ARIZONA RADIATION REGUALTORY AGENCY (F-17-0101)
Title 12, Chapter 1, Article 8, Radiation Safety Requirements for Analytical X-Ray Operations; Article 10, Notices, Instructions, and Reports to Ionizing Radiation Workers; Inspections

GOVERNOR'S REGULATORY REVIEW COUNCIL
ANALYSIS OF FIVE-YEAR REVIEW REPORT

MEETING DATE: January 4, 2017 **AGENDA ITEM: F-1**

TO: Members of the Governor's Regulatory Review Council ("Council")

FROM: Chris Kleminich, Staff Attorney

DATE: December 20, 2016

SUBJECT: **RADIATION REGULATORY AGENCY (F-17-0101)**
Title 12, Chapter 1, Article 8, Radiation Safety Requirements for Analytical X-Ray Operations; Article 10, Notices, Instructions, and Reports to Ionizing Radiation Workers; Inspections

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COMMENTS ON THE FIVE-YEAR-REVIEW REPORT

Purpose of the Agency and Number of Rules in the Report

The purpose of the Arizona Radiation Regulatory Agency ("Agency") is "to protect the public health and safety by regulating the use and sources of radiation in order to provide for:

1. The use of demonstrably safe methods and procedures relating to radiation.
2. The exposure to sources of radiation to levels as low as is reasonably achievable by means of good planning, practice and enforcement."

Laws 2006, Ch. 60, § 3.

This five-year-review report covers nine rules in Article 8, related to radiation safety requirements for analytical x-ray operations. The report also covers eight rules and one exhibit in Article 10, related to notices, instructions, and reports to ionizing radiation workers.

Proposed Action

The Agency has filed a Notice of Proposed Rulemaking with the Secretary of State in which it plans to make the following changes, among others, to Article 8:

- In Section 802, a definition will be added for "handheld analytical x-ray unit."
- In Section 804, handheld analytical x-ray units will be exempted from Sections D, F, and H, which relate to various components of open beam x-ray systems. Open beam x-ray systems permit individuals to place a body part in the primary beam path during normal operation.

- Section 807 will be amended to remove the Agency as the determining agent for ALARA (as low as reasonably achievable) for the amount of radiation exposure levels, and require instead that the registrant's safety committee set such limits.
- Section 808 will clarify that close beam and handheld e-ray units are exempt from requirements related to the conspicuous posting of x-ray equipment warning signs.

Once the Agency secures an exception from the rulemaking moratorium, it intends to make the following changes to Article 10:

- Section 1002, related to the posting of notices for radiation workers, will be amended to require non-ionizing sources of radiation to be included within posting requirements.
- Sections 1007 and 1008 will be updated to correct minor typographical errors.

Substantive or Procedural Concerns

None.

Analysis of the agency's report pursuant to criteria in A.R.S. § 41-1056 and R1-6-301:

1. **Has the agency certified that it is in compliance with A.R.S. § 41-1091?**

Yes. The Agency has certified its compliance with A.R.S. § 41-1091.

2. **Has the agency analyzed whether the rules are authorized by statute?**

Yes. The Agency cites general statutory authority for the rules reviewed. Under A.R.S. § 30-654(A)(2), the Agency may "[d]o all things necessary, within the limitations of this chapter [Title 30, Chapter 4, Control of Ionizing Radiation], to carry out the powers and duties of the agency." In addition, the Agency cites a number of provisions in A.R.S. § 30-654(B), including subsection (5), under which the Agency shall adopt rules it deems necessary to administer the chapter.

3. **Has the agency received any written criticisms of the rules during the last five years, including any written analysis questioning whether the rules are based on valid scientific or reliable principles or methods?**

No. The Agency notes that it has not received any written criticisms of the rules during the last five years.

4. **Has the agency analyzed the rules' effectiveness in achieving their objectives?**

Yes. The Agency indicates that the following rules are not entirely effective:

- Section 802: Lacks a definition for "handheld analytical x-ray unit."
- Section 804: Add a subsection that exempts handheld open beam x-ray units from certain requirements. Also, parts of the rule that do not apply to x-ray units should be removed.

- Section 807: Removing the Agency from the determination of proper ALARA levels will standardize the ALARA requirements in a way that is similar to other x-ray units.
- Section 808: Exempt closed beam and handheld x-ray units from posting requirements.
- Section 1002: Non-ionizing sources of radiation should be included in posting requirements.

5. Has the agency analyzed the rules' consistency with other rules and statutes?

Yes. The Agency states that there are no known federal statutes or rules specific to the subject matter of these rules, and that the rules are consistent with other state rules.

6. Has the agency analyzed the current enforcement status of the rules?

Yes. The Agency indicates that, due to the effectiveness issues identified above, Sections 802, 804, 807, 808, and 1002 are not entirely enforced as written. In addition, due to typographical errors, Sections 1007 and 1008 are not entirely enforced as written.

7. Has the agency analyzed whether the rules are clear, concise, and understandable?

Yes. The Agency indicates that Sections 1007 and 1008 need amendment in order to be clear, concise and understandable. In addition, the effectiveness issues identified above negatively affect the overall clarity of the rules.

8. Stringency of the Rules:

a. Are the rules more stringent than corresponding federal law?

No. The Agency indicates that there are no directly corresponding federal laws.

b. If so, is there statutory authority to exceed the requirements of federal law?

Not applicable.

9. For rules adopted after July 29, 2010:

a. Do the rules require issuance of a regulatory permit, license or agency authorization?

Yes. The Agency issues registrations in Article 8.

b. If so, are the general permit requirements of A.R.S. § 41-1037 met or does an exception apply?

The Agency indicates that such registrations are exempt from general permit requirements under A.R.S. § 41-1037(A)(2), as the issuance of an alternative type of permit is

authorized under A.R.S. §§ 30-672, 32-516(A), and 32-3233(E) in order to protect the public health and safety.

10. Has the agency indicated whether it completed the course of action identified in the previous five-year-review report?

Yes. In the previous five-year-review report, the Agency provided the same proposed course of action that it did in this report. The proposed actions have not yet been completed, though progress is being made.

Conclusion

The Agency plans to submit a rulemaking to the Council amending Article 8 once the public comment period has concluded for the Notice of Proposed Rulemaking. The Agency intends to amend Article 10 once it secures an exception from the rulemaking moratorium. The report meets the requirements of A.R.S. § 41-1056 and R1-6-301. This analyst recommends that the report be approved.

GOVERNOR'S REGULATORY REVIEW COUNCIL
M E M O R A N D U M

MEETING DATE: January 4, 2017 **AGENDA ITEM: F-1**

TO: Members of the Governor's Regulatory Review Council ("Council")

FROM: GRRC Economic Team

DATE: December 20, 2016

SUBJECT: **RADIATION REGULATORY AGENCY (F-17-0101)**
Title 12, Chapter 1, Article 8, Radiation Safety Requirements for Analytical X-Ray Operations; Article 10, Notices, Instructions, and Reports to Ionizing Radiation Workers; Inspections

I reviewed the five-year-review report's economic, small business, and consumer impact comparison for compliance with A.R.S. § 41-1056 and make the following comments.

1. Economic Impact Comparison

Economic, small business, and consumer impact statements (EIS) from the most recent rulemakings were available for the Article 8 and 10 rules contained in the five-year-review report.

The rules contained in Articles 8 and 10 provide standards for registration, shielding, operation, quality control requirements for protection, describe the radiation protection standards for operating analytical x-ray devices in industry, as well as the posting requirements for all registrants that operate ionizing radiation in a facility.

Currently there are approximately 5,500 registrants in the State of Arizona that use the rules and incorporated material in Article 8; 7,000 registrants, 400 licensees, 8,000 technologists licensed by the Medical Radiologic Technology Board of Examiners (MRTBE), 1,600 technicians certified as cosmetic laser techs, and 1,500 nonionizing facilities using the rules and incorporated materials in Article 10.

2. Has the agency determined that the rules impose the least burden and costs to persons regulated by the rules?

The Agency has determined that the rules in Articles 8 and 10 are mostly effective and impose the least burden and costs to the regulated community. The cost to comply with these rules is minimal and necessary to protect public health and safety.

In order to maintain consistency throughout its other rules, the Agency intends to amend Articles 8 and 10 in early 2017.

3. Was an analysis submitted to the agency under A.R.S. § 41-1056(A)(7)?

No analysis was submitted to the agency by another person that compares the rules' impact on this state's business competitiveness to the impact on businesses in other states under A.R.S. § 41-1056(A)(7).

4. Conclusion

After review, staff concludes that the report complies with A.R.S. § 41-1056 and recommends approval.

ARIZONA
RADIATION REGULATORY AGENCY

Douglas A. Ducey
Governor

Brian D. Goretzki
Interim Director

October 24, 2016

Nicole A. Ong, Council Chair
Governor's Regulatory Review Council
100 N. 15th Avenue, Suite 402
Phoenix, Arizona 85007

Dear Ms. Ong:

A review of the rules contained in A.A.C Title 12, Chapter 1, Article 8, "Radiation Safety Requirements for Analytical X-Ray Operations", and Article 10, "Notices, Instructions, and Reports to Ionizing Radiation Workers; Inspections" has been conducted by the Arizona Radiation Regulatory Agency.

In accordance with A.R.S. § 41-1056, a review of each rule was conducted to determine whether it should be amended or repealed. This report summarizes the Agency's findings with supporting reasons. A concise analysis of each rule is provided summarizing the essential elements of this five-year review in accordance with A.A.C. R1-6-301. In addition, the Agency is in compliance with A.R.S. § 41-1091 and all incorporated material is open to the public and available at the Agency location.

Finally, there are several changes needed in these articles. The changes are required to provide clarity and to address updates to incorporated materials.

Please feel free to contact me if you have any questions regarding this five-year review.

Sincerely,

Brian D. Goretzki,
Interim Director

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FIVE-YEAR-REVIEW REPORT

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

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

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

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FIVE-YEAR-REVIEW SUMMARY

The rules contained in Articles 8 and 10 describe the radiation protection standards for operating analytical x-ray devices in industry, as well as the posting requirements for all registrants that operate ionizing radiation in a facility. These rules follow the guidelines set by the Food and Drug Administration (FDA) for safe operation of x-ray equipment as well as meet the Agreement State status required by the Nuclear Regulatory Commission (NRC) for posting requirements related to radiation areas.

The rules contained in Articles 8 and 10 provide standards for registration, shielding, operation, quality control requirements for protection, and notices to workers against radiation from radiation devices or radioactive material. These rules were developed to meet standards as set forth by Part H and J of the SSR's for control of radiation as presented by the CRCPD in order to meet the intended registration and regulatory oversight described in §30-671, 30-6722 and defined in 30-651 .

Article 8

R12-1-802 was last amended in 1999. R12-1-801, R12-1-803, R12-1-804, R12-1-805, R12-1-806, R12-1-807, R12-1-808, and R12-1-809 were last amended in 2004.

Article 10

R12-1-1001, R12-1-1002, R12-1-1005, R12-1-1006, R12-1-1007, R12-1-1008, were last amended in 1999. R12-1-1003, were last amended in 2006. Exhibit A was last amended in 2012. R12-1-1004 was last amended in 2014.

Exhibit 1

Prior communication with GRRC staff indicated that these EIS statements were already on file and did not need to be submitted again historically. Therefore, the EIS statements submitted in this Exhibit are those that affect the amendments of these articles since 2010 to current date.

FIVE-YEAR-REVIEW REPORT

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

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

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R12-1-802. Definitions

R12-1-803. Enclosed-beam X-ray Systems

R12-1-804. Open-beam X-ray Systems

R12-1-805. Administrative Responsibilities

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

R12-1-1002. Posting Notices for Workers

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R12-1-1004. Notifications and Reports to Individuals

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During Agency Inspection

R12-1-1006. Consultation with Workers During Inspections

R12-1-1007. Inspection Requests by Workers

R12-1-1008. Inspection not Warranted; Review

Exhibit A. Form ARRA-6 (2012) Notice to Employees

INFORMATION THAT IS IDENTICAL FOR ALL THE RULES

The following information is the same for all of the rules and is not restated in the analysis of each rule:

1. General and Specific Statutes Authorizing the Rules:

All of the rules have general authority in A.R.S. §§ 30-654(A)(2), 30-654(B)(5), 30-654(B)(9), 30-654(B)(13), 30-657(A), 30-671(B), 30-672, 30-672.01, and 30-673. Any specific authority is stated in the applicable rule.

4. Consistency of the Rules with State and Federal Statutes and Rules:

The rules contained in Article 8 and 10 consistent with other relevant agency rules posted in Title 12. There are not federal statutes and regulations specific to radiation safety requirements for analytical x-ray operations described in Article 8 as the regulatory authority is held at the state level. The rules in Article 10 are compatible with like rules in 10 CFR related to posting requirements as a portion the state of Arizona's Agreement with the US. Nuclear Regulatory Commission.

7. Summary of Written Criticisms of the Rules Received Within the Last Five Years:

The Agency has not received any written criticisms concerning the rules contained in Articles 8, and 10.

8. Estimated Economic, Small Business, and Consumer Impact of the Rules Compared to the Economic Impact Statement Prepared on the Last Revision or Creation of the Rules:

Currently there are approximately 5,500 registrants in the State of Arizona that use the rules and incorporated material in Article 8; 7,000 registrants, 400 licensees, 8000 technologists licensed by MRTBE, 1600 technicians certified as cosmetic laser techs, and 1,500 nonionizing facilities using the rules and incorporated materials in Article 10. Analysis of the economic impact statement for the rules created or last amended since the last report is attached as Exhibit 1.

The Agency believes that economic impact is as predicted on the last making of the rules in Articles 8, and 10 and is consistent with the actual economic impact expressed in EIS reports submitted prior to 2010 already on file with GRRC or with Exhibit 1 in relation to Articles 8, and 10 except as expressed below.

The rules last amended in 1999 (R12-1-802, R12-1-1001, R12-1-1002, R12-1-1005, R12-1-1006, R12-1-1007, R12-1-1008) are not monetary in nature and only apply to registrants or licensees that repeatedly fail to meet compliance with a specific rule. These rules have an economic impact on the regulated community by levying penalties for noncompliance. In the last three years the total amount of fines levied by these rules averaged $70,000 per year. It is assumed by the Agency that those that repeated violated code would be aware of the financial costs of paying penalties. Further, it is the Agency's belief that the economic impact of these rules has been consistent with the economic impact that was predicted at the time of the last rulemaking.

9. Analysis Submitted to the Agency Comparing the Economic Impact on this State's Businesses to the Impact to Businesses in Other States:

The Agency has not received any analysis comparing the economic impact to this state's businesses with businesses in other states.

10. Completion of Course of Action from a Previous Five year Report:

The actions addressed in the previous 5 year report related to Article 8 and 10 were not complete but are a portion of the proposed rulemaking package RMP-0079 currently under consideration in the Office of the Governor for exemption to the rulemaking moratorium.

12. Stringency of the Rules Compared with Federal Laws or Regulations:

The Agency has determined that the rules in Article 8, and 10 are not more stringent than corresponding federal regulations as there are not known corresponding federal regulations.

13. For Rules Adopted After July 29, 2010 that Require Issuance of a Regulatory Authorization, Whether the Rules Comply with A.R.S. § 41-1037:

The Agency believes that the registrations issued by Article 8 are exempt from A.R.S. § 41-1037 due to paragraph (A)(2) as the issuance of an alternative type of permit is authorized under the statutory requirement of A.R.S. §§ 30-672, 32-516(A), and 32-3233(E) to protect the public health and safety or to certify laser technicians and laser technician training schools. A registration is not issued in Article 10 as these are considered in other Articles of the rules.

14. Course of Action for Rule Making:

The Agency would like to amend the existing rules once the Governor's Offices provide approval. It is believed that the Governor's office will likely support the rulemaking in 2017, following the passage of the existing RMP-0079 and after approval to proceed with the elimination/amendments of the rules identified in the September report as a part of the 2015-01 Executive Order. The GRRC could see this rulemaking in January of 2017. The rulemaking that is needed includes the following amendments or adoptions:

ARTICLE 8

R12-1-802: Add a definition for a handheld analytical x-ray unit.

R12-1-804: An amendment to the rule to exempt handheld analytical x-ray units from sections D, F, and H.

R12-1-807: An amendment of the rule that removes the Agency as the determining agent for ALARA (As Low As Reasonably Achievable) for the amount of radiation exposure levels and requires instead that the registrant's safety committee set the limits.

R12-1-808: Add a clarification that closed beam and handheld x-ray units are exempt from posting requirements.

ARTICLE 10

R12-1-1002: An update to include non-ionizing sources of radiation in this posting requirement.

R12-1-1007: An update to correct minor typographical errors in the rule.

R12-1-1008: An update to correct minor typographical errors in the rule.

INFORMATION THAT IS IDENTICAL WITHIN GROUPS OF RULES

3. Effectiveness of the Rules in Achieving the Objectives:

The following rules are effective in achieving their objectives:
R12-1-801, R12-1-803, R12-1-805 through R12-1-806, and R12-1-809; R12-1-1001, R12-1-1003 through R12-1-1006 and Exhibit A.

5. Status of enforcement of the rule

The following rules are enforced as written:
R12-1-801, R12-1-803, R12-1-805 through R12-1-806, and R12-1-809; R12-1-1001, R12-1-1003 through R12-1-1006 and Exhibit A.

6. Analysis of clarity, conciseness, and understandability

The following rules are clear, concise, and understandable:
R12-1-801, R12-1-803, R12-1-805 through R12-1-806, and R12-1-809; R12-1-1001, R12-1-1003 through R12-1-1006 and Exhibit A.

10. Whether the agency completed the course of action proposed in the previous Five-year-review Report

The Agency has not completed the rule amendments listed in the previous five year report for Articles 8 and 10. These actions are a portion of RMP-0079 currently under review for a moratorium override in the Governor's office.

11. Probable Benefit of the Rules in Meeting Regulatory Objective and Determination that the Rules Impose the Least Burden and Costs to the Regulated Community to Achieve Objective:

The following rules impose the least burden and costs on the public:
R12-1-801, R12-1-803, R12-1-805 through R12-1-806, and R12-1-809; R12-1-1001, R12-1-1003 through R12-1-1006 and Exhibit A.

The following rules will impose the least burden and costs on the public when the issues identified in this report are addressed:

R12-1-802, R12-1-804, R12-1-807, R12-1-808, R12-1-1002, R12-1-1007, and R12-1-1008.

ANALYSIS OF INDIVIDUAL RULES

ARTICLE 8

R12-1-802. Definitions

1. Authorization of the rule by existing statute

A.R.S. §§ 30-654(A)(2), 30-654(B)(5), 30-654(B)(9), 30-654(B)(13), 30-657(A), 30-671(B), 30-672, 30-672.01, 30-673, and 30-686.

2. Objective

This rule provides the definitions for analytical x-ray units regulated and described in Article 8.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because it is missing a definition for handheld x-ray units.

5. Status of enforcement of the rule

The rule is not enforced as written. As an alternative, the condition of a hand-held analytical unit is currently listed on a registration, Agency forms, and is generally known in the industry that uses analytical x-ray units.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable and thereby does not fulfill its objective.

10. Whether the agency completed the course of action proposed in the previous Five-year-review Report

No.

R12-1-804. Open-beam X-ray Systems

1. Authorization of the rule by existing statute

A.R.S. §§ 30-654(A)(2), 30-654(B)(5), 30-654(B)(9), 30-654(B)(13), 30-657(A), 30-671(B), 30-672, 30-672.01, 30-673, and 30-686.

2. Objective

This rule describes the basic use requirements of an open beam x-ray unit.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because it needs a clarification subsection that would exempt hand held open beam x-ray units from the requirements stated in this rule. The rule also requires editing to remove a subsection of the rule that does not apply to x-ray units.

5. Status of enforcement of the rule

The rule is not enforced as written.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable and thereby does not fulfill its objective.

10. Whether the agency completed the course of action proposed in the previous Five-year-review Report

No.

R12-1-807. Surveys

1. Authorization of the rule by existing statute

A.R.S. §§ 30-654(A)(2), 30-654(B)(5), 30-654(B)(9), 30-654(B)(13), 30-657(A), 30-671(B), 30-672, 30-672.01, 30-673, and 30-686.

2. Objective

This rule describes survey requirements of open bean analytical units.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because a removal of Agency determination of ALARA levels is needed to standardize the ALARA requirements in a manner similar to other x-ray units.

5. Status of enforcement of the rule

The rule is not enforced as written.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable and thereby does not fulfill its objective.

10. Whether the agency completed the course of action proposed in the previous Five-year-review Report

No.

R12-1-808. Posting

1. Authorization of the rule by existing statute

A.R.S. §§ 30-654(A)(2), 30-654(B)(5), 30-654(B)(9), 30-654(B)(13), 30-657(A), 30-671(B), 30-672, 30-672.01, 30-673, and 30-686.

2. Objective

This rule describes the posting requirements for open beam x-ray units.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because a clarification to exclude closed beam and hand held open beam units is needed.

5. Status of enforcement of the rule

The rule is not enforced as written.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable and thereby does not fulfill its objective.

10. Whether the agency completed the course of action proposed in the previous Five-year-review Report

No.

ARTICLE 10

R12-1-1002. Posting of Notices for Workers

1. Authorization of the rule by existing statute

A.R.S. §§ 30-654(A)(2), 30-654(B)(5), 30-654(B)(9), 30-654(B)(13), 30-654(B)(18), 30-657(A), 30-671(B), 30-672, 30-672.01, 30-673, and 30-686.

2. Objective

This rule lists the posting requirements for possession of radioactive material or x-ray units.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because an update to include non-ionizing radiation in this rule is needed.

5. Status of enforcement of the rule

The rule is not enforced as written.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable and thereby does not fulfill its objective.

10. Whether the agency completed the course of action proposed in the previous Five-year-review Report

No.

R12-1-1007. Inspection Requests by Workers

1. Authorization of the rule by existing statute

A.R.S. §§ 30-654(A)(2), 30-654(B)(5), 30-654(B)(9), 30-654(B)(13), 30-654(B)(18), 30-657(A), 30-671(B), 30-672, 30-672.01, 30-673, and 30-686.

2. Objective

This rule provides the opportunity for employees to notify the Agency of potential violations of rules without jeopardy to their employment. It also provides that the Agency will inspect the facility or operation as warranted.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because there is a need to correct minor typographical errors in this rule.

5. Status of enforcement of the rule

The rule is not enforced as written.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable and thereby does not fulfill its objective.

10. Whether the agency completed the course of action proposed in the previous Five-year-review Report

No.

R12-1-1008. Inspection not Warranted; Review

1. Authorization of the rule by existing statute

A.R.S. §§ 30-654(A)(2), 30-654(B)(5), 30-654(B)(9), 30-654(B)(13), 30-654(B)(18), 30-657(A), 30-671(B), 30-672, 30-672.01, 30-673, 30-686, 32-516, and 32-3233.

2. Objective

This rule describes the Agency requirements if there is not cause to inspect because of a complaint filed in accordance with R12-1-1007.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because there is a need to correct minor typographical errors in this rule such as making determines a single word.

5. Status of enforcement of the rule

The rule is not enforced as written.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable and thereby does not fulfill its objective.

10. Whether the agency completed the course of action proposed in the previous Five-year-review Report

No.

Radiation Regulatory Agency

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

R12-1-801. Scope

The rules in this Article establish requirements for the use of analytical x-ray equipment by persons registered under R12-1-204. The provisions of this Article supplement other applicable provisions of this Chapter.

Historical Note

Former Rule Section H.1; Former Section R12-1-801 repealed, new Section R12-1-801 adopted effective June 30, 1977 (Supp. 77-3). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 10 A.A.R. 2122, effective July 3, 2004 (Supp. 04-2).

R12-1-802. Definitions

"Analytical x-ray equipment" means devices or machines used for x-ray diffraction or x-ray induced fluorescence analysis.

"Analytical x-ray system" means a group of components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials.

"Enclosed beam x-ray system" means an analytical x-ray system constructed in such a way that access to the interior of the enclosure housing the x-ray source is precluded during operation except through bypassing of interlocks or other safety devices to perform maintenance or servicing.

"Fail-safe characteristic" means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

"Local component" means part of an analytical x-ray system and includes each area that is struck by x-rays, such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, but does not include power supplies, transformers, amplifiers, readout devices, and control panels.

"Normal operating procedures" means instructions or procedures including, but not limited to, sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data recording procedures which are related to radiation safety.

"Open beam x-ray system" means an analytical x-ray system which permits an individual to place some body part in the primary beam path during normal operation.

"Primary beam" means radiation which passes through an aperture of the source housing on a direct path from the x-ray tube.

Historical Note

Former Rule Section H.2; Former Section R12-1-802 repealed, new Section R12-1-802 adopted effective June 30, 1977 (Supp. 77-3). Amended effective Aug. 8, 1986 (Supp. 86-4). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2).

R12-1-803. Enclosed-beam X-ray Systems

A. Enclosed beam x-ray systems are exempt from other equipment requirements contained in this Article provided the enclosed beam x-ray systems are designed and constructed so that radiation levels measured at 5 cm from any accessible surface of the enclosure housing the x-ray source do not exceed 5 μSv (0.5 mrem) in one hour.

B. A registrant using enclosed beam x-ray systems shall comply with applicable provisions of R12-1-804(A), R12-1-805(B), and 12 A.A.C. 1, Article 4.

C. A person who maintains or services analytical x-ray systems, shall:

1. Obtain permission in advance from the radiation safety officer before bypassing interlocks or other safety devices,
2. Label equipment as "out of service" until maintenance or service is completed,
3. Wear extremity personnel monitoring devices, and
4. Ensure that interlocks or other safety devices are operating upon completion of maintenance or service.

Historical Note

Former Rule Section H.3; Former Section R12-1-803 repealed, new Section R12-1-803 adopted effective June 30, 1977 (Supp. 77-3). Former Section R12-1-803 repealed, new Section R12-1-803 adopted effective Aug. 8, 1986 (Supp. 86-4). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 10 A.A.R. 2122, effective July 3, 2004 (Supp. 04-2).

R12-1-804. Open-beam X-ray Systems

A. A registrant shall label open beam x-ray systems with a readily discernible sign or signs bearing the radiation symbol and the words:

1. "CAUTION -- HIGH INTENSITY X-RAY BEAM," or a similar warning, on the x-ray source housing; and
2. "CAUTION RADIATION -- THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" or a similar warning, near any switch that energizes an x-ray tube if the radiation source is an x-ray tube.

B. A registrant shall ensure that an open beam x-ray system has all of the following warning devices:

1. X-ray tube status (On-Off) indicator in systems where the primary beam is controlled in this fashion;
2. Shutter status (Open-Closed) indicators near each port on the radiation housing for systems which control the primary beam; and
3. A clearly visible warning light labeled with the words "X-RAY ON," or a similar warning located near any switch that energizes an x-ray tube, illuminated only when the tube is energized; and
4. The warning devices in subsections (B)(1) through (3) shall be labeled so that their purpose is easily identified.

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C. A registrant shall ensure that any apparatus utilized in beam alignment procedures is designed in such a way that excessive radiation will not strike the operator. Particular attention shall be given to viewing devices, in order to ascertain that lenses and other transparent components attenuate the beam to an acceptable level.

D. A registrant shall provide an interlock device which prevents entry of any portion of an individual's body into the primary beam or causes the primary beam to be shut off upon entry into its path on all open-beam x-ray systems. A registrant may apply to the Agency for an exemption from the requirements of a safety device. An application for exemption shall include:
1. A description of the various safety devices that have been evaluated;
2. The reason each device cannot be used; and
3. A description of the alternative methods that will be used to minimize accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

E. A registrant shall use only systems constructed so that:
1. Each x-ray tube housing is equipped with an interlock that automatically shuts off the tube if the tube is removed from the radiation source housing or the housing is disassembled; and
2. With all shutters closed, radiation measured at a distance of 5 centimeters from the surface of the system is not capable of producing a dose that exceeds 25 Sv (2.5 mRem) in one hour for the specified tube rating of the x-ray tube.

F. A registrant shall supply each x-ray generating system with a protective cabinet that limits leakage radiation measured at a distance of 5 cm (2 in) from the cabinet surface, so that the system is not capable of producing a dose equivalent that exceeds 25 µSv (2.5 mrem) in one hour.

G. A registrant shall ensure that the local components of an analytical x-ray system are located and arranged and have sufficient shielding or access control for the specified tube rating to prevent the radiation level in any area adjacent to the local component group from exceeding the dose limits in R12-1-416.

H. A registrant shall perform a radiation survey of the local component group of each analytical x-ray system to demonstrate compliance with subsection (G) upon:
1. Installation,
2. Change in configuration, or
3. Maintenance that affects the radiation level in any area adjacent to the local component group.

I. A registrant shall maintain a record of each survey for three years or until the analytical x-ray system is no longer used, whichever period is shorter.

Historical Note

Former Rule Section H.4; Former Section R12-1-804 repealed, new Section R12-1-804 adopted effective June 30, 1977 (Supp. 77-3). Former Section R12-1-804 renumbered as Section R12-1-805 without change, new Section R12-1-804 adopted effective Aug. 8, 1986 (Supp. 86-4). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 10 A.A.R. 2122, effective July 3, 2004 (Supp. 04-2).

R12-1-805. Administrative Responsibilities

A. A registrant shall designate a radiation safety officer who shall:
1. Establish and maintain operational procedures so that the radiation exposure of each worker is kept ALARA;
2. Instruct all personnel who work with or near radiation producing machines in safety practices;
3. Maintain a system of personnel monitoring;
4. Establish radiation control areas, including placement of appropriate radiation warning signs or devices;
5. Provide a radiation safety inspection of radiation producing machines on a routine basis;
6. Review modifications to x-ray systems, including x-ray tube housing, cameras, diffractometers, shielding, and safety interlocks;
7. Investigate and report proper authorities any case of excessive exposure to personnel and take remedial action; and,
8. Be familiar with all applicable rules for control of ionizing radiation.

