diagnostic studies; or
      iv. The calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation, or diagnostic instrumentation;
   b. The ~~physician~~ authorized user brings the radioactive material and removes the radioactive material upon departure; and
   c. The medical institution does not hold a radioactive materials license under subsection (A).

C. Specific licenses for certain groups of medical uses of radioactive material

1. ~~Subject to the provisions of subsections (C)(2), (3), and (4), the~~ The Agency shall approve an application for a specific license under subsections (A) or (B), for any medical use or uses of radioactive material specified in ~~1 or more of Groups I to V inclusive,~~ Groups 100 to 600, in Exhibit A of this Article for all of the materials within the ~~group or groups~~ group(s) requested in the application if:
   a. The applicant satisfies the requirements of subsections ~~(A), (B), and (D)~~ (A) and (B);
   ~~b. The applicant, or any physician designated in the application as an individual user meets the qualifications in R12-1-704;~~
   ~~c.~~b. All ~~other~~ personnel who will be involved in the preparation and use of the radioactive material ~~have adequate training and experience in the handling of radioactive material appropriate to their participation in the uses included in the group or groups~~ if they are not an authorized user, an authorized nuclear pharmacist, or certified

as a nuclear medicine technologist by the Medical Radiologic Technology Board of Examiners (MRTBE);

~~d.~~c. The applicant's radiation detection and measuring instrumentation is adequate for conducting the procedures involved in the uses included in the ~~group or groups~~ group(s); and

~~e.~~d. The applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the uses included in the ~~group or groups~~ group(s).

~~2. Any licensee or registrant who is authorized to use radioactive material according to 1 or more groups in subsection (C)(1), and Exhibit A of this Article is subject to the following conditions:~~

~~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~~ NRC ~~under 10 CFR 32.72, 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of Secretary of State (this incorporation by reference contains no future editions or amendments), or a specific license issued by an Agreement State or a Licensing State under equivalent rules.~~ ; and

~~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.~~

~~3.~~2. Any licensee who is licensed according to subsection (C)(1), for 1 or more of the medical use groups in Exhibit A also is authorized to use radioactive material under the general license in R12-1-306(F) for the specified in vitro uses without filing Form ARRA-9 as required by R12-1-306(F)(2); provided, that the licensee is subject to the other provisions of R12-1-306(F)).

~~4. Any licensee who is licensed according to this Section is authorized to receive, possess, and use calibration and reference radioactive sealed sources in accordance with R12-1-711.~~

D. ~~In addition to the requirements set forth in R12-1-309, the Agency shall issue a specific license for medical use of sealed sources only if the applicant or, if the application is made by a medical institution, the individual user has the qualifications listed in R12-1-704.~~

In addition to the other license application requirements in this Section, each applicant shall include in their radiation safety program a system for ensuring that each syringe and vial that contains unsealed radioactive material is labeled in accordance with R12-1-431(D).

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

~~**A.** For purposes of this rule "supervision" means the exercise of control over or direction of the use of radioactive material in the practice of medicine by an authorized user named on a radioactive material license. Supervision does not require a supervising physician's constant physical presence if the supervising physician can be easily contacted by radio, telephone, or telecommunication.~~

~~**B.** A physician may use radioactive material if he or she is licensed by the Arizona Board of Medical Examiners or Board of Osteopathic Examiners in Medicine and Surgery and is listed as an authorized user on a radioactive material license issued by the Agency, NRC, or Agreement State, authorizing the use of radioactive material for medical purposes.~~

~~**C.** A physician, having the training and experience listed in 10 CFR 35, 1998 Edition, published January 1, 1998, which is incorporated by reference and on file with the Agency and the Office of Secretary of State, or a physician under the supervision of a physician having the qualifications listed above, may use radioactive material for medical purposes. This incorporation by reference contains no future editions or amendments.~~

~~**D.** An authorized user, approved to prescribe radiopharmaceuticals for therapy purposes on a radioactive materials license, shall be physically present when a radiopharmaceutical is administered to a human being for therapeutic purposes.~~

~~**E.** A limited-service nuclear pharmacy permittee shall dispense radiopharmaceuticals only to a physician listed as an authorized user on a valid radioactive material license issued by the Agency, an Agreement State, or the NRC.~~

A. A licensee may conduct research involving human research subjects only if it uses the radioactive materials specified on its license for the uses authorized on its license.

B. Before conducting research the licensee shall:

1. Obtain review and approval of the research from a RDRC as defined; and
2. Obtain informed consent from the human research subject.

C. Before conducting research the licensee shall apply 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 review and approval of the research from a RDRC, and
2. Obtain informed consent from the human research subject.

D. Nothing in this Section relieves licensees 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 Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. Each time the Radiation Safety Officer is changed, the licensee shall provide to the Agency with the amendment request a copy of the correspondence between the licensee's management and the candidate accepting the position of Radiation Safety Officer.

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 to oversee all uses of radioactive material permitted by the license. As a minimum, the Committee 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.

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

~~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 Board of Medical Examiners or Board of Osteopathic Examiners in Medicine and Surgery and is listed as an authorized user on the Arizona radioactive material license under which the radioactive material is obtained.

C. A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user, shall:
1. Instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, rules, and license conditions with respect to the use of radioactive material; and
2. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures established by the licensee, written directive procedures, rules, and license conditions with respect to the medical use of radioactive material.

D. A licensee that permits the preparation of radioactive material for medical use by an individual who is supervised by an authorized nuclear pharmacist or a physician who is an authorized user, shall:
1. Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and
2. Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, written radiation protection procedures established by the licensee, the rules, and license conditions.

E. A licensee that permits supervised activities under subsections (C) and (D) is responsible for the acts and omissions of the supervised individual.

F. A limited-service nuclear pharmacy licensee shall dispense radiopharmaceuticals only to a physician listed as an authorized user on a valid radioactive material license issued by the Agency, an Agreement State, or the NRC. For purposes of this rule "limited service" is defined in A.A.C. 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 3 years after creation of the record.

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

~~**A.** Reports of therapy misadministrations.~~

~~1. When a administration involves any therapy procedure, the licensee shall notify the Agency by telephone. The licensee shall also notify the referring physician of the affected patient and the patient or a responsible relative or guardian, unless the referring physician personally informs the licensee either that he or she will inform the patient, or that in his or her medical judgment, telling the patient or the patient's responsible relative or guardian would be harmful to one or the other, respectively. These notifications shall be made within 24 hours after the licensee discovers the misadministration. If the referring physician or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee shall not delay medical care for the patient because of notification problems.~~

~~2. Within 15 days after the initial therapy misadministration report to the Agency, the licensee shall report, in writing, to the Agency and to the referring physician and furnish a copy of the report to the patient or the patient's responsible relative or guardian, depending on who was previously notified by the licensee under subsection (A)(1). The written report shall include the licensee's name, the referring physician's name, a brief description of the event, the effect on the patient, the action taken to prevent recurrence, whether the licensee informed the patient or the patient's responsible relative or guardian, and if not, why not. The report shall not include the patient's name or other information that could lead to identification of the patient.~~

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

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

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

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

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

A licensee may 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 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 licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in R12-1-705 to be an individual who:

1. Is certified by a specialty board whose certification process includes all of the requirements in subsection (2) and whose certification has been recognized by the Agency, NRC, or an Agreement State; or

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

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

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

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

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

1. Is certified by a specialty board whose certification process includes all of the training and experience requirements in subsection (B) and whose certification has been recognized by the Agency, NRC or an Agreement State; or
2. Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics and has completed 1 year of full-time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of an authorized medical physicist at a medical institution that includes the physics tasks associated with the sealed source radiation therapy procedures regulated in this Article; and
3. Has obtained written certification that the individual has satisfactorily completed the requirements in subsection (B) and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written certification shall be signed by a preceptor authorized medical physicist who meets the requirements in this

Section or equivalent NRC or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

4. An individual identified as a teletherapy or medical physicist on an Agency, NRC, or Agreement State license or a permit issued by a Agency, NRC, or Agreement State broad scope licensee or NRC master material license permit or by a NRC master material license permittee of broad scope before the effective date of these rules need not comply with the training requirements in subsections (A) through (C)
5. The training and experience shall have been obtained within the 7 years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

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

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

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

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

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

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

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

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

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

1. Direct measurement of radioactivity; or
2. Decay correction, based on the activity or activity concentration determined by:
   a. A manufacturer or preparer licensed under R12-1-311or 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. Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use;
2. 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;
3. 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);
4. 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.
5. Perform appropriate checks and tests required by this Section following adjustment or repair of the dose calibrator; and
6. 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.
7. A licensee using a dose calibrator to "verify" a dosage prepared by a supplier authorized in subsection (B)(2) shall maintain the dose calibrator in accordance with this subsection.
8. A licensee who chooses to use nationally recognized standards or the manufacturer's instructions to maintain the dose calibrator used to meet the requirements in this subsection, shall maintain for Agency review, a copy of the nationally recognized standards or the manufacturer's instructions with the dose calibrator maintenance records.