B. An individual shall not be permitted to operate or maintain an open beam analytical x-ray system unless the individual has received instruction in and demonstrated competence in all of the following:
1. Identification of radiation hazards associated with the use of the equipment;
2. Significance of all radiation warning and safety devices, interlocks incorporated into the equipment, or the reasons that devices or interlocks have not been installed on certain pieces of equipment and the extra precautions required in lieu of these precautions;
3. Proper operating procedures for the equipment;
4. Recognition of symptoms of acute localized radiation exposure; and
5. Proper procedure for reporting an actual or suspected exposure.

C. A registrant shall maintain records of instruction and competence for Agency inspection for three years from the date of course completion or demonstration.

Historical Note

Adopted effective June 30, 1977 (Supp. 77-3). Former Section R12-1-805 renumbered as Section R12-1-806 without change. Former Section R12-1-804 renumbered as Section R12-1-805 without change effective Aug. 8, 1986 (Supp. 86-4). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 10 A.A.R. 2122, effective July 3, 2004 (Supp. 04-2).

R12-1-806. Operating Requirements

A. A radiation safety officer shall establish written emergency procedures and post the procedures in a conspicuous location. The procedures shall include the telephone number of the radiation safety officer.

B. A registrant shall ensure that written operating procedures are available for all analytical x-ray equipment workers. An individual shall not operate analytical x-ray equipment in any manner other than that specified in the procedures unless the individual obtains the radiation safety officer's written approval.

C. An individual shall not bypass a safety device or interlock unless the individual has obtained Radiation Safety Officer approval. The approval shall be for a specific period of time. When a safety device or interlock has been bypassed, the Radiation Safety Officer shall place a readily discernible sign on the radiation source housing, warning the reader of the unsafe condition. A registrant shall maintain the written record of the bypass approval for three years after the approval expires.

D. Except as authorized in subsection (C), an individual shall not perform an operation involving removal of covers, shielding materials, or tube housings or modification of shutters, collimators, or beam stops without ascertaining that the tube is off and that it will remain off until all protective devices have been restored to the normal operating condition. An individual repairing analytical x-ray equipment shall use the main switch, rather than interlocks, for routine shutdown in preparation for repairs.

E. A registrant shall ensure that unused ports on radiation source housings are closed and secured against unauthorized access to the radiation source.

F. Finger or wrist personnel monitoring devices shall be used by:

1. Operators of open beam analytical x-ray equipment not equipped with a safety device; and
2. Personnel performing maintenance procedures that require the presence of a primary x-ray beam when any local component is disassembled or removed.

G. A registrant shall ensure that each safety and warning device is tested for proper operation at intervals that do not exceed one month and maintain a record of each test for three years from the date the test is completed.

Historical Note

Former Section R12-1-805 renumbered as Section R12-1-806 without change effective Aug. 8, 1986 (Supp. 86-4). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 10 A.A.R. 2122, effective July 3, 2004 (Supp. 04-2).

R12-1-807. Surveys

A. To ensure that personnel exposure does not result in a dose to an individual that exceeds the dose limits specified in Article 4, a registrant shall perform a radiation survey upon:

1. Installation of the equipment and at least once each year after installation;
2. Change in the initial arrangement, number, or type of local components in the system;
3. Maintenance that involves disassembly or removal of a local component in the system;
4. Maintenance that involves alignment, if alignment requires the generation of the primary x-ray beam while any local component of the system is disassembled or removed;
5. A visual inspection of the local components in the system that reveals an abnormal condition; or
6. Determination that personnel are being exposed to radiation in excess of established levels recorded in monitoring records for personnel during previous monitoring periods or the occupational dose limits specified in Article 4.

B. The radiation surveys in subsection (A) are not required if the registrant demonstrates that the local components of an analytical x-ray system are located and arranged, and have sufficient shielding or access control, to limit personnel exposure to a level that is ALARA and below the occupational dose limits in Article 4. The Agency shall determine ALARA radiation levels based on the specified x-ray tube rating.

Historical Note

New Section made by final rulemaking at 10 A.A.R. 2122, effective July 3, 2004 (Supp. 04-2).

R12-1-808. Posting

A registrant shall conspicuously post each area or room that contains analytical x-ray equipment with a sign or signs that bear the radiation symbol and the words "CAUTION – X-RAY EQUIPMENT" or words with a similar meaning.

Historical Note

New Section made by final rulemaking at 10 A.A.R. 2122, effective July 3, 2004 (Supp. 04-2).

R12-1-809. Training

A registrant shall not be allow an individual to operate or maintain analytical x-ray equipment unless the individual has received training and demonstrated competence in:

1. Identifying radiation hazards associated with use of the equipment;
2. Recognizing and using radiation warning and safety devices, including interlocks that are incorporated into the equipment, and understanding why these devices are sometimes not installed;
3. Taking precautions associated with use of the equipment;
4. Recognizing symptoms of an acute localized exposure; and
5. Following proper procedure for reporting a suspected personnel exposure.

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Historical Note

New Section made by final rulemaking at 10 A.A.R. 2122, effective July 3, 2004 (Supp. 04-2).

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

R12-1-1001. Purpose and Scope

This Article establishes requirements for notices, instructions, and reports by licensees or registrants to individuals working for a licensee or registrant. This Article explains the options available to these individuals in connection with ARRA inspections of licensees or registrants regarding radiological working conditions. The rules in this Article apply to all persons who receive, possess, use, own, or transfer sources of radiation licensed or registered by the ARRA.

Historical Note

Adopted effective June 30, 1977 (Supp. 77-3). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2).

R12-1-1002. Posting of Notices for Workers

A. Each licensee or registrant shall post current copies of the following documents:
1. The rules in this Chapter;
2. The license, certificate of registration, conditions, or documents incorporated into the license or registration by reference, and any amendments to the license or registration;
3. The operating procedures applicable to work under the license or registration;
4. Any notice of violation involving radiological working conditions, proposed imposition of a civil penalty, or order issued under 12 A.A.C. 1, Article 12, and any response from the licensee or registrant.

B. If posting of a document specified in subsections (A)(1), (2) and (3) is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

C. Form ARRA-6 (shown following R12-1-1008), "Notice to Employees" shall be posted by each licensee or registrant wherever individuals work in or frequent any portion of a restricted area.

D. Each licensee or registrant shall post documents, notices, or forms, as required by this Section, so that they are conspicuous and appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies and shall replace any document if it is defaced or altered.

E. Agency documents posted as required in subsection (A)(4) shall be posted within two working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted within two working days after dispatch from the licensee or registrant. The documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

Historical Note

Adopted effective June 30, 1977 (Supp. 77-3). Amended effective February 25, 1985 (Supp. 85-1). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2).

R12-1-1003. Instructions for Workers

A. A licensee or registrant shall ensure that each individual who, in the course of employment, is likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem), receives instruction in all of the following subjects:
1. Storage, transfer, or use of radiation and radioactive material;
2. Health protection problems associated with exposure to radiation or radioactive material, precautions or procedures to minimize exposure, and purposes and functions of protective devices;
3. Applicable provisions in Agency rules, licenses, and registrations that protect of personnel from exposure to radiation or radioactive material, with an emphasis on the duties of workers;
4. The duty to promptly report to the licensee or registrant any condition that may lead to or cause a violation of a provision in an Agency rule, license, or registration or unnecessary exposure to radiation or radioactive material;
5. Correct response to warnings in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and
6. Radiation exposure reports that a worker may request according to R12-1-1004.

B. In determining whether subsection (A) applies to an individual, a licensee or registrant shall take into consideration assigned activities during normal and abnormal situations that involve exposure to radiation or radioactive material and could reasonably be expected to occur during the life of a facility. The licensee or registrant shall provide instruction that is commensurate with potential radiological health protection problems present in the work place.

Historical Note

Adopted effective June 30, 1977 (Supp. 77-3). Amended effective February 25, 1985 (Supp. 85-1). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 12 A.A.R. 75, effective February 7, 2006 (Supp. 05-4).

R12-1-1004. Notifications and Reports to Individuals

A. A licensee or registrant shall report radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body to the individual as specified in this Section. The information reported shall include data and results obtained under Agency rules, orders, or license conditions, as shown in records maintained by the licensee or registrant. Each notification and report shall be in writing; include appropriate identifying data, such as the name of the li-

censee or registrant, the name of the individual, and the individual's Social Security number; include the individual's exposure information; and contain the following statement:

"This report is furnished to you under the provisions of 12 A.A.C. 1. You should preserve this report for future reference."

B. Each licensee or registrant shall make dose information available to workers as shown in records maintained by the licensee or registrant under the provisions of Article 4. Each licensee or registrant shall provide annual notification of exposure to radiation or radioactive material for each worker, as shown in records maintained by the licensee or registrant under R12-1-419(E) if:

1. The individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue; or
2. The individual requests his or her annual dose report.

C. At the request of a worker formerly engaged in work controlled by the licensee or the registrant, each licensee or registrant shall furnish to the worker a report of the worker's exposure to radiation or radioactive material. The report shall be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later; the report shall cover, within the period of time specified in the request, each calendar quarter in which the worker's activities involved exposure to radiation from radioactive material licensed by, or radiation machines registered with, the Agency; and the report shall include the dates and locations of work under the license or registration in which the worker participated during this period.

D. Reports to individuals of their exposure to radiation shall be made according to R12-1-446.

Historical Note

Adopted effective June 30, 1977 (Supp. 77-3) Amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 20 A.A.R. 324, effective March 8, 2014 (Supp. 14-1).

R12-1-1005. Licensee, Registrant, and Worker Representation During Agency Inspection

A. As a condition of licensure or registration, each licensee or registrant shall afford to the Agency, at all reasonable times and without undue delay, an opportunity to inspect materials, machines, activities, facilities, premises, and records.

B. During an inspection, the licensee or registrant shall permit Agency inspectors to consult privately with workers as specified in Section R12-1-1006. The licensee or registrant may accompany Agency inspectors during other phases of an inspection.

C. A worker authorized to consult with an Agency inspector under R12-1-1006 may authorize another individual to represent the worker's interests during the Agency inspection. The licensee or registrant shall notify the inspectors of the worker's authorization and give the worker's representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

D. Each worker's representative shall be routinely engaged in work under control of the licensee or registrant or shall have received instructions under R12-1-1003.

E. Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the inspection. However, only one worker's representative at a time may accompany the inspectors.

F. With the approval of the licensee or registrant and the worker's representative an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the worker's representative, shall be afforded the opportunity to accompany Agency inspectors during the inspection of physical working conditions.

G. Notwithstanding the other provisions of this Section, Agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information the worker's representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, any individual who accompanies an inspector may have access to such information only if authorized by the classifying agency.

Historical Note

Adopted effective June 30, 1977 (Supp. 77-3). Amended effective February 25, 1985 (Supp. 85-1). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2).

R12-1-1006. Consultation with Workers During Inspections

A. A licensee or registrant shall afford Agency inspectors talking to a licensee or registrant representative the opportunity to consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Agency rules, licenses, and registrations to the extent the inspectors deem consultation necessary for conducting an effective and thorough inspection.

B. During the course of an inspection, any worker may privately bring to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of the Act, these rules, or a license or registration condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material or a registered radiation machine under the licensee's or registrant's control. If this notification is in writing, the worker shall comply with the requirements of R12-1-1007(A).

C. The provisions of R12-1-1006(B) shall not be interpreted as authorization to disregard instructions required by R12-1-1003.

Historical Note

Adopted effective June 30, 1977 (Supp. 77-3). Amended effective February 25, 1985 (Supp. 85-1). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2).

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R12-1-1007. Inspection Requests by Workers

A. Any worker or representative of workers who believes that a violation of the Act, these rules, license, or registration conditions exists, or has occurred with regard to radiological working conditions in which the worker is engaged, may request an inspection of the facility by the Agency. Any request shall be in writing, addressed to the Director, set forth the specific grounds for the request, and be signed by the worker or representative of the workers. The Agency shall provide a copy to the licensee or registrant no later than at the time of inspection except that, upon the request of the worker, the Agency shall protect the worker's name and the name of individuals referred to in the request to the extent authorized by law, except for good cause shown.

B. If, upon receipt of a request for inspection, the Agency's Director deter mines that there are reasonable grounds to believe that the alleged violation exists or has occurred, the Director shall initiate an inspection as soon as practicable, to determine if the alleged violation exists or has occurred. Inspections performed under this subsection need not be limited to matters referred to in the complaint.

C. A licensee or registrant shall not discharge or in any manner discriminate against any worker because the worker has filed any complaint or caused to be instituted any proceeding under these rules or has testified or is about to testify in the instituted proceeding or because the worker exercises on behalf of the worker or others, any option afforded by this Article.

Historical Note

Adopted effective June 30, 1977 (Supp. 77-3). Amended effective February 25, 1985 (Supp. 85-1). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2).

R12-1-1008. Inspection not Warranted; Review

If the Agency determines, with respect to a complaint under R12-1-1007, that an inspection is not warranted or there are no reasonable grounds to believe that a violation exists or has occurred, the Agency shall notify the complainant in writing of the determination. The complainant may obtain review of the determination by submitting a written request for hearing to the Agency. The Agency shall provide for a hearing before the Radiation Regulatory Hearing Board under 12 A.A.C. 1, Article 12 and A.R.S. Title 41, Chapter 6, Article 10.

Historical Note

Adopted effective June 30, 1977 (Supp. 77-3). Amended effective February 25, 1985 (Supp. 85-1). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). R12-1-1008 updated to reflect a corrected Arizona Revised Statute article number
(Supp. 07-1).

Radiation Regulatory Agency

Exhibit A. Form ARRA-6 (2012) Notice to Employees
ARRA-6 (2012) ARIZONA RADIATION REGULATORY AGENCY

NOTICE TO EMPLOYEES

STANDARDS FOR PROTECTION AGAINST RADIATION; NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

In Article 4 of the Arizona Radiation Regulatory Agency (ARRA) rules for the Control of Radiation, the Arizona Radiation Regulatory Agency has established standards for your protection against radiation hazards. In Article 10 of the rules for the Control of Radiation, the Arizona Radiation Regulatory Agency has established certain provisions for the options of workers engaged in work under an ARRA license or registration.

YOUR EMPLOYER'S RESPONSIBILITY

Your employer is required to -

1. Apply these rules to work involving sources of radiation.
2. Post or otherwise make available to you a copy of the Arizona Radiation Regulatory Agency rules, licenses, and operating procedures which apply to work you are engaged in, and explain their provisions to you.
3. Post notice of violation involving radiological working conditions, proposed imposition of civil penalties, and orders.

YOUR RESPONSIBILITY AS A WORKER

You should familiarize yourself with those provisions of the Arizona Radiation Regulatory Agency rules and the operating procedures which apply to the work you are engaged in. You should observe their provisions for your own protection and protection of your co-workers.

WHAT IS COVERED BY THESE RULES

1. Limits on exposure to radiation and radioactive material in restricted and unrestricted areas;
2. Measures to be taken after accidental exposure;
3. Personnel monitoring, surveys, and equipment;
4. Caution signs, labels, and safety interlock equipment;
5. Exposure records and reports;
6. Options for workers regarding ARRA inspections; and
7. Related matters.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY

1. The Arizona Radiation Regulatory Agency rules require that your employer give you a written report if you receive an exposure in excess of any applicable limit set forth in the rules or in the license. The basic limits for exposure to employees are set forth in Article 4 of the rules. These Sections specify limits on exposure to radiation and exposure to concentrations of radioactive material in air and water.
2. If you work where personnel monitoring is required, and if you request information on your radiation exposures,
   a. Your employer must give you a written report, upon termination of your employment, of your radiation exposures; and
   b. Your employer must advise you annually of your exposure to radiation.

INSPECTIONS

All licensed or registered activities are subject to inspection by representatives of the Arizona Radiation Regulatory Agency. In addition, any worker or representative of workers who believes that there is a violation of the regulations issued thereunder, or the terms of the employer's license or rules with regard to radiological working conditions in which the worker is engaged, may request an inspection by sending a notice of the alleged violation to the Arizona Radiation Regulatory Agency. The request must set forth the specific grounds for the notice and must be signed by the worker on his own behalf or as a representative of the workers. During inspections, ARRA inspectors may confer privately with workers, and any worker may bring to the attention of the inspectors any past or present condition which he believes contributed to or caused any violation as described above.

INQUIRIES

Inquiries dealing with the matters outlined above can be sent to the:

ARIZONA RADIATION REGULATORY AGENCY

POSTING REQUIREMENT

IN ACCORDANCE WITH A.A.C. R12-1-1002, COPIES OF THIS NOTICE SHALL BE POSTED IN SUCH A MANNER TO PERMIT EMPLOYEES WORKING IN OR FREQUENTING ANY PORTION OF A RESTRICTED AREA, USED FOR ACTIVITIES LICENSED OR REGISTERED PURSUANT TO ARTICLE 2 OR ARTICLE 3 OF THE AGENCY'S RULES, TO OBSERVE A COPY OR COPIES ON THE WAY TO OR FROM THEIR WORK AREA.

Historical Note

Exhibit A amended by final rulemaking at 18 A.A.R. 1895, effective September 10, 2012 (Supp. 12-3).

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30-654. Powers and duties of the agency

A. The agency may:

1. Accept grants or other contributions from the federal government or other sources, public or private, to be used by the agency to carry out any of the purposes of this chapter.

2. Do all things necessary, within the limitations of this chapter, to carry out the powers and duties of the agency.

3. Conduct an information program, including but not limited to:

(a) Providing information on the control and regulation of sources of radiation and related health and safety matters, on request, to members of the legislature, the executive offices, state departments and agencies and county and municipal governments.

(b) Providing such published information, audiovisual presentations, exhibits and speakers on the control and regulation of sources of radiation and related health and safety matters to the state's educational system at all educational levels as may be arranged.

(c) Furnishing to citizen groups, on request, speakers and such audiovisual presentations or published materials on the control and regulation of sources of radiation and related health and safety matters as may be available.

(d) Conducting, sponsoring or cosponsoring and actively participating in the professional meetings, symposia, workshops, forums and other group informational activities concerned with the control and regulation of sources of radiation and related health and safety matters when representation from this state at such meetings is determined to be important by the agency.

B. The agency shall:

1. Regulate the use, storage and disposal of sources of radiation.

2. Establish procedures for purposes of selecting any proposed permanent disposal site located within this state for low level radioactive waste.

3. Coordinate with the department of transportation and the corporation commission in regulating the transportation of sources of radiation.

4. Assume primary responsibility for and provide necessary technical assistance to handle any incidents, accidents and emergencies involving radiation or sources of radiation occurring within this state.

5. Adopt rules deemed necessary to administer this chapter in accordance with title 41, chapter 6.

6. Adopt uniform radiation protection and radiation dose standards to be as nearly as possible in conformity with, and in no case inconsistent with, the standards contained in the regulations of the United States nuclear regulatory commission and the standards of the United States public health service. In the adoption of the standards, the agency shall consider the total occupational radiation exposure of individuals, including that from sources not regulated by the agency.

7. Adopt rules for personnel monitoring under the close supervision of technically competent people in order to determine compliance with safety rules adopted under this chapter.

8. Adopt a uniform system of labels, signs and symbols and the posting of the labels, signs and symbols to be affixed to radioactive products, especially those transferred from person to person.

9. By rule require adequate training and experience of persons utilizing sources of radiation with respect to the hazards of excessive exposure to radiation in order to protect health and safety.

10. Adopt standards for the storage of radioactive material and for security against unauthorized removal.

11. Adopt standards for the disposal of radioactive materials into the air, water and sewers and burial in the soil in accordance with 10 Code of Federal Regulations part 20.

12. Adopt rules applicable to the shipment of radioactive materials in conformity with and compatible with those established by the United States nuclear regulatory commission, the department of transportation, the United States treasury department and the United States postal service.

13. In individual cases, impose additional requirements to protect health and safety or grant necessary exemptions which will not jeopardize health or safety, or both.

14. Make recommendations to the governor and furnish such technical advice as required on matters relating to the utilization and regulation of sources of radiation.

15. Conduct or cause to be conducted off-site radiological environmental monitoring of the air, water and soil surrounding any fixed nuclear facility, any uranium milling and tailing site and any uranium leaching operation, and maintain and report the data or results obtained by the monitoring as deemed appropriate by the agency.

16. Develop and utilize information resources concerning radiation and radioactive sources.

17. Prescribe by rule a schedule of fees to be charged to categories of licensees and registrants of radiation sources, including academic, medical, industrial, waste, distribution and imaging categories. The fees shall cover a significant portion of the reasonable costs associated with processing the application for license or registration, renewal or amendment of the license or registration and the costs of inspecting the licensee or registrant activities and facilities, including the cost to the agency of employing clerical help, consultants and persons possessing technical expertise and using analytical instrumentation and information processing systems.

18. Adopt rules establishing radiological standards, personnel standards and quality assurance programs to assure the accuracy and safety of screening and diagnostic mammography.

C. All fees collected under subsection B, paragraph 18 shall be deposited, pursuant to sections 35-146 and 35-147, in the state general fund.

30-657. Records

A. Each person who possesses or uses a source of radiation shall maintain records relating to its receipt, storage, transfer or disposal and such other records as the agency provides by rules and regulations.

B. The agency shall require each person who possesses or uses a source of radiation to maintain appropriate records showing the radiation exposure of all individuals for whom personnel monitoring is required by rules and regulations promulgated by the agency. Copies of records required by this section shall be submitted to the agency on request by the agency.

C. Any person who possesses or uses a source of radiation shall furnish to each employee for whom personnel monitoring is required a copy of the employee's personal exposure record at such times as prescribed by rules and regulations promulgated by the agency.

D. Any person who possesses or uses a source of radiation shall, when requested, submit to the agency copies of records or reports submitted to the United States nuclear regulatory commission regardless of whether the person is subject to regulation by the agency. The agency shall, by rule and regulation, specify the records or reports required to be submitted to the agency under this subsection.

30-671. Exceptions; radiation standards

A. Radiation protection standards adopted in rules and regulations promulgated by the agency under this chapter shall not be construed to limit the kind or amount of radiation that may be intentionally applied to a person or animal for diagnostic or therapeutic purposes by or under the direction of a licensed practitioner of the healing arts.

B. Radiation sources shall be registered, licensed or exempt at the discretion of the agency and shall be available for inspection as specified in this chapter or rules and regulations adopted under this chapter.

30-672. Licensing and registration of sources of radiation; exemptions

A. The agency by rule shall provide for general or specific licensing of by-product, source, special nuclear materials or devices or equipment utilizing such materials. The rules shall provide for amendment, suspension or revocation of the licenses. The agency shall require from the applicant satisfactory evidence that the applicant is using methods and techniques that are demonstrated to be safe and that the applicant is familiar with the rules adopted by the agency under section 30-654, subsection B, paragraph 5 relative to uniform radiation standards, total occupational radiation exposure norms, labels, signs and symbols, storage, waste disposal and shipment of radioactive materials. The agency may require that before the agency issues a license the employees or other personnel of an applicant who may deal with sources of radiation receive a course of instruction approved by the agency concerning agency rules. The agency shall require that the applicant's proposed equipment and facilities be adequate to protect health and safety and that the applicant's proposed administrative controls over the use of the sources of radiation requested be adequate to protect health and safety.

B. The agency may require registration or licensing of other sources of radiation if it has been determined necessary to protect public health or safety.

C. The agency may exempt certain sources of radiation or kinds of uses or users from the licensing or registration requirements set forth in this section when it finds that the exemption of such sources of radiation or kinds of uses or users will not constitute a significant risk to the health and safety of the public.

D. The agency shall not require persons licensed in this state to practice as a dentist, physician assistant, chiropodist or veterinarian or licensed in this state to practice medicine, surgery, osteopathy, chiropractic or naturopathic medicine to obtain any other license for the use of a diagnostic x-ray machine, but these persons are governed by their own licensing acts.

E. Persons licensed by the federal communications commission with respect to the activities for which they are licensed by that commission are exempted from this chapter.

F. Rules adopted pursuant to this chapter may provide for recognition of other state or federal licenses as the agency deems desirable, subject to such registration requirements as the agency prescribes.

G. Any licenses issued by the agency shall state the nature, use and extent of use of the source of radiation. If at any time subsequent to the issuance of a license the licensee desires any change in the nature, use or extent, the licensee shall seek an amendment or a new license under this section.

H. The agency shall prescribe by rule requirements for financial security as a condition for licensure under this article. The agency shall deposit all amounts posted, paid or forfeited as financial security into the radiation regulatory and perpetual care fund under section 30-694.

I. Persons applying for licensure shall provide notice to the city or town where the applicant proposes to operate as part of the application process.

J. Any facility that provides diagnostic or screening mammography examinations by or under the direction of a person exempted from further licensure under subsection D of this section shall obtain certification by the agency. The agency shall prescribe by rule the requirements of certification in order to ensure the accuracy and safety of diagnostic and screening mammography.

30-672.01. Registration of persons who install or service radiation machines; exception; roster

A. A person who is in the business of installing or servicing radiation machines which are defined in section 30-651 and which are required to be registered by the agency shall register with the agency on a form provided by the agency.

B. Notwithstanding subsection A, a person who is subject to the jurisdiction of the medical radiologic technology board of examiners and is engaged in operation of a radiation machine shall not be required to register with the agency.

C. The registration form required pursuant to subsection A shall be limited to the following information:

1. The full business name of the registrant.

2. The names of the owners if the registrant is a corporation or partnership.

3. The names of employees who carry out installation or service work for the registrant.

4. The business address of the registrant.

D. The agency shall maintain a roster of all registrants, including the date of initial registration. The roster shall be available for public inspection.

E. A registrant must reregister with the agency whenever there is a change in the information provided under subsection C.

30-673. Unlawful acts

It is unlawful for any person to receive, use, possess, transfer, install or service any source of radiation unless registered, licensed or exempted by the agency in accordance with this chapter and rules and regulations adopted under this chapter.

ARIZONA HEALTH CARE CONTAINMENT SYSTEM (F-17-0102)
Title 9, Chapter 22, Article 1, Definitions

GOVERNOR'S REGULATORY REVIEW COUNCIL
ANALYSIS OF FIVE-YEAR REVIEW REPORT

MEETING DATE: January 4, 2017 **AGENDA ITEM: F-2**

TO: Governor's Regulatory Review Council (Council)

FROM: Marcus McGillivray, Legal Intern

DATE : December 20, 2016

SUBJECT: **ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM**
Title 9, Chapter 22, Article 1, Definitions

COMMENTS ON THE FIVE-YEAR-REVIEW REPORT

This five-year-review report from the Arizona Health Care Cost Containment System (AHCCCS) is regarding A.A.C. Title 9, Chapter 22, Article 1, Rule 101: the location of definitions. AHCCCS is Arizona's Medicaid program. Medicaid is a federal social healthcare program, funded jointly by federal and state governments, designed to provide healthcare plans for individuals with limited means. As of October 2016, approximately 1.9 million individuals were enrolled in AHCCCS programs, with an estimated 60,000 participating service providers, including private physician offices. AHCCCS has operated under a Research and Demonstration Waiver under Section 1115 of the Social Security Act. Section 1115 of the Demonstration program was renewed in September 2016.

The subject matter of this report is a single rule in Article 1, which provides the statutory location of common terms used by AHCCCS within their rules. AHCCCS plans to remove some definitions in future rulemakings due to their age, and plans to update location references for certain terms.

Proposed Actions:

AHCCCS plans multiple amendments to ensure the terms and location of definitions within Article 1 are current.

- "Adult behavioral health therapeutic home" 9 A.A.C. 10, Article 1 – Change this citation to R9-10-101.
- "Chronis" R9-22-1301 – Remove this definition because it no longer has a corresponding definition in section 1301.
- "Clinical oversight" 9 A.A.C. 10 – Change this citation to R9-10-101 for clarity.

- "CRS provider" R9-22-1301 –Remove this definition as it no longer has corresponding definition in section 1301 as of October 2015.
- "Grievance" A.A.C. Chapter 34 – Change this citation to R9-34-202 for clarity
- "Total Inpatient payments" R9-22-712.07 – Remove this definition because it has been deleted from the code.

Analysis of the agency's report pursuant to criteria in A.R.S. § 41-1056 and R1-6-301:

1. Has the agency certified that it is in compliance with A.R.S. § 41-1091?

Yes. AHCCCS has certified compliance with A.R.S. § 41-1091.

2. Has the agency analyzed the rules' effectiveness in achieving their objectives?

Yes. AHCCCS states that the rule is generally effective in achieving its objective.

3. Has the agency received any written criticisms of the rules during the last five years, including any written analysis questioning whether the rules are based on valid scientific or reliable principles or methods?

No written criticisms have been submitted regarding this rule in the previous five years.

4. Has the agency analyzed whether the rules are authorized by statute?

Yes. A.R.S. § 36-2903.01(F) grants the director of AHCCCS with the authority to adopt necessary rules to carry out the duties of AHCCCS.

5. Has the agency analyzed the rules' consistency with other rules and statutes?

Yes. AHCCCS has certified that the rule is consistent with other rules and statutes, including 42 U.S.C. § 1396 et seq, which is the federal Medicaid establishment statute.

6. Has the agency analyzed the current enforcement status of the rules?

Yes. AHCCCS states that the rule is enforced with no issues.

7. Has the agency analyzed whether the rules are clear, concise, and understandable?

AHCCCS is proposing the six changes described above to the rule to improve clarity, conciseness, and understandability.

8. Has the agency analyzed whether:

a. The rules are more stringent than corresponding federal law?

The rule is not more stringent than corresponding federal law 42 U.S.C. § 1396.

b. There is statutory authority to exceed the requirements of federal law?

N/A.

9. For rules adopted after July 29, 2010, has the agency analyzed whether:

This rule was amended by final rulemaking in January 2015.

a. The rules require issuance of a regulatory permit, license or agency authorization?

N/A.

b. It is in compliance with the general permit requirements of A.R.S. § 41-1037 or explained why it believes an exception applies?

N/A.

10. Has the agency indicated whether it completed the course of action identified in the previous five-year-review report?

AHCCCS has not completed the course of action described in the previous 5YRR, because the federal government keeps publishing final regulations implicating Medicaid Programs under the Affordable Care Act (ACA). In the last report, AHCCCS indicated its intention to update and relocate some of the defined terms used in this rule by 2014.

11. Has the agency included a proposed course of action?

Due to the renewal of the section 1115, Demonstration Program, AHCCCS will be initiating a new rulemaking in 2017 to establish program requirements under the new section 1115 waiver, and to conform to the federal Medicaid updates made under the ACA.

Conclusion

This Report meets the requirements of A.R.S. § 41-1056 and R1-6-301. This analyst recommends approval.

GOVERNOR'S REGULATORY REVIEW COUNCIL
M E M O R A N D U M

MEETING DATE: January 4, 2017 **AGENDA ITEM: F-2**

TO: Governor's Regulatory Review Council (Council)

FROM: GRRC Economic Team

DATE : December 20, 2016

SUBJECT: **ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM**
Title 9, Chapter 22, Article 1, Definitions

I have reviewed the five-year-review report's economic, small business, and consumer impact comparison for compliance with A.R.S. § 41-1056 and make the following comments.

1. Economic Impact Comparison

No economic, small business, and consumer impact statement (EIS) from the most recent rulemaking was available.

This review covers definitions for requirements of AHCCCS related to the delivery of services to acute care populations. As of October 1, 2016 approximately 1.9 million individuals were enrolled in the AHCCCS program. Article 1 was amended by exempt rulemaking at 18 A.A.R. 461, effective April 1, 2012.

2. Has the agency determined that the rules impose the least burden and costs to persons regulated by the rules?

AHCCCS believes the rules as written impose the least burden and cost when meeting their objectives.

3. Was an analysis submitted to the agency under A.R.S. § 41-1056(A)(7)?

No analysis was received that compares the rules' impact on this state's business competitiveness to the impact on businesses in other states under A.R.S. § 41-1056(A)(7).

4. Conclusion

After review, staff concludes that the report complies with A.R.S. § 41-1056 and recommends approval.

AHCCCS
Arizona Health Care Cost Containment System

Douglas A. Ducey, Governor
Thomas J. Betlach, Director

October 28, 2016

Ms. Nicole Ong, Chair
Governor's Regulatory Review Council
100 N. 15th Ave, Suite 402
Phoenix, AZ 85007

Dear Ms. Ong:

Pursuant to requirements in R1-6-301, attached is a copy of the 5-Year Review Report for Title 9, Chapter 22, Article 1. The report includes all of the documentation required by R1-6-301 (C) and (D).

As required by A.R.S. § 41-1056, the Administration certifies that the agency is in compliance with A.R.S. § 41-1091.

If you have any questions or comments regarding this report, please contact Gina Relkin, Office of Administrative Legal Services at (602)-417-4575.

Sincerely,

Matthew Devlin
Assistant Director

Attachments

Arizona Health Care Cost Containment System (AHCCCS)

5 YEAR REVIEW REPORT

A.A.C. Title 9, Chapter 22, Article 1

October 2016

I. General Information about 9 A.A.C. 22, Article 1

Overview:

On October 1, 1982, AHCCCS became the first statewide Medicaid managed care system in the nation. AHCCCS has operated under a Research and Demonstration Waiver under Section 1115 of the Social Security Act since 1982 when the original Waiver was granted by the Centers for Medicare and Medicaid Services (CMS). During that period, a number of waiver extensions have been approved by CMS. AHCCCS was created as a partnership between the state and private and public managed care Health Plans that mainstreamed Medicaid members into private physician offices. This arrangement opened up the private physician network to Medicaid recipients and allowed AHCCCS members to choose a Health Plan and a primary care provider. AHCCCS oversees contracted health plans in the delivery of both acute care and long term care services to persons who qualify for Medicaid. The Agency also oversees the delivery of behavioral health services to persons who have a Serious Mental Illness as a result of the transition of those responsibilities from the Arizona Department of Health Services to the AHCCCS Administration effective July 1, 2016 pursuant to Senate Bill Senate Bill 1257 (Laws 2015, Chapter 195).

As of October 1, 2016 approximately 1.9 million individuals were enrolled in the AHCCCS Program. Article 1 was created to define terms concerning requirements of the AHCCCS Program related to the delivery of services to acute care populations. This Article was amended by exempt rulemaking at 18 A.A.R. 461, effective April 1, 2012.

II. Five Year Report on 9 A.A.C. 22 Art 1 rules:

General and specific statutes authorizing the rule:
A.R.S. § 36-2903.01(F) provides general authority to AHCCCS to adopt rules.

Objective of the rule:
R9-22-101 – The objective of the rule is to provide definitions for terms used in Title 9

Chapter 22 specific to the AHCCCS Program .

Effectively meets its objectives, including any available data supporting conclusion:

Chapter 22, Article 1 rule meets the objective listed above. No data was attained.

Consistent with Statutes, rules, (including Federal, State, Waiver, Policy)

Chapter 22, Article 1 rule is consistent with statutes and federal regulations.

Is enforced:

Chapter 22, Article 1 rules is enforced with no issues.

Clarity, conciseness and understandability of the rule:

R9-22-101 – The Administration recommends the following changes to improve clarity, conciseness, and understandability of the rule:

"Adult behavioral health therapeutic home" 9 A.A.C. 10, Article 1 – Change this citation to R9-10-101 for greater clarity.

"Chronic" R9-22-1301 – Remove this definition as it no longer has a corresponding definition in section 1301 as of October 2015.

"Clinical oversight" 9 A.A.C. 10 – Change this citation to R9-10-101 for clarity.

"CRS provider" R9-22-1301 – Remove this definition as it no longer has a corresponding definition in section 1301 as of October 2015.

"Grievance" A.A.C. Chapter 34 – Change this citation to R9-34-202 for clarity.

"Total Inpatient payments" R9-22-712.07 – Remove this definition because it has been deleted from the code.

Had written criticisms in the past five years, including written analyses submitted questioning if the rule is based on valid scientific or reliable principles or methods:

Written criticisms or written analyses for Chapter 22, Article have not been submitted in the past five years.

Comparison of estimated economic, small business, and consumer impact.

The economic impact estimated at the time of rule promulgation has not been significantly different than the actual economic impact.

Was there any analysis submitted to the agency by another person regarding the rule's impact on this state's business competiveness as compared to the competitiveness of businesses in other states:

No.

If applicable, has the agency completed the course of action indicated in the agency's previous five-year review:

The Administration has not completed the recommended course of action described in the previous 5yr report. Since the submission of the previous five-year review, the federal

government has published, and continues to publish, proposed and final regulations implicating Medicaid Program operations and requirements as a result of the Affordable Care Act and other laws. Examples include Medicaid Managed Care final rules, Access to Care final rules, Nondiscrimination final rules, Copayment final rules, and final rules regarding eligibility requirements. Additionally, the federal government approved Arizona's Section 1115 Demonstration program in September 2016 due to the expiration of the prior Demonstration Program on September 30, 2016. As a result, the Agency will be initiating rulemaking to establish program requirements as a result of the new Waiver and to comply with the aforementioned federal rules. The recommendations for Article 1 will be addressed as part of the upcoming rulemakings.

Has there been a determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs necessary to achieve the underlying regulatory objective:

The Administration believes the rules as written impose the least burden and cost when meeting their objectives.

A determination after analysis that the rule is not more stringent than a corresponding federal law. Are the rules more stringent than a corresponding federal law? Is there a statutory authority that exceeds the requirements of that federal law?:

The rule is not more stringent than corresponding federal law 42 USC 1396 et seq.

Does the rule comply with section 41-1037 for issuance of permit, license or agency authorization?

Not applicable, the Administration does not issue permits, license or agency authorization for the imposition the definitions section of Chapter 22.

Course of action, including the month and year when the agency anticipates submitting rules to the GRRC to amend repeal or make a rule:

R9-22-101 – The Administration intends to update this rule as stated above, and these activities are anticipated to begin in 2017.

ECONOMIC, SMALL BUSINESS, AND CONSUMER IMPACT STATEMENT

TITLE 9. HEALTH SERVICES

CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM ADMINISTRATION

Introduction:

The AHCCCS Administration operates the Medicaid Program for Arizona. Included as covered services through the AHCCCS Program are behavioral health services. As of August 2014, approximately 1,591,593 l AHCCCS members qualify for medically necessary covered behavioral health services. The Administration provides medically necessary behavioral health services for its acute care members through the Arizona Department of Health Services (ADHS) by contract.

Purpose of Rule:

HB 2634 (Law 2011, Chapter 96) requires ADHS to reduce monetary or regulatory costs on persons or individuals receiving behavioral health services, streamline the regulation process, and facilitate licensure of integrated health programs that provide both behavioral and physical health services. As a result, ADHS made various changes to its administrative regulations consistent with Arizona laws.

Because the Administration cross references ADHS rules in AHCCCS regulations, it was necessary for the Administration to update its rules to correctly reference changes made by ADHS. In addition, various revisions recommended during a 5 year review of these rules have also been made along with any technical changes required to make the rulemaking clear.

1. Identification of rulemaking.

These rules define the behavioral health service requirements. The Administration is amending these rules to make the rules more clear, concise, and understandable by:

- Grouping like concepts to provide clarity and conciseness to the rule language,
- Clarifying language that does not clearly present policies or procedures, and
- Updating citations to documents, as needed.

Following is an explanation of the changes:

9 A.A.C. 22, Article 1

R9-22-101 - The Administration modified, added new terms used by ADHS, or deleted definitions to improve the clarity and conciseness of the rule language, such as “behavioral health paraprofessional”.

9 A.A.C. 22, Article 2

R9-22-201 The Administration modified, or deleted definitions to improve the clarity and conciseness of the rule language, such as, “clinical supervision”, which is no longer used by ADHS.

R9-22-202 Subsection (B)(10) specifies that behavioral health services are not covered for a person age 21-64 who is in an IMD. The Administration chose to strike this verbiage since this language is not required in rule.

Subsection (J)(3) was added to clarify that if a service is not covered, but the member nevertheless requests this service, the requirements described under R9-22-702 must be followed for the member to be financially responsible for the service.

R9-22-210.01 Subsection (A)(3)(a)(i) and (ii) were updated to reflect that ADHS is the entity responsible for providing inpatient emergency behavioral health services to non-FES members.

Subsection (A)(3)(b) was updated to reflect that ADHS is responsible for providing inpatient emergency behavioral health services to a FFS member except when provided in an IHS or tribally operated 638 facility. When the service is provided through one of these facilities, the services are paid by the Administration.

Subsection (A)(7) was updated by stating that in addition to the entities already identified, a TRBHA or the Administration cannot limit or deny payment under the circumstances listed in rule.

Subsection (A)(9)(b) was added to clarify that notification to the Administration is required within 72 hours for a FFS member receiving emergency medical services at a hospital.

Subsection (A)(10) was stricken since this requirement is no longer necessary because ADHS is responsible for behavioral health services from the beginning of the stay.

R9-22-217 Subsection (A) was updated to cross-reference the definitions under R9-22-201, since the definition of emergency services for a FES member is different than the definition in R9-22-201.

<u>9 A.A.C. 22, Article 12</u>

R9-22-1201 The General Requirements section was stricken in an effort to reorganize these rules as in other Articles. This section was made for Definitions related to behavioral health services described within this Article and to make the terms consistent with the ADHS terms used and defined by ADHS. . The reference to statute is not necessary in rule.

R9-22-1202 This section was updated to delineate the responsibilities of ADHS, the Administration and CRS responsibilities for payment of behavioral health services. Subsection (D) was added to clarify that the Administration is responsible for payment of behavioral health services received by an ALTCS FFS or FES member and that CRS is responsible for payment of behavioral health services provided to members enrolled with CRS..

R9-22-1203 Subsection (B) was stricken and combined with Subsection (A) for clarify when a member is eligible to receive behavioral health covered services.

R9-22-1204 Subsection (A) was clarified to describe and cross-reference other Articles for the provision of behavioral health services.

Subsection (B) and (C) were stricken since the same requirements are covered under subsection (A) through the cross-reference.

Subsection New (B) was added to clarify describe that a 72 hour notification to the Administration of the admission for behavioral health services for an American Indian is required.

Subsection (D) through (J) have been stricken since these requirements are described within Article 2 and 5 as cross-referenced under subsection (A).

Subsection New (C)(1) was stricken since all entities are responsible for behavioral health services as described under R9-22-1202, all restrictions and limitations apply to all entities.

R9-22-1205 Subsection (A)(2)(c) was stricken since the referenced Waiver has expired and is therefore no longer in effect.

Subsection (B)(4)(c) was stricken since it is not necessary to list psychotropic medications that can be billed independently, many medications can be billed and it is not necessary to list this one.

Subsection (C)(5) was stricken since the referenced Waiver has expired and is therefore no longer in effect..

Subsection (D) and (E) have been stricken since Level 2 and 3 behavioral health residential agency services no longer exist. ADHS has combined the different level into one and is only referred to as Behavioral Health residential agency services.

Subsection (H)(7) has been stricken since personal care services are not a behavioral health service and are therefore inapplicable to this article.

R9-22-1206 This section was repealed since the provider standards and the quality and utilization management requirements are the same as described under article 5.

R9-22-1207 Subsection (A) was stricken since it is not necessary to describe in rule the ADHS terms of payment which are described in contract.

Subsection New (A) was updated to clarify the timeframe and to which entity a claim must be submitted to for behavioral health services.

Subsection (B) was updated to add “the Administration” as an entity that the provider must seek prior authorization from for a behavioral health service.

a. The conduct and its frequency of occurrence that the rule is designed to change:

The majority of the proposed changes are for clarification purposes and do not change the current process. These changes were intended to clarify the requirements and coincide with the terms used by ADHS. These rules regulate the conduct of the Administration, contractors, and providers and do not change the frequency of any occurrence related to the subject matter of the rule.

b. The harm resulting from the conduct the rule is designed to change and the likelihood it will continue to occur if the rule is not changed:

The conduct of the Administration, contractors, and providers does not change as a result of this rulemaking therefore not resulting in a harm to members or any entity enforcing this rulemaking.

c. The estimated change in frequency of the targeted conduct expected from the rule change:

The agency does not expect the frequency of the conducts described within these rules to change since the rulemaking was intended for clarification and to coincide with ADHS' terminology.

A brief summary of the information included in the economic, small business, and consumer impact statement.

The Administration anticipates minimal economic impact on the implementing agency, small businesses and consumers; because this rulemaking was made for clarification and technical changes required as a result of ADHS rule changes. The changes made in this proposed rulemaking are not substantive changes.

2. Identification of the persons who will be directly affected by, bear the costs of or directly benefit from the rule making.

The amendments are primarily made to make the rules more clear, concise, and understandable. Minimal impact is anticipated. The small business community as a whole is not impacted by the clarifications. All affected entities benefit from the additional clarity and conciseness of the rule language.

The Administration, providers and contractors are directly affected by and benefit from the clarifications.

3. Cost benefit analysis.

a. Probable costs and benefits to implementing agency and other agencies directly affected. The probable costs to the implementing agency shall include the number of new full-time employees necessary to implement and enforce the proposed rule. The preparer of the economic, small business and consumer impact statement shall notify the Joint Legislative Budget Committee (JLBC) of the number of new

full-time employees necessary to implement and enforce the rule before the rule is approved by the council:

The Administration anticipates that adding the clarifications to the rule language assists the Administration, contractors, and providers to more easily understand and comply with the rules. The Administration does not anticipate fiscal impact to either itself or its contractors at this time.

i. Cost:

The Administration does not anticipate a cost to be incurred from the proposed rule changes.

ii. Benefit:

The Administration, providers and contractors will benefit from a better understanding of the provision, responsibility and payment of behavioral health services and will comply with the proposed rule changes. In addition, providers and members will benefit from this change as there will be an increase of the types of service received in one location as a result of combining the different level of behavioral health services.

.

iii. Do any Full-time Employees need to be hired?

The Administration does not anticipate the need to hire full-time employees as a result of the proposed rule changes.

b. Probable costs and benefits to political subdivision directly affected.

This proposed rule revision does not directly affect political subdivisions.

c. Probable costs and benefits to businesses directly affected, including anticipated effect on revenues or payroll for employers.

The Administration anticipates that businesses will not be impacted by the changes. The Administration anticipates that adding the clarifications permits entities to more easily understand the rules.

4. General description of the probable impact on private and public employment in business, agencies, and political subdivisions directly affected by the rulemaking.

The Administration anticipates that public and private employment will not be impacted by the changes. The Administration anticipates that adding the clarifications to the rule language permits the Administration employees, contractors, and providers to more easily understand and comply with rules.

5. Statement of probable impact of the rule on small businesses, including:

a. Identification of the small businesses subject to the rulemaking.

The Administration anticipates no fiscal impact on small businesses because the proposed rule language changes are intended to streamline and clarify the existing rules.

b. Administrative and other costs required for compliance with the rulemaking.

The Administration anticipates no impact upon the administrative expenses of the small business community because the proposed rule language changes are intended to streamline and clarify the existing rules.

c. Description of methods agency may use to reduce the impact on small business, which may include:

i. Establishing less costly compliance requirements;

The changes represent the most cost-effective and efficient method of fulfilling the agency's responsibilities and impose only those requirements that are necessary to comply with federal law and state statute.

ii. Establishing less costly schedules or less stringent deadlines for compliance; and

The changes represent the most cost-effective and efficient method of fulfilling the agency's responsibilities and impose only those requirements that are necessary to comply with federal law and state statute.

iii. Exempting small businesses from any or all requirements.

The Administration cannot exempt small businesses from any rule requirements.

d. The probable cost and benefit to private persons and consumers who are directly affected by the rulemaking.

Private persons, consumers and AHCCCS members are not impacted by the clarifications, which provide additional clarity and conciseness to rule language enabling contractors and providers to more easily understand and comply with rules.

6. Statement of the probable effect on state revenues.

The Administration anticipates no fiscal impact upon state revenues. The clarifications are designed to deliver health care in the most cost-effective and efficient manner while complying with the state and federal requirements.

7. Description of any less intrusive or less costly alternative, including the monetizing of the costs and benefits for each option and providing the rationale for not using nonselected alternatives.

The Administration did not consider other alternatives because the changes are the most cost effective and efficient method of complying with federal law and state statute.

ARTICLE 1. DEFINITIONS

R9-22-101. Location of Definitions

A. Location of definitions. Definitions applicable to this Chapter
are found in the following:

Definition Section or Citation
"Accommodation" R9-22-701
"Active treatment" R9-22-1301
"ADHS" R9-22-101
"Administration" A.R.S. § 36-2901
"Adult behavioral health therapeutic home" 9 A.A.C. 10, Article 1
"Adverse action" R9-22-101

"Affiliated corporate organization" R9-22-101
"Aged" 42 U.S.C. 1382c(a)(1)(A) and R9-22-1501
"Agency" R9-22-1201
"Aggregate" R9-22-701
"AHCCCS" R9-22-101
"AHCCCS inpatient hospital day or days of care" R9-22-701
"AHCCCS registered provider" R9-22-101
"Ambulance" A.R.S. § 36-2201
"Ancillary service" R9-22-101
"Anticipatory guidance" R9-22-201
"Annual enrollment choice" R9-22-1701
"APC" R9-22-701
"Applicant" R9-22-101 or R9-22-301
"Application" R9-22-101
"Assessment" R9-22-1101 or R9-22-1201
"Assignment" R9-22-101
"Attending physician" R9-22-101 or R9-22-202
"Authorized representative" R9-22-101
"Authorization" R9-22-202
"Auto-assignment algorithm" R9-22-1701
"AZ-NBCCEDP" R9-22-2001
"Behavior management services" R9-22-1201
"Behavioral health therapeutic home care services" R9-22-1201
"Behavioral health paraprofessional" R9-22-101
"Behavioral health professional" R9-22-101
"Behavioral health recipient" R9-22-201
"Behavioral health services" R9-22-1201
"Behavioral health technician" R9-22-1201
"Benefit year" R9-22-201
"BHS" R9-22-301
"Billed charges" R9-22-701
"Blind" R9-22-1501
"Burial plot" R9-22-1401
"Business agent" R9-22-701
"Calculated inpatient costs" R9-22-712.07
"Capital costs" R9-22-701
"Capped fee-for-service" R9-22-101
"Caretaker relative" R9-22-1401
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B. General definitions. In addition to definitions contained in A.R.S. § 36-2901, the words and phrases in this Chapter have the following meanings unless the context explicitly requires another meaning:

"ADHS" means the Arizona Department of Health Services.

"Adverse action" means an action taken by the Department or Administration to deny, discontinue, or reduce medical assistance.

"Affiliated corporate organization" means any organization that has ownership or control interests as defined in 42 CFR 455.101, and includes a parent and subsidiary corporation.

"AHCCCS" means the Arizona Health Care Cost Containment System, which is composed of the Administration, contractors, and other arrangements through which health care services are provided to a member.

"AHCCCS registered provider" means a provider or noncontracting provider who:

Enters into a provider agreement with the Administration under R9-22-703(A), and

Meets license or certification requirements to provide covered services.

"Ancillary service" means all hospital services for patient care other than room and board and nursing services, including but not limited to, laboratory, radiology, drugs, delivery room (including maternity labor room), operating room (including postanesthesia and postoperative recovery rooms), and therapy services (physical, speech, and occupational).

"Applicant" means a person who submits or whose authorized representative submits a written, signed, and dated application for AHCCCS benefits.

"Application" means an official request for AHCCCS medical coverage made under this Chapter.

"Assignment" means enrollment of a member with a contractor by the Administration.

"Attending physician" means a licensed allopathic or

osteopathic doctor of medicine who has primary responsibility
for providing or directing preventive and treatment services for a Fee-For-Service member.
"Authorized representative" means a person who is authorized to apply for medical assistance or act on behalf of another person.
"Behavioral health paraprofessional" means an individual who is not a behavioral health professional who provides behavioral health services at or for a health care institution according to the health care institution's policies and procedures that:
If the behavioral health services were provided in a setting other than a licensed health care institution,
If the individual would be required to be licensed as a behavioral professional under A.R.S. Title 32, Chapter 33,
If the behavioral health services were provided in a setting other than a licensed health care institution; and
Are provided under supervision by a behavioral health professional R9-10-101.
"Behavioral Health Professional" has the same meaning as defined A.A.C. R9-10-101 excluding subsection (g).
"Capped fee-for-service" means the payment mechanism by which a provider of care is reimbursed upon submission of a valid claim for a specific covered service or equipment provided to a member. A payment is made in accordance with an upper or capped limit established by the Director. This capped limit can either be a specific dollar amount or a percentage of billed charges.
"Case record" means an individual or family file retained by the Department that contains all pertinent eligibility information, including electronically stored data.
"Children's Rehabilitative Services" or "CRS" means the program that provides covered medical services and covered
support services in accordance with A.R.S. § 36-261.
"CMS" means the Centers for Medicare and Medicaid Services.
"Continuous stay" means a period during which a member receives inpatient hospital services without interruption beginning with the date of admission and ending with the date of discharge or date of death.
"Contract" means a written agreement entered into between a person, an organization, or other entity and the Administration to provide health care services to a member under A.R.S. Title 36, Chapter 29, and this Chapter.
"Contract year" means the period beginning on October 1 of a year and continuing until September 30 of the following
year.
"Covered services" means the health and medical services described in Articles 2 and 12 of this Chapter as being eligible for reimbursement by AHCCCS.
"Day" means a calendar day unless otherwise specified.
"DBHS" means the Division of Behavioral Health Services within the Arizona Department of Health Services.
"DES" means the Department of Economic Security.
"Diagnostic services" means services provided for the purpose of determining the nature and cause of a condition, illness, or injury.
"Director" means the Director of the Administration or the Director's designee.
"Discussion" means an oral or written exchange of information
or any form of negotiation.
"DME" means durable medical equipment, which is an item or appliance that can withstand repeated use, is designed to serve a medical purpose, and is not generally useful to a person in the absence of a medical condition, illness, or injury.
"Equity" means the county assessor full cash value or market value of a resource minus valid liens, encumbrances,
or both.
"Facility" means a building or portion of a building licensed or certified by the Arizona Department of Health Services as a health care institution under A.R.S. Title 36, Chapter 4, to provide a medical service, a nursing service, or other health care or health-related service.
"FBR" means Federal Benefit Rate, the maximum monthly Supplemental Security Income payment rate for a member or a married couple.

"Fee-For-Service" or "FFS" means a method of payment by the AHCCCS Administration to a registered provider on an amount-per-service basis for a member not enrolled with a contractor.
"FES member" means a person who is eligible to receive emergency medical and behavioral health services through the FESP under R9-22-217.
"FESP" means the federal emergency services program under R9-22-217 which covers services to treat an emergency
medical or behavioral health condition for a member who is determined eligible under A.R.S. § 36-2903.03(D).
"FQHC" means federally qualified health center.
"GSA" means a geographical service area designated by the Administration within which a contractor provides, directly or through a subcontract, a covered health care service to a member enrolled with the contractor.
"Hospital" means a health care institution that is licensed as a hospital by the Arizona Department of Health Services under A.R.S. Title 36, Chapter 4, Article 2, and certified as a provider under Title XVIII of the Social Security Act, as amended, or is currently determined, by the Arizona Department of Health Services as the CMS designee, to meet the requirements of certification.
"IHS" means Indian Health Service.
"IMD" or "Institution for Mental Diseases" means an Institution for Mental Diseases as described in 42 CFR 435.1010 that is licensed by ADHS.
"Legal representative" means a custodial parent of a child under 18, a guardian, or a conservator.
"License" or "licensure" means a nontransferable authorization
that is granted based on established standards in law by a state or a county regulatory agency or board and

allows a health care provider to lawfully render a health care service.
"Mailing date" when used in reference to a document sent first class, postage prepaid, through the United States mail, means the date:
Shown on the postmark;
Shown on the postage meter mark of the envelope, if no postmark; or
Entered as the date on the document, if there is no legible postmark or postage meter mark.
"Medical record" means a document that relates to medical or behavioral health services provided to a member by a physician or other licensed practitioner of the healing arts and that is kept at the site of the provider.
"Medical supplies" means consumable items that are designed specifically to meet a medical purpose.
"Medically necessary" means a covered service is provided by a physician or other licensed practitioner of the healing arts within the scope of practice under state law to prevent disease, disability, or other adverse health conditions
or their progression, or to prolong life.
"Medicare claim" means a claim for Medicare-covered services for a member with Medicare coverage.
"Non-FES member" means an eligible person who is entitled to full AHCCCS services.
"Offeror" means an individual or entity that submits a proposal to the Administration in response to an RFP.
"Physician" means a person licensed as an allopathic or osteopathic physician under A.R.S. Title 32, Chapter 13 or Chapter 17.
"Practitioner" means a physician assistant licensed under A.R.S. Title 32, Chapter 25, or a registered nurse practitioner
certified under A.R.S. Title 32, Chapter 15.
"Prescription" means an order to provide covered services that is signed or transmitted by a provider authorized to prescribe the services.
"Primary care provider" or "PCP" means an individual who meets the requirements of A.R.S. § 36-2901 (14), and who is responsible for the management of a member's health care.
"Prior authorization" means the process by which the Administration or contractor, whichever is applicable, authorizes, in advance, the delivery of covered services based on factors including but not limited to medical necessity, cost effectiveness, compliance with this Article and any applicable contract provisions. Prior authorization is not a guarantee of payment.
"Prior period coverage" means the period prior to the member's enrollment during which a member is eligible for covered services. PPC begins on the first day of the month of application or the first eligible month, whichever is later, and continues until the day the member is enrolled with a contractor.
"Proposal" means all documents, including best and final offers, submitted by an offeror in response to an RFP by the Administration.
"Radiology" means professional and technical services rendered to provide medical imaging, radiation oncology, and radioisotope services.
"Referral" means the process by which a member is directed by a primary care provider or an attending physician
to another appropriate provider or resource for diagnosis or treatment.
"Rehabilitation services" means physical, occupational, and speech therapies, and items to assist in improving or restoring a person's functional level.
"Responsible offeror" means an individual or entity that has the capability to perform the requirements of a contract and that ensures good faith performance.
"Responsive offeror" means an individual or entity that submits a proposal that conforms in all material respects to an RFP.
"Review" means a review of all factors affecting a member's
eligibility.
"Review month" means the month in which the individual's
or family's circumstances and case record are reviewed.
"RFP" means Request for Proposals, including all documents,
whether attached or incorporated by reference,
that are used by the Administration for soliciting a proposal under 9 A.A.C. 22, Article 6.
"Service location" means a location at which a member obtains a covered service provided by a physician or other licensed practitioner of the healing arts under the terms of a contract.
"Service site" means a location designated by a contractor as the location at which a member is to receive covered services.

"S.O.B.R.A." means Section 9401 of the Sixth Omnibus Budget Reconciliation Act, 1986, amended by the Medicare
Catastrophic Coverage Act of 1988, 42 U.S.C. 1396a(a)(10)(A)(i)(IV), 42 U.S.C. 1396a(a)(10)(A)(i)(VI), and 42 U.S.C. 1396a(a)(10)(A)(i)(VII).
"Specialist" means a Board-eligible or certified physician who declares himself or herself as a specialist and practices a specific medical specialty. For the purposes of this definition, Board-eligible means a physician who meets all the requirements for certification but has not tested for or has not been issued certification.
"Spouse" means a person who has entered into a contract of marriage recognized as valid by this state.
"SSN" means Social Security number.
"Standard of care" means a medical procedure or process that is accepted as treatment for a specific illness, injury, or medical condition through custom, peer review, or consensus by the professional medical community.
"Subcontract" means an agreement entered into by a contractor
with any of the following:
A provider of health care services who agrees to furnish covered services to a member,
A marketing organization, or

Any other organization or person that agrees to perform any administrative function or service for the contractor specifically related to securing or fulfilling the contractor's obligation to the Administration under the terms of a contract.

"Taxi" is as defined in A.R.S. § 28-101(53).