H. A licensee shall calibrate the survey instruments before first use, annually, and following a repair that affects the calibration. A licensee shall:

1. Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source;
2. Calibrate two separated readings on each scale or decade that will be used to show compliance; and
3. Conspicuously note on the instrument the date of calibration.

I. A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

J. A licensee shall retain records of instrument calibration for three years following the calibration.

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

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

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

~~2. When not in use, the licensee shall keep sealed sources and applicators containing sealed sources in a protective enclosure of such material and wall thickness as is necessary to assure compliance with the provisions of 12 A.A.C. 1, Article 4.~~

~~3. Each licensee shall conduct a quarterly physical inventory to account for all brachytherapy sources and devices containing brachytherapy sources received and possessed. Records of the inventories shall be maintained for inspection by the Agency and shall include the quantities and kinds of radioactive material, location of sources and devices, and the date of the inventory.~~

~~4. Each licensee shall follow the radiation safety and handling instructions approved by the Agency; or follow the radiation safety and handling instructions furnished by the manufacturer on the label attached to the brachytherapy source, the device containing a brachytherapy source, the permanent container containing the brachytherapy source, or in the leaflet or brochure which accompanies the brachytherapy source or device, and maintain these such instructions in a legible and easily accessible form. If the handling instructions, leaflet, or brochure is no longer available or a copy cannot be obtained from the manufacturer, the Agency shall be notified the source information is no longer available.~~

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

~~**B.** A licensee shall perform leak testing on brachytherapy sources for radioactive contamination as required in R12-1-417.~~
~~**C.** Radiation surveys.~~
~~1. A physician on a radioactive material license, qualified expert, or person approved by the licensee's radiation safety officer shall measure the maximum radiation level at a distance of 1 meter (40 in.) from the patient in whom brachytherapy sources have been inserted, using a calibrated survey instrument. This radiation level shall be entered on the patient's chart and other signs posted as required in subsection (E).~~
~~2. A physician on a radioactive material license, qualified expert, or person approved by the licensee's radiation safety officer shall measure and record the radiation level in the patient's room and the surrounding area. The licensee shall maintain the record for Agency inspection.~~
~~3. The licensee shall assure that patients treated with cobalt-60, cesium-137, iridium-192, or radium-226 implants remain hospitalized until a source count and a radiation survey of the patient, using a calibrated survey instrument, confirm that all radiation emitting implants have been removed.~~
~~**D.** A qualified expert who meets the following training and experience requirements shall perform all physics procedures necessary to prepare a patient for a therapeutic application of radiation. The qualified expert shall:~~
~~1. Be certified by the American Board of Radiology in: Therapeutic Radiological Physics, Radiological Physics, Roentgen-Ray and Gamma-Ray Physics, or X-ray and Radium Physics; or the American Board of Medical Physicists in Radiation Oncology Physics; or~~
~~2. Have the following minimum training and experience:~~
~~a. A Master's or Doctor's degree in physics, biophysics, radiological physics, or health physics;~~
~~b. One year of full-time training in therapeutic radiological physics; and~~
~~c. One year of full-time experience at a radiotherapy facility, including personal experience calibrating brachytherapy radiation sources and planning associated patient treatment.~~
~~3. A candidate who does not meet the standards in subsections (D)(1) and (D)(2), may request a license amendment for an exemption from these training or experience requirements in accordance with A.R.S. § 30-654(B)(13). The request shall include the name of the proposed qualified expert, a description of the individual's training and experience, including information similar to that specified in subsection (D)(2), and a written endorsement, based on personal knowledge of the individual's qualifications, by a physicist certified by the American Board of Radiology in one of the specialties listed in subsection (D)(1).~~
~~**E.** Signs and records.~~
~~1. In addition to the requirements in R12-1-429, the licensee shall mark the bed, cubicle or room of the hospital brachytherapy patient with a sign indicating the presence of brachytherapy sources. This sign shall incorporate the radiation symbol and specify the radionuclide, activity, date, and individual to contact for radiation safety instructions. The sign is not required if any of the exceptions in R12-1-430 apply.~~
~~2. A physician on a radioactive material license, qualified expert, or person approved by the licensee's radiation safety officer shall include the following information in the patient's records when the patient is undergoing brachytherapy:~~
~~a. The radionuclide administered, the number of sources, the activity in millicuries, and the time and date of administration;~~
~~b. The exposure or dose rate at 1 meter, the time the measurement was made, and by whom;~~
~~c. The radiation symbol; and~~
~~d. The precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted in Article 4.~~

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

1. Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under Article 3 of this Chapter or equivalent NRC or Agreement State regulations.
2. Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under Article 3 of this Chapter, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.
3. Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).
4. Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 µCi) or 1000 times the quantities in Article 4, Appendix B of this Chapter.
5. Technetium-99m in amounts as needed.

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 sources for leakage in accordance with R12-1-417.

C. A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a physical inventory every 6 months of all sources in its possession. During the period of time between the inventories the licensee shall add each acquired sealed source to the inventory record and remove from the inventory record each source that leaves the licensee's control.

D. A licensee shall document the inventories conducted under subsection (C) and maintain inventory records in accordance with R12-1-450.

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

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

~~1. The teletherapy equipment housing is constructed so that, at 1 meter (40 in.) from the teletherapy source, the maximum exposure rate does not exceed 100 iSv (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 iSv (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 iC/kg (1 R) per hour or 0.1 percent of the useful beam exposure rate, whichever is less.~~

~~3. Adjustable or removable beam-defining diaphragms allow transmission of not more than 5% of the useful beam exposure rate.~~

~~4. The beam control mechanism is of a design capable of acting in any orientation of the housing. The mechanism is designed so that it can be manually returned to the "off" position with a minimum risk of exposure.~~

~~5. The closing device is designed to return automatically to the "off" position in the event of any breakdown or interruption of power and stays in the "off" position until activated from the control panel.~~

~~6. When any door to the treatment room is opened, the beam control mechanism automatically and rapidly restores the unit to the "off" position and causes it to remain there until the unit is reactivated from the control panel.~~

~~7. There is at the housing and at the control panel a warning device that plainly indicates whether the beam is on or off and an independent radiation monitoring device which:~~

~~a. Continuously monitors the condition of the teletherapy beam and~~

~~b. Provides a continuously visible signal to the operator.~~

~~8. The equipment has a locking device to prevent unauthorized use.~~

~~9. The control panel has a timer that automatically terminates the exposure after a preset time.~~

~~10. The equipment permits continuous observation of patients during irradiation.~~

~~**B.** The authorized user shall ensure that no individual is in the treatment room during irradiation unless that individual is the patient. Mechanical restraining or supporting devices shall be used for positioning the patient, if necessary.~~

~~**C.** The licensee shall test the teletherapy sources for leakage and contamination as required in R12-1-417. The licensee shall also wipe accessible surfaces of the housing port or collimator while the source is in the "off" position, measuring the wipe samples for transferred contamination.~~

~~**D.** Calibration requirements.~~

~~1. The licensee's expert, qualified by training and experience under subsection (G), shall perform full calibration measurements on each teletherapy unit:~~

~~a. Prior to the first use of the unit for treating humans.~~

~~b. Prior to treating humans:~~

~~i. Whenever spot-check measurements indicate that the output value differs by more than 5% from the value obtained at the last full calibration, corrected mathematically for decay;~~

~~ii. Following replacement of the radiation source or following reinstallation of the teletherapy unit in a new location; or~~

~~iii. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and~~

~~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. Reserved.~~

~~4. The expert shall correct the exposure rate or dose rate values mathematically for intervals not exceeding one month.~~

~~**E.** Spot check measurements.~~

1. ~~The licensee's expert or other authorized agent shall perform spot check measurements on each teletherapy unit at intervals not exceeding one month.~~
2. ~~Spot check measurements shall include determination of:~~
   a. ~~Timer accuracy;~~
   b. ~~The congruence between the radiation field and the field indicated by the light beam localizing device;~~
   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 expert shall establish spot check measurement procedures. If the expert does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by the expert within 15 days.~~

~~F.~~ ~~Dosimetry systems.~~

1. ~~The licensee's expert shall perform full calibration measurements using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system shall have been calibrated within the previous two years and after any servicing that may have affected system calibration.~~
2. ~~Spot check measurements shall be performed using a dosimetry system that has been calibrated as required in subsection (F)(1). Alternatively a dosimetry system used solely for spot check measurements may be calibrated by direct intercomparison with a system that has been calibrated according to the standards in subsection (F)(1). This alternative calibration method shall have been performed within the previous one year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.~~