Historical Note

Adopted as an emergency effective May 20, 1982 pursuant to A.R.S. § 41-1003, valid for only 90 days (Supp. 82-3). Former Section R9-22-101 adopted as an emergency now adopted and amended as a permanent rule effective August 30, 1982 (Supp. 82-4). Former Section R9-22-101 repealed, former Sections R9-22-102 and R9-22-301 renumbered as Section R9-22-101 and amended effective October 1, 1983 (Supp. 83-5). Adopted as an emergency effective May 18, 1984, pursuant to A.R.S. § 41-1003, valid for only 90 days (Supp. 84-3). Amended as an emergency by adding new paragraphs (24), (46), (84) and (91) and renumbering accordingly effective August 16, 1984, pursuant to A.R.S. § 41-1003, valid for only 90 days (Supp. 84-4). Amended as an emergency by adding new paragraphs (2) and (15) and renumbering accordingly effective October 25, 1984, pursuant to A.R.S. § 41-1003, valid for only 90 days (Supp. 84-5). Emergency expired. Permanent amendment added paragraphs (2) and (15) and renumbered accordingly effective February 1, 1985 (Supp. 85-1). Amended effective October 1, 1985 (Supp. 85-5). Amended paragraphs (10) and (15) effective October 1, 1986 (Supp. 86-5). Amended effective January 1, 1987, filed December 31, 1986 (Supp. 86-6). Amended effective October 1, 1987; amended effective December 22, 1987 (Supp. 87-4). Amended by deleting paragraphs (39) and (62) and renumbering accordingly effective July 1, 1988 (Supp. 88-3). Amended effective May 30, 1989 (Supp. 89-2). Amended effective April 13, 1990 (Supp. 90-2). Amended effective September 29, 1992 (Supp. 92-3). Amended under an exemption from the provisions of the Administrative Procedure Act, effective March 1, 1993 (Supp. 93-1). Amended under an exemption from the provisions of the Administrative Procedure Act, effective July 1, 1993 (Supp. 93-3). Amended under an exemption from the provisions of the Administrative Procedure Act, effective October 26, 1993 (Supp. 93-4). Amended effective December 13, 1993 (Supp. 93-4). Amended effective January 14, 1997 (Supp. 97-1). Section repealed; new Section adopted effective December 8, 1997 (Supp. 97-4). Section repealed, new Section adopted by final rulemaking at 5 A.A.R. 294, effective January 8, 1999 (Supp. 99-1). Amended by final rulemaking at 5 A.A.R. 607, effective February 5, 1999 (Supp. 99-1). Amended by final rulemaking at 5 A.A.R. 867, effective March 4, 1999 (Supp. 99-1). Amended by final rulemaking at 5 A.A.R. 4061, effective October 8, 1999 (Supp. 99-4). Amended by final rulemaking at 6 A.A.R. 179, effective December 13, 1999 (Supp. 99-4). Amended by final rulemaking at 6 A.A.R. 2435, effective June 9, 2000 (Supp. 00-2). Amended by final rulemaking at 6 A.A.R. 3317, effective August 7, 2000 (Supp. 00-3). Amended by exempt rulemaking at 7 A.A.R. 4593, effective October 1, 2001 (Supp. 01-3). Amended by exempt rulemaking at 7 A.A.R. 5701, effective December 1, 2001 (Supp. 01-4). Amended by final rulemaking at 7 A.A.R. 5814, effective December 6, 2001 (Supp. 01-4). Amended by final rulemaking at 8 A.A.R. 424, effective January 10, 2002 (Supp. 02-1). Amended by final rulemaking at 8 A.A.R. 2325, effective May 9, 2002 (Supp. 02-2). Amended by final rulemaking at 8 A.A.R. 3317, effective July 15, 2002 (Supp. 02-3). Amended by exempt rulemaking at 9 A.A.R. 4001, effective October 19, 2003 (Supp. 03-3). Amended by exempt rulemaking at 10 A.A.R. 4588, effective October 12, 2004 (Supp. 04-4). Amended by final rulemaking at 11 A.A.R. 3830, effective November 12, 2005 (Supp. 05-3). Amended by final rulemaking at 11 A.A.R. 5467, effective December 6, 2005 (Supp. 05-4). Amended by final rulemaking at 13 A.A.R. 836, effective May 5, 2007 (Supp. 07-1). Amended by final rulemaking at 13 A.A.R. 3351, effective November 10, 2007 (Supp. 07-3). Amended by final rulemaking at 14 A.A.R. 1598, effective May 31, 2008 (Supp. 08-2). Amended by exempt rulemaking at 16 A.A.R. 1638, effective October 1, 2010 (Supp. 10-3). Amended by final rulemaking at 17 A.A.R. 1658, effective August 2, 2011 (Supp. 11-3). Amended by exempt rulemaking at 18 A.A.R. 461, effective April 1, 2012 (Supp. 12-1). Amended by final rulemaking at 20 A.A.R. 3098, effective January 4, 2015 (Supp. 14-4).

A.R.S. § 36-2903.01(F)

F. In addition to the rules otherwise specified in this article, the director may adopt necessary rules pursuant to title 41, chapter 6 to carry out this article. Rules adopted by the director pursuant to this subsection shall consider the differences between rural and urban conditions on the delivery of hospitalization and medical care.

ARIZONA STATE RETIREMENT SYSTEM (F-17-0103)
Title 2, Chapter 8, Article 7, Contributions Not Withheld

GOVERNOR'S REGULATORY REVIEW COUNCIL
ANALYSIS OF FIVE-YEAR REVIEW REPORT

MEETING DATE: January 4, 2017 **AGENDA ITEM: F-3**

TO: The Governor's Regulatory Review Council (Council)

FROM: Marcus McGillivray, Legal Intern

DATE : December 20, 2016

SUBJECT: **ARIZONA STATE RETIREMENT SYSTEM (F-17-0103)**
Title 2, Chapter 8, Article 7, Contributions Not Withheld

COMMENTS ON THE FIVE-YEAR-REVIEW REPORT

This five-year-review report relates to eight rules in A.A.C. Title 2, Chapter 8, Article 7 about determining Contributions Not Withheld (CNW). The Arizona State Retirement System (ASRS) was created by the state legislature in 1953 to provide retirement and medical benefits to eligible state employees. The ASRS and the ASRS Board (Board) act as a trust and invests employee and employer contributions to maximize the yield. A CNW occurs when an employer fails to make obligatory contributions to employee benefit plans. These rules give the public notice regarding the process of reporting a CNW and the documentation which the ASRS requires to determine the validity of a claim.

Analysis of the agency's report pursuant to criteria in A.R.S. § 41-1056 and R1-6-301:

1. Has the agency certified that it is in compliance with A.R.S. § 41-1091?

Yes. The ASRS has certified compliance with A.R.S. § 41-1091.

2. Has the agency analyzed the rules' effectiveness in achieving their objectives?

Yes. The ASRS indicates that the rules are effective in achieving their objectives.

3. Has the agency received any written criticisms of the rules during the last five years, including any written analysis questioning whether the rules are based on valid scientific or reliable principles or methods?

No. The ASRS has not received any written criticism on the rules in the last five years.

4. Has the agency analyzed whether the rules are authorized by statute?

Yes. The ASRS cites to both general and specific statutory authority.

- A.R.S. § 38-738 gives the ASRS general authority to make contributions not withheld determinations.
- A.R.S. § 38-715 gives the director, under the supervision of the Board, authority to prescribe procedures for applicants to receive benefits from the ASRS.
- A.R.S. § 38-736 requires the members to contribute to the ASRS benefit plan as a condition of employment.
- A.R.S. § 38-737 requires employer contributions to the ASRS benefit plan of their employees.
- A.R.S. § 38-747 sets forth the methods by which members and employers can make payments to ASRS.

5. Has the agency analyzed the rules' consistency with other rules and statutes?

Yes. The rules are consistent with state rules and statutes. There is no corresponding federal law.

6. Has the agency analyzed the current enforcement status of the rules?

Yes. The ASRS certifies that the rules are enforced as written.

7. Has the agency analyzed whether the rules are clear, concise, and understandable?

Yes. The ASRS certifies that the rules are clear, concise, and understandable.

8. Has the agency analyzed whether:

a. The rules are more stringent than corresponding federal law?

There is no corresponding federal law.

b. There is statutory authority to exceed the requirements of federal law?

N/A

9. For rules adopted after July 29, 2010, has the agency analyzed whether:

R2-8-701 was last amended in December 2015, and the remainder of the rules were implemented by ruling making in December 2006.

a. **The rules require issuance of a regulatory permit, license or agency authorization?**

R2-8-701 provides definitions and does not require the issuance of a regulatory permit, license, or agency authorization.

b. It is in compliance with the general permit requirements of A.R.S. § 41-1037 or explained why it believes an exception applies?

N/A.

10. Has the agency indicated whether it completed the course of action identified in the previous five-year-review report?

Yes. Consistent with the proposed action in the previous five-year-review report, the ASRS completed a rulemaking for R2-8-704 and R2-8-706 in October 2016.

11. Has the agency included a proposed course of action?

The ASRS proposes no course of action at this time.

Conclusion

This report meets the requirements of A.R.S. § 41-1056 and R1-6-301. This analyst recommends approval.

GOVERNOR'S REGULATORY REVIEW COUNCIL
M E M O R A N D U M

MEETING DATE: January 4, 2017 **AGENDA ITEM: F-3**

TO: The Governor's Regulatory Review Council (Council)

FROM: GRRC Economic Team

DATE : December 20, 2016

SUBJECT: **ARIZONA STATE RETIREMENT SYSTEM (F-17-0103)**
Title 2, Chapter 8, Article 7, Contributions Not Withheld

I have reviewed the five-year-review report's economic, small business, and consumer impact comparison for compliance with A.R.S. § 41-1056 and make the following comments.

1. Economic Impact Comparison

The economic, small business, and consumer impact statement (EIS) from the most recent Board rulemaking completed in 2006 was reviewed for Article 7.

The Article 7 rules reviewed address procedures involved when member contributions are not withheld for a period of creditable service under the Arizona State Retirement System (ASRS). ASRS provides a pension plan, long term disability insurance, retiree health insurance, and other benefits to Arizona's public servants.

Key stakeholders that are impacted are the Board, ASRS members, ASRS employers, and taxpayers. The Board notes that these rules are effective, impose the least burden and costs on the public, and do not require revision.

In 2015, 683 employers participated in ASRS. A total of 578,677 members include:

- 211,300 active members
- 225,328 inactive members
- 137,942 retirement members and survivor beneficiaries
- 4,107 long term disability members

The Board concludes that the economic impact has generally been as predicted in the prior EIS for the rules in the Article cited above.

2. Has the agency determined that the rules impose the least burden and costs to persons regulated by the rules?

The Board determines that the rules are effective and impose the least burden and costs on the public. The Board does not plan to amend the Article 7 rules.

3. Was an analysis submitted to the agency under A.R.S. § 41-1056(A)(7)?

No analysis was submitted to the Board by another person that compares the rules' impact on this state's business competitiveness to the impact on businesses in other states under A.R.S. § 41-1056(A)(7).

4. Conclusion

After review, staff concludes that the report complies with A.R.S. § 41-1056 and recommends approval.

ARIZONA STATE RETIREMENT SYSTEM

3300 NORTH CENTRAL AVENUE • PO BOX 33910 • PHOENIX, AZ 85067-3910 • PHONE (602) 240-2000
7660 EAST BROADWAY BOULEVARD • SUITE 108 • TUCSON, AZ 85710-3776 • PHONE (520) 239-3100
TOLL FREE OUTSIDE METRO PHOENIX AND TUCSON 1 (800) 621-3778
EMAIL ADDRESS: ASKMAC@AZASRS.GOV • WEB ADDRESS: WWW. AZASRS.GOV

Paul Matson
Director

December 20, 2016

Nicole A. Ong, Chair
Governor's Regulatory Review Council
Arizona Department of Administration
100 N. 15th Ave., Ste. 402
Phoenix, AZ 85007

RE: Five-year-review Report for Article 7

In compliance with A.R.S. § 41-1056(A), the Arizona State Retirement System (ASRS) has reviewed all of the rules in A.A.C. Title 2, Chapter 8, Article 7 and submits the enclosed report to the Council for approval. The ASRS does not intend for any rules in Article 7 to expire at this time and the ASRS certifies that it is in compliance with A.R.S. § 41-1091. The ASRS contact person for this report is Jessica Thomas, Rules Writer, who may be reached at (602) 240-2039.

Sincerely,

Paul Matson
Director
Arizona State Retirement System

Enclosure

FIVE-YEAR-REVIEW REPORT

TITLE 2. ADMINISTRATION

CHAPTER 8. STATE RETIREMENT SYSTEM BOARD

ARTICLE 7. CONTRIBUTIONS NOT WITHHELD

TABLE OF CONTENTS

FIVE-YEAR-REVIEW SUMMARY

The state legislature created the Arizona State Retirement System (ASRS) in 1953 in order to provide defined contribution retirement (defined contribution plan) benefits for state employees and teachers, as well as employees of political subdivisions that elected coverage. The defined contribution plan was closed to new members in 1972. At that time, members of the defined contribution plan who elected to, and all new members, became part of the defined benefit plan. At the end of Fiscal Year 2014-2015 there were approximately 558,136 ASRS members.

The ASRS Board (Board) is appointed by the Governor. The Board consists of nine members who qualify according to A.R.S. § 38-713. The Board is responsible for supervising the administration of the ASRS, including the defined contribution plan, defined benefit plan, long-term disability income plan, and health benefit supplement plan. Investment responsibilities include:

1. Prescribing investment goals, objectives, and policies;
2. Allocating assets to meet investment goals;
3. Adopting specific policy directives for the guidance of investment management;
4. Appointing investment managers;
5. Prescribing investment diversification programs; and
6. Assigning investment responsibilities.

Enabling statutes for the Board are set forth in A.R.S. §§ Title 38, Chapter 5, Articles 1 and 2. The Board implements its statutes with rules located in A.A.C. Title 2, Chapter 8 as necessary

This report covers all eight rules in 2 A.A.C. 8, Article 7 and with the exception of R2-8-701, all the rules were made by final rulemaking effective December 5, 2006. R2-8-701 was last amended by final rulemaking effective December 5, 2015. The ASRS requested the Governor's Regulatory Review Council (GRRC) to expire R2-8-708 because it was redundant of the appeals process described in 2 A.A.C. 8, Article 4. GRRC expired R2-8-708 on October 4, 2016. The ASRS is completed the rulemaking process in order to amend R2-8-704 and R2-8-706 in October 2016.

FIVE-YEAR-REVIEW REPORT

TITLE 2. ADMINISTRATION

CHAPTER 8. STATE RETIREMENT SYSTEM BOARD

ARTICLE 7. CONTRIBUTIONS NOT WITHHELD

INFORMATION THAT IS IDENTICAL FOR ALL THE RULES

The following information is the same for all of the rules and is not restated in the analysis of each rule:

3. Analysis of effectiveness in achieving the objective

The rules are effective in achieving their objectives.

4. Analysis of consistency with state and federal statutes and rules

The rules are consistent with state and federal statutes and rules.

5. Status of enforcement of the rule

The rules are enforced as written.

6. Analysis of clarity, conciseness, and understandability

The rule is clear, concise, and understandable.

7. Analysis of any written criticisms the agency received on the rule

No written criticisms were received.

8. Estimated economic, small business, and consumer impact statement comparison

Analysis of the economic impact statement for the rules is included as Exhibit 1.

9. Analysis of any analyses the agency received regarding the rule's impact on this state's business competitiveness as compared to the competitiveness of businesses in other states

No analyses were received.

10. Whether the agency completed the course of action proposed in the previous Five-year-review Report

Yes. Consistent with issues identified in the previous Five-year-review Report, the ASRS completed a rulemaking for R2-8-704 and R2-8-706 in October 2016.

11. Determination that the probable benefits of the rule outweigh the probable costs and the rule imposes the least burden and costs

The rules impose least burden and costs on the public.

12. Determination that the rule is not more stringent than a corresponding federal law

There is no corresponding federal law for the rules.

13. Whether the rule complies with A.R.S. § 41-1037

The ASRS does not issue permits or licenses.

14. Proposed course of action

The ASRS does not plan to further amend the rules in Article 7 at this time.

ARTICLE 7. CONTRIBUTIONS NOT WITHHELD

R2-8-701. Definitions

1. Authorization of the rule by existing statute

A.R.S. §§ 38-711, 38-715, and 38-738

2. Objective

The objective of the rule is to provide notice to the public of how the ASRS is using certain terms throughout its rules.

R2-8-702. General Information

1. Authorization of the rule by existing statute

A.R.S. §§ 38-738, 38-743

2. Objective

The objective of the rule is to provide notice to the public of requirements and/or limitations that apply to contributions not withheld.

R2-8-703. ASRS Employer's Discovery of Error

1. Authorization of the rule by existing statute

A.R.S. § 38-738

2. Objective

The objective of the rule is to provide notice to the public of how the Employer must notify the ASRS of any Contributions Not Withheld error the Employer discovers.

R2-8-704. Member's Discovery of Error

1. Authorization of the rule by existing statute

A.R.S. § 38-738

2. Objective

The objective of the rule is to provide notice to the public of the information that should be provided to the ASRS when a member discovers a Contributions Not Withheld error.

R2-8-705. ASRS' Discovery of Error

1. Authorization of the rule by existing statute

A.R.S. § 38-738

2. Objective

The objective of the rule is to provide notice to the public of how the member and Employer will be notified when the ASRS discovers a Contributions Not Withheld error and identifies the information the ASRS will request.

R2-8-706. Determination of Contributions Not Withheld

1. Authorization of the rule by existing statute

A.R.S. §§ 38-736, 38-737, 38-738, 38-766.01

2. Objective

The objective of the rule is to provide notice to the public of how the ASRS will make a Contributions Not Withheld determination and how the Employer and member will be notified.

R2-8-707. Submission of Payment

1. Authorization of the rule by existing statute

A.R.S. §§ 38-738 and 38-747

2. Objective

The objective of the rule is to provide notice to the public of the deadlines and methods for the Employer and member to submit payment and the penalties if payment is not submitted timely.

R2-8-709. Nonpayment of Contributions

1. Authorization of the rule by existing statute

A.R.S. § 38-738

2. Objective

The objective of the rule is to provide notice to the public of when the member will be granted service credit for a Contributions Not Withheld correction and the steps the ASRS will take to obtain payment.

ECOMONIC IMPACT STATEMENT
Arizona State Retirement System

Title and its heading: Title 2, Administration
Chapter and its heading: Chapter 8, State Retirement System Board
Article and its heading: Article 7, Contributions Not Withheld
Section Numbers: R2-8-701 through R2-8-707 and R2-8-709

A.R.S. §38-736 establishes when member contributions should begin. Under A.R.S. §§ 38-736 and 38-737, Employers and Members are required to contribute a percentage of the Member's compensation to fund the benefits and administrative costs of the ASRS. Member and Employer contributions are established annually through an annual actuarial valuation of the assets and liabilities of the ASRS. A.R.S. § 38-738 identifies what happens if less than the correct amount of Employer or Member contributions are made.

Clear and concise rules provide Members and Employers with a consistent process for identifying and paying contributions that should have been previously withheld but were not. Having clear and concise rules benefits the agency by requiring less staff time to answer questions from the public. The ASRS issued 1,161 Contributions Not Withheld invoices in fiscal year 2011-12; 870 invoices in fiscal year 2012-13; 512 invoices in fiscal year 2013-14; 339 invoices in fiscal year 2014-15; and 492 invoices in fiscal year 2015-16. The cost of each invoice depends on the salary involved, length of time involved, how long it had been since contributions should have been withheld, and how long the Employer and Member take to remit the contribution amount.

R2-8-701

R2-8-701, Definitions, was last amended by final rulemaking effective December 5, 2015. The estimated economic impact in the Economic, Small Business, and Consumer Impact Statement provided to GRRC with the 2015 Notice of Final Rulemaking for this rule has not changed since it was provided to GRRC and no A.R.S. §§ 41-1033 or 41-1056.01 petitions have been received.

R2-8-702, R2-8-703, R2-8-705, R2-8-707, and R2-8-709

R2-8-702, General Information, R2-8-703, ASRS Employer's Discovery of Error, R2-8-705, ASRS' Discovery of Error, R2-8-707 Submission of Payment, and R2-8-709, Nonpayment of Contributions were made by Final Rulemaking December 5, 2006 and have not been amended since that time. The economic impact of these rules has not differed from the impact estimated in the Economic, Small Business, and Consumer Impact Statement provided to the Governor's Regulatory Review Council (GRRC) with the 2006 Notice of Final Rulemaking.

R2-8-704 and R2-8-706

R2-8-704, Member's Discovery of Error, and R2-8-706, Determination of Contributions Not Withheld were last amended by final rulemaking effective January 1, 2017. The estimated economic impact in the Economic, Small Business, and Consumer Impact Statement provided to GRRC with the 2016 Notice of Final Rulemaking for these rules has not changed since it was provided to GRRC and no A.R.S. §§ 41-1033 or 41-1056.01 petitions have been received.

ARTICLE 7. CONTRIBUTIONS NOT WITHHELD

R2-8-701. Definitions

The following definitions apply to this Article unless otherwise specified:

1. "218 agreement" means a written agreement between the state, political subdivision, or political subdivision entity and the Social Security Administration, under the provisions of § 418 of the Social Security Act, to provide Social Security and Medicare or Medicare-only coverage to employees of the state, political subdivision, or political subdivision entity.
2. "Documentation" means a pay stub, completed W-2 form, completed Verification of Contributions Not Withheld form, employer letter or spreadsheet, completed State Personnel Action Form, Social Security Earnings Report, employment contract, payroll record, timesheet, or other ASRS employer-provided form that includes:
   a. Whether the employee was covered under the ASRS employer's 218 agreement prior to July 24, 2014,
   b. The number of hours worked or length of time the member was employed by the ASRS employer, or
   c. The compensation paid to the member by the ASRS employer.
3. "Eligible service" means employment with an ASRS employer:
   a. That is no more than 15 years before the date the ASRS receives written credible evidence that less than the correct amount of contributions were paid into the ASRS or the ASRS otherwise determines that less than the correct amount of contributions were made as specified in A.R.S. § 38-738(C); and
   b. In which the member worked a minimum of 20 hours per week for at least 20 weeks in a service year for at least one ASRS employer from 7/1/1999 to the present.

Historical Note

New Section made by final rulemaking at 12 A.A.R. 4793, effective December 5, 2006 (Supp. 06-4). Amended by final rulemaking at 21 A.A.R. 2515, effective December 5, 2015 (Supp. XX)

R2-8-702. General Information

A. Verified eligible service that occurred more than 15 years before the date ASRS receives the information identified in R2-8-704(A)(1) is considered public service credit as provided in A.R.S. § 38-738(D), and is not applied under this Article.

B. The ASRS employer shall pay the ASRS employer's portion of the contributions the ASRS determines is owed under R2-8-706 whether or not:
   1. The member has withdrawn contributions as specified in R2-8-115; or
   2. The member pays the member's portion of the contributions.

C. The person who initiates the claim that contributions were not withheld for eligible service has the burden to prove a contribution error was made.

D. ASRS shall not waive payment of contributions or interest owed under this Article.

E. If a member is not able to establish eligibility for service credit for which contributions were not withheld, but is able to establish a period of employment by an ASRS employer the member may request to purchase service credit for that period under A.R.S. § 38-743 and Article 5 of this Chapter.

Historical Note

New Section made by final rulemaking at 12 A.A.R. 4793, effective December 5, 2006 (Supp. 06-4).

R2-8-703. ASRS Employer's Discovery of Error

If an ASRS employer determines that contributions have not been withheld for a member for a period of eligible service, the ASRS employer shall notify ASRS in writing, and shall provide ASRS with the member's full name, Social Security number, months, years, and hours per week worked, the compensation each fiscal year for the time periods worked, and the member's position title and status at the time contributions should have been withheld.

Historical Note

New Section made by final rulemaking at 12 A.A.R. 4793, effective December 5, 2006 (Supp. 06-4).

R2-8-704. Member's Discovery of Error

If a member believes that an Employer has not withheld contributions for the member for a period of eligible service, the member shall:

A. Provide the Employer with documentation of the member's claim and request that the Employer provide a letter that includes the information in the Verification of Contributions Not Withheld form or complete a Verification of Contributions Not Withheld form that includes:
   1. The member's full name;
   2. Other names used by the member;
   3. The member's Social Security number;
   4. Whether the position was covered under the Employer's 218 agreement prior to July 24, 2014;
   5. The position title the member held at the time the contributions should have been withheld;
   6. The eligibility of the member at the time the contributions should have been withheld;
   7. The following statements of understanding and agreements to be certified by the authorized Employer representative's signature indicating:

a. I understand it is my responsibility to verify the accuracy of the information I am providing on this form. I understand any individual who knowingly makes a false statement, or who falsifies or permits to be falsified any record of the ASRS with an intent to defraud the ASRS, is guilty of a Class 6 felony pursuant to A.R.S. § 38-793; and

b. I understand that, based on the information provided on this form, the ASRS may determine that contributions are owed on behalf of the member listed on this form, and the Employer may incur a substantial financial obligation. I understand that I may receive an invoice for the member contributions I owe;

8. The following information by fiscal year:
   a. All pay period end dates;
   b. The hours per week worked within each pay period; and
   c. The compensation earned by the member within each pay period;
9. The name of the Employer;
10. The printed name and signature of the authorized Employer representative;
11. The daytime telephone number of the authorized Employer representative;
12. The title of the authorized Employer representative; and
13. The date the authorized Employer representative signed the form;

B. Provide the ASRS with the completed Verification of Contributions Not Withheld form; and

C. If the Employer refuses to fill out the Verification of Contributions Not Withheld form, or if the member disputes the information the Employer completes on the form, the member shall provide the ASRS with the documentation the member believes supports the allegation that contributions should have been withheld, that includes proof:
   1. That the employee was covered under the Employer's 218 agreement prior to July 24, 2014,
   2. Of the number of hours worked;
   3. Of the length of time the member was employed by the Employer; and
   4. Of the compensation paid to the member by the Employer.

Historical Note

New Section made by final rulemaking at 12 A.A.R. 4793, effective December 5, 2006 (Supp. 06-4). Amended by final rulemaking at XX A.A.R. XXXX, effective January 1, 2017 (Supp. XX).

R2-8-705. ASRS' Discovery of Error

If the ASRS determines, as specified in A.R.S. § 38-738(B)(7), that contributions have not been withheld for a member for a period of eligible service, the ASRS shall notify the member and the ASRS employer in writing and shall request the following information:

1. The months, years and hours per week worked;
2. The compensation earned by the member each fiscal year for the time periods worked; and
3. The member's position title at the time contributions should have been withheld.

Historical Note

New Section made by final rulemaking at 12 A.A.R. 4793, effective December 5, 2006 (Supp. 06-4).

R2-8-706. Determination of Contributions Not Withheld

A. Upon receipt of the information listed in R2-8-703, R2-8-704, or R2-8-705, the ASRS shall review the information to determine whether or not member contributions should have been withheld by the Employer, the length of time those contributions should have been withheld, and the amount of contributions that should have been withheld.

B. Except for a member who met active membership requirements while simultaneously contributing to another retirement plan listed in subsection (B)(2), for purposes of this Article, the ASRS shall determine that contributions should not have been withheld for the period of service in question if:
   1. An Employer remits an accurate ACR amount pursuant to R2-8-116; or
   2. The employee participates in:
      a. Another Arizona retirement plan listed in A.R.S. Title 38, Chapter 5, Articles 3, 4, or 6; or
      b. In an optional retirement plan listed in A.R.S. Title 15, Chapter 12, Article 3 or A.R.S. Title 15, Chapter 13, Article 2.

C. Except for returning to work under A.R.S. § 38-766.01(D), the presence of a contract between a member and the Employer does not alter the contribution requirements of A.R.S. §§ 38-736 and 38-737.

D. If there is any discrepancy between the documentation provided by the Employer and the documentation provided by the member, a document used in the usual course of business prepared at the time in question is controlling.

E. The ASRS shall provide to the Employer and the member a written statement that includes:
   1. The dates of eligible service for which contributions were not withheld;
   2. The dollar amount of contributions that should have been made;
   3. The dollar amount of the contributions to be paid by the Employer;
   4. The interest on the Employer contributions and member contributions to be paid by the Employer;
   5. The dollar amount of contributions to be paid by the member; and
   6. The various payment options that may apply to the member, as specified in R2-8-512 through R2-8-519.

Historical Note

New Section made by final rulemaking at 12 A.A.R. 4793, effective December 5, 2006 (Supp. 06-4). Amended by final rulemaking at XX A.A.R. XXXX, effective January 1, 2017 (Supp. XX).

R2-8-707. Submission of Payment

A. Within 90 calendar days after the ASRS notifies the ASRS employer in writing of the amount due, the ASRS employer shall pay all ASRS employer contributions, including accrued interest on both the ASRS employer and member contributions, from the date the contributions were due to the date the ASRS notifies the ASRS employer of the amount due. An ASRS employer who makes payment under A.R.S. § 38-738(B)(3) is not liable for additional interest that may accrue as a result of a member's failure to remit payment required by A.R.S. § 38-738(B)(1). If the ASRS does not receive full payment of the ASRS employer's amount due within 90 calendar days after the ASRS notifies the ASRS employer of the amount due, interest on the amount not paid, as provided in A.R.S. § 38-738(B)(3), will accrue from the 91st day until the ASRS employer pays the full amount.

B. An ASRS employer may pay the amount the ASRS employer believes may be due at any time before ASRS's notification of the amount due in order to prevent the accrual of interest after the date of the payment. Any amount the ASRS employer pays that the ASRS determines is not owed shall be refunded to the ASRS employer.

C. A member may purchase eligible service for which contributions were not withheld in accordance with the requirements of Article 5 of this Chapter for purchase of service credit. If the ASRS does not receive full payment of the ASRS employee's amount due within 90 calendar days after the ASRS notifies the member that the ASRS received the ASRS employer's full payment, interest on the amount not paid, as provided in A.R.S. § 38-738(B)(1), will accrue from the 91st day until the member pays the full amount.

Historical Note

New Section made by final rulemaking at 12 A.A.R. 4793, effective December 5, 2006 (Supp. 06-4).

R2-8-708. Expired

Historical Note

New Section made by final rulemaking at 12 A.A.R. 4793, effective December 5, 2006 (Supp. 06-4). Section expired under A.R.S. § 41-1056(E) at 22 A.A.R. XX, effective September 15, 2016 (Supp. 16-X).

R2-8-709. Nonpayment of Contributions

A. A member receives service credit only for the portion of service the ASRS has determined is eligible and that the member has paid for.

B. A member does not receive service credit until both the ASRS employer and member portions of the contributions have been paid.

C. If the ASRS employer does not pay, the ASRS shall take any steps legally authorized to collect payment. Any steps the ASRS may take to collect payment are separate from any action a member may elect to take against the ASRS employer.

Historical Note

New Section made by final rulemaking at 12 A.A.R. 4793, effective December 5, 2006 (Supp. 06-4).

38-711. Definitions

In this article, unless the context otherwise requires:

1. "Active member" means a member as defined in paragraph 23, subdivision (b) of this section who satisfies the eligibility criteria prescribed in section 38-727 and who is currently making member contributions as prescribed in section 38-736.

2. "Actuarial equivalent" means equality in value of the aggregate amounts expected to be received under two different forms of payment, based on mortality and interest rate assumptions approved from time to time by the board.

3. "ASRS" means the Arizona state retirement system established by this article.

4. "Assets" means the resources of ASRS including all cash, investments or securities.

5. "Average monthly compensation" means:

(a) For a member whose membership in ASRS commenced before January 1, 1984 and who left the member's contributions on deposit or reinstated forfeited credited service pursuant to section 38-742 for a period of employment that commenced before January 1, 1984, the higher of either:

(i) The monthly average of compensation that is calculated pursuant to subdivision (b) of this paragraph.

(ii) The monthly average of compensation on which contributions were remitted during a period of sixty consecutive months during which the member receives the highest compensation within the last one hundred twenty months of credited service. Any month for which no contributions are reported to ASRS or that falls within a period of nonpaid or partially paid leave of absence or sabbatical leave shall be excluded from the computation. The sixty consecutive months may entirely precede, may be both before and after or may be completely after any excluded months. If the member was employed for less than sixty consecutive months, the average monthly compensation is based on the total consecutive months worked. Payments for accumulated vacation or annual leave, sick leave, compensatory time or other forms of termination pay that, before August 12, 2005, constitute compensation for members whose membership in ASRS commenced before January 1, 1984, do not cease to be included as compensation if paid in the form of nonelective employer contributions under a 26 United States Code section 403(b) plan if all payments of employer and employee contributions are made at the time of termination. Contributions shall be made to ASRS on these amounts pursuant to sections 38-735, 38-736 and 38-737.

(b) For a member whose membership in ASRS commenced on or after January 1, 1984 but before July 1, 2011, the monthly average of compensation on which contributions were remitted during a period of thirty-six consecutive months during which a member receives the highest compensation within the last one hundred twenty months of credited service. Any month for which no contributions are reported to ASRS or that falls within a period of nonpaid or partially paid leave of absence or sabbatical leave shall be excluded from the computation. The thirty-six consecutive months may entirely precede, may be both before and after or may be completely after any excluded months. If the member was employed for less than thirty-six consecutive months, the average monthly compensation shall be based on the total consecutive months worked.

(c) For a member whose membership in ASRS commenced on or after July 1, 2011, the monthly average of compensation on which contributions were remitted during

a period of sixty consecutive months during which a member receives the highest compensation within the last one hundred twenty months of credited service. Any month for which no contributions are reported to ASRS or that falls within a period of nonpaid or partially paid leave of absence or sabbatical leave shall be excluded from the computation. The sixty consecutive months may entirely precede, may be both before and after or may be completely after any excluded months. If the member was employed for less than sixty consecutive months, the average monthly compensation shall be based on the total consecutive months worked.
6. "Board" means the ASRS board established in section 38-713.
7. "Compensation" means the gross amount paid to a member by an employer as salary or wages, including amounts that are subject to deferred compensation or tax shelter agreements, for services rendered to or for an employer, or that would have been paid to the member except for the member's election or a legal requirement that all or part of the gross amount be used for other purposes, but does not include amounts paid in excess of compensation limits established in section 38-746. Compensation includes amounts paid as salary or wages to a member by a second employer if the member meets the requirements prescribed in paragraph 23, subdivision (b) of this section with that second employer. Compensation, as provided in paragraph 5, subdivision (b) or (c) of this section, does not include:
(a) Lump sum payments, on termination of employment, for accumulated vacation or annual leave, sick leave, compensatory time or any other form of termination pay whether the payments are made in one payment or by installments over a period of time.
(b) Damages, costs, attorney fees, interest or other penalties paid pursuant to a court order or a compromise settlement or agreement to satisfy a grievance or claim even though the amount of the payment is based in whole or in part on previous salary or wage levels, except that, if the court order or compromise settlement or agreement directs salary or wages to be paid for a specific period of time, the payment is compensation for that specific period of time. If the amount directed to be paid is less than the actual salary or wages that would have been paid for the period if service had been performed, the contributions for the period shall be based on the amount of compensation that would have been paid if the service had been performed.
(c) Payment, at the member's option, in lieu of fringe benefits that are normally paid for or provided by the employer.
(d) Merit awards pursuant to section 38-613 and performance bonuses paid to assistant attorneys general pursuant to section 41-192.
(e) Amounts that are paid as salary or wages to a member for which employer contributions have not been paid.
8. "Contingent annuitant" means the person named by a member to receive retirement income payable following a member's death after retirement as provided in section 38-760.
9. "Credited service" means, subject to section 38-739, the number of years standing to the member's credit on the books of ASRS during which the member made the required contributions.
10. "Current annual compensation" means the greater of:

(a) Annualized compensation of the typical pay period amount immediately before the date of a request to ASRS to purchase credited service pursuant to section 38-743, 38-744 or 38-745. The typical pay period amount shall be determined by taking the five pay periods immediately before the date of a request, disregarding the highest and lowest compensation amount pay periods and averaging the three remaining pay periods.
(b) Annualized compensation of the partial year, disregarding the first compensation amount pay period, if the member has less than twelve months total compensation on the date of a request to purchase credited service pursuant to section 38-743, 38-744 or 38-745.
(c) The sum of the twelve months of compensation immediately before the date of a request to ASRS to purchase credited service pursuant to section 38-743, 38-744 or 38-745.
(d) The sum of the thirty-six months of compensation immediately before the date of a request to ASRS to purchase credited service pursuant to section 38-743, 38-744 or 38-745 divided by three.
(e) If the member has retired one or more times from ASRS, the average monthly compensation that was used for calculating the member's last pension benefit times twelve.
11. "Early retirement" means retirement before a member's normal retirement date after five years of total credited service and attainment of age fifty.
12. "Effective date" means July 1, 1970, except with respect to employers and members whose contributions to ASRS commence thereafter, the effective date of their membership in ASRS is as specified in the applicable joinder agreement.
13. "Employer" means:
(a) This state.
(b) Participating political subdivisions.
(c) Participating political subdivision entities.
14. "Employer contributions" means all amounts paid into ASRS by an employer on behalf of a member.
15. "Fiscal year" means the period from July 1 of any year to June 30 of the following year.
16. "Inactive member" means a member who previously made contributions to ASRS and who satisfies each of the following:
(a) Has not retired.
(b) Is not eligible for active membership in ASRS.
(c) Is not currently making contributions to ASRS.
(d) Has not withdrawn contributions from ASRS.
17. "Interest" means the assumed actuarial investment earnings rate approved by the board.
18. "Internal revenue code" means the United States internal revenue code of 1986, as amended.
19. "Investment manager" means the persons, companies, banks, insurance company investment funds, mutual fund companies, management or any combinations of those entities that are appointed by ASRS and that have responsibility and authority for investment of the monies of ASRS.
20. "Late retirement" means retirement after normal retirement.

21. "Leave of absence" means any unpaid leave authorized by the employer, including leaves authorized for sickness or disability or to pursue education or training.
22. "Life annuity" means equal monthly installments payable during the member's lifetime after retirement.
23. "Member":
(a) Means any employee of an employer on the effective date.
(b) Means all employees of an employer who are eligible for membership pursuant to section 38-727 and who are engaged to work at least twenty weeks in each fiscal year and at least twenty hours each week.
(c) Means any person receiving a benefit under ASRS.
(d) Means any person who is a former active member of ASRS and who has not withdrawn contributions from ASRS pursuant to section 38-740.
(e) Does not include any employee of an employer who is otherwise eligible pursuant to this article and who begins service in a limited appointment for not more than eighteen months on or after July 1, 1979. If the employment exceeds eighteen months, the employee shall be covered by ASRS as of the beginning of the nineteenth month of employment. In order to be excluded under this subdivision, classifications of employees designated by employers as limited appointments must be approved by the director.
(f) Does not include any leased employee. For the purposes of section 414(n) of the internal revenue code, "leased employee" means an individual who:
(i) Is not otherwise an employee of an employer.
(ii) Pursuant to a leasing agreement between the employer and another person, performs services for the employer on a substantially full-time basis for at least one year.
(iii) Performs services under the primary direction or control of the employer.
24. "Member contributions" means all amounts paid to ASRS by a member.
25. "Normal costs" means the sum of the individual normal costs for all active members for each fiscal year. The normal cost for an individual active member is the cost that is assigned to the fiscal year, through June 29, 2016, using the projected unit credit method and, beginning June 30, 2016, using the actuarial cost method determined by the board pursuant to section 38-714.
26. "Normal retirement age" means the age at which a member reaches the member's normal retirement date.
27. "Normal retirement date" means the earliest of the following:
(a) For a member whose membership commenced before July 1, 2011:
(i) A member's sixty-fifth birthday.
(ii) A member's sixty-second birthday and completion of at least ten years of credited service.
(iii) The first day that the sum of a member's age and years of total credited service equals eighty.
(b) For a member whose membership commenced on or after July 1, 2011:
(i) A member's sixty-fifth birthday.
(ii) A member's sixty-second birthday and completion of at least ten years of credited service.
(iii) A member's sixtieth birthday and completion of at least twenty-five years of credited service.

(iv) A member's fifty-fifth birthday and completion of at least thirty years of credited service.
28. "Political subdivision" means any political subdivision of this state and includes a political subdivision entity.
29. "Political subdivision entity" means an entity:
(a) That is located in this state.
(b) That is created in whole or in part by political subdivisions, including instrumentalities of political subdivisions.
(c) Where a majority of the membership of the entity is composed of political subdivisions.
(d) Whose primary purpose is the performance of a government related service.
30. "Retired member" means a member who is receiving retirement benefits pursuant to this article.
31. "Service year" means fiscal year, except that:
(a) If the normal work year required of a member is less than the full fiscal year but is for a period of at least nine months, the service year is the normal work year.
(b) For a salaried member employed on a contract basis under one contract, or two or more consecutive contracts, for a total period of at least nine months, the service year is the total period of the contract or consecutive contracts.
(c) In determining average monthly compensation pursuant to paragraph 5 of this section, the service year is considered to be twelve months of compensation.
32. "State" means this state, including any department, office, board, commission, agency, institution or other instrumentality of this state.
33. "Vested" means that a member is eligible to receive a future retirement benefit.

38-714. Powers and duties of ASRS and board
A. ASRS shall have the powers and privileges of a corporation, shall have an official seal and shall transact all business in the name "Arizona state retirement system", and in that name may sue and be sued.
B. The board is responsible for supervising the administration of this article by the director of ASRS.
C. The board is responsible for the performance of fiduciary duties and other responsibilities required to preserve and protect the retirement trust fund established by section 38-712.
D. The board shall not advocate for or against legislation providing for benefit modifications, except that the board shall provide technical and administrative information regarding the impact of benefit modification legislation.
E. The board may:
1. Determine the rights, benefits or obligations of any person under this article and afford any person dissatisfied with a determination a hearing on the determination. The board may delegate the duty and authority to act on the board's behalf to a committee of the board for the purposes of this paragraph and title 41, chapter 6, article 10 relating to any decision made under this paragraph by that committee of the board.
2. Determine the amount, manner and time of payment of any benefits under this article.

3. Recommend amendments to this article and articles 2.1 and 7 of this chapter that are required for efficient and effective administration.
4. Adopt, amend or repeal rules for the administration of the plan, this article and articles 2.1 and 7 of this chapter.
F. Beginning June 30, 2016, the board shall determine which of the generally accepted actuarial cost methods shall be used in the annual actuarial valuation of the plan.
G. The board and ASRS are not subject to title 41, chapter 6, except title 41, chapter 6, article 10, for actuarial assumptions and calculations, investment strategy and decisions and accounting methodology.
H. The board shall submit to the governor and legislature for each fiscal year no later than eight months after the close of the fiscal year a report of its operations and the operations of ASRS. The report shall follow generally accepted accounting principles and generally accepted financial reporting standards and shall include:
1. A report on an actuarial valuation of ASRS assets and liabilities.
2. Any other statistical and financial data that may be necessary for the proper understanding of the financial condition of ASRS and the results of board operations.
3. On request of the governor or the legislature, a list of investments owned. This list shall be provided in an electronic format.
4. An estimate of the aggregate fees paid for private equity investments, including management fees and performance fees.
I. The board shall:
1. Prepare and publish a synopsis of the annual report for the information of ASRS members.
2. Contract for a study of the mortality, disability, service and other experiences of the members and employers participating in ASRS. The study shall be conducted for fiscal year 1990-1991 and for at least every fifth fiscal year thereafter. A report of the study shall be completed within eight months after the close of the applicable fiscal year and shall be submitted to the governor and the legislature.
3. Conduct an annual actuarial valuation of ASRS assets and liabilities.
J. The auditor general may make an annual audit of ASRS and transmit the results to the governor and the legislature.

38-738. Adjustment and refund

A. If more than the correct amount of employer or member contributions is paid into ASRS by an employer through a mistake of fact, ASRS shall return those contributions to the employer if the employer requests return of the contributions within one year after the date of overpayment. ASRS shall not pay an employer earnings attributable to excess contributions but shall reduce the amount returned to an employer pursuant to this section by the amount of losses attributable to the excess contributions.
B. If less than the correct amount of employer or member contributions is paid into ASRS by an employer, the following apply:
1. The member shall pay an amount that is equal to the amount that would have been paid in member contributions for the period in question. The member's payments shall be made as provided in section 38-747. If the member does not

make the payment within ninety days of being notified by ASRS that the employer has paid all amounts due from the employer, the unpaid amount accrues interest until the amount is paid in full. The member is responsible for payment of the unpaid amount and interest. The interest rate is the interest rate assumption that is approved by the board for actuarial equivalency for the period in question to the date payment is received.

2. If the member contributions to ASRS made pursuant to this subsection exceed the limits prescribed in section 38-747, subsection E when taking into account other annual additions of the member for the limitation year, the amount to be paid by the member shall be adjusted as provided in section 38-747. For the purposes of this subsection, "limitation year" has the same meaning prescribed in section 38-769.

3. The employer shall pay to ASRS an amount equal to the amount that would have been paid in employer contributions for the period in question together with accumulated interest that would have accrued on both the employer and member contributions due. If the employer does not remit full payment of all employer contributions and all interest due within ninety days of being notified by ASRS of the amount due, the unpaid amount accrues interest until the amount is paid in full. The interest rate is the interest rate assumption that is approved by the board for actuarial equivalency for the period in question to the date payment is received.

4. On satisfaction of the requirements of this subsection, the member's salary history on the records of ASRS shall be adjusted and any additional service credits acquired by the member shall be reinstated.

5. If the member retires before all contributions are made pursuant to this subsection, the member's benefits shall be calculated only based on the contributions actually made.

6. Annual additions shall be determined as provided in section 38-747, subsection O.

7. The initiator of the request for correction of salary history and service credits on records of ASRS is responsible for providing credible evidence of past employment and compensation to ASRS in a form or forms that would lead a reasonable person to conclude that a period of employment occurred under circumstances that made the employee eligible for membership in ASRS during that period. A determination of eligibility by ASRS may be appealed to the ASRS board in a manner prescribed by the board.

C. Subsection B of this section applies to eligible verified service that occurred less than or equal to fifteen years before the date the initiator of the request for correction of salary history and service credits on the records of ASRS provides ASRS with credible evidence in writing that less than the correct amount of contributions were paid into ASRS or ASRS otherwise determines that less than the correct amount of contributions were made.

D. Eligible verified service that is more than fifteen years before the date the initiator of the request for correction of salary history and service credits on the records of ASRS provides ASRS with credible evidence in writing that less than the correct amount of contributions were paid into ASRS or ASRS otherwise determines that less than the correct amount of contributions were made is considered public service credit. The member may purchase this service pursuant to section 38-743.

38-783. Retired members; dependents; health insurance; premium payment; separate account; definitions

A. Subject to subsections G, H and I of this section, the board shall pay from ASRS assets part of the single coverage premium of any health and accident insurance for each retired member, contingent annuitant or member with a disability of ASRS if the member elects to participate in the coverage provided by ASRS or section 38-651.01 or elects to participate in a health and accident insurance program provided or administered by an employer or paid for, in whole or in part, by an employer to an insurer. A contingent annuitant must be receiving a monthly retirement benefit from ASRS in order to obtain any premium payment provided by this section. The board shall pay:

1. Up to one hundred fifty dollars per month for a member of ASRS who is not eligible for medicare if the retired member or member with a disability has ten or more years of credited service.
2. Up to one hundred dollars per month for each member of ASRS who is eligible for medicare if the retired member or member with a disability has ten or more years of credited service.

B. Subject to subsections G, H and I of this section, the board shall pay from ASRS assets part of the family coverage premium of any health and accident insurance for a retired member, contingent annuitant or member with a disability of ASRS who elects family coverage and who otherwise qualifies for payment pursuant to subsection A of this section. If a member of ASRS and the member's spouse are both either retired or have disabilities under ASRS and apply for family coverage, the member who elects family coverage is entitled to receive the payments under this section as if they were both applying under a single coverage premium unless the payment under this section for family coverage is greater. Payment under this subsection is in the following amounts:

1. Up to two hundred sixty dollars per month if the member of ASRS and one or more dependents are not eligible for medicare.
2. Up to one hundred seventy dollars per month if the member of ASRS and one or more dependents are eligible for medicare.
3. Up to two hundred fifteen dollars per month if either:

(a) The member of ASRS is not eligible for medicare and one or more dependents are eligible for medicare.
(b) The member of ASRS is eligible for medicare and one or more dependents are not eligible for medicare.

C. In addition each retired member, contingent annuitant or member with a disability of ASRS with less than ten years of credited service and a dependent of such a retired member, contingent annuitant or member with a disability who elects to participate in the coverage provided by ASRS or section 38-651.01 or who elects to participate in a health and accident insurance program provided or administered by an employer or paid for, in whole or in part, by an employer to an insurer is entitled to receive a proportion of the full benefit prescribed by subsection A or B of this section according to the following schedule:

1. 9.0 to 9.9 years of credited service, ninety percent.
2. 8.0 to 8.9 years of credited service, eighty percent.
3. 7.0 to 7.9 years of credited service, seventy percent.
4. 6.0 to 6.9 years of credited service, sixty percent.

5. 5.0 to 5.9 years of credited service, fifty percent.
6. Those with less than five years of credited service do not qualify for the benefit.
D. The board shall not pay more than the amount prescribed in this section for a member of ASRS.
E. Notwithstanding subsections A, B and C of this section, for a member who retires on or after August 2, 2012, the board shall not make a payment under this section to a retired member, contingent annuitant or member with a disability who is enrolled in an employer's active employee group health and accident insurance program either as the insured or as a dependent, except that if the retired member, contingent annuitant or member with a disability is enrolled as a dependent and the premium paid to the employer's active employee group health and accident insurance program is not subsidized by the employer, the retired member, contingent annuitant or member with a disability is entitled to receive the amount provided in subsection A of this section.
F. The board shall establish a separate account that consists of the benefits provided by this section. The board shall not use or divert any part of the corpus or income of the account for any purpose other than the provision of benefits under this section unless the liabilities of ASRS to provide the benefits are satisfied. If the liabilities of ASRS to provide the benefits described in this section are satisfied, the board shall return any amount remaining in the account to the employer.
G. Payment of the benefits provided by this section is subject to the following conditions:
1. The payment of the benefits is subordinate to the payment of retirement benefits payable by ASRS.
2. The total of contributions for the benefits and actual contributions for life insurance protection, if any, shall not exceed twenty-five percent of the total actual employer and employee contributions to ASRS, less contributions to fund past service credits, after the day the account is established.
3. The board shall deposit the benefits provided by this section in the account.
4. The contributions by the employer to the account shall be reasonable and ascertainable.
H. A member who elects to receive a retirement benefit pursuant to section 38-760, subsection B, paragraph 1 may elect at the time of retirement an optional form of health and accident insurance premium benefit payment pursuant to this subsection as follows:
1. The optional premium benefit payment shall be an amount prescribed by subsection A, B or C of this section that is actuarially reduced to the retiring member for life. The amount of the optional premium benefit payment shall be the actuarial equivalent of the premium benefit payment to which the retired member would otherwise be entitled. The election in a manner prescribed by the board shall name the contingent annuitant and may be revoked at any time before the retiring member's effective date of retirement. At any time after benefits have commenced, the member may name a different contingent annuitant or rescind the election by written notice to the board as follows:
(a) If the retired member names a different contingent annuitant, the optional premium benefit payment shall be adjusted to the actuarial equivalent of the original premium benefit payment based on the age of the new contingent annuitant. The adjustment shall include all postretirement increases or decreases in

amounts prescribed by subsection A, B or C of this section that are authorized by law after the retired member's date of retirement. Payment of this adjusted premium benefit payment shall continue under the provisions of the optional premium benefit payment previously elected by the retired member. A retired member cannot name a different contingent annuitant if the retired member has at any time rescinded the optional form of health and accident insurance premium benefit payment.

(b) If the retired member rescinds the election, the retired member shall thereafter receive the premium benefit payment that the retired member would otherwise be entitled to receive if the retired member had not elected the optional premium benefit payment, including all postretirement increases or decreases in amounts prescribed by subsection A, B or C of this section that are authorized by law after the member's date of retirement. The increased benefit payment shall continue during the remainder of the retired member's lifetime. The decision to rescind shall be irrevocable.

2. If, at the time of the retired member's death:

(a) The retired member was receiving a reduced premium benefit payment based on an amount prescribed in subsection B or C of this section and the contingent annuitant is eligible for family health and accident insurance coverage, the contingent annuitant is entitled to receive a premium benefit payment based on an amount prescribed in subsection B or C of this section times the reduction factor applied to the retired member's premium benefit payment times the joint and survivor option reduction factor elected by the retired member at the time of retirement pursuant to section 38-760, subsection B, paragraph 1.

(b) The retired member was receiving a reduced premium benefit payment based on an amount prescribed in subsection A or C of this section and the contingent annuitant is eligible for single health and accident insurance coverage, the contingent annuitant is entitled to receive a premium benefit payment based on an amount prescribed in subsection A or C of this section times the reduction factor applied to the retired member's premium benefit payment times the joint and survivor option reduction factor elected by the retired member at the time of retirement pursuant to section 38-760, subsection B, paragraph 1.

(c) The retired member was receiving a reduced premium benefit payment based on an amount prescribed in subsection B or C of this section and the contingent annuitant is not eligible for family health and accident insurance coverage, the contingent annuitant is entitled to receive a premium benefit payment based on an amount prescribed in subsection A or C of this section times the reduction factor applied to the retired member's premium benefit payment times the joint and survivor option reduction factor elected by the retired member at the time of retirement pursuant to section 38-760, subsection B, paragraph 1.

I. A member who elects to receive a retirement benefit pursuant to section 38-760, subsection B, paragraph 2 may elect at the time of retirement an optional form of health and accident insurance premium benefit payment pursuant to this subsection as follows:

1. The optional premium benefit payment shall be an amount prescribed by subsection A, B or C of this section that is actuarially reduced with payments for five, ten or fifteen years that are not dependent on the continued lifetime of the retired member but whose payments continue for the retired member's lifetime

beyond the five, ten or fifteen year period. The election in a manner prescribed by the board shall name the contingent annuitant and may be revoked at any time before the retiring member's effective date of retirement. At any time after benefits have commenced, the member may name a different contingent annuitant or rescind the election by written notice to the board. If the retired member rescinds the election, the retired member shall thereafter receive the premium benefit payment that the retired member would otherwise be entitled to receive if the retired member had not elected the optional premium benefit payment, including all postretirement increases or decreases in amounts prescribed by subsection A, B or C of this section that are authorized by law after the member's date of retirement. The increased benefit payment shall continue during the remainder of the retired member's lifetime. The decision to rescind shall be irrevocable.

2. If, at the time of the retired member's death:

(a) The retired member was receiving a reduced premium benefit payment based on an amount prescribed in subsection B or C of this section and the contingent annuitant is eligible for family health and accident insurance coverage, the contingent annuitant is entitled to receive a premium benefit payment based on an amount prescribed in subsection B or C of this section times the period certain and life option reduction factor elected by the retired member at the time of retirement pursuant to section 38-760, subsection B, paragraph 2.

(b) The retired member was receiving a reduced premium benefit payment based on an amount prescribed in subsection A or C of this section and the contingent annuitant is eligible for single health and accident insurance coverage, the contingent annuitant is entitled to receive a premium benefit payment based on an amount prescribed in subsection A or C of this section times the period certain and life option reduction factor elected by the retired member at the time of retirement pursuant to section 38-760, subsection B, paragraph 2.

(c) The retired member was receiving a reduced premium benefit payment based on an amount prescribed in subsection B or C of this section and the contingent annuitant is not eligible for family health and accident insurance coverage, the contingent annuitant is entitled to receive a premium benefit payment based on an amount prescribed in subsection A or C of this section times the period certain and life option reduction factor elected by the retired member at the time of retirement pursuant to section 38-760, subsection B, paragraph 2.

J. If, at the time of retirement, a retiring member does not elect to receive a reduced premium benefit payment pursuant to subsection H or I of this section, the retired member's contingent annuitant is not eligible at any time for the optional premium benefit payment.

K. If a member who is eligible for benefits pursuant to this section forfeits the member's interest in the account before the termination of ASRS, an amount equal to the amount of the forfeiture shall be applied as soon as possible to reduce employer contributions to fund the benefits provided by this section.

L. A contingent annuitant is not eligible for any premium benefit payment if the contingent annuitant was not enrolled in an eligible health and accident insurance plan at the time of the retired member's death or if the contingent annuitant is not the dependent beneficiary or insured surviving dependent as provided in section 38-782.

M. For the purposes of this section:

1. "Account" means the separate account established pursuant to subsection F of this section.
2. "Credited service" includes prior service.
3. "Prior service" means service for this state or a political subdivision of this state before membership in the defined contribution program administered by ASRS.
4. "Subsidized" means a portion of the total premium is paid by the employer, but does not necessarily mean a plan in which the employer uses blended rates to determine the total premium.

ARIZONA RADIATION REGULATORY AGENCY (F-17-0104)
Title 12, Chapter 1, Article 7, Medical Uses of Radioactive Material; Article 13, License and Registration Fees

GOVERNOR'S REGULATORY REVIEW COUNCIL
ANALYSIS OF FIVE-YEAR REVIEW REPORT

MEETING DATE: January 4, 2017 **AGENDA ITEM: F-4**

TO: Members of the Governor's Regulatory Review Council ("Council")

FROM: Chris Kleminich, Staff Attorney

DATE: December 20, 2016

SUBJECT: **RADIATION REGULATORY AGENCY (F-17-0104)**
Title 12, Chapter 1, Article 7, Medical Uses of Radioactive Material; Article 13, License and Registration Fees

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COMMENTS ON THE FIVE-YEAR-REVIEW REPORT

Purpose of the Agency and Number of Rules in the Report

The purpose of the Arizona Radiation Regulatory Agency ("Agency") is "to protect the public health and safety by regulating the use and sources of radiation in order to provide for:

1. The use of demonstrably safe methods and procedures relating to radiation.
2. The exposure to sources of radiation to levels as low as is reasonably achievable by means of good planning, practice and enforcement."

Laws 2006, Ch. 60, § 3.

This five-year-review report covers 46 rules and one exhibit in Article 7, related to medical uses of radioactive material. The report also covers nine rules and one table in Article 13, related to license and registration fees.

Proposed Action

The Agency plans to submit a rulemaking to the Council, pending receipt of an exception from the moratorium, in June 2017. Several amendments are proposed in order to maintain compliance with the federal rules of the Nuclear Regulatory Commission (NRC):

- Section 702: Additional definitions will be needed to make this rule compatible with the federal definitions provided in 10 CFR 35.2.
- Section 703: The rule should require patient release criteria in license applications.

- Section 704: The rule should provide information on what an approved license does to relieve the user from compliance with Food and Drug Administration (FDA) and other federal and state regulations governing radioactive drugs or devices.
- Section 705: The use of a temporary Radiation Safety Officer (RSO) should be allowed for up to 60 days each calendar year.
- Section 707: The rule should allow a written order to be changed prior to the administration of therapy to a patient.
- Section 708: The rule should include verification of dose calculations and the transcription of doses into consoles of therapeutic medical units.
- Section 710: To make the rule compatible with 10 CFR 35.50, several additions will be made, including minimum education requirements.
- Section 711: To make the rule compatible with 10 CFR 35.51, several additions will be made, including additional training requirements.
- Section 712: To make the rule compatible with 10 CFR 35.55, several additions will be made, including a requirement to hold an active license to practice pharmacy prior to creating medical radioactive doses.
- Section 715: Several additions will be made to make the rule compatible with 10 CFR 35.67, which relates to requirements for possession of sealed sources and brachytherapy sources. Brachytherapy is a form of radiotherapy commonly used in cancer treatment.
- Section 719: The federal rule incorporated by reference, 10 CFR 135.190, should be updated in order for the rule to meet all training requirements currently mandated.
- Section 720: The concentration limits of strontium-82 and strontium-85 should be included in the rule, in order to be in compliance with 10 CFR 35.204.
- Section 721: An update to the rule, to add incorporated material, is necessary. In addition, Section B should be eliminated in order to maintain compatibility with 10 CFR 35.290.
- Section 723: An update to the rule, to add incorporated material, is necessary.
- Section 727: The federal rule incorporated by reference, 10 CFR 35.491, should be updated.
- Section 728: An update to the rule, to add incorporated material, is necessary.
- Section 745: The rule should ensure that, in the case of a medical event, an individual is notified at the Agency or the after-hours duty officer is directly spoken to.
- Section 746: The rule should ensure that, in the case of a radiation dose to an embryo, fetus, or nursing child, an individual is notified at the Agency or the after-hours duty officer is directly spoken to.
- Exhibit A: The exhibit currently provides information related to each type of radioactive material used in medicine from group 100 to group 600. An addition of group 1000 is needed in order to include NRC-specific licensed uses of certain materials.
- Section 1302: The rule should include the category “certification” and the listing of fees currently listed in Article 14 for laser technologists and laser technology training schools.
- Section 1303: The application fees for laser technologists should be listed, based upon the type of application that is requested. In addition, renewal and duplicate copy fees should be listed and described.