~~G.~~ ~~The licensee shall determine if a person is an expert, qualified by training and experience to calibrate a teletherapy unit, establish procedures for spot check measurements, and review the results of such measurements. The licensee shall determine that the qualified expert:~~

1. ~~Is certified by the American Board of Radiology in: Therapeutic Radiological Physics, Radiological Physics, Roentgen Ray and Gamma Ray Physics, or X ray and Radium Physics; or the American Board of Medical Physicists in Radiation Oncology Physics; or~~
2. ~~Has the following minimum training and experience:~~
   a. ~~A Master's or Doctor's degree in physics, biophysics, radiological physics or health physics;~~
   b. ~~One year of full-time training in therapeutic radiological physics; and~~
   c. ~~One year of full-time experience in radiotherapy facility, including personal calibration and spot check of at least one teletherapy unit.~~
3. ~~Licensees, that have their teletherapy units calibrated by persons who do not meet the criteria in subsections (G)(1) and (2) for minimum training experience, may request a license amendment excepting them from these training requirements. The request should include the name of the proposed qualified expert, a description of the expert's training and experience, including information similar to that specified in subsection (G)(2), reports of at least one calibration and one spot check, based on measurements personally made by the proposed expert within the last 10 years, and a written endorsement of the expert's qualifications by a physicist certified by the American Board of Radiology in one of the specialties listed in subsection (G)(1), based on personal knowledge.~~

~~H.~~ ~~The licensee shall maintain for inspection by the Agency: records of measurements, tests, corrective actions, and instrument calibrations made under subsections (D) and (E), and records of the licensee's evaluation of the qualified expert's training and experience under subsection (G).~~

1. ~~The licensee shall preserve records of the following for three years after completion of each full calibration:~~
   a. ~~Full calibration measurements; and~~
   b. ~~Calibration of the instruments used to make the full calibration measurements.~~
2. ~~The licensee shall preserve records of the following for three years after completion of each spot check:~~
   a. ~~Spot check measurements and corrective actions; and~~
   b. ~~Calibration of instruments used to make spot check measurements.~~
3. ~~The licensee shall preserve records of the licensee's evaluation of the qualified expert's training and experience for three years after the qualified expert's last performance of a full calibration on the licensee's teletherapy unit.~~

A. In addition to the surveys required in Article 4 of this Chapter, a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where unsealed radioactive material, requiring a written directive, is prepared for use or is administered. In areas of routine use, that are released for unrestricted use, a licensee shall perform a survey of the area using an instrument appropriate for detecting contamination before releasing the area for unrestricted use.

B. A licensee shall obtain the services of a person experienced in the principles of radiation protection and installation design, to design a PET facility and to perform a radiation survey when the facility is ready for patient imaging. The licensee shall provide a copy of the installation radiation survey to the Agency within 30 days of imaging the first patient.

C. The licensee shall use engineering controls or shield each PET use area with protective barriers necessary to comply with the radiation exposure limits in R12-1-408 and R12-1-416.
1. At the time of application for a new license or amendment to an existing license, and before treatment of the first patient, the licensee shall provide to the Agency a copy of the installation report signed by the contractor who installed the shielding material recommended by the consultant and a report of the survey required in subsection (B).
2. The licensee shall perform shielding calculations in accordance with *AAPM Task Group on PET and PET/CT Shielding Requirements,* which is incorporated by reference, published by the American Association of Physicists in Medicine, One Physics Ellipse, College Park, MD 20740, and on file with the Agency. In lieu of these procedures the licensee may use equivalent calculations approved by the Agency. This incorporation by reference contains no future editions or amendments.

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, Roent-~~

~~gen-Ray and Gamma-Ray Physics, or X-ray and Radium Physics; or the American Board of Medical Physicists in Radiation Oncology Physics; or~~

~~2. Have the following minimum training and experience:~~

~~a. A Master's or Doctor's degree in physics, biophysics, radiological physics, or health physics;~~

~~b. One year of full-time training in therapeutic radiological physics; and~~

~~c. One year of full-time experience at a radiotherapy facility, including personal experience calibrating brachytherapy radiation sources and planning associated patient treatment.~~

~~3. A candidate who does not meet the standards in subsections (I)(1) and (I)(2), may request a license amendment for an exemption from these training or experience requirements in accordance with A.R.S. § 30-654(B)(13). The request should include the name of the proposed qualified expert, a description of the individual's training and experience, including information similar to that specified in subsection (I)(2), and a written endorsement, based on personal knowledge of the individual's qualifications, by a physicist certified by the American Board of Radiology in one of the specialties listed in subsection (I)(1).~~

A. A licensee may authorize the release from its control any individual who has been administered unsealed radioactive material or implants containing radioactive material, if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 1 mSv (0.1 rem).

B. A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include:

1. Guidance on the interruption or discontinuation of breast-feeding; and
2. Information on the potential consequences, if any, of failure to follow the guidance.

C. A licensee shall maintain a record of the basis for authorizing the release of an individual and instructions given to a breast feeding female for 3 years from the date of the administration performed under subsection (A). Nothing in this rule relieves the licensee from the personnel exposure requirements in Article 4.

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

~~**A.** A licensee shall provide the manufacturer's written radiological safety and operating instructions to each person responsible for operation of a stereotactic radiosurgery system.~~

~~**B.** A person licensed by the Agency shall install the stereotactic radiosurgery system and perform all service and maintenance involving exposure to persons in the treatment room beyond normal "Beam-off" conditions.~~

~~**C.** In lieu of a direct source inventory, the licensee shall perform an indirect source inventory through completion of absolute calibrations of the radiation dose rate at the intersection of all beam axes of the radiosurgery radiation unit on a six month basis. The magnitude of this dose-rate shall be compared with the appropriately decayed value of the initial or acceptance date, calibrated dose-rate at the intersection of all beam axes. This measured dose-rate serves as verification that all sources inserted into the gamma knife are still present.~~

~~**D.** A licensee shall ensure that a stereotactic radiosurgery facility has the following safeguards:~~

~~1. Access to the radiosurgery room is controlled by a door at each entrance. The doors are normally closed.~~

~~2. Each entrance to the radiosurgery room is equipped with an electrical interlock system that will turn the unit's primary beam of radiation off immediately if any entrance door is opened. The interlock system is connected in such a manner that the machine's primary beam of radiation cannot be turned on until all treatment room entrance doors are closed and the beam "ON-OFF" control is reset at the control panel.~~

~~3. In the event of malfunction of any door interlock, the radiosurgery system control is locked in the "OFF" position and not used, except as may be necessary to the repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.~~

~~4. The radiosurgery room has a system permitting continuous observation of the patient from outside the radiosurgery room during patient irradiation.~~

~~5. Written instructions, including the manufacturer's radiological safety and operating procedures, are available at the stereotactic radiosurgery controls. These instructions inform the operator of the procedure to be followed in the event of malfunction. These instructions caution individuals on how to avoid exposure to radiation in the treatment room and include specific instructions for:~~

~~a. Removing the patient from the treatment room;~~

~~b. Securing the room against unauthorized entry; and~~

~~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 3 years from the date of the recording.

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

~~A. A licensee may authorize the release of any individual who has received radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem) or an amount specified in license conditions.~~

~~B. The licensee shall provide the released individual with oral and written instructions, on recommended actions that will make doses to other individuals as low as is reasonably achievable, if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem).~~

~~C. The licensee shall maintain a record of the criteria used to authorize the release of an individual containing radioactive material. The record shall be maintained for three years after the date of release if the total effective dose equivalent is cal-~~

~~culated 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 35.910, January 1, 2005, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

B. The training and experience shall have been obtained within the 7 years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

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

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

A. A licensee may not administer to humans a radiopharmaceutical that contains more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m).

B. A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with subsection (A).

C. A licensee shall maintain a record of each molybdenum-99 concentration measurement for 3 years following completion of the measurement.

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

A. Except as provided in R12-1-710, a licensee shall require an authorized user of unsealed radioactive material for the uses authorized under Group 200 to be a physician who has completed the training requirements in 10 CFR 35.920, January 1, 2005, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

B. The training and experience shall have been obtained within the 7 years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

C. The licensee shall require an authorized user of radiopharmaceuticals for use in nuclear cardiology to be a physician who:

1. Has completed certification by a medical specialty board whose certification process has been recognized by the Agency; or
2. Is an authorized user on an equivalent NRC or Agreement State radioactive material license; or
3. Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques, applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include:
   a. Work experience, under the supervision of a preceptor who is an authorized user, who meets the requirements of this Section, or similar NRC or Agreement State requirements. The work experience shall involve at a minimum:
      i. Performing quality control procedures on instruments used to determine the activity of dosages; and
      ii. Performing checks for proper operation of survey meters; and
   b. Upon completion of the training and experience, written attestation that the individual has satisfactorily completed the requirements in this subsection and has achieved a level of competency sufficient to function independently as a nuclear cardiology authorized user. The written attestation shall be signed by the preceptor who is, at a minimum, listed on a radioactive material license authorizing the preceptor to perform imaging and localization studies.