- Section 1304: A clarification of due dates to reflect the expiration dates of certifications should be added, as certifications expire one year after the date of issue. A reference to the annual fee payment due date of January 1 for registrations and licenses should be added.
- Section 1305: The rule should include other payee accounts for fee payments to the Agency, and should account for refunds in accordance with A.R.S. § 41-1077.
- Section 1306: An update to the definition of "full cost" should be made to include applicable mileage. In addition, the category of certification is needed in the table of fees.
- Section 1308: Updates are needed to reflect both federal and state mileage rates.

Substantive or Procedural Concerns

None.

Analysis of the agency's report pursuant to criteria in A.R.S. § 41-1056 and R1-6-301:

1. **Has the agency certified that it is in compliance with A.R.S. § 41-1091?**

Yes. The Agency has certified its compliance with A.R.S. § 41-1091.

2. **Has the agency analyzed whether the rules are authorized by statute?**

Yes. The Agency cites general statutory authority for the rules reviewed. Under A.R.S. § 30-654(A)(2), the Agency may "[d]o all things necessary, within the limitations of this chapter [Title 30, Chapter 4, Control of Ionizing Radiation], to carry out the powers and duties of the agency." In addition, the Agency cites a number of provisions in A.R.S. § 30-654(B), including subsection (5), under which the Agency shall adopt rules it deems necessary to administer the chapter.

3. **Has the agency received any written criticisms of the rules during the last five years, including any written analysis questioning whether the rules are based on valid scientific or reliable principles or methods?**

No. The Agency notes that it has not received any written criticisms of the rules during the last five years.

4. **Has the agency analyzed the rules' effectiveness in achieving their objectives?**

Yes. The Agency indicates that the rules are generally effective in achieving their objectives. Proposed changes are intended to conform to NRC regulations that are due in fiscal years 2017 and 2018, and the current rules are sufficient through FY 2018.

5. **Has the agency analyzed the rules' consistency with other rules and statutes?**

Yes. The Agency states that there are no known federal statutes or rules specific to the subject matter of these rules, and that the rules are consistent with other state rules.

6. Has the agency analyzed the current enforcement status of the rules?

Yes. The Agency indicates that the rules are enforced as written except for the instances identified above where state rules are incompatible with federal regulations.

7. Has the agency analyzed whether the rules are clear, concise, and understandable?

Yes. The Agency indicates that the rules are generally clear, concise and understandable as written, though amendments should provide an additional level of clarity.

8. Stringency of the Rules:

a. Are the rules more stringent than corresponding federal law?

No. The Agency indicates that there are no directly corresponding federal laws.

b. If so, is there statutory authority to exceed the requirements of federal law?

Not applicable.

9. For rules adopted after July 29, 2010:

a. Do the rules require issuance of a regulatory permit, license or agency authorization?

Yes. The Agency issues registrations in Article 7.

b. If so, are the general permit requirements of A.R.S. § 41-1037 met or does an exception apply?

The Agency indicates that such registrations are exempt from general permit requirements under A.R.S. § 41-1037(A)(2), as the issuance of an alternative type of permit is authorized under A.R.S. §§ 30-672, 32-516(A), and 32-3233(E) in order to protect the public health and safety, and to certify laser technicians and laser technician training schools.

10. Has the agency indicated whether it completed the course of action identified in the previous five-year-review report?

Yes. In the previous five-year-review report, the Agency indicated that it would amend the rules by July 2013. No action has yet been taken.

Conclusion

The Agency plans to submit a rulemaking to the Council, pending receipt of an exception from the moratorium, in June 2017. The report meets the requirements of A.R.S. § 41-1056 and R1-6-301. This analyst recommends that the report be approved.

GOVERNOR'S REGULATORY REVIEW COUNCIL
M E M O R A N D U M

MEETING DATE: January 4, 2017 **AGENDA ITEM: F-4**

TO: Members of the Governor's Regulatory Review Council ("Council")

FROM: GRRC Economic Team

DATE: December 20, 2016

SUBJECT: **RADIATION REGULATORY AGENCY (F-17-0104)**
Title 12, Chapter 1, Article 7, Medical Uses of Radioactive Material; Article 13, License and Registration Fees

I reviewed the five-year-review report's economic, small business, and consumer impact comparison for compliance with A.R.S. § 41-1056 and make the following comments.

1. Economic Impact Comparison

Economic, small business, and consumer impact statements (EIS) from the most recent rulemakings were available for the Article 7 and 13 rules contained in the five-year-review report.

The rules contained in Article 7 provide general safeguards for the medical use of radioactive material (byproduct material). The rules contained in Article 13 provide the general fee information used to cover application and renewal of registrations and licenses issued by the Agency. These rules were developed to meet standards as set forth by the U.S Nuclear Regulatory Commission in order to meet the intended registration and regulatory oversight described in §30-671, 30-6722 and defined in 30-651.

There are approximately 380 licensees in the State of Arizona that use the rules and incorporated material in Article 7; 7,000 registrants, 400 licensees, 8,000 technologists licensed by the Medical Radiologic Technology Board of Examiners, 1,600 technicians certified as cosmetic laser techs, and 1,500 nonionizing facilities using the rules and incorporated materials in Article 13.

These rules have an economic impact on the regulated community by levying penalties for noncompliance. In the last three years, the total amount of fines levied by these rules averaged $70,000 per year**.** The fees were based upon the approximated costs the Agency expended to issue, renew, and conduct safety inspections for registrants and licensees. In most cases the fees are lower than the Nuclear Regulatory Commission (NRC), Agreement States, or other states with similar radiation protection programs in our region.

2. Has the agency determined that the rules impose the least burden and costs to persons regulated by the rules?

The Agency has determined that the rules in Articles 7 and 13 are mostly effective and impose the least burden and costs to the regulated community. The cost to comply with these rules is minimal and necessary to protect public health and safety.

In order to maintain consistency throughout its other rules, the Agency intends to amend Articles 7 and 13 by June 2017.

3. Was an analysis submitted to the agency under A.R.S. § 41-1056(A)(7)?

No analysis was submitted to the agency by another person that compares the rules' impact on this state's business competitiveness to the impact on businesses in other states under A.R.S. § 41-1056(A)(7).

4. Conclusion

After review, staff concludes that the report complies with A.R.S. § 41-1056 and recommends approval.

ARIZONA RADIATION REGULATORY AGENCY

Douglas A. Ducey
Governor

Brian D. Goretzki
Interim Director

November 16, 2016, 2016

Nicole A. Ong, Council Chair
Governor's Regulatory Review Council
100 N. 15th Avenue, Suite 402
Phoenix, Arizona 85007

Dear Ms. Ong:

A review of the rules contained in A.A.C Title 12, Chapter 1, Article 7, "Medical Uses of Radioactive Material", and Article 13, "License and Registration Fees" has been conducted by the Arizona Radiation Regulatory Agency.

In accordance with A.R.S. § 41-1056, a review of each rule was conducted to determine whether it should be amended or repealed. This report summarizes the Agency's findings with supporting reasons. A concise analysis of each rule is provided summarizing the essential elements of this five-year review in accordance with A.A.C. R1-6-301. In addition, the Agency is in compliance with A.R.S. § 41-1091 and all incorporated material is open to the public and available at the Agency location.

Finally, there are several changes needed in this article. The changes are required to maintain compliance with the Agreement State Document that allows Arizona to regulate radioactive material on behalf of the Federal Government's agency tasked with that duty. These changes ensure that Arizona reviews and accepts the same training and certification requirements that the Nuclear Regulatory Commission and other Agreement States use for the use of radioactive material in medicine.

Please feel free to contact me if you have any questions regarding this five-year review.

Sincerely,

Brian D. Goretzki,
Interim Director

CAM:BDG:cam

4814 South 40th Street • Phoenix, Arizona 85040-2940 • Telephone (602) 255-4845 • Fax (602) 437-0705
Arra.az.gov

FIVE-YEAR REVIEW REPORT

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

ARTICLE 7. MEDICAL USES OF RADIOACTIVE MATERIAL

ARTICLE 13. LICENSE AND REGISTRATION FEES

TABLE OF CONTENTS

FIVE-YEAR REVIEW SUMMARY

The rules contained in Article 7 provide general safeguards for the medical use of radioactive material (byproduct material). Arizona is an Agreement State and as such the federal government has delegated the licensing and enforcement of regulations governing this material to be conducted by the state provided that the state program is significantly compatible according to NRC guidelines with the federal program. The rules in this article were adopted in May of 2007 to meet the new category of regulations implemented at the federal level.

The rules contained in Article 13 provide the general fee information used to cover application and renewal of registrations and licenses issued by the Agency. The fees were based upon the approximated costs the Agency expended to issue, renew, and conduct safety inspections for registrants and licensees. In most cases the fees are lower than the Nuclear Regulatory Commission (NRC), Agreement States, or other states with similar radiation protection programs in our region.

The rules contained in Articles 7 and 13 provide standards for registration, shielding, operation, quality control requirements for protection, and fees. These rules were developed to meet standards as set forth by the NRC in order to meet the intended registration and regulatory oversight described in §30-671, 30-6722 and defined in 30-651 .

FIVE-YEAR-REVIEW REPORT

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

ARTICLE 7. MEDICAL USES OF RADIOACTIVE MATERIAL

Section

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

R12-1-717. Release of Individuals Containing Radioactive Material or Implants Containing Radioactive Material

R12-1-718. Mobile Medical Service

R12-1-719. Training for Uptake, Dilution, and Excretion Studies

R12-1-720. Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations

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

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

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

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

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

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

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

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

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

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

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

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

R12-1-733. Dosimetry Equipment

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

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

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

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

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

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

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

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

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

R12-1-743. Therapy-related Computer Systems

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

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

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

Exhibit A. Medical Use Groups

ARTICLE 13. LICENSE AND REGISTRATION FEES

R12-1-1301. Definition

R12-1-1302. License and Registration Categories

R12-1-1303. Fee for Initial License and Initial Registration

R12-1-1304. Annual Fees for Licenses and Registrations

R12-1-1305. Method of Payment

R12-1-1306. Table of Fees

R12-1-1307. Special License Fees

R12-1-1308. Fee for Requested Inspections

R12-1-1309. Abandonment of License or Registration Application

Table 1

. Small Entity Fees

INFORMATION THAT IS IDENTICAL FOR ALL THE RULES

The following information is the same for all of the rules and is not restated in the analysis of each rule:

1. <u>General and Specific Statutes Authorizing the Rules:</u>

All of the rules have general authority in A.R.S. §§ 30-654(A)(2), 30-654(B)(5), 30-654(B)(9), 30-654(B)(13), 30-657(A), 30-671(B), 30-672, 30-672.01, and 30-673. Any specific authority is stated in the applicable rule.

4. Consistency of the Rules with State and Federal Statutes and Rules:

The rules contained in Article 7 and 13 consistent with other relevant agency rules posted in Title 12. The rules in Article 13 are compatible with like rules in 10 CFR related to FEE requirements as a portion the state of Arizona's Agreement with the U.S. Nuclear Regulatory Commission. Changes to R12-1-702, R12-1-704, R12-1-705, R12-1-708, R12-1-710, R12-1-711, R12-1-712, R12-1-715, R12-1-719, R12-1-720, R12-1-723, Exhibit A, R12-1-1306, and R12-1-1308 are being proposed to increase consistency with federal regulations.

7. Summary of Written Criticisms of the Rules Received Within the Last Five Years:

The Agency has not received any written criticisms concerning the rules contained in Articles 7 and 13.

8. Estimated Economic, Small Business, and Consumer Impact of the Rules Compared to the Economic Impact Statement Prepared on the Last Revision or Creation of the Rules:

Currently there are approximately 380 licensees in the State of Arizona that use the rules and incorporated material in Article 7; 7,000 registrants, 400 licensees, 8000 technologists licensed by MRTBE, 1600 technicians certified as cosmetic laser techs, and 1,500 nonionizing facilities using the rules and incorporated materials in Article 13. Analysis of the economic impact statement for the rules created or last amended since the last report is attached as Exhibit 1.

The Agency believes that economic impact is as predicted on the last making of the rules in Articles 7, and 13 and is consistent with the actual economic impact expressed in EIS reports submitted prior to 2011 already on file with GRRC or with Exhibit 1 in relation to Articles 7, and 13 except as expressed below.

The rules in Article 7 that were last amended in 2007 are not monetary in nature and only apply to registrants or licensees that repeatedly fail to meet compliance with a specific rule. These rules have an economic impact on the regulated community by levying penalties for noncompliance. In the last three years, the total amount of fines levied by these rules averaged $70,000 per year. It is assumed by the Agency that those that repeated violated code would be aware of the financial costs of paying penalties. Further, it is the Agency's belief that the economic impact of these rules has been consistent with the economic impact that was predicted at the time of the last rulemaking.

9. Analysis Submitted to the Agency Comparing the Economic Impact on this State's Businesses to the Impact to Businesses in Other States:

The Agency has not received any analysis comparing the economic impact to this state's businesses with businesses in other states.

10. Completion of Course of Action from a Previous Five year Report:

The actions addressed in the previous 5 year report related to Article 7 and 13 were addressed in 2007 and 2014 respectively.

12. Stringency of the Rules Compared with Federal Laws or Regulations:

The Agency has determined that the rules in Article 7, and 13 are not more stringent than corresponding federal regulations as there are not known corresponding federal regulations.

13. For Rules Adopted After July 29, 2010 that Require Issuance of a Regulatory Authorization, Whether the Rules Comply with A.R.S. § 41-1037:

The Agency believes that the registrations issued by Article 7 are exempt from A.R.S. § 41-1037 due to paragraph (A)(2) as the issuance of an alternative type of permit is authorized under the statutory requirement of A.R.S. §§ 30-672, 32-516(A), and 32-3233(E) to protect the public health and safety or to certify laser technicians and laser technician training schools. A registration is not issued in Article 13 as these are considered in other Articles of the rules.

14. Course of Action for Rule Making:

The Agency would like to amend the existing rules once the Governor's Offices provide approval. It is believed that the Governor's office will likely support the rulemaking in 2017, following the passage of the proposed RMP-0080 and after approval to proceed with the elimination/amendments of the rules identified in the September report as a part of the 2015-01 Executive Order. The GRRC could see this rulemaking in June of 2017. The rulemaking that is needed includes the following amendments or adoptions:

ARTICLE 7

R12-1-702: Several additional definitions are needed to make this rule compatible with 10 CFR 35.2 when other changes are made to Article 7.

R12-1-703: An addition to this rule is needed for this rule to contain a requirement of patient release criteria in a license application.

R12-1-704: An amendment to add information that an approved license does to relieve the user from compliance with FDA, other Federal, and state regulations governing radioactive drugs or devices is needed.

R12-1-705: An amendment to this rule is needed to allow for the use of a temporary RSO for up to 60 days each calendar year.

R12-1-707: An amendment to this rule is needed to include verbiage that allows a written order to be changed prior to administration of therapy to a patient.

R12-1-708: An addition to this rule is needed to include verification of dose calculations and transcription of dose into consoles of therapeutic medical units.

R12-1-710: Several changes are needed to this rule to make it compatible with 10 CFR 35.50 including minimum education requirements.

R12-1-711: Several changes are needed to this rule to make it compatible with 10 CFR 35.51 including additional training requirements.

R12-1-712: Several changes are needed to this rule to make it compatible with 10 CFR 35.55 including a requirement to hold an active license to practice pharmacy prior to creating medical radioactive doses.

R12-1-715: Additional requirements are needed to this rule to make it compatible with 10 CFR 35.67.

R12-1-719: An update of the incorporated material (10 CFR 135.190) is needed for this rule to meet all training requirements currently mandated.

R12-1-720: An addition to this rule is needed to provide the concentration limits of strontium-82, and strontium-85 to be in compliance with 10 CFR 35.204.

R12-1-721: An update to incorporated material is needed for this rule.

R12-1-723: An update of incorporated materials is needed for this rule. In addition, an incorporation of 10 CFR 35.396 is needed for this rule.

R12-1-727: Updates to the incorporated material are needed.

R12-1-728: Updates to the incorporated material are needed.

R12-1-745: An amendment to ensure an individual is notified at the Agency or the after hours duty officer is spoken to directly is needed.

R12-1-746: An amendment to ensure an individual is notified at the Agency or the after hours duty officer is spoken to directly by the licensee is needed.

Exhibit A: This exhibit provides the information related to each type of radioactive

material used in medicine from group 100 to group 600. An addition of group 1000 is needed to update this list to include NRC specific licensed uses of certain materials.

R12-1-721: Eliminate section B to remain compatible to 10 CFR 35.290.

ARTICLE 13

R12-1-1302: Inclusion of the category "certification" and the listing of the fees currently listed in Article 14 for laser technologists and laser technology training schools and an update of incorporated materials.

R12-1-1303: An amendment to the rule to describe the application fees for laser technologists based upon the type of application that is requested. In addition, the renewal and duplicate copy fees will be listed and described.

R12-1-1304: A clarification of due dates to reflect the expiration dates of certifications will need to be added to this rule. Certifications expire one year after the date of issue. Registrations and licenses have an annual fee payment due date of January 1.

R12-1-1305: An update to include other payee accounts for fee payments to the Agency and account for refunds under A.R.S. § 41-1077. In addition to the "State of Arizona", fees may be paid to ARRA, Arizona Radiation Regulatory Agency, Laser Safety Fund, or LSF depending upon the type of registration, license or certificate.

R12-1-1306: An update to full cost to include applicable mileage is needed. In certain cases the rate is federal or state and currently only the state rate is reflected. In addition, the category of certification is needed in the table of fees.

R12-1-1308: An update of applicable mileage is needed. In certain cases the rate is federal or state and currently only the state rate is reflected.

INFORMATION THAT IS IDENTICAL WITHIN GROUPS OF RULES

3. Effectiveness of the Rules in Achieving the Objectives:

The rules in Articles 7 and 13 are generally effective in achieving their objectives. The proposed changes to Articles 7 and 13 will be used to conform to NRC regulations that are due by 2017 and 2018 fiscal years. Current regulations, in lieu of amended state regulations, are sufficient until fiscal year 2018.

5. Status of enforcement of the rule

The rules in Article 7 and 13 are enforced in accordance with A.R.S. § 30-687 and the procedures set forth in Article 12. In instances where state regulations are not compatible with federal regulations, federal regulations supersede state regulations.

6. Analysis of clarity, conciseness, and understandability

The rules in Articles 7 and 13 are generally clear, concise and understandable as written. Proposed rule changes for Articles 7 and 13 will keep Arizona in compliance with the NRC's Agreement State compact. This is not to suggest that the amendments will provide an added level of clarity.

10. Whether the agency completed the course of action proposed in the previous Five-year-review Report

The Agency has not completed the rule amendments listed in the previous five year report for Articles 7 and 13. These actions are a portion of RMP-0080 currently under review for a moratorium override in the Governor's office.

11. Probable Benefit of the Rules in Meeting Regulatory Objective and Determination that the Rules Impose the Least Burden and Costs to the Regulated Community to Achieve Objective:

The Agency believes that the rules contained in Article 7 and 13, after amendments consistent with this report, will impose the least burden and costs to the regulated

community but will continue to protect the public health and safety from unsafe use of radiation sources by those not adequately trained.

If additional information is needed concerning this five-year review, please feel free to contact the Agency director at:

Name: Brian D. Goretzki

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

Telephone Number: (602) 255-4840

Fax Number: (602) 437-0705

E-mail: bg@azrra.gov

Or the Agency rule writer at:

Name: Colby A. McCormick

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

Telephone Number: (602) 826-3229

Fax Number: (602) 437-0705

E-mail: cmccormick@azrra.gov

Five-Year Review of Article 7 & 13
ARRA
November 8, 2016

Radiation Regulatory Agency

ARTICLE 7. MEDICAL USES OF RADIOACTIVE MATERIAL

R12-1-701. License Required

A. A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer radioactive material for medical use only in accordance with a specific license issued by the Agency, the NRC, or another Agreement State, or as allowed in subsection (B)(1) or (B)(2)

.

B. A specific license is not needed for an individual who:

1. Receives, possesses, uses, or transfers radioactive material in accordance with the rules in this Chapter under the supervision of an authorized user as provided in R12-1-706, unless prohibited by license condition; or
2. Prepares unsealed radioactive material for medical use in accordance with the rules in this Chapter under the supervision of an authorized nuclear pharmacist or authorized user.

Historical Note

Former Rule Section G.1. Former Section R12-1-701 repealed, new Section R12-1-701 adopted effective June 30, 1977 (Supp. 77-3). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Section repealed; new Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (07-1).

R12-1-702. Definitions

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

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

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

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

"CT" means computerized tomography.

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

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

"Institutional review board" (IRB) is defined in R12-1-704(B).

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

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

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

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

"Nuclear cardiology" means the diagnosis of cardiac disease using radiopharmaceuticals.

"PET" means positron emission tomography.

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

"Prescribed dosage" means the specified activity or range of activity of unsealed radioactive material as documented:

In a written directive; or
In accordance with the directions of the authorized user for procedures performed in accordance with the uses described in Exhibit A.

"Prescribed dose" means:

For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
For teletherapy, the total dose and dose per fraction as documented in the written directive;
For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or
For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

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

Meets the requirements in R12-1-710, or

Is identified as a radiation safety officer on:

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

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

"Radioactive drug" is defined in 21 CFR 310.3(c) and includes a "radioactive biological product" as defined in 21 CFR 600.3, April 1, 2006, both of which are incorporated by reference, published by the Office of Federal Register, National Archives and Records Administration, Washington, DC 20408, and on file with the Agency. These incorporated materials contain no future editions or amendments.

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

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

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

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

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

"Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a

radiation dose to a patient or human research subject for palliative or curative treatment.

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

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

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

"Written directive" means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in R12-1-707.

Historical Note

Former Rule Section G.2; Former Section R12-1-702 repealed, new Section R12-1-702 adopted effective June 30, 1977 (Supp. 77-3). Former Section R121-702 renumbered and amended as Section R12-1-703, new Section R12-1-702 adopted effective December 20, 1985 (Supp. 85-6). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 7 A.A.R. 2584, effective June 8, 2001 (Supp. 01-2). Amended by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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

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

1. The applicant has appointed a radiation safety committee, meeting the requirements in R12-1-705, that will oversee the use of licensed material throughout the licensee's facility and associated radiation safety program;
2. The applicant possesses facilities for the clinical care of patients or human research subjects; and
3. The individual designated on the application as an authorized user has 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.

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

1. The Agency shall approve an application by 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 meets the training and experience requirements in subsection (A)(3); and
   d. The applicant has a radiation safety committee, if the criteria in R12-1-705 are applicable and a RDRC, if the use is basic research involving humans.

2. The Agency shall not approve an application by 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 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. 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 Groups 100 through 1,000, in Exhibit A of this Article, for all of the materials within each group requested in the application if:
   a. The applicant satisfies the requirements of subsections (A) and (B);
   b. Each person involved in the preparation and use of the radioactive material is an authorized user, an authorized nuclear pharmacist, or certified as a nuclear medicine technologist by the Medical Radiologic Technology Board of Examiners (MRTBE);
   c. The applicant's radiation detection and measuring instrumentation is adequate for conducting the procedures involved in the authorized uses selected from Group 100 through Group 1,000; and
   d. The applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the authorized uses selected from Group 100 through Group 1,000.
2. Any licensee who is authorized to use radioactive material:
   a. In unsealed form under Groups 100, 200, 300 or 1,000 listed in Exhibit A of this Article, shall do so using radiopharmaceuticals prepared in accordance with R12-1-311(I); or
   b. In sealed source form under Groups 400, 500, 600, or 1,000 listed in Exhibit A of this Article, shall do so using sealed sources that have been manufactured and distributed in accordance with R12-1-311(K);
   c. In any form under group 1,000 listed in Exhibit A of this Article, shall do so using sealed and unsealed sources that have been manufactured and distributed in accordance with the specific license issued by the Agency.
3. Any licensee who is licensed according to subsection (C)(1), for one or more of the medical use groups in Exhibit A also is authorized to use radioactive material under the general license in R12-1-306(E) for the specified in vitro uses without filing Form ARRA-9 as required by R12-1-306(E)(2); provided, that the licensee is subject to the other provisions of R12-1-306(E).

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

Historical Note

Former Rule Section G.3; Former Section R12-1-703 repealed, new Section R12-1-703 adopted effective June 30, 1977 (Supp. 77-3). Former Section R12-1-703 renumbered and amended as Section R12-1-704, former Section R12-1-702 renumbered and amended as Section R12-1-703 effective December 20, 1985 (Supp. 85-6). Section repealed and new Section adopted by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 9 A.A.R. 1126, effective May 9, 2003 (Supp. 03-1). Amended by final rulemaking at 10 A.A.R. 2122, effective July 3, 2004 (Supp. 04-2). Amended by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1). Amended by final rulemaking at 20 A.A.R. 324, effective March 8, 2014 (Supp. 14-1). Amended by final rulemaking at 22 A.A.R. 603, effective February 2, 2016 (Supp. 16-1).

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

A. A licensee may conduct basic research involving human research subjects and research involving patients receiving investigational new drugs or devices if the licensee only uses the radioactive material specified on the license for the uses authorized on the license.

B. If research is conducted, funded, supported, or regulated by a federal agency that has implemented the federal Policy for Protection of Human Research Subjects (45 CFR 46, June 23, 2005, which is incorporated by reference, published by the Office of Federal Register, National Archives and Records Administration, Washington, DC 20408, on file with the Agency, and contains no future editions or amendments), the licensee shall:
1. Obtain review and approval of the research from an Institutional Review Board (IRB); and
2. Obtain informed consent from the human research subject.

C. If research will not be conducted, funded, supported, or regulated by a federal agency that has implemented the federal policy in subsection (B), a medical licensee shall, before conducting research, apply for and receive a specific amendment to its use license. The amendment request shall include a written commitment that the licensee will, before conducting research:
1. Obtain review and approval of the research from an IRB, as defined and described in the federal policy; and
2. Obtain informed consent from the human research subject.

D. Before conducting the research described in subsection (A) the licensee shall apply to the Agency for and receive a specific amendment to its medical use license. The amendment request shall include a written commitment that the licensee will, before conducting research:
1. Obtain any review and approval required by this Section, and

2. Obtain informed consent from the human research subject if applicable.

E. Nothing in this Section relieves a licensee from complying with the other requirements in this Article.

Historical Note

Repealed effective June 30, 1977 (Supp. 77-3). Former Section R12-1-703 renumbered and amended as Section R12-1-704 effective December 20, 1985 (Supp. 85-6). Section repealed and new Section adopted by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 9 A.A.R. 1126, effective May 9, 2003 (Supp. 03-1). Amended by final rulemaking at 10 A.A.R. 2122, effective July 3, 2004 (Supp. 04-2). Section repealed; new Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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

A. A licensee's management shall appoint in writing a radiation safety officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. Each time the RSO is changed, the licensee shall provide to the Agency within 30 days an amendment request and a copy of the correspondence between the licensee's management and the candidate, accepting the position of RSO.

B. Licensees that are authorized for two or more different types of uses of radioactive material listed in Groups 300, 400, 600, and 1,000, or two or more types of units under group 600 or 1,000, shall establish a Radiation Safety Committee (RSC) to oversee all uses of radioactive material permitted by the license. At a minimum, the RSC shall include an authorized user of each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor a RSO.

C. If a licensee or applicant is not a health care institution and is unable to meet the RSC membership requirements in subsection (B), the licensee or applicant may request an exemption in accordance with A.R.S. § 30-654(B)(13). The request for exemption shall be made to the Agency in writing and list the reasons why the health care institution is unable to meet the requirements.

D. A licensee shall ensure that the RSC meets, at a minimum, on an annual basis and maintain the RSC meeting minutes for Agency review for three years after the date of the RSC meeting.

Historical Note

New Section adopted by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Section repealed; new Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1). Amended by final rulemaking at 20 A.A.R. 324, effective March 8, 2014 (Supp. 14-1).

R12-1-706. Supervision

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

B. A physician may use radioactive material if the person is licensed by the Arizona Medical Board or Board of Osteopathic Examiners in Medicine and Surgery and is listed as an authorized user on the Arizona radioactive material license under which the radioactive material is obtained.

C. A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user, shall:

1. Instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, rules, and license conditions with respect to the use of radioactive material; and
2. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures established by the licensee, written directive procedures, rules, and license conditions with respect to the medical use of radioactive material.

D. A licensee that permits the preparation of radioactive material for medical use by an individual who is supervised by an authorized nuclear pharmacist or a physician, who is an authorized user, shall:

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

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

F. A limited-service nuclear pharmacy licensee shall dispense radiopharmaceuticals only to a physician listed as an authorized user on a valid radioactive material license issued by the Agency, an Agreement State, or the NRC. For purposes of this rule "limited-service nuclear pharmacy" is defined in R4-23-110.

Historical Note

New Section adopted by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 10 A.A.R. 2122, effective July 3, 2004 (Supp. 04-2). Section repealed; new Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

R12-1-707. Written Directives

A. A licensee shall ensure that a written directive is dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 MBq (30 microcuries (μCi)), any therapeutic dosage of unsealed radioactive material or any therapeutic dose of radiation from radioactive material. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive shall be documented as soon as possible in writing in the patient's record. A written directive shall be prepared within 48 hours of the oral directive.

B. A written directive shall contain the patient or human research subject's name and the following information:
1. For any administration of quantities greater than 1.11 MBq (30 μCi) of sodium iodide I-131: the dosage;
2. For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide I-131: the radiopharmaceutical, dosage, and route of administration;
3. For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;
4. For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;
5. For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
6. For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:
   a. Before implantation: treatment site, the radionuclide, and dose; and
   b. After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

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

Historical Note

New Section adopted by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 9 A.A.R. 1126, effective May 9, 2003 (Supp. 03-1). Section repealed; new Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

R12-1-708. Procedures for Administrations Requiring a Written Directive

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.

Historical Note

New Section adopted by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Section repealed; new Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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

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

Historical Note

New Section adopted by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

R12-1-710. Radiation Safety Officer Training

A. A licensee shall require an individual fulfilling the responsibilities of the radiation safety officer, described in R12-1-705, to be an individual who:
1. Is certified by a specialty board whose certification process includes all of the requirements in subsection (A)(2) and whose certification has been recognized by the Agency, NRC, or an Agreement State. To have its certification process recognized, a specialty board shall require all candidates for certification to:
   a. Meet the following minimum requirements:
      i. Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;
      ii Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and
      iii. Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or
   b. Meet the following minimum requirements:

i. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
ii. Have two years of full-time practical training and/or supervised experience in medical physics;
(1) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or
(2) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users qualified under section R12-1-710(B), R12-1-721, or R12-1-723;
iii. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

2. Has completed a structured educational program consisting of both:
a. 200 hours of didactic and laboratory 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; or
c. Has obtained written certification, signed by a preceptor radiation safety officer, that the individual has satisfactorily completed the requirements in subsection (A)(2)(a) and (A)(2)(b) and has achieved a level of radiation safety knowledge sufficient to function independently as a radiation safety officer for a medical use licensee; or

3. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has radiation safety officer responsibilities.

B. Exceptions.
1. An individual identified as a radiation safety officer on an Agency, a NRC, or an Agreement State license or a permit issued by the NRC or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before the effective date of these rules need not comply with the training requirements in subsections (A)(1) through (A)(3).
2. A physician, dentist, or podiatrist identified as an authorized user for the medical use of radioactive material on a license issued by the Agency, NRC, or Agreement State, a permit issued by a NRC master material licensee, a permit issued by an Agency, NRC, or Agreement State broad scope licensee, or a permit issued by a NRC master material license broad scope permittee before the effective date of these rules need not comply with the training requirements in this Article.

C. The training and experience required in this Section shall be obtained within the seven years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

D. Individuals who, under subsection (B), need not comply with training requirements described in this Section may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.

Historical Note

New Section adopted by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Section repealed; new Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1). Amended by final rulemaking at 18 A.A.R. 1895, effective September 10, 2012 (Supp. 12-3). Amended by final rulemaking at 20 A.A.R. 324, effective March 8, 2014 (Supp. 14-1).

R12-1-711. Authorized Medical Physicist Training

A. A licensee shall require an authorized medical physicist to be an individual who:
1. Is certified by a specialty board whose certification process includes all of the training and experience requirements in subsection (A)(3)(b) and (A)(3)(c) and whose certification has been recognized by the Agency, NRC or an Agreement State; or
2. Training requirements.
a. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
b. Have two years of full-time practical training and/or supervised experience in medical physics:
i. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the NRC or an Agreement State; or

ii. In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in R12-1-710, R12-1-719, R12-1-721, R12-1-723, R12-1-727, R12-1-728, or R12-1-744; and

c. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

3. Training requirements alternative.

a. Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:

i. Performing sealed source leak tests and inventories;

ii. Performing decay corrections;

iii. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

iv. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

b. Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (A)(3)(c) and (A)(2)(a) and (A)(2)(b) and (A)(3)(c), or (A)(3)(a) and (A)(3)(c); 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 attestation must be signed by a preceptor authorized medical physicist who meets the requirements in section, or equivalent 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; and

c. Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

B. Exceptions. An individual identified as a teletherapy or medical physicist on an Agency, a NRC, or an Agreement State license or a permit issued by the NRC or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before the effective date of these rules need not comply with the training requirements in subsection (A).

C. The training and experience required in this Section shall be obtained within the seven years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

D. Individuals who, under subsection (B), need not comply with training requirements described in this Section may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.

Historical Note

New Section adopted by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Section repealed; new Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1). Amended by final rulemaking at 20 A.A.R. 324, effective March 8, 2014 (Supp. 14-1).

R12-1-712. Authorized Nuclear Pharmacist Training

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 has been recognized by the Agency, NRC, or an Agreement State. To have its certification process recognized, a specialty board shall require all candidates for certification to:

a. Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

b. Hold a current, active license to practice pharmacy in Arizona;

c. Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

d. Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

2. Has completed 700 hours in a structured educational program consisting of both:

a. 200 hours of classroom and laboratory 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 attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subsection (A)(2) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

B. Exceptions. An individual identified as a nuclear pharmacist on an Agency, a NRC or an Agreement State license or a permit issued by the NRC or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before the effective date of these rules need not comply with the training requirements in subsections (A)(1) through (A)(3).

C. The training and experience required in this Section shall be obtained within the seven years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

D. Individuals who, under subsection (B), need not comply with training requirements described in this Section may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.

Historical Note

New Section adopted by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 10 A.A.R. 2122, effective July 3, 2004 (Supp. 04-2). Section repealed; new Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1). Amended by final rulemaking at 20 A.A.R. 324, effective March 8, 2014 (Supp. 14-1). Amended by final rulemaking at 20 A.A.R. 324, effective March 8, 2014 (Supp. 14-1).

R12-1-713. Determination of Prescribed Dosages, and Possession, Use, and Calibration of Instruments

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

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

1. Direct measurement of radioactivity; or
2. Decay correction, based on the activity or activity concentration determined by
:
   a. A manufacturer or preparer licensed under R12-1-311 or equivalent NRC or Agreement State requirements; or
   b. An Agency, NRC, or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA or;
   c. A PET radioactive drug producer licensed under R12-1-311 or equivalent NRC or Agreement State requirements.

C. For other than unit dosages, this determination shall be made by:

1. Direct measurement of radioactivity;
2. Combination of measurement of radioactivity and mathematical calculations; or
3. Combination of volumetric measurements and mathematical calculations based on the measurement made by a manufacturer or preparer licensed under R12-1-311, or equivalent NRC or Agreement State requirements.

D. Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

E. A licensee shall retain a record of the dosage determination required by this Section for Agency inspection for three years.

F. For direct measurements performed in accordance with subsection (B)(1), a licensee shall possess and use instrumentation to measure the activity of the dosage before it is administered to each patient or human research subject.

G. A licensee shall calibrate the instrumentation required in subsection (F) in accordance with nationally recognized standards, the manufacturer's instructions, or the following procedures.

1. The procedures that may be followed are:
   a. Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use;
   b. Test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least two sealed sources containing different radionuclides whose activity the manufacturer has determined within 5 percent of its stated activity, whose activity is at least 10 microcuries for radium-226 and 50 microcuries for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;
   c. Test each dose calibrator for linearity upon installation and at least quarterly thereafter over a range from the highest dosage that will be administered to a patient or human research subject to 1.1 megabecquerels (30 microcuries);
   d. Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.
   e. Perform appropriate checks and tests required by this Section following adjustment or repair of the dose calibrator; and
   f. Mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.
2. A licensee shall maintain the dose calibrator in accordance with this subsection, even though the dose calibrator is only used to "verify" a dosage prepared by a supplier authorized in subsection (B)(2).
3. A licensee shall maintain on file for Agency review nationally recognized standards or manufacturer's instructions used to maintain a dose calibrator and meet the requirements of subsection (G).

H. A licensee shall calibrate the survey instruments before first use, annually, and following a repair that affects the calibration. A licensee shall:
1. Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source;
2. Calibrate two separated readings on each scale or decade that will be used to show compliance; and
3. Conspicuously note on the instrument the date of calibration.

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

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

Historical Note

New Section adopted by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 10 A.A.R. 2122, effective July 3, 2004 (Supp. 04-2). Section repealed; new Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1). Amended by final rulemaking at 20 A.A.R. 324, effective March 8, 2014 (Supp. 14-1).

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

Any person authorized by R12-1-703 for medical use of radioactive material may receive, possess, and use any of the following radioactive material for check, calibration, transmission, and reference use.
1. Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under Article 3 of this Chapter or equivalent NRC or Agreement State regulations.
2. Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under Article 3 of this Chapter, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.
3. Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).
4. Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 µCi) or 1000 times the quantities in Article 4, Appendix B of this Chapter.
5. Technetium-99m in amounts as needed.
6. A licensee is limited to five sources of radiation authorized under subsections (1) through (3), unless otherwise specified in the licensee's radioactive material license.

Historical Note

New Section adopted by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 9 A.A.R. 1126, effective May 9, 2003 (Supp. 03-1). Amended by final rulemaking at 10 A.A.R. 2122, effective July 3, 2004 (Supp. 04-2). Section repealed; new Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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

A. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.

B. A licensee in possession of a sealed source shall test the source for leakage in accordance with R12-1-417.

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

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

Historical Note

New Section adopted by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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

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

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

C. The licensee shall use engineering controls or shield each PET use area with protective barriers necessary to comply with the radiation exposure limits in R12-1-408 and R12-1-416.
1. At the time of application for a new license or amendment to an existing license, and before imaging of the first patient, the licensee shall provide to the Agency a copy of the installation report signed by the contractor who installed the shielding material recommended by a person meeting the requirements in subsection (B) and a copy of the installation radiation survey required in subsection (B).
2. The licensee shall perform shielding calculations in accordance with *AAPM Task Group 108: PET and PET/CT Shielding Requirements*, in Medical Physics, Vol. 33, No. 1, January 2006, which is incorporated by reference, published by the American

Association of Physicists in Medicine, One Physics Ellipse, College Park, MD 20740, and on file with the Agency. This incorporation by reference contains no future editions or amendments. In lieu of these procedures, the licensee may use equivalent calculations approved by the Agency.

D. As part of the annual ALARA review required in R12-1-407, the licensee shall document a review of the PET patient workload and associated change, if any, in public exposure resulting from the installed facility shielding and other public radiation exposure controls in use at the time of the review.

Historical Note

New Section adopted by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 10 A.A.R. 2122, effective July 3, 2004 (Supp. 04-2). Section repealed; new Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

R12-1-717. Release of Individuals Containing Radioactive Material or Implants Containing Radioactive Material

A. A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material, if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).

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

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

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

Historical Note

New Section adopted by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 9 A.A.R. 1126, effective May 9, 2003 (Supp. 03-1). Section repealed; new Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1). Amended by final rulemaking at 20 A.A.R. 324, effective March 8, 2014 (Supp. 14-1).

R12-1-718. Mobile Medical Service

A. A licensee providing mobile medical service shall:

1. Obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;
2. Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this subsection shall include a constancy check;
3. Check survey instruments for proper operation with a dedicated check source before use at each client's address; and
4. Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in Article 4 of this Chapter.

B. A mobile medical service may not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a license allowing its possession. If applicable, radioactive material delivered to the client shall be received and handled in conformance with the client's license.

C. A licensee providing mobile medical services shall retain the letter required in subsection (A)(1) and the record of each survey required in subsection (A)(4) for three years from the date of the survey.

Historical Note

New Section adopted by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 9 A.A.R. 1126, effective May 9, 2003 (Supp. 03-1). Section repealed; new Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

R12-1-719. Training for Uptake, Dilution, and Excretion Studies

A. Except as provided in R12-1-710, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under Group 100 to be a physician who:

1. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in subsection (A)(3). To have its certification process recognized, a specialty board shall require all candidates for certification to:
   a. Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in subsection (A)(3); and
   b. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or
2. Is an authorized user under R12-1-721, R12-1-723, NRC, or equivalent Agreement State requirements; or
3. Has completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

a. Classroom and laboratory 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. Work experience, under the supervision of an authorized user who meets the requirements in this Article, NRC, or equivalent Agreement State requirements, involving:
   i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
   ii. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
   iii. Calculating, measuring, and safely preparing patient or human research subject dosages;
   iv. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
   v. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
   vi. Administering dosages of radioactive drugs to patients or human research subjects; and
c. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements of R12-1-710, R12-1-719, R12-1-721, or R12-1-723, NRC, or equivalent Agreement State requirements; that the individual has satisfactorily completed the requirements in subsection (A)(1) or (A)(3) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Exhibit A of this Article.

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.

C. Individuals who, under R12-1-710(B), need not comply with training requirements described in this Section may serve as preceptors for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which these individuals are authorized.

Historical Note

New Section adopted by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Section repealed; new Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1). Amended by final rulemaking at 20 A.A.R. 324, effective March 8, 2014 (Supp. 14-1).

R12-1-720. Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations

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) or, more than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).

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 that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with subsection (A).

D. A licensee shall maintain a record of each molybdenum-99 concentration measurement or strontium-82 and strontium-85 concentrations measurements for three years following completion of the measurement.

Historical Note

New Section made by final rulemaking at 7 A.A.R. 2584, effective June 8, 2001 (Supp. 01-2). Section repealed; new Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1). Amended by final rulemaking at 20 A.A.R. 324, effective March 8, 2014 (Supp. 14-1).

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

A. Except as provided in R12-1-710, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under Group 200 to be a physician who:
1. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in subsection (A)(3). To have its certification process recognized, a specialty board shall require all candidates for certification to:
   a. Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in subsection (3); and
   b. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or
2. Is an authorized user under this Chapter and R12-1-723, NRC, or equivalent Agreement State requirements; or
3. Has completed 700 hours of training and experience, including a minimum of 80 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. Classroom and laboratory 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. Work experience, under the supervision of an authorized user who meets the requirements in R12-1-710, R12-1-721, or R12-1-723 and R12-1-721(A)(3)(b)(vii), NRC, or equivalent Agreement State requirements, involving:
i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
ii. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
iii. Calculating, measuring, and safely preparing patient or human research subject dosages;
iv. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
v. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
vi. Administering dosages of radioactive drugs to patients or human research subjects; and
vii. Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the elate for radionuclide purity, and processing the elate with reagent kits to prepare labeled radioactive drugs; and,

c. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements as an authorized user for Exhibit A group 200 nuclides, NRC, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in subsection (A)(1) or (A)(3) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Exhibit A of this Article.

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.

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1). Amended by final rulemaking at 20 A.A.R. 324, effective March 8, 2014 (Supp. 14-1).

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

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

B. For each patient or human research subject who cannot be released under R12-1-717, a licensee shall:
1. Quarter the patient or the human research subject in a private room with a private sanitary facility;
2. Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign.
3. Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and
4. Monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste.

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

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

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under Group 300 to be a physician who:
1. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in subsection (A)(2). To have its certification process recognized, a specialty board shall require all candidates for certification to:
a. Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in (A)(2). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and

b. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, and quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

2. 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 requiring a written directive. The training and experience must include:
   a. Classroom and laboratory 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. Work experience, under the supervision of an authorized user who meets the requirements in this Article, NRC, or equivalent Agreement State requirements, involving:
      i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
      ii. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
      iii. Calculating, measuring, and safely preparing patient or human research subject dosages;
      iv. Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
      v. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
      vi. Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:
         (1) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required (Experience with at least three cases in Category (A)(2)(b)(vi)(2) also satisfies this requirement);
         (2) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;
         (3) Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or
         (4) Parenteral administration of any other radionuclide, for which a written directive is required; and
   c. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements as an authorized user for Exhibit A group 300 nuclides, NRC, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in subsection (A)(1) or (A)(2) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Exhibit A of this Article. The written attestation must be signed by a preceptor authorized user who meets the requirements in this Section, NRC, or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in subsection (B) must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

B. Except as provided in R12-1-710, a licensee shall require an authorized user of iodine-131 for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) to be a physician who has completed the training requirements in 10 CFR 35.392, January 1, 2013, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.

C. Except as provided in R12-1-710, a licensee shall require an authorized user of iodine-131 for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries) to be a physician who has completed the training requirements in 10 CFR 35.394, January 1, 2013, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.

D. Except as provided in R12-1-710, a licensee shall require an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive to be a physician who has completed the training requirements in 10 CFR 35.396, January 1, 2013, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.

E. 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.

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1). Amended by final rulemaking at 20 A.A.R. 324, effective March 8, 2014 (Supp. 14-1).

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

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

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

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

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

E. A licensee shall record the procedures performed in subsections (A) through (D) and retain the records for three years following completion of the record.

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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

A. In addition to the training requirements in Article 10, a licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under R12-1-717. To satisfy this requirement, the instruction shall be commensurate with the duties of the personnel and include the:
1. Size and appearance of the brachytherapy sources;
2. Safe handling and shielding instructions;
3. Patient or human research subject control;
4. Visitor control, including both:
   a. Routine visitation of hospitalized individuals in accordance with Article 4 of this Chapter,
   b. Visitation authorized in accordance with Article 4 of this Chapter, and
5. Notification of the radiation safety officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

B. For each patient or human research subject who is receiving brachytherapy and cannot be released under R12-1-717, a licensee shall:
1. Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy;
2. Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and
3. Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

C. A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source:
1. Dislodged from the patient; and
2. Lodged within the patient following removal of the source applicators.

D. A licensee shall notify the radiation safety officer, or the RSO's designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

E. A licensee shall record the instructions given under subsection (A) and retain the records for three years after recording the instructions.

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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

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

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

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

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

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

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

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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

A. Except as provided in R12-1-710, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under this Article to be a physician who:

1. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in subsection (A)(2). To have its certification process recognized, a specialty board shall require all candidates for certification to:
   a. Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and
   b. Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or
2. Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:
   a. 200 hours of classroom and laboratory 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
   b. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this Section, or equivalent NRC or Agreement State requirements at a medical institution, involving:
      i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
      ii. Checking survey meters for proper operation;
      iii. Preparing, implanting, and removing brachytherapy sources;
      iv. Maintaining running inventories of material on hand;
      v. Using administrative controls to prevent a medical event involving the use of radioactive material;
      vi. Using emergency procedures to control radioactive material; and
   c. Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in this Section, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subsection (A)(2)(b); and
   d. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in this Section, NRC, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in subsection (A)(1) or (A)(2) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under Exhibit A of this Article.

B. Except as provided in R12-1-710, a licensee shall require an authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who has completed the training requirements in 10 CFR 35.491, January 1, 2013, incorporated by reference, and available under R12-1-101. This incorporated material 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.

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1). Amended by final rulemaking at 20 A.A.R. 324, effective March 8, 2014 (Supp. 14-1).

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

A. Except as provided in R12-1-710, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under Group 500 to be a physician, dentist, or podiatrist who

is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in subsections (A)(1) and (2); or

1. Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:
   a. Radiation physics and instrumentation;
   b. Radiation protection;
   c. Mathematics pertaining to the use and measurement of radioactivity;
   d. Radiation biology; and
2. Has completed training in the use of the device for the uses requested.

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.

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1). Amended by final rulemaking at 20 A.A.R. 324, effective March 8, 2014 (Supp. 14-1).

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

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

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

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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

A. Only a person specifically licensed by the Agency, NRC, or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on any source shielding, the source's driving unit, or other electronic or mechanical component that could expose a source, reduce the shielding around a source, or compromise the radiation safety of a unit or a source.

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

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

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

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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

A. A licensee shall:

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

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

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

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

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

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

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

F. A licensee shall maintain a copy of the procedures required by subsections (A)(4) and (C)(2) for Agency review. The copy shall be maintained for three years beyond the termination date of the activities for which the procedures were written.

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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

A. A licensee shall control access at each entrance to a treatment room.

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

1. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
2. Cause each source to be shielded when an entrance door is opened; and

3. Prevent any source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source's on-off control is reset at the console.

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

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

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

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

1. For medium dose-rate and pulsed dose-rate remote afterloader units, require:
   a. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during the initiation of all patient treatments involving the unit; and
   b. An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove each source applicator in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.
2. For high dose-rate remote afterloader units, require:
   a. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and
   b. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.
3. For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit. As used in this provision, physically present means to be within hearing distance of normal voice, and does not include the use of portable communication devices, intercoms, or other devices that could be used to amplify the human voice.
4. Notify the radiation safety officer, or radiation safety officer's designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

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

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

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

R12-1-733. Dosimetry Equipment

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

1. The system shall have been calibrated using a system or source traceable to the National Institute of Science and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration shall have been performed within the previous two years and after any servicing that may have affected system calibration; or
2. The system shall have been calibrated within the previous four years. Eighteen to 30 months after that calibration, the system shall have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison shall indicate that the calibration factor of the licensee's system had not changed by more than two percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

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

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

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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

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

1. Before the first medical use of the unit; and
2. Before medical use under the following conditions:
   a. Whenever spot-check measurements indicate that the output differs by more than 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 one month for cobalt-60, six 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 an authorized medical physicist.

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

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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

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

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

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

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

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

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

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

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

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

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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 one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

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

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

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

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

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

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

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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

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

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

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

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

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

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

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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

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

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

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

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

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

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

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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

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

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

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

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

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

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

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

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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

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

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

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

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

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

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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

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

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

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

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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.

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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.

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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

A. Except as provided in R12-1-710, a licensee shall require an authorized user of a sealed source for a use authorized under Group 600 to be a physician who:

1. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in subsection (A)(2). To have its certification process recognized, a specialty board shall require all candidates to:
   a. Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and
   b. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or
2. Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:
   a. 200 hours of classroom and laboratory 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. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this Section, or equivalent Agreement State or NRC requirements at a medical institution, involving:
      i. Reviewing full calibration measurements and periodic spot-checks;
      ii. Preparing treatment plans and calculating treatment doses and times;
      iii. Using administrative controls to prevent a medical event involving the use of radioactive material;
      iv. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
      v. Checking and using survey meters; and
      vi. Selecting the proper dose and how it is to be administered; and
   c. Has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in this Section, or equivalent Agreement State or NRC requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subsection (A)(2)(b); and
   d. Has obtained written attestation that the individual has satisfactorily completed the requirements in subsection (A)(1) or (A)(2), and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in this Section, or equivalent Agreement State or NRC requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and
   e. Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

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.

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1). Amended by final rulemaking at 20 A.A.R. 324, effective March 8, 2014 (Supp. 14-1).

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

A. A licensee shall report any "medical" event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material results in:

1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and
   a. The total dose delivered differs from the prescribed dose by 20 percent or more;
   b. The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
   c. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

2. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:
   a. An administration of a wrong radiopharmaceutical containing radioactive material;
   b. An administration of a radiopharmaceutical containing radioactive material by the wrong route of administration;
   c. An administration of a dose or dosage to the wrong individual or human research subject;
   d. An administration of a dose or dosage delivered by the wrong mode of treatment; or
   e. A leaking sealed source.
3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

B. A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

C. The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of the medical event.

D. The licensee shall submit a written report to the Agency within 15 days after discovery of the medical event.

1. The written report shall include:
   a. The licensee's name;
   b. The name of the prescribing physician;
   c. A brief description of the event;
   d. Why the event occurred;
   e. The effect, if any, on each individual who received the administration;
   f. What actions, if any, have been taken or are planned to prevent recurrence; and
   g. Certification that the licensee notified each individual (or the individual's responsible relative or guardian), and if not, why not.
2. The report may not contain an individual's name or any other information that could lead to identification of the individual.

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

F. Aside from the notification requirement, nothing in this Section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

G. A licensee shall:

1. Annotate a copy of the report provided to the Agency with the:
   a. Name of the individual who is the subject of the event; and
   b. Social Security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and
2. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

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

A. A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

B. A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

1. Is greater than 50 mSv (5 rem) total effective dose equivalent; or
2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

C. The licensee shall notify the Agency by telephone no later than the next calendar day after discovery of a dose to the embryo, fetus, or nursing child that requires a report in subsections (A) or (B).

D. The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo, fetus, or nursing child that requires a report in subsections (A) or (B). The written report shall include

:

1. The licensee's name;

2. The name of the prescribing physician;
3. A brief description of the event;
4. Why the event occurred;
5. The effect, if any, on the embryo/fetus or the nursing child;
6. What actions, if any, have been taken or are planned to prevent recurrence; and
7. Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

E. The report, required in subsection (D), shall not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

F. The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under subsections (A) or (B), unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee shall not delay any appropriate medical care for the embryo, fetus, or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this subsection, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide the written description upon request.

G. A licensee shall:

1. Make a copy of the report provided to the Agency and include with it the:
   a. Name of the pregnant individual or the nursing child who is the subject of the event; and
   b. Social Security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and
2. Provide the copy of the information required in subsection (G)(1) to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

Historical Note

New Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1).

Exhibit A. Medical Use Groups

Group 100

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

1. Obtained from a manufacturer or preparer licensed under R12-1-703(C)(2)(a), or equivalent NRC or Agreement State requirements; or
2. Obtained from a PET radioactive drug producer licensed under R12-1-703 or equivalent NRC or an Agreement State license excluding production of PET radionuclides prepared by an authorized nuclear pharmacist who meets the requirements in R12-1-712, a physician who is an authorized user and who meets the requirements specified in R12-1-721, or R12-1-723 and R12-1-721(A)(3)(b)(vii), or an individual under the supervision of either as specified in R12-1-706; or
3. If a research protocol:
   a 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
   b. 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 use in imaging and localization not requiring a written directive. PET radiopharmaceuticals may be used if the licensee meets the requirements in R12-1-716. The radioactive material in this group shall be:

1. Obtained from a manufacturer or preparer licensed under R12-1-703(C)(2)(a), or equivalent NRC or Agreement State requirements; or
2. Obtained from a PET radioactive drug producer licensed under R12-1-703 or equivalent NRC or an Agreement State license excluding production of PET radionuclides prepared by an authorized nuclear pharmacist who meets the requirements in R12-1-712, a physician who is an authorized user and who meets the requirements specified in R12-1-721 or R12-1-723 and R12-1-721(A)(3)(b)(vii), or an individual under the supervision of either as specified in R12-1-706; or
3. If a research protocol:
   a. Obtained from and prepared by an Agreement State or NRC 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; or
   b. 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 radioactive material in this group shall be:

1. Obtained from a manufacturer or preparer licensed under R12-1-703(C)(2)(a) or equivalent NRC or Agreement State requirements; or
2. Obtained from a PET radioactive drug producer licensed under R12-1-703 or equivalent NRC or an Agreement State license excluding production of PET radionuclides prepared by an authorized nuclear pharmacist who meets the requirements in R12-1-712, a physician who is an authorized user and who meets the requirements specified in R12-1-721 or R12-1-723, or an individual under the supervision of either as specified in R12-1-706; or
3. If a research protocol:
   a. 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
   b. 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 manufactured in accordance with R12-1-703(C)(2)(b) and:

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

Group 500

Included is the use of any sealed source that is manufactured in accordance with R12-1-703(C)(2)(b), and is approved for diagnostic use in the Sealed Source and Device Registry.

Group 600

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

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

Group 1000

A licensee may use radioactive material or a radiation source approved for medical use which is not specifically addressed in R12-1-309(A)(4) if:

1. The applicant or licensee has submitted the information required by this Article; and
2. The applicant or licensee has received written approval from the Agency in a license or license amendment and uses the material in accordance with the rules and specific conditions the Agency considers necessary for the medical use of the material.

Historical Note

New Exhibit adopted by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 10 A.A.R. 2122, effective July 3, 2004 (Supp. 04-2). Section repealed; new Section made by final rulemaking at 13 A.A.R. 1217, effective May 5, 2007 (Supp. 07-1). Amended by final rulemaking at 20 A.A.R. 324, effective March 8, 2014 (Supp. 14-1).

ARTICLE 13. LICENSE AND REGISTRATION FEES

R12-1-1301. Definition

"Combined" means the Agency has granted authorized activities contained in two or more license types in a single license document, requiring the payment of a single license fee for the more expensive license of the planned combination.

Historical Note

Adopted effective November 19, 1982 (Supp. 82-6). Amended effective November 28, 1983 (Supp. 83-6). Amended subsection (B) and added a new subsection (C) effective November 28, 1986 (Supp. 86-6). Section repealed, new Section adopted effective November 5, 1993 (Supp. 93-4). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2).

R12-1-1302. License and Registration Categories

A. Category A licenses are those specific licenses which authorize a school, college, university, or other teaching facility to possess and use radioactive materials for instructional or research purposes.

1. A broad academic class A license is any category A license which meets the specifications of R12-1-310(A)(1).
2. A broad academic class B license is any category A license other than a broad academic class A license which meets the specifications of R12-1-310(A)(2).
3. A broad academic class C license is any category A license other than a broad academic class A or B license which meets the specifications of R12-1-310(A)(3).
4. A limited academic license is any category A license which authorizes only those radioisotopes, forms, and quantities individually specified in the license.

B. Category B licenses are those specific or general licenses which authorize the application of radioactive material or the radiation from it to a human being for medical diagnostic, therapeutic, or research purposes, or the use of radioactive material in medical laboratory testing. Except for a type B6, general medical license, the Agency shall not combine a category B license with a license of any other category.

1. A broad medical license is any category B license which meets the specifications of R12-1-310(A)(1) and meets the requirements of 12 A.A.C. 1, Article 7. A broad medical license may authorize any medical use other than teletherapy.

2. A medical materials class A license is any specific category B license other than a broad medical license, which authorizes the use of radiopharmaceuticals and sealed sources containing radioactive materials for a therapeutic purpose in quantities which require hospitalization of the patient for radiation safety purposes. The license may authorize other radioactive materials and other medical uses, except teletherapy.
3. A medical materials class B license is any specific category B license which authorizes the diagnostic or therapeutic use, other than teletherapy, of radioactive materials only in limited quantities such that the patient need not be hospitalized for radiation safety purposes.
4. A medical materials class C license is any specific category B license which authorizes possession of specified radioisotopes only in the form of sealed sources for treatment of the eye or skin or for use in diagnostic medical imaging devices.
5. A medical teletherapy license is a specific category B license which solely authorizes radioisotopes in the form of multi-curie sealed sources for use in external beam therapy. The Agency shall not combine a medical teletherapy license with any other type of category B license.
6. A general medical license is a registration of the use of radioactive material pursuant to R12-1-306(D) or R12-1-306(E). A general medical license may be combined into a broad medical, medical materials class A, or medical materials class B license.

C. Category C licenses are those specific or general licenses authorizing the use of radioactive materials in any activity other than those authorized by a category A, B, or D license. Except as specifically authorized in this Section, the Agency shall not combine a category C license with any other type of license.