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

A. A licensee shall provide radiation safety instruction, initially and at least annually, for all personnel caring for the patient or the human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with R12-1-717. To satisfy this requirement, the instruction shall describe the licensee's procedures for:

1. Patient or human research subject control;
2. Visitor control;
3. Contamination control;
4. Waste control; and

B. For each patient or human research subject who cannot be released under R12-1-717, a licensee shall:

1. Quarter the patient or the human research subject either 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. Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste.

C. A licensee shall notify the Radiation Safety Officer, or his or her designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

D. A licensee shall retain records of instruction and safety procedures performed under this rule for 3 years from the date of the activity.

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

A. Except as provided in R12-1-710, a licensee shall require an authorized user of unsealed radioactive material for the uses authorized under Group 300 to be a physician who has completed the training requirements in 10 CFR 35.930, January 1, 2005, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

B. Except as provided in R12-1-710, a licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician who has completed the training requirements in 10 CFR 35.932, January 1, 2005, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

C. Except as provided in R12-1-710, a licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician who has completed the training requirements in 10 CFR 35.934, January 1, 2005, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

D. The training and experience shall have been obtained within the 7 years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

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

A. A licensee shall make a survey to locate and account for all sources that have not been implanted immediately after implanting sources in a patient or a human research subject.

B. A licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument immediately after removing the last temporary implant source to confirm that all sources have been removed.

C. A licensee shall maintain accountability at all times for all sources in storage or use.

D. A licensee shall return brachytherapy sources to a secure storage area as soon as possible after removing sources from a patient or a human research subject.

E. A licensee shall record the procedures performed in subsections (A) through (D) and retain the records for 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 instruction.

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

A. Before the first medical use of a brachytherapy source after the effective date of this rule, a licensee shall have:
1. Determined the source output or activity using a dosimetry system that meets the requirements of R12-1-733(A);
2. Determined source positioning accuracy within applicators; and
3. Used published protocols currently accepted by nationally recognized bodies to meet the requirements of subsection (A)(1) and (2).

B. A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with subsection (A).

C. A licensee shall mathematically correct the outputs or activities determined in subsection (A) for physical decay at intervals consistent with 1 percent physical decay.

D. Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay shall be based on the activity determined under subsection (A).

E. A licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of:
1. The source-specific input parameters required by the dose calculation algorithm;
2. The accuracy of dose, dwell time, and treatment time calculations at representative points;
3. The accuracy of isodose plots and graphic displays; and
4. The accuracy of the software used to determine sealed source positions from radiographic images.

F. A licensee shall retain records of each source activity determination and ophthalmic source decay correction, and documented the acceptance testing protocol required under subsection (E) for 3 years after the date of the procedure required in subsections (A) and (D), and for the records created in conjunction with subsection (E) the record shall be maintained for 3 years from the last date of the protocol's use.

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

A. Except as provided in A.A.C.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 35.940, January 1, 2005, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

B. Except as provided in R12-1-710, a licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who has completed the training requirements in 10 CFR 35.941, January 1, 2005, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

C. The training and experience shall have been obtained within the 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 who has completed the training requirements in 10 CFR 35.950, January 1, 2005, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

B. The training and experience shall have been obtained within the 7 years preceding the date of application or the individual

shall have had related continuing education and experience since the required training and experience was completed.

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

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

B. A licensee shall make records of these surveys conducted under subsection (A) and retain them for 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 the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

B. Except for low dose-rate remote afterloader units, only a person specifically licensed by the Agency, NRC, or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

C. For a low dose-rate remote afterloader unit, only a person specifically licensed by the Agency, NRC, or an Agreement State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

D. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units for three years from the completion date of the activity listed in this subsection.

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

A. A licensee shall:

1. Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;
2. Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);
3. Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and
4. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures shall include:
   a. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
   b. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
   c. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

B. A licensee shall post instructions at the unit console to inform the operator of:

1. The location of the procedures required by subsection (A)(4); and
2. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

C. A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

1. The procedures identified in subsection (A)(4); and
2. The operating procedures for the unit.

D. A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

E. A licensee shall retain a record of individuals receiving instruction required by subsection (C) for three years from the date of the instruction.

F. A licensee shall retain a copy of the procedures required by subsection (A)(4) and (C)(2) for Agency review, and 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 to the treatment room by a door at each entrance.

B. A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:

1. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

2. Cause the source(s) to be shielded when an entrance door is opened; and
3. Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

C. A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

D. Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

E. For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

F. In addition to the requirements specified in subsections (A) through (E), a licensee shall:

1. For medium dose-rate and pulsed dose-rate remote afterloader units, require:
   a. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and
   b. An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.
2. For high dose-rate remote afterloader units, require:
   a. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and
   b. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.
3. For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.
4. Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

G. A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:

1. Remaining in the unshielded position; or
2. Lodged within the patient following completion of the treatment.

R12-1-733. Dosimetry Equipment

A. Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met.

1. The system shall have been calibrated using a system or source traceable to the National Institute of Science and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration shall have been performed within the previous 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 thirty months after that calibration, the system shall have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison shall indicate that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

B. The licensee shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with subsection (A). This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in subsection (A).

C. The licensee shall retain, for three years from the date of the procedure, a record of each calibration, intercomparison, and comparison.

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

A. A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

1. Before the first medical use of the unit; and

2. Before medical use under the following conditions:
   a. Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output 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 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

F. Full calibration measurements required by subsection (A) and physical decay corrections required by subsection (E) shall be performed by the authorized medical physicist.

G. A licensee shall retain a record of each calibration for 3 years from the date it was completed.

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

A. A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:
1. Before the first medical use of the unit;
2. Before medical use under the following conditions:
   a. Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
   b. Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
3. At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and
4. At intervals not exceeding 1 year for low dose-rate remote afterloader units.

B. To satisfy the requirement of subsection (A), full calibration measurements shall include, as applicable, determination of:
1. The output within ± 5 percent;
2. Source positioning accuracy to within ±1 millimeter;
3. Source retraction with backup battery upon power failure;
4. Length of the source transfer tubes;
5. Timer accuracy and linearity over the typical range of use;
6. Length of the applicators; and
7. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

C. A licensee shall use the dosimetry system described in R12-1-733(A) to measure the output.

D. A licensee shall make full calibration measurements required by subsection (A) in accordance with published protocols accepted by nationally recognized bodies.

E. In addition to the requirements for full calibrations for low dose-rate remote afterloader units in subsection (B), a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

F. For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with subsection (A) through (E).

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

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

I. A licensee shall retain a record of each calibration for 3 years from the date it was completed.

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

A. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:
1. Before the first medical use of the unit;
2. Before medical use under the following conditions:
   a. Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
   b. Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and
   c. Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and
3. At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

B. To satisfy the requirement of subsection (A), full calibration measurements shall include determination of:
1. The output within ±3 percent;
2. Relative helmet factors;
3. Isocenter coincidence;
4. Timer accuracy and linearity over the range of use;
5. On-off error;
6. Trunnion centricity;
7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
8. Helmet microswitches;
9. Emergency timing circuits; and
10. Stereotactic frames and localizing devices (trunnions).

C. A licensee shall use the dosimetry system described in R12-1-733(A) to measure the output for one set of exposure conditions. The remaining radiation measurements required in subsection (B)(1) may be made using a dosimetry system that indicates relative dose rates.

D. A licensee shall make full calibration measurements required by subsection (A) in accordance with published protocols accepted by nationally recognized bodies.

E. A licensee shall mathematically correct the outputs determined in subsection (B)(1) at intervals not exceeding one month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

F. Full calibration measurements required by subsection (A) and physical decay corrections required by subsection (E) shall be performed by the authorized medical physicist.

G. A licensee shall retain a record of each calibration for 3 years from the date of the procedure.

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

A. A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:
1. Timer accuracy, and timer linearity over the range of use;
2. On-off error;
3. The coincidence of the radiation field and the field indicated by the light beam localizing device;
4. The accuracy of all distance measuring and localization devices used for medical use;
5. The output for one typical set of operating conditions measured with the dosimetry system described in R12-1-733(B); and
6. The difference between the measurement made in subsection (A)(5) and the anticipated output, expressed as a percentage of the anticipated output.

B. A licensee shall perform measurements required by subsection (A) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

C. A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

D. A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:
1. Electrical interlocks at each teletherapy room entrance;
2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);
3. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
4. Viewing and intercom systems;

5. Treatment room doors from inside and outside the treatment room; and
6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

E. If the results of the checks required in subsection (D) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

F. A licensee shall retain a record of each spot-check required by subsections (A) and (D) for 3 years from the date of the procedure, and a copy of the procedures required by subsection (B) until licensee terminates all medical activities involving the teletherapy unit.