1. A broad industrial class A license is any category C license which meets the specifications of R12-1-310(A)(1). The Agency may combine a broad industrial class A license with any other category C license except industrial radiography, open field irradiator, or well logging licenses.
2. A broad industrial class B license is any category C license other than a broad industrial class A license which meets the specifications of R12-1-310(A)(2). The Agency may combine a broad industrial class B license with any other category C license except industrial radiography, open field irradiator, or well logging licenses.
3. A broad industrial class C license is any category C license other than a broad industrial class A or B license which meets the specifications of R12-1-310(A)(3). The Agency may combine a broad industrial class C license with any other category C license except industrial radiography, open field irradiator, or well logging licenses.
4. A limited industrial license is a specific category C license authorizing the possession of the radioactive materials authorized in R12-1-305(A), or R12-1-306(A), (C) or (F) for uses authorized in those subsections, but in quantities greater than authorized by those subsections.
5. A portable gauge license is a specific category C license which authorizes radioactive materials in the form of sealed sources for use in measuring or gauging devices designed and manufactured to be transported to the location of use. The Agency may combine a portable gauge license with any broad scope industrial license or a fixed gauge class A license.
6. A fixed gauge class A license is a specific category C license which authorizes the possession of 50 or more measuring or gauging devices containing radioactive materials, where each device is permanently mounted for use at a single location.
7. A fixed gauge class B license is a specific category C license which authorizes the possession of 1 through 49 measuring or gauging devices containing radioactive materials, where each device is permanently mounted for use at a single location.
8. A leak detector license is a specific category C license which authorizes the use of radioisotopes in the form of a gas to test hermetic seals on electronic packages.
9. A gas chromatograph license is a specific category C license which authorizes the use of radioactive materials as ionization sources in gas chromatography or electron capture devices.
10. A general industrial license means a registration of the use of a material, source, or device generally licensed pursuant to R12-1-305 or R12-1-306, except R12-1-305(B), R12-1-306(D), or R12-1-306(E).
11. An industrial radiography class A license is a specific category C license which authorizes industrial radiography using sealed radioisotope sources at specific facilities identified in the license conditions or at temporary field job sites.
12. An industrial radiography class B license is a specific category C license which authorizes industrial radiography using sealed radioisotope sources only at specific facilities identified in the license conditions.
13. An open field irradiator license is a specific category C license authorizing the use of radioisotopes in the form of sealed sources not permanently mounted within a shielding container, for irradiation of materials.
14. A self-shielded irradiator license is a specific category C license authorizing the use of radioisotopes in the form of sealed sources for irradiation of materials in a shielding device from which the sources are not removed during irradiation. The Agency may combine a self-shielded irradiator license with any broad license.
15. A well logging license is a specific category C license which authorizes the use of radioactive material in sealed or unsealed sources for wireline services or field tracer studies.
16. A research and development license is a specific category C license which authorizes a licensee to utilize radioactive material in unsealed and sealed form for industrial, scientific, or biomedical research, not including administration of radiation or radioactive material to human beings.
17. A laboratory license is a specific category C license which authorizes a licensee to perform specific in-vitro or in-vivo medical or veterinary testing, while possessing quantities of radioactive material greater than the general license quantities authorized in R12-1-306.

D. Category D licenses are the following specific radioactive material licenses. Except for type D4, general industrial; type D5, depleted uranium; type D8 and D9, health physics; and type D14, additional facilities licenses, the Agency shall not combine a category D license with any other license.

1. A distribution license is one which authorizes the commercial distribution of radioactive materials or radioisotopes in products to persons holding an appropriate general or specific license. The Agency shall ensure that a distribution license does not:
   a. Authorize distribution of radiopharmaceuticals or distribution to persons exempt from regulatory control, or
   b. Authorize any other use of the radioactive material. An appropriate category C license is required for possession of radioisotopes and their incorporation into products.
2. A nuclear pharmacy license is one which authorizes the preparation, compounding, packaging, or dispensing of radiopharmaceuticals for use by other licensees.
3. A nuclear laundry license is one authorizing the collection and cleaning of items contaminated with radioactive materials.
4. A general industrial license is a registration of a gauging device in accordance with R12-1-306(A). The Agency may combine a general industrial license with a Class A, B, or C broad industrial, limited industrial, portable gauge, or Class A or B fixed gauge license.
5. A depleted uranium general license is a registration of the use of the general license authorized pursuant to R12-1-305(C) or the use of depleted uranium as a concentrated mass or as shielding for another radiation source within a device or machine. The Agency may combine a depleted uranium general license with a medical teletherapy; Class A, B, or C broad industrial; portable gauge; Class A or B fixed gauge; Class A or B industrial radiography; or self-shielded irradiator license. For registration purposes an applicant shall follow the registration instructions in R12-1-305(C).
6. A veterinary medicine license is one which authorizes the use of radioactive materials for specific applications in veterinary medicine as authorized in the license.
7. A general veterinary medicine license is a registration of the use of the general license authorized in R12-1-306(E) in veterinary medicine.
8. A health physics class A license is one which authorizes the use of radioactive materials for performing instrument calibrations, processing leak test or environmental samples, or providing radiation dosimetry services.
9. A health physics class B license is one which authorizes only the collection, possession, and transfer of radioactive materials in the form of leak test samples for processing by others.
10. A secondary uranium recovery license is one which authorizes the extraction of natural uranium or thorium from an ore stream or tailing which is being or has been processed primarily for the extraction of another mineral. The Agency shall not combine a secondary uranium recovery license with any other license.
11. A low-level, radioactive waste disposal facility license is a license that is issued for a "disposal facility," as that term is used in R12-1-439 and R12-1-442, which has a closure or long-term care plan and is constructed and operated according to the requirements in 10 CFR 61, revised January 1, 2015, incorporated by reference, and available under R12-1-101. This incorporated material contains no future editions or amendments.
12. A waste processor class A license is one authorizing the incineration, compaction, repackaging, or any other treatment or processing of low-level radioactive waste prior to transfer to another person authorized to receive or dispose of the waste. The Agency shall not combine a waste processor class A license with any other license.
13. A waste processor class B license is one which authorizes a waste broker to receive prepackaged, low-level radioactive waste from other licensees; combine the waste into shipments; and transfer the waste without treating or processing the waste in any manner and without repackaging except to place damaged or leaking packages into overpacks. The Agency shall not combine a waste processor class B license with any other license.
14. An additional facility license is an endorsement, by license condition to an existing specific license, authorizing one or more additional separate facilities where radioactive material may be stored or used for a period exceeding six months.
15. A possession-only license is a license of any other category which authorizes only the possession in storage, but no use of, the authorized materials. A license which has been suspended as an enforcement action is not considered a possession-only license.
16. A reciprocal license is the registration of the general license authorized by R12-1-320. This license is subject to a special fee as provided by R12-1-1307 but is exempt from annual fees.
17. Reserved
18. An "unclassified" radioactive material license is one authorizing radioisotopes, physical or chemical forms, possession limits, or uses not included in any other type of license specified in this Section.
19. A NORM commercial disposal site license is one that authorizes the receipt of waste material contaminated with naturally occurring radioactive material from other licensees for permanent disposal, provided the concentration of the radioactive material does not exceed 74kBq (2,000 picocuries)/gram.

E. Category E registrations are those that register the possession of x-ray machine(s) under 12 A.A.C. 1, Article 2. The Agency shall not combine Category E registrations with any other registration.

1. An X-ray machine class A registration is one authorizing the possession of X-ray machines in a hospital or other facility offering inpatient care.
2. An X-ray machine class B registration is one authorizing the possession of X-ray machines in a medical, osteopathic, or chiropractic office or clinic not offering inpatient care; or the possession of X-ray machines in a school, college, university, or other teaching facility.
3. An X-ray machine class C registration is one authorizing the possession of X-ray machines in dental, podiatry, and veterinarian offices or clinics.
4. An industrial radiation machine registration is one authorizing the possession of X-ray machines, or the possession of particle accelerators not capable of producing a high radiation area, in a nonmedical facility.

5. An accelerator facility registration is one authorizing the possession and operation of one or more particle accelerators of any kind capable of accelerating any particle and producing a high radiation area.
6. A radiation machine, "other," is one authorizing possession or use of an ionizing radiation machine not included in any other category specified in subsection (E).

F. Category F registrations are those that register nonionizing radiation producing sources regulated under 12 A.A.C. 1, Article 14. The Agency shall not combine Category F registrations with any other registration categories that have a difference in fee per unit.

1. A tanning registration authorizes the commercial operation of any number of tanning booths, beds, cabinets, or other devices in a single establishment.
2. A Class A laser registration authorizes the operation of one to 10 laser devices subject to R12-1-1433.
3. A Class B laser registration authorizes the operation of 11 to 49 laser devices subject to R12-1-1433.
4. A Class C laser registration authorizes operation of 50 or more laser devices subject to R12-1-1433.
5. A laser light show registration authorizes the operation of a laser device subject to R12-1-1441.
6. A medical laser registration authorizes the operation of one or more laser devices subject to R12-1-1440.
7. A Class II surgical device registration authorizes the operation of one or more Class II surgical devices subject to R12-1-1438. A device is designated as a Class II surgical device by the USFDA and is labeled as such by the manufacturer.
8. A medical radiofrequency device registration authorizes the operation of one or more medical radiofrequency devices.
9. A class A industrial radiofrequency device registration authorizes the operation of one to five radiofrequency heat sealers or industrial microwave ovens.
10. A class B industrial radiofrequency device registration authorizes the operation of six to 20 radiofrequency heat sealers or industrial microwave ovens.
11. A class C industrial radiofrequency device registration authorizes the operation more than 20 radiofrequency heat sealers or industrial microwave ovens.
12. A class A medical radiofrequency device registration authorizes the operation of one or two radiofrequency diathermy or electrocoagulation units not used in non-ionizing cosmetic procedures.
13. A class B medical radiofrequency device registration authorizes the operation of three to nine radiofrequency diathermy or electrocoagulation units not used in non-ionizing cosmetic procedures.
14. A class C medical radiofrequency device registration authorizes the operation of 10 to 19 radiofrequency diathermy or electrocoagulation units not used in non-ionizing cosmetic procedures.
15. A class D medical radiofrequency device registration authorizes the operation of 20 or more radiofrequency diathermy or electrocoagulation units not used in non-ionizing cosmetic procedures.
16. An "other" nonionizing radiation device authorizes the operation of a nonionizing radiation device or other device not included in any other category specified in subsection (F).

Historical Note

Adopted effective November 19, 1982 (Supp. 82-6). Amended effective November 28, 1983 (Supp. 83-6). Section repealed, new Section adopted effective November 5, 1993 (Supp. 93-4). Amended effective June 13, 1997 (Supp. 97-2). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 9 A.A.R. 1126, effective May 9, 2003 (Supp. 03-1). Amended by final rulemaking at 10 A.A.R. 2122, effective July 3, 2004 (Supp. 04-2). Amended by final rulemaking at 11 A.A.R. 978, effective April 3, 2005 (05-1). Amended by final rulemaking at 12 A.A.R. 75, effective February 7, 2006 (Supp. 05-4). Amended by exempt rulemaking at 14 A.A.R. 4243, effective November 17, 2008 (Supp. 08-4). Amended by final rulemaking at 21 A.A.R. 289, effective April 6, 2015 (Supp. 15-1). Amended by final rulemaking at 22 A.A.R. 603, effective February 2, 2016 (Supp. 16-1).

R12-1-1303. Fee for Initial License and Initial Registration

An applicant shall remit for a new license or new registration the appropriate fee as prescribed in R12-1-1306.

Historical Note

Adopted effective November 19, 1982 (Supp. 82-6). Amended effective November 28, 1983 (Supp. 83-6). Amended subsections (A), (C), and (D) effective November 28, 1986 (Supp. 86-6). Section repealed, new Section adopted effective November 5, 1993 (Supp. 93-4). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by exempt rulemaking at 14 A.A.R. 4243, effective November 17, 2008 (Supp. 08-4).

R12-1-1304. Annual Fees for Licenses and Registrations

A. Each license or registration issued by the Agency shall identify the category by a letter and number corresponding to the appropriate subsection of R12-1-1302 or category type listed in R12-1-1306.

B. Except for types D16 and D17, each licensee or registrant shall submit payment of the annual fee in the amount prescribed in R12-1-1306(A) on or before January 1 of each year. This single annual fee will cover any and all renewals, amendments, and regular inspections of the license during the forthcoming calendar year.

C. If a licensee or registrant fails to pay the annual fee by January 1, the license is not current.

D. If a licensee or registrant fails to pay the annual fee by April 1, the Agency shall apply administrative sanction provisions of 12 A.A.C. 1, Article 12.

E. A licensee who is required to pay an annual fee under this Article may qualify as a small entity. If a licensee qualifies as a small entity and provides the Agency with proper certification along with its annual fee payment, the licensee may pay reduced annual fees as shown in Table 1 to this Article. Failure to file a small entity certification in a timely manner may result in the denial of any refund.

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Historical Note

Adopted effective November 5, 1993 (Supp. 93-4). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by exempt rulemaking at 14 A.A.R. 4243, effective November 17, 2008 (Supp. 08-4).

R12-1-1305. Method of Payment

A. An applicant licensee or registrant shall pay fees by check or money order, payable to the "State of Arizona" at the address shown on the application, license, registration, or renewal notice.

B. Once a license or registration has been issued, no portion of the application fee or any annual fee will be refunded.

Historical Note

Adopted effective November 5, 1993 (Supp. 93-4). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2).

R12-1-1306. Table of Fees

A. The application and annual fee for each category and type are shown in Table 13-1.

Table 13-1

Category	Type		Annual fee
	A1.	Broad academic class A	$5,800
	A2.	Broad academic class B	$5,800
	A3.	Broad academic class C	$5,800
	A4.	Limited academic	$1,000
	B1.	Broad medical	$11,000
	B2.	Medical materials class A	$1,900
	B3.	Medical materials class B	$1,900
	B4.	Medical materials class C	$1,900
	B5.	Medical teletherapy	$5,200
	B6.	General medical	$250
C1.		Broad industrial class A	$11,400
C2.		Broad industrial class B	$11,400
C3.		Broad industrial class C	$3,200
C4.		Limited industrial	$700
C5.		Portable gauge	$1,000
C6.		Fixed gauge class A	$1,000
C7.		Fixed gauge class B	$1,000
C8.		Leak detector	$1,330
C9.		Gas chromatograph	$1,000
C10.		General industrial	No Fee
C11.		Industrial radiography class A	$5,500
C12.		Industrial radiography class B	$5,500
C13.		Open field irradiator	$3,000
C14.		Self-shielded irradiator	$1,500
C15.		Well logging	$2,000
C16.		Research and development	$2,100
C17.		Laboratory	$1,000
D1.		Distribution	$2,600
D2.		Nuclear pharmacy	$4,600
D3.		Nuclear laundry	$10,300
D4.		General industrial (with fee)	$300
D5.		General depleted uranium	$200
	D6.	Veterinary medicine	$1,000
	D7.	General veterinary medicine	$200
	D8.	Health physics class A	$3,200
	D9.	Health physics class B	$1,000
	D10.	Secondary uranium recovery	$5,100
	D11.	Low-level radioactive waste disposal site	(3)
	D12.	Waste processor class A	$4,600
	D13.	Waste processor class B	$3,600
	D14.	Additional storage and use site	(1)
	D15.	Possession only	(2)
	D16.	Reciprocal	(3)
	D17.	Reserved	

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D18.	Unclassified	Full Cost
D19.	NORM commercial disposal site	$600,000
E1.	X-ray machine class A (per tube)	$75
E2.	X-ray machine class B (per tube)	$51
E3.	X-ray machine class C (per tube)	$42
E4.	Industrial radiation machine (per device)	$42
E5.	Accelerator facility	$750
E6.	Other ionizing radiation machine	Full Cost
F1.	Tanning device (per device)	$28
F2.	Class A (1 to 10 laser devices)	$175
F3.	Class B (11 to 49 laser devices)	$408
F4.	Class C (50 or more laser devices)	$699
F5.	Laser light show or laser demonstration	$408
F6.	Medical laser (per laser device)	$47
F7.	Class II surgical (per device)	$47
F8.	Medical RF surgical and cosmetic (per device)	$47
F9.	Class A industrial (1 to 5 radiofrequency devices)	$70
F10.	Class B industrial (6 to 20 radiofrequency devices)	$210
F11.	Class C industrial more than 20 radiofrequency devices)	$349
F12.	Class A medical (1 or 2 non-cosmetic radiofrequency devices) (per device)	$0
F13.	Class B medical (3 to 9 non-cosmetic radiofrequency devices)	$0
F14.	Class C medical (10 to 19 non-cosmetic radiofrequency devices)	$0
F15.	Class D medical (20 or more non-cosmetic radiofrequency devices)	$0
F16.	Other nonionizing radiation device or other device	Full Cost

Notes: (1) An additional 30% of the annual base fee is added to the annual base fee for each additional site.
(2) The fee is 50% of the annual base fee for the category under which the radioactive material will be stored.
(3) See R12-1-1307.

B. The application fee for a licensee or registrant is the annual fee as shown in R12-1-1306. “Full Cost” is based on professional personnel time for preparation, travel, onsite inspection, any reports, review of findings, and preparation of the license or registration or denial charged at $99 per hour and mileage charged at 44.5¢ per mile. The Agency shall assess the licensee or registrant 90% of the estimated full cost of issuing the license or registration. The Agency will assess for any remaining costs when it is prepared to issue the license, registration, denial, or if Agency costs for the requested activity exceed $10,000.

C. The annual fee for a licensee or registrant for which the scheduled fee is “Full Cost” is based on professional personnel time for preparation, travel, onsite inspection, preparation of reports, review of findings, and preparation for any inspections or completion of any amendments to the license, registration or denials charged at $99 per hour and mileage charged at 44.5¢ per mile for the preceding 12 months.

Historical Note

Amended effective November 5, 1993 (Supp. 93-4). Amended effective June 13, 1997 (Supp. 97-2). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by final rulemaking at 9 A.A.R. 1126, effective May 9, 2003 (Supp. 03-1). Amended by final rulemaking at 12 A.A.R. 75, effective February 7, 2006 (Supp. 05-4). Amended by exempt rulemaking at 14 A.A.R. 4243, effective November 17, 2008 (Supp. 08-4). Amended by final rulemaking at 21 A.A.R. 289, effective April 6, 2015 (Supp. 15-1).

R12-1-1307. Special License Fees

A. The fee for a Type D16 license providing reciprocal recognition under R12-1-320 of a radioactive materials license issued by the U.S. NRC or another state is half of the annual fee for an Arizona license of the appropriate type. The fee is due and payable at the time reciprocity is requested, and the general license does not become current until the fee is paid.

B. For a low-level radioactive waste disposal site the initial application fee is $6,000,000. The annual fee for the second through fifth years is $6,000,000. The Agency shall promulgate a new fee rule for years subsequent to year five. Based on data gathered during the first five years, the Agency shall set a reasonable fee after consideration of the following factors:

1. Unrecovered costs which the Agency may charge under A.R.S. § 30-654(B)(18).
2. Actual costs incurred by the Agency.

Historical Note

Adopted effective November 5, 1993 (Supp. 93-4). Amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by exempt rulemaking at 14 A.A.R. 4243, effective November 17, 2008 (Supp. 08-4).

R12-1-1308. Fee for Requested Inspections

A. A licensee or registrant may request an inspection of its facility at any time. The Agency shall assess the licensee or registrant the full cost of the inspection, based on personnel time for preparation, travel, onsite inspection, review of findings, and preparation of a report, charged at $99 per hour and mileage charged at 44.5¢ per mile.

B. The fee specified in this Section does not apply to:
1. Regular inspections as scheduled by the Agency,
2. Enforcement reinspections conducted to ensure the correction of violations or safety hazards, or
3. Inspections requested by workers pursuant to R12-1-1007.

Historical Note

Adopted effective November 5, 1993 (Supp. 93-4). Amended by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2). Amended by exempt rulemaking at 14 A.A.R. 4243, effective November 17, 2008 (Supp. 08-4).

R12-1-1309. Abandonment of License or Registration Application

A. Any license or registration application for which the applicant has been provided a written notification of deficiencies in the application and for which the applicant does not make a written attempt to supply the requested information or request an extension in writing within 90 days of the date of the written notice of deficiencies, is considered abandoned and will not be processed.

B. If an applicant does not act in the time-frame specified in subsection (A), the applicant shall submit a new application with the appropriate fee.

Historical Note

New Section adopted by final rulemaking at 5 A.A.R. 1817, effective May 12, 1999 (Supp. 99-2).

Table 1. Small Entity Fees[1]

Small Businesses Not Engaged in Manufacturing and Small Not-for-profit Organizations (Gross Annual Receipts, three-year average):	
>$6.5 million	Pay the fee listed in R12-1-1306
$350,000 to $6.5 million	$2,200
<$350,000	$500
Manufacturing Entities that Have an Annual Average of 500 Employees or Less:	
>500 employees	Pay the fee listed in R12-1-1306
35 to 500 employees	$2,200
<35 employees	$500
Small Government Jurisdictions (including publicly supported educational institutions) (Population in Jurisdiction):	
>50,000	Pay the fee listed in R12-1-1306
20,000 to 50,000	$2,200
<20,000	$500
Educational Institutions that Are Not State or Publicly Supported, and Have 500 Employees or Less:	
>500 employees	Pay the fee listed in R12-1-1306
35 to 500 employees	$2,200
<35 employees	$500

1. A licensee who seeks to establish status as a small entity for the purpose of paying the annual fees required under R12-1-1304 as shown in R12-1-1306 must file a certification statement with the Agency each year. The licensee must file the required certification on Agency Form 333 for each license under which it was billed. Agency Form 333 can be accessed through the Agency web site at http://www.azrra.gov. For licensees who cannot access the Agency web site, Agency Form 333 may be obtained by writing to the Agency or by telephoning the Agency at (602) 255-4845, or by e-mailing the Agency at webcontactform@arrawebsite.com.

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Historical Note
New Table made by exempt rulemaking at 14 A.A.R. 4243, effective November 17, 2008 (Supp. 08-4).

30-654. Powers and duties of the agency

A. The agency may:

1. Accept grants or other contributions from the federal government or other sources, public or private, to be used by the agency to carry out any of the purposes of this chapter.

2. Do all things necessary, within the limitations of this chapter, to carry out the powers and duties of the agency.

3. Conduct an information program, including but not limited to:

(a) Providing information on the control and regulation of sources of radiation and related health and safety matters, on request, to members of the legislature, the executive offices, state departments and agencies and county and municipal governments.

(b) Providing such published information, audiovisual presentations, exhibits and speakers on the control and regulation of sources of radiation and related health and safety matters to the state's educational system at all educational levels as may be arranged.

(c) Furnishing to citizen groups, on request, speakers and such audiovisual presentations or published materials on the control and regulation of sources of radiation and related health and safety matters as may be available.

(d) Conducting, sponsoring or cosponsoring and actively participating in the professional meetings, symposia, workshops, forums and other group informational activities concerned with the control and regulation of sources of radiation and related health and safety matters when representation from this state at such meetings is determined to be important by the agency.

B. The agency shall:

1. Regulate the use, storage and disposal of sources of radiation.

2. Establish procedures for purposes of selecting any proposed permanent disposal site located within this state for low level radioactive waste.

3. Coordinate with the department of transportation and the corporation commission in regulating the transportation of sources of radiation.

4. Assume primary responsibility for and provide necessary technical assistance to handle any incidents, accidents and emergencies involving radiation or sources of radiation occurring within this state.

5. Adopt rules deemed necessary to administer this chapter in accordance with title 41, chapter 6.

6. Adopt uniform radiation protection and radiation dose standards to be as nearly as possible in conformity with, and in no case inconsistent with, the standards contained in the regulations of the United States nuclear regulatory commission and the standards of the United States public health service. In the adoption of the standards, the agency shall consider the total occupational radiation exposure of individuals, including that from sources not regulated by the agency.

7. Adopt rules for personnel monitoring under the close supervision of technically competent people in order to determine compliance with safety rules adopted under this chapter.

8. Adopt a uniform system of labels, signs and symbols and the posting of the labels, signs and symbols to be affixed to radioactive products, especially those transferred from person to person.

9. By rule require adequate training and experience of persons utilizing sources of radiation with respect to the hazards of excessive exposure to radiation in order to protect health and safety.

10. Adopt standards for the storage of radioactive material and for security against unauthorized removal.

11. Adopt standards for the disposal of radioactive materials into the air, water and sewers and burial in the soil in accordance with 10 Code of Federal Regulations part 20.

12. Adopt rules applicable to the shipment of radioactive materials in conformity with and compatible with those established by the United States nuclear regulatory commission, the department of transportation, the United States treasury department and the United States postal service.

13. In individual cases, impose additional requirements to protect health and safety or grant necessary exemptions which will not jeopardize health or safety, or both.

14. Make recommendations to the governor and furnish such technical advice as required on matters relating to the utilization and regulation of sources of radiation.

15. Conduct or cause to be conducted off-site radiological environmental monitoring of the air, water and soil surrounding any fixed nuclear facility, any uranium milling and tailing site and any uranium leaching operation, and maintain and report the data or results obtained by the monitoring as deemed appropriate by the agency.

16. Develop and utilize information resources concerning radiation and radioactive sources.

17. Prescribe by rule a schedule of fees to be charged to categories of licensees and registrants of radiation sources, including academic, medical, industrial, waste, distribution and imaging categories. The fees shall cover a significant portion of the reasonable costs associated with processing the application for license or registration, renewal or amendment of the license or registration and the costs of inspecting the licensee or registrant activities and facilities, including the cost to the agency of employing clerical help, consultants and persons possessing technical expertise and using analytical instrumentation and information processing systems.

18. Adopt rules establishing radiological standards, personnel standards and quality assurance programs to assure the accuracy and safety of screening and diagnostic mammography.

C. All fees collected under subsection B, paragraph 18 shall be deposited, pursuant to sections 35-146 and 35-147, in the state general fund.

30-657. Records

A. Each person who possesses or uses a source of radiation shall maintain records relating to its receipt, storage, transfer or disposal and such other records as the agency provides by rules and regulations.

B. The agency shall require each person who possesses or uses a source of radiation to maintain appropriate records showing the radiation exposure of all individuals for whom personnel monitoring is required by rules and regulations promulgated by the agency. Copies of records required by this section shall be submitted to the agency on request by the agency.

C. Any person who possesses or uses a source of radiation shall furnish to each employee for whom personnel monitoring is required a copy of the employee's personal exposure record at such times as prescribed by rules and regulations promulgated by the agency.

D. Any person who possesses or uses a source of radiation shall, when requested, submit to the agency copies of records or reports submitted to the United States nuclear regulatory commission regardless of whether the person is subject to regulation by the agency. The agency shall, by rule and regulation, specify the records or reports required to be submitted to the agency under this subsection.

30-671. Exceptions; radiation standards

A. Radiation protection standards adopted in rules and regulations promulgated by the agency under this chapter shall not be construed to limit the kind or amount of radiation that may be intentionally applied to a person or animal for diagnostic or therapeutic purposes by or under the direction of a licensed practitioner of the healing arts.

B. Radiation sources shall be registered, licensed or exempt at the discretion of the agency and shall be available for inspection as specified in this chapter or rules and regulations adopted under this chapter.

30-672. Licensing and registration of sources of radiation; exemptions

A. The agency by rule shall provide for general or specific licensing of by-product, source, special nuclear materials or devices or equipment utilizing such materials. The rules shall provide for amendment, suspension or revocation of the licenses. The agency shall require from the applicant satisfactory evidence that the applicant is using methods and techniques that are demonstrated to be safe and that the applicant is familiar with the rules adopted by the agency under section 30-654, subsection B, paragraph 5 relative to uniform radiation standards, total occupational radiation exposure norms, labels, signs and symbols, storage, waste disposal and shipment of radioactive materials. The agency may require that before the agency issues a license the employees or other personnel of an applicant who may deal with sources of radiation receive a course of instruction approved by the agency concerning agency rules. The agency shall require that the applicant's proposed equipment and facilities be adequate to protect health and safety and that the applicant's proposed administrative controls over the use of the sources of radiation requested be adequate to protect health and safety.

B. The agency may require registration or licensing of other sources of radiation if it has been determined necessary to protect public health or safety.

C. The agency may exempt certain sources of radiation or kinds of uses or users from the licensing or registration requirements set forth in this section when it finds that the exemption of such sources of radiation or kinds of uses or users will not constitute a significant risk to the health and safety of the public.

D. The agency shall not require persons licensed in this state to practice as a dentist, physician assistant, chiropodist or veterinarian or licensed in this state to practice medicine, surgery, osteopathy, chiropractic or naturopathic medicine to obtain any other license for the use of a diagnostic x-ray machine, but these persons are governed by their own licensing acts.

E. Persons licensed by the federal communications commission with respect to the activities for which they are licensed by that commission are exempted from this chapter.

F. Rules adopted pursuant to this chapter may provide for recognition of other state or federal licenses as the agency deems desirable, subject to such registration requirements as the agency prescribes.

G. Any licenses issued by the agency shall state the nature, use and extent of use of the source of radiation. If at any time subsequent to the issuance of a license the licensee desires any change in the nature, use or extent, the licensee shall seek an amendment or a new license under this section.

H. The agency shall prescribe by rule requirements for financial security as a condition for licensure under this article. The agency shall deposit all amounts posted, paid or forfeited as financial security into the radiation regulatory and perpetual care fund under section 30-694.

I. Persons applying for licensure shall provide notice to the city or town where the applicant proposes to operate as part of the application process.

J. Any facility that provides diagnostic or screening mammography examinations by or under the direction of a person exempted from further licensure under subsection D of this section shall obtain certification by the agency. The agency shall prescribe by rule the requirements of certification in order to ensure the accuracy and safety of diagnostic and screening mammography.

30-672.01. Registration of persons who install or service radiation machines; exception; roster

A. A person who is in the business of installing or servicing radiation machines which are defined in section 30-651 and which are required to be registered by the agency shall register with the agency on a form provided by the agency.

B. Notwithstanding subsection A, a person who is subject to the jurisdiction of the medical radiologic technology board of examiners and is engaged in operation of a radiation machine shall not be required to register with the agency.

C. The registration form required pursuant to subsection A shall be limited to the following information:

1. The full business name of the registrant.

2. The names of the owners if the registrant is a corporation or partnership.

3. The names of employees who carry out installation or service work for the registrant.

4. The business address of the registrant.

D. The agency shall maintain a roster of all registrants, including the date of initial registration. The roster shall be available for public inspection.

E. A registrant must reregister with the agency whenever there is a change in the information provided under subsection C.

30-673. Unlawful acts

It is unlawful for any person to receive, use, possess, transfer, install or service any source of radiation unless registered, licensed or exempted by the agency in accordance with this chapter and rules and regulations adopted under this chapter.