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

A. A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit:
1. Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;
2. Before each patient treatment with a low dose-rate remote afterloader unit; and
3. After each source installation.

B. A licensee shall perform the measurements required by subsection (A) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

C. A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

D. To satisfy the requirements of subsection (A), spot-checks shall, at a minimum, assure proper operation of:
1. Electrical interlocks at each remote afterloader unit room entrance;
2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
3. Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;
4. Emergency response equipment;
5. Radiation monitors used to indicate the source position;
6. Timer accuracy;
7. Clock (date and time) in the unit's computer; and
8. Decayed source(s) activity in the unit's computer.

E. If the results of the checks required in subsection (D) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

F. A licensee shall retain a record of each spot-check required by subsections (A) and (D) for 3 years from the date of the procedure, and a copy of the procedures required by subsection (B) until licensee terminates all medical activities involving the afterloader unit.

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

A. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:
1. Monthly;
2. Before the first use of the unit on a given day; and
3. After each source installation.

B. A licensee shall:
1. Perform the measurements required by subsection (A) in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.
2. Have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

C. To satisfy the requirements of subsection (A)(1), spot-checks shall, at a minimum:
1. Assure proper operation of:
   a. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
   b. Helmet microswitches;
   c. Emergency timing circuits; and
   d. Stereotactic frames and localizing devices (trunnions).
2. Determine:
   a. The output for one typical set of operating conditions measured with the dosimetry system described in R12-1-733(B);
   b. The difference between the measurement made in subsection (C)(2)(i) and the anticipated output, expressed as a percentage of the anticipated output;
   c. Source output against computer calculation;

d. Timer accuracy and linearity over the range of use;
e. On-off error; and
f. Trunnion centricity.

D. To satisfy the requirements of subsections (A)(2) and (A)(3), spot-checks shall assure proper operation of:
1. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
2. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
3. Viewing and intercom systems;
4. Timer termination;
5. Radiation monitors used to indicate room exposures; and
6. Emergency off buttons.

E. A licensee shall arrange for the repair of any system identified in subsection (C) that is not operating properly as soon as possible.

F. If the results of the checks required in subsection (D) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

G. A licensee shall retain a record of each check required by subsections (C) and (D for 3 years from the date of the procedure, and a copy of the procedures required by subsection (B) until licensee terminates all medical activities involving the radiosurgery unit.

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

A. A licensee providing mobile remote afterloader service shall:
1. Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and
2. Account for all sources before departure from a client's address of use.

B. In addition to the periodic spot-checks required by R12-1-738, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks shall be made to verify the operation of:
1. Electrical interlocks on treatment area access points;
2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
3. Viewing and intercom systems;
4. Applicators, source transfer tubes, and transfer tube-applicator interfaces;
5. Radiation monitors used to indicate room exposures;
6. Source positioning (accuracy); and
7. Radiation monitors used to indicate whether the source has returned to a safe shielded position.

C. In addition to the requirements for checks in subsection (B), a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

D. If the results of the checks required in subsection (B) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

E. A licensee shall retain a record of each check required by subsection (B) for 3 years from the date of the procedure.

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

A. In addition to the survey requirement in Article 4 of this Chapter, a person licensed to use sealed sources in the practice radiation therapy shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

B. A licensee shall make the survey required by subsection (A) at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

C. A licensee shall retain a record of the radiation surveys required by subsection (A) for 3 years from the date of each survey.

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

A. A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 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 treatment planning system.

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

A. Except as provided in R12-1-710, the licensee shall require an authorized user of a sealed source for a use authorized under Group 600 to be a physician who has completed the training requirements in 10 CFR 35.960, January 1, 2005, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

B. The training and experience shall have been obtained within the 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 must include:
   a. The licensee's name;
   b. The name of the prescribing physician;
   c. A brief description of the event;
   d. Why the event occurred;
   e. The effect, if any, on the individual(s) who received the administration;
   f. What actions, if any, have been taken or are planned to prevent recurrence; and
   g. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

2. The report may not contain the individual's name or any other information that could lead to identification of the individual.

E. The licensee shall provide notification of the event to the referring physician and also notify the individual who is the 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.

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

~~Group I.~~

~~A.~~ ~~Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution, and excretion. This group does not include uses involving diagnostic study imaging, and tumor localization.~~

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

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

1. ~~Obtained from a manufacturer or preparer licensed according to 10 CFR 32.72, 1998 Edition, published January 1, 1998, or equivalent Agreement State requirements. This incorporation by reference is on file with the Agency and the Office of Secretary of State, and contains no future editions or amendments; or~~
2. ~~Prepared by a nuclear pharmacist or a physician who is an authorized user on a radioactive material license, and meets the training and experience requirements in 10 CFR 35(J), or an individual under the supervision of either as specified in 10 CFR 35.25, 1998 Edition, published January 1, 1998, both references are incorporated by reference, and on file with the Agency and the Office of Secretary of State. These incorporations contain no future editions or amendments.~~

~~Group II.~~

~~C.~~ ~~A use of prepared radiopharmaceuticals for diagnostic study, imaging, and tumor localization.~~

1. ~~Iodine-123~~
2. ~~Iodine-125~~
3. ~~Iodine-131~~
4. ~~Selenium-75~~
5. ~~Technetium-99m~~
6. ~~Ytterbium-169~~
7. ~~Indium-111~~
8. ~~Indium-113m~~

~~9. Chromium-51~~
~~10. Fluorine-18~~
~~11. Gallium-67~~
~~12. Gold-198~~
~~13. Thallium-201~~
~~14. Rubidium-82~~
~~15. Carbon-11~~

~~**D.** A licensee shall use a radioactive material listed in subsection (C) in the form of a radiopharmaceutical prepared for medical purposes that is:~~
~~1. Obtained from a manufacturer or preparer according to subsection (B)(1); or~~
~~2. Prepared by a nuclear pharmacist or a physician who is authorized according to subsection (B)(2)~~

~~**Group III.**~~

~~**E.** Use of generators and reagent kits for the preparation and use of radiopharmaceuticals containing radioactive material for certain diagnostic uses.~~
~~1. Molybdenum-99/Technetium-99m generators~~
~~2. Tin-113/Indium-113m generators~~
~~3. Technetium-99m (in bulk)~~
~~4. Rubidium-81/Krypton-81m~~

~~**F.** A licensee shall acquire and use a radioactive material listed in subsection (E) in the form of a radiopharmaceutical prepared for medical purposes that is:~~
~~1. Obtained from a manufacturer or preparer according to subsection (B)(1); or~~
~~2. Prepared by a nuclear pharmacist or a physician who is authorized according to subsection (B)(2)~~

~~**Group IV.**~~

~~**G.** Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety.~~
~~1. Iodine-131, in quantities less than 33 millicuries~~
~~2. Phosphorus-32~~
~~3. Strontium-89~~
~~4. Samarium-153~~

~~**H.** A licensee shall use a radioactive material listed in subsection (G) in the form of a radiopharmaceutical prepared for medical purposes that is:~~
~~1. Obtained from a manufacturer or preparer according to subsection (B)(1); or~~
~~2. Prepared by a nuclear pharmacist or a physician who is authorized according to subsection (B)(2)~~

~~**Group V.**~~

~~**I.** Use of prepared radiopharmaceuticals for certain therapeutic procedures that normally require hospitalization for purposes of radiation safety.~~
~~1. Iodine-131~~
~~2. Gold-198~~

~~**J.** A licensee shall use a radioactive material listed in subsection (I) in the form of a radiopharmaceutical prepared for medical purposes that is:~~
~~1. Obtained from a manufacturer or preparer according to subsection (B)(1); or~~
~~2. Prepared by a nuclear pharmacist or a physician who is authorized according to subsection (B)(2).~~

Group 100

Included is the use of any unsealed radioactive material for medical use (radiopharmaceutical) not requiring a written directive. The radiopharmaceuticals, prepared for uptake, dilution, or excretion studies, are:

1. Obtained from a manufacturer or preparer licensed under Article 3 of this Chapter or equivalent NRC or Agreement State requirements; or
2. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in R12-1-721 and R12-1-723, or an individual under the supervision of either as specified in R12-1-706; or
3. Obtained from and prepared by an Agreement State or NRC 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; or
4. Prepared by the licensee for use in 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 medical use (radiopharmaceutical), not requiring a written directive according to R12-1-707, PET radiopharmaceuticals may be used if the licensee meets the requirements in R12-1-716. The radiopharmaceuticals, prepared for imaging and localization, are:

1. Obtained from a manufacturer or preparer licensed under Article 3 of this Chapter, or equivalent NRC or Agreement

State requirements; or
2. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in R12-1-721 and R12-1-723, or an individual under the supervision of either as specified in R12-1-706;
3. Obtained from and prepared by an Agreement State or NRC 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; or
4. Prepared by the licensee for use in 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 radiopharmaceuticals are:
1. Obtained from a manufacturer or preparer licensed under Article 3 of this Chapter or equivalent NRC or Agreement State requirements; or
2. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in R12-1-721 and R12-1-723, or an individual under the supervision of either as specified in R12-1-706; or
3. Obtained from and prepared by an Agreement State or NRC licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or
4. Prepared by the licensee for use in 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:
1. Approved in the Sealed Source and Device Registry; or
2. Part of a research protocol that is approved for use under an active Investigational Device Exemption (IDE) application accepted by the FDA, and provided the requirements of R12-1-709 are met.

Group 500

Included is the use of any sealed source for diagnostic medical purposes approved in the Sealed Source and Device Registry.

Group 600

Included is the use of any sealed source in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units approved for therapeutic medical uses in:
1. The Sealed Source and Device Registry; or
2. Research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA and provided the requirements of R12-1- 709 are met.

NOTICE OF PROPOSED RULEMAKING

TITLE 13. PUBLIC SAFETY

CHAPTER 5. LAW ENFORCEMENT MERIT SYSTEM COUNCIL

[R05-386]

PREAMBLE

1. Sections Affected	Rulemaking Action
R13-5-101	Amend
R13-5-201	Amend
R13-5-302	Amend
R13-5-305	Amend
R13-5-307	Amend
R13-5-309	Amend
R13-5-312	Amend
R13-5-501	Amend
R13-5-503	Amend
R13-5-507	Amend
R13-5-513	Amend
R13-5-702	Amend
R13-5-703	Amend
R13-5-804	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. § 41-1830.12(A)

Implementing statutes: A.R.S. §§ 38-1101, 41-382(19)(a), 41-1714, 41-1830.11, 41-1830.12, 41-1830.13, and 41-1830.14

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

Notice of Rulemaking Docket Opening: 11 A.A.R. 4310, October 28, 2005

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

Name:	Commander. C. H. Johnston, Business Manager
Address:	Law Enforcement Merit System Council P.O. Box 6638 Phoenix, AZ 85005
Telephone:	(602) 223-2286
Fax:	(602) 223-2096
E-mail:	Cjohnston@azdps.gov

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

The Law Enforcement Merit System Council (Council) completed a major rewrite of the rules on May 10, 2000. It was anticipated that some minor revisions would be needed following such a major rewrite. A rule revision committee was created to provide an annual review of the rules to assure the rules remained current and clear. This is another revision intended to clarify the rules as proposed by the rules revision committee. Changes to A.R.S. § 38-1101 made in the 2004 and 2005 legislative sessions necessitate changes to the discipline and hearing rules (R13-5-702 and R13-5-703).

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

Not applicable

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

Not applicable

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

Throughout the proposed rulemaking, numbers have been changed to conform with the format established by the Secretary of State and the Governor's Regulatory Review Council. Other changes were made to correct punctuation or misuse of words, in order to clarify the rule. These will now be addressed individually.

R13-5-101

The revision to R13-5-101 will not have an economic impact. It revises four definitions and adds one additional definition that clarifies the rules.

R13-5-201

The revisions to R13-5-307 will have minimal economic impact on the agencies. The revision to R13-5-201will have a minor economic impact upon the Department by reducing the cost of reproducing paper copies of job descriptions that exist on the DPS web site.

R13-5-302

The revision to R13-5-302 will not have an economic impact. The revision merely eliminates or relocates a portion of the rule that is duplication of another rule (R13-5-305). To assure that the inspection of examination results is available to employees of the agency, a new subsection (I) is added that refers the employee to R13-5-305 (G).

R13-5-305

The revision to R13-5-305 will not have an economic impact. This revision combines language from R13-4-302 (H), R13-5-305(F), and R13-5-305(H) into one place. This is the new R13-5-305 (G) dealing with the inspection of examination results. This revision also clarifies how an employee returning from military leave is to be given an opportunity to take any promotional exam that was missed and how that employee's placement on any existing list will occur. It also makes it clear that an employee who is terminated will be removed from any promotion list. Subsection (P) is also being deleted in order to conform with actual practice. In order to avoid the need for the Human Resources Bureau to produce a new eligibility list, the old list is normally certified as being valid until it is expired.

R13-5-307

The revision to R13-5-307 will not have an economic impact. This revision merely brings the length of a reinstatement list to match other eligibility lists.

R132-5-309

The revision to R13-5-309 will not have an economic impact. This change is merely clarifying the process of interviewing potential employees.

R13-5-312

The revisions to R13-5-307 will have minimal economic impact on the agencies. It will provide a benefit to both the agencies and the employees alike. Employees will be afforded protection during a reduction-in-force. Agencies will find that employees are more willing to accept these positions that were formerly considered to be limited-term positions.

R13-5-501

The revision to R13-5-501 will not have an economic impact. It will have a benefit for agencies and employees alike by clarifying the intent of the rules regarding accrual of leave time for both full-time and part-time employees

R13-5-503

The revision to R13-5-503 will not have an economic impact. This revision, along with the revision in R13-5-501 will help clarify the method of accruing leave time. There are also some minor changes that are being made to bring the rule in line with the intent of the rule revision of July 7, 2003.

R13-5-507

The revision to R13-5-507 will not have an economic impact. It will, however, provide a benefit to the agency by clarifying that the holiday cannot be used to accrue the hours necessary to gain the holiday.

R5-13-513

The revision to R13-5-513 will not have an economic impact. This revision changes the definition of "family member" to be consistent with the statutory definition and with that used in R13-5-506.

R13-5-702

The revision to R13-5-702 will have a minimal economic impact upon the agencies. The revision will have a benefit to both the employee and the agency alike by allowing the agency more time to handle investigations and to serve discipline notices when an employee is absent from the agency and an investigation is not possible due to this absence. This revision also will result in a better structural organization of the rule regarding exceptions to the time limit for filing a disciplinary action. It also clarifies that service of disciplinary action shall be completed in accordance with R13-5-104 (D).

R13-5-703

The revision to R13-5-703 will not have an economic impact. This revisions is necessitated by legislative action in revising A.R.S. § 38-1101. The agency was already required to perform these things, but with different time limits. Everything required by the statute was already being done by the agency. This revision also establishes a more reasonable time period for the Council to provide a written decision after a hearing.

R13-5-804

The revision to R13-5-804 will not have an economic impact. This revision makes it easier to deal with those employees who are eligible for the Public Safety Personnel Retirement System when changes are made to job titles.

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

Name: Commander. C. H. Johnston, Business Manager

Address: Law Enforcement Merit System Council
P.O. Box 6638
Phoenix, Arizona 85005

Telephone: (602) 223-2286

Fax: (602) 223-2096

E-mail: Cjohnston@azdps.gov

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

Following submission to the Secretary of State and the rules being published in the Arizona Administrative Register, written comments will be received at the address listed in item #9 for a period of 30 days after publication. A public hearing will be scheduled if one is requested. Otherwise, the record will be closed at the end of the 30-day period following the publication in the Arizona Administrative Register. If a public meeting is requested, the record will be closed at the end of the public meeting.

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

Not applicable

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

Not applicable

13. The full text of the rules follows:

TITLE 13. PUBLIC SAFETY

CHAPTER 5. LAW ENFORCEMENT MERIT SYSTEM COUNCIL

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ARTICLE 2. CLASSIFICATION AND COMPENSATION

Section
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R13-5-804. Public Safety Personnel Retirement System Eligibility

ARTICLE 1. GENERAL PROVISIONS

R13-5-101. Definitions

In this Chapter, unless otherwise specified, the following terms mean:

"Break-in-service" means a period of absence from agency service of more than ~~30 consecutive working days~~ 240 consecutive working hours resulting from an employee's resignation, retirement, suspension, layoff, or leave of absence without pay.

"Commissioned employee" means a person who is appointed to a classification that requires ~~officer status as defined in A.R.S. § 41-1822 (A) (3).~~ Arizona Peace Officer Standards and Training Board certification as a peace officer.

"Limited-term appointment" means an appointment to a position that is designated as temporary. ~~or is not funded by the agency's legislative appropriation.~~

"Qualifying pay period" means a pay period in which an employee is in pay status for at least one-half of the employee's normally scheduled work week.

"Reappointment" means appointment to a classification previously held by ~~a permanent status~~ an employee who was reassigned to a different classification. ~~during a reduction in force.~~

ARTICLE 2. CLASSIFICATION AND COMPENSATION

R13-5-201. Classification

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

B. Classification Specifications. The business manager shall document the date of adoption and the latest revision of each classification specification, and shall maintain the master set of all approved classification specifications. Human Resources shall also maintain a set of all approved classification specifications. Copies of a classification specification are open for inspection by an employee ~~and the public during normal business hours.~~ and are available on the DPS web site.

C. No change
1. No change
2. No change
3. No change
4. No change

D. No change

E. No change

F. No change

G. No change

H. No change
1. No change
   a. No change
   b. No change
   c. No change
2. No change

I. No change
1. No change
2. No change

J. No change

K. No change

ARTICLE 3. EMPLOYMENT

R13-5-302. Examinations

A. No change

B. No change

C. No change
1. No change

2. No change
3. No change
4. No change

D. No change

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

F. No change
1. No change
2. No change
3. No change
4. No change

G. No change
1. No change
2. No change

H. Examination results notification. Human Resources shall mail notification of examination results to each competitor. ~~Within 10 business days after the examination results are mailed, a competitor may file with the business manager a written request that the business manager review all examination questions, answers, scoring methods, procedures, and decisions. A competitor requesting a business manager's review shall outline the specific areas the competitor believes are in error.~~
~~1. If the business manager's review discloses an error, the business manager shall return the examination to Human Resources for correction.~~
~~2. If an error affects the scores of other competitors, Human Resources shall revise all incorrect scores.~~
~~3. If the business manager determines the error is not correctable and the defective portion of the exam is critical to the examination process, Human Resources shall re-administer that portion of the examination under guidelines provided by the business manager.~~

I. Review of examinations. Any employee who has tested for promotion may request an examination review under R13-5-305(D) and (G).

~~**I.**~~**J.** No change

~~**J.**~~**K.** No change

R13-5-305. Promotion

A. No change

B. No change
1. No change
   a. No change
   b. No change
   c. No change
2. No change

C. No change

D. No change

E. No change

~~**F.** Inspecting an examination. Within 10 days after taking a written promotional examination, a competitor may request permission from the business manager to inspect a copy of the exam for the purpose of identifying an item the competitor believes is incorrect.~~
~~1. The business manager shall arrange an inspection of an exam during business hours, in an agency office, and in the presence of the business manager or an employee authorized by the business manager.~~
~~2. The competitor shall advise the business manager of the questions or answers challenged.~~
~~3. The competitor may make notes concerning items the competitor plans to challenge but shall not otherwise copy a question in the examination.~~
~~4. The competitor may file a written notice with the business manager questioning an item in the examination and explaining the basis for any challenge. The business manager shall process the challenge consistent with the procedure in R13-5-302.~~

~~**G.**~~**F.** No change

~~**H.**~~**G.** Inspection of examination results. ~~Within 10 days after notice of the results of an examination, a competitor may request to review the competitor's examination with the business manager, or an employee authorized by the business manager.~~ Within 10 days after the examination results are mailed, a competitor may file with the business manager a written request that the business manager review all examination questions, answers, scoring methods, procedures, and decisions. A com-

petitor requesting a business manager's review shall outline the specific areas the competitor believes are in error.

1. ~~The business manager or the authorized employee shall oversee the competitor's examination inspection.~~ The business manager shall arrange an inspection of an exam during business hours, in an agency office, and in the presence of the business manager or an employee authorized by the business manager.
2. An employee shall not copy questions or answers, nor make any alterations to the examination papers.
3. Only the Council, business manager, competitor, competitor's attorney and the agency head may inspect a competitor's examination.
4. Within 10 days of a review, a competitor may file a written notice with the business manager questioning examination results on the basis of irregularity, bias, fraud, or scoring error and explaining the basis for any challenge. The business manager shall correct any error in the scoring of the examination.
5. If an error affects the scores of other competitors, Human Resources shall revise all incorrect scores.
6. If the business manager determines the error is not correctable and the defective portion of the exam is critical to the examination process, Human Resources shall re-administer that portion of the examination under guidelines provided by the business manager.

~~I.~~**H.** No change

~~J.~~**I.** Military leave. Human Resources shall allow an employee returning from military leave to take any examination that the employee could have taken if military service had not intervened. If the employee passes the examination, the business manager shall add the employee's name to the appropriate internal eligibility list subject to the original promulgation of the list.

~~K.~~**J.** No change

~~L.~~**K.** No change

~~M.~~**L.** No change

~~N.~~**M.** No change

~~O.~~**N.** No change

~~P. Revising a classification. If the Council orders that a classification be revised, Human Resources shall establish a new list for the revised classification and cancel any existing list.~~

~~Q.~~**O.** Removing a candidate from an internal list. The business manager shall remove a candidate from an internal list if:

1. The candidate fails to maintain required qualifications for the classification, or
2. The candidate resigns or is terminated from agency service. ~~or~~
3. ~~The internal list expires.~~

~~R.~~**P.** No change

~~S.~~**Q.** No change

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

~~T.~~**R.** No change

R13-5-307. Reinstatement

A. No change

B. Duration of the list. A reinstatement list shall remain in force for a maximum of ~~1 year.~~ 18 months. ~~At the agency head's request, the Council may extend the duration of the list for 6 months periods at a time.~~

C. No change

R13-5-309. Selection

A. No change

B. Interviewing. ~~If the hiring manager does not select a transfer or the top candidate from the certified list, the~~ A hiring manager shall interview all candidates requesting a transfer, and ~~at least one but no more than~~ and may interview up to three candidates from each certified list.

C. No change

D. No change

E. No change

F. No change

R13-5-312. Limited-Term Appointments

A. Limited-term ~~position~~ appointment. A limited-term ~~position is either~~ appointment is an appointment to a position designated as temporary ~~or funded from a source outside an agency's regular legislative appropriation~~. An appointee to a limited-term position shall, after successfully completing initial probation, ~~have~~ obtain the rights of a permanent employee,

except for the opportunity to compete for retention against regular employees in a case of layoff due to a reduction-in-force.

B. No change
C. No change
D. No change
1. No change
2. No change

E. No change
1. No change
2. No change
   a. No change
   b. No change

ARTICLE 5. EMPLOYEE LEAVE

R13-5-501. Employee Leave Guidelines

A. ~~Full-time employee.~~ Accrual of leave. ~~A full-time~~ An employee may accrue the following types of paid leave:
1. Annual leave,
2. Holiday leave, and
3. ~~Recognition leave, and~~
~~4~~ 3. Sick leave.

B. Accruing leave. An eligible employee shall accrue leave for a pay period if the employee is in pay status for at least one half the employee's normal scheduled work week.

C. Part-time employees. A part time employee scheduled to work 20 or more hours in a week shall accrue leave based on the percentage of full-time hours specified in the appointment. An employee scheduled to work less than 20 hours in a week shall not accrue leave.

~~**B.**~~**D.** No change

~~**C.**~~**E.** Time accounting record. An agency shall maintain a record of time worked, leave earned, leave taken, and accrued leave balances. ~~The agency shall periodically provide a leave balance statement to an eligible employee.~~ A non-exempt employee shall report all time worked and all leave taken on a weekly basis. An exempt employee shall report leave taken as directed by agency policy.

R13-5-503. Annual Leave

A. Computing length of service. For determining an annual leave accrual rate, an employee's length of service shall begin on the first day of the first ~~complete month~~ qualifying pay period of employment. Only a ~~complete month of qualifying service~~ qualifying pay period is counted before and after a break-in-service. Previous periods of service as a state employee are counted toward annual leave accrual. Periods of military leave and active military service are included in computing annual leave if the employee complies with the requirements of A.R.S. § 38-610.

B. Accruing annual leave. An eligible employee shall accrue leave if the employee is in pay status for at least one-half of the employees' scheduled work week in that pay period. ~~A part-time employee scheduled to work 20 or more hours in a week shall accrue annual leave based on the percentage of full-time hours specified in the appointment. A part-time employee scheduled to work less than 20 hours in a week shall not accrue annual leave~~. A full-time employee shall accrue annual leave under the following schedule:

Beginning	Completion	Biweekly accrual rate
1st year	5th year	4.62 hours
6th year	10th year	5.54 hours
11th year	20th year	6.47 hours
21st year		7.39 hours

C. Progression of annual leave. An employee shall progress to the next higher accrual rate on the first day of the ~~month~~ pay period following completion of the required length of service.

D. No change
E. No change
F. No change

13-5-507. Holiday Leave

A. No change

B. Eligibility. To be eligible for holiday leave, ~~an~~ a full-time employee shall be in pay status 10 or more hours in the work week. A part-time employee shall be in pay status 5 or more hours in the work week. The holiday hours that would be accrued cannot be used to satisfy any part of this requirement.

1. If a holiday occurs on an employee's regular work day, the employee may be absent with pay for the number of hours regularly scheduled to work, up to a maximum of 8 hours, unless the employee is required to work to maintain essential State services.
2. An employee required to work on a holiday shall receive pay for the time worked, and leave credits for the number of hours regularly scheduled to work on that day, up to a maximum of 8 hours.
3. If a holiday occurs on a day when an employee is scheduled to work, but the employee is unable to work because of an illness or injury, the employee may take sick leave and accrue holiday leave credits as provided under subsection (C) for the number of hours regularly scheduled to work on that day, up to a maximum of 8 hours.
4. An employee not scheduled to work on a holiday shall receive leave credits, up to a maximum of 8 hours.
5. ~~A part-time employee shall accrue prorated leave based on hours authorized to work.~~

C. No change

D. No change

R13-5-513. Sick Leave

A. Definitions. The following definitions shall apply in this Section:

1. "Family sick leave" means:
   a. Providing personal care or attending to an employee's family member who has a serious illness, injury, or temporary disability;
   b. A medical appointment or transporting a family member for consultation, examination or treatment by a licensed health care provider; or
   c. Attendance at the death or funeral of an employee's family member.
2. ~~"Family member" means an employee's spouse, child, brother, sister, and parent by blood, marriage, adoption, or an individual for whom the employee has legal guardianship.~~ "Family member" means a spouse, natural child, adopted child, foster child, stepchild, natural parent, stepparent, adoptive parent, grandparent, grandchild, brother, sister, sister-in-law, brother-in-law, son-in-law, daughter-in-law, mother-in-law, or father-in-law.

B. Accruing sick leave.

1. A full-time employee shall receive 4.62 hours of sick leave biweekly.
2. ~~A part-time employee working more than 20 hours per week shall receive sick leave based upon the proportion of full-time hours worked.~~
3.2. The following employees are not eligible for sick leave:
   a. A part-time employee working less than 20 hours in a week,
   b. An Intern, and
   c. An Intermittent employee.
4.3. An eligible employee shall receive sick leave credit if the employee is in pay status for at least one half of the employee's ~~working days in that month.~~ normally scheduled work week.
5.4. Sick leave may be accrued without limit.

C. Using sick leave. ~~An eligible employee may use accrued sick leave after 1 month of service~~. A supervisor shall authorize sick leave if an employee is absent because of:

1. A medical condition that makes the employee unable to perform official duties;
2. An appointment with a licensed health care provider for consultation, examination, or treatment, or
3. Family sick leave.

D. No change

E. No change

F. No change

G. No change

H. Forfeiture of sick leave. An employee shall forfeit accumulated sick leave upon separation from State service, unless eligible for payment under the provisions of A.R.S. § 38-615.

I. No change

J. No change

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

K. No change

ARTICLE 7. DISCIPLINE AND APPEALS

R13-5-702. Disciplinary Procedures

A. No Change

B. No Change

C. Interview of an employee. An agency shall be governed in the interview of an employee being investigated for possible disciplinary action by A.R.S. § 38-1101(A) and (B).

~~C.~~D. Time limit for filing a disciplinary action. An agency shall not file a disciplinary action later than 120 days after the date the agency discovers or should have discovered that the employee engaged in alleged activity constituting cause for discipline. The disciplinary action is deemed to be filed when the notice is filed with the Council. ~~, except that:~~

~~1. The 120-day time limit does not run during any criminal investigation by the employee's agency, or any other agency, if the disciplining agency informs the business manager of the pending criminal investigation and provides the business manager with all relevant case numbers and any other information requested by the Council. The agency shall provide a status report every 30 days to the business manager. The agency shall notify the business manager when a case is taken off criminal hold.~~

~~2. At the request of an agency, the Council may, upon a showing of good cause, extend time for an agency to file a disciplinary action up to an additional 60 days.~~

~~3. If a manager or a supervisor is aware of the employee's alleged actions that constitutes criminal offense but fails to act, the 120-day time limit does not run during the period of the manager or supervisor's inaction, if:~~

~~a. The supervisor or manager is disciplined for failure to act.~~

~~b. The offense is a misdemeanor involving theft or moral turpitude and is discovered within 120 days after the end of the 120-day period for taking disciplinary action.~~

~~c. The offense is a felony.~~

E. Exceptions to the 120-day rule.

1. The 120-day time limit does not run:
   a. during any criminal investigation by any police or prosecutorial agency, or
   b. during any period of time the employee who is the subject of an investigation is absent from the agency on leave, if that absence prevents the agency from proceeding with the normal investigation and disciplinary review process.
2. At the request of an agency, the Council may, upon a showing of good cause, extend the time for an agency to file a disciplinary action up to up to a maximum of 90 days beyond the original 120-day period.
3. If a manager or a supervisor is aware of the employee's alleged actions that constitutes a criminal offense but fails to act, the 120-day time limit does not run during the period of the manager or supervisor's inaction if the supervisor or manager is disciplined for failure to act, and
   a. The offense is a misdemeanor involving theft or moral turpitude and is discovered within 120 days after the end of the 120-day period for taking disciplinary action., or
   b. The offense is a felony.
4. It shall be the responsibility of the agency to maintain sufficient documentation to support the placement of the investigation on hold, including the beginning and ending dates of the hold.

~~D.~~F. Notice of disciplinary action. An agency head shall serve a written notice on the employee within 10 days after the agency files the notice of disciplinary action with the Council. Service shall be completed in accordance with R13-5-104(D). The agency head's notice shall include:

1. A statement of the nature of the disciplinary action;
2. Any prior disciplinary action on which the current discipline is based;
3 The effective date of the action;
4. A specific statement of the causes; and
5. A statement of the employee's right to appeal and the time limit in which the employee must file an appeal with the Council under R13-5-703 (A), (B), and (C).

~~E.~~G. No Change

~~F.~~H. No Change

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

R13-5-703. Appeal to the Council

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
K. No change
L. Discovery.
1. ~~Within 20 days~~ Within three business days after receiving a written request from the employee, ~~after receiving a notice of appeal, the agency shall provide all material relating to the case, including all investigation materials,~~ the agency shall provide a complete copy of the investigative file, as well as the names and home or work mailing addresses of all persons interviewed during the course of the investigation, to the employee. For the purpose of this subsection, hand-written notes substantially incorporated within a report are not considered investigation materials.
2. Within 20 days after receiving the agency's discovery, the employee shall provide all material relating to the defense of the employee to the agency.
3. After initial discovery, each party shall provide all new material relating to the case to the other party within 10 days after receipt.
4. No later than five business days before the appeal hearing, or, if the appeal hearing is scheduled more than 20 days after the notice of appeal was filed, no later than 10 business days before the appeal hearing, the agency and the employee shall exchange copies of any documents that may be introduced at the hearing and that have not been previously disclosed.
5. No later than five business days before the appeal hearing, or, if the appeal hearing is scheduled more than 20 days after the notice of appeal was filed, no later than 10 business days before the appeal hearing, the agency and the employee shall exchange the names of all witnesses who may be called to testify. A witness may be interviewed at the discretion of the witness. The parties shall not interfere with any decision of a witness regarding whether to be interviewed. An agency shall not discipline, retaliate against or threaten to retaliate against any witness for agreeing to be interviewed or for testifying or providing evidence in the appeal hearing.
6. No later than five business days before the appeal hearing, the agency and the employee shall provide all documents that will be used at the hearing and a list of intended witnesses to the office of the Council.
~~4.~~7. If a party fails to provide material as required, the Council may preclude its use at the hearing.

M. No change
N. No change
O. No change
1. No change
   a. No change
   b. No change
   c. No change
2. No change
3. No change

P. No change
Q. No change
R. No change
S. No change
T. No change
U. Decision. The Council shall state its decision in an open meeting and shall issue the decision in writing within 45 days after the hearing. ~~The Council shall render a decision in writing within 20 days after a hearing.~~ In arriving at a decision, the Council may consider any disciplinary action taken within the previous 10 years against the employee, if the information is introduced at the hearing. ~~The Council shall state its decision in an open meeting and shall issue the decision in writing within a reasonable time, but not to exceed 45 days, after the hearing.~~ The Council's decision shall contain findings of fact and its order for disposition of the case.

ARTICLE 8. SEPARATION FROM EMPLOYMENT

R13-5-804. Public Safety Personnel Retirement System Eligibility

A. Membership in the Arizona Public Safety Personnel Retirement System is designated by the Council under ~~A.R.S. § 38-842 (19)(a).~~ A.R.S. § 38-842 (20)(a) Commissioned employees ~~in the following classifications~~ are eligible for membership in the Public Safety Personnel Retirement System~~:~~ .
~~1. Director,~~

~~2. Deputy Director,~~
~~3. Assistant Director,~~
~~4. Bureau Chief,~~
~~5. Commander,~~
~~6 Lieutenant,~~
~~7. Sergeant II,~~
~~8. Sergeant I,~~
~~9. Officer,~~
~~10. Fixed Wing Pilot, and~~
~~11. Rotary Wing Pilot.~~

B. Employees who were in the following non-commissioned classifications on December 1, 1972, shall be eligible for membership in the Public Safety Personnel Retirement System:

1. Communications Technician
2. Radio Mechanic