

Five-year Review of Article 1, & 15
ARRA
April 20, 2016

FIVE-YEAR-REVIEW REPORT
TITLE 12. NATURAL RESOURCES
CHAPTER 1. RADIATION REGULATORY AGENCY

ARTICLE 1. GENERAL PROVISIONS
ARTICLE 15. TRANSPORTATION

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FIVE-YEAR-REVIEW SUMMARY

The rules contained in Article 1 provide general definitions used throughout the chapter, prohibitions on radiation uses and a general dose table used in all sections of the chapter. These rules were developed to provide standards as set forth by the Agreement signed by Arizona and the Nuclear Regulatory Agency (NRC) as well as general portions of the Suggested State Regulations (SSR's) for control of radiation as presented by the Conference of Radiation Control Program Directors (CRCPD).

The rules contained in Article 15 provide standards for transportation of radioactive material in accordance with NRC regulations and the federal Department of Transportation (DOT). These rules were developed to meet standards as set forth by Part A and T 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 1

R12-1-104, R12-1-105, and R12-1-106 were last amended in 2003. R12-1-207 was last amended in 2004. R12-1-101, and R12-1-103 were last amended in 2009. R12-1-102 was last amended in 2016.

Article 15

R12-1-1502 through R12-1-1508, R12-1-1511, and R12-1-1515 were last amended in 2009. R12-1-1501, R12-1-1509 through R12-1-1510, and R12-1-1513 were last amended in 2012. R12-1-1512 was last amended in 2016.

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 2011 to current date.

FIVE-YEAR-REVIEW REPORT
TITLE 12. NATURAL RESOURCES
CHAPTER 1. RADIATION REGULATORY AGENCY

ARTICLE 1. GENERAL PROVISIONS

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R12-1-1508. Advance Notification of Nuclear Waste Transportation

R12-1-1509. General License: Plutonium-Beryllium Special Form Material

R12-1-1510. Packaging

R12-1-1511. Air Transportation of Plutonium

R12-1-1512. Advance Notification of Shipment of Irradiated Reactor Fuel and Nuclear Waste

R12-1-1513. Opening Instructions

R12-1-1514. Reserved

R12-1-1515. Exemption for Low-level Radioactive Materials

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 1 and 15 consistent with other relevant agency rules posted in Title 12 and with federal statutes and regulations in accordance with the Agreement State document that Arizona entered into with the U.S. Nuclear Regulatory Commission (formerly the Atomic Energy Commission) authorized by A.R.S. §30-656 authorizing the governor of Arizona to enter into the agreement. In accordance with Public Law 83-703, Title 1- Atomic Energy, Chapter 19, Section 274, as well as Article VI of the Agreement signed the 30th day of March 1967 by Jack Williams, Governor of Arizona [F.R. Doc. 67-4212; Filed, Apr. 17, 1967 8:48 a.m.], Agreement States delegated authority to regulate nuclear material will substantially adopt the rules and language used by the U.S. NRC in order to be compatible nationally to standards of protection. In addition, A.R.S. §30-654(B)(6) requires the Agency to be as nearly as possible in conformity with the regulations of the NRC except for those types of radiation protection use whose regulation is authorized by Arizona statute that are not in the jurisdiction of an equivalent federal regulating body.

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 1, and 15.

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 7,000 registrants, 400 licensees, 8,000 technologists licensed by MRTBE, 1,600 technicians certified as cosmetic laser techs, and 1,500 nonionizing facilities using the rules and incorporated materials in Article 1; 400 approximate licensees use the rules and incorporated materials in Article 15.

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 1, and 15 and are 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 1, and 15 except as expressed below.

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 1 were completed or are no longer under consideration for modification except as expressed in this report.

The updates for Article 15 have not been completed but will be added into the next rulemaking package related to Radioactive Materials following the conclusion of the U.S. NRC IMPEP audit currently in process and anticipated to conclude June, 2016.

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

The Agency has determined that the rules in Article 1, and 15 are not more stringent than 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 15 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 1 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 the mid-portion of 2016, 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 October of 2016. The rulemaking that is needed includes the following amendments or adoptions:

ARTICLE 1

R12-1-102: Inclusion of definitions from Article 14 that will apply to both Article 14 and a newly created article 16. In addition, modifications of the definitions based upon updates to title 10 of the Code of Federal Regulations related to compatibility issues between Arizona and the U.S. Nuclear Regulatory Commission.

ARTICLE 15

R12-1-1501: An addition to this rule is required because of Arizona's Agreement State status to meet a compatibility code B classification and add verbiage that clarifies that Article 15 does not authorize possession of licensed material outside of the limits set forth for transportation as stated in 10 CFR 71.3.

R12-1-1503: An update of the incorporated material to 10 CFR 71.5 revised January 1, 2016 is needed.

R12-1-1504: An update of the incorporated material to 49 CFR 171 through 180, revised October 1, 2015 is needed.

R12-1-1505: An update of the incorporated material to 49 CFR 177.848,

revised October 1, 2015 is needed.

R12-1-1506: An update of the incorporated material to 49 CFR 171 through 180, revised October 1, 2015 and 39 CFR 111.1, revised July 1, 2015 is needed.

R12-1-1507: An update of the incorporated material to 10 CFR 71, revised January 1, 2016 is needed.

R12-1-1508: An update of the incorporated material to 49 CFR 172.202 and 49 CFR 172.203, revised October 1, 2015 is needed.

R12-1-1509: An update of the incorporated material to 49 CFR 173.417(a), revised October 1, 2015 is needed.

R12-1-1510: Additional language to address Type “A” packaging to remain in compliance with the Agreement State Status is needed for this rule. In addition, an update of the incorporated material to 10 CFR 71, all portions or subdivisions, revised January 1, 2016 is needed. In addition, an update to 49 CFR 171, 173, and 178, revised October 1, 2015 is needed.

R12-1-1511: An update of the incorporated material to 10 CFR 71 and 73, all portions or subdivisions, revised January 1, 2016 is needed. In addition, an update to 49 CFR 107 and 171 through 180, revised October 1, 2015 is needed.

R12-1-1512: An update of the incorporated material to 10 CFR 71.97, revised January 1, 2016 is needed.

R12-1-1513: An update of the incorporated material to 10 CFR 20.1906(e), revised January 1, 2016 is needed.

R12-1-1515: An update of the incorporated material to 10 CFR 71, revised January 1, 2016 is needed.

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:

R12-1-101, R12-1-103 through R12-1-107, and R12-1-1502.

5. **Status of enforcement of the rule**

The following rules are enforced as written:

R12-1-101, R12-1-103 through R12-1-107, and R12-1-1502.

6. **Analysis of clarity, conciseness, and understandability**

The following rules are clear, concise, and understandable:

R12-1-101, R12-1-103 through R12-1-107, and R12-1-1502.

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 1 and 15. These actions will be taken following the completion of the current IMPEP review of the Arizona Agreement State status.

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:

R12-1-101, R12-1-103 through R12-1-107, and R12-1-1502.

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

R12-1-102, R12-1-1501, R12-1-1503, R12-1-1504, R12-1-1505, R12-1-1506, R12-1-1507, R12-1-1508, R12-1-1509, R12-1-1510, R12-1-1511, R12-1-1512, R12-1-1513, and R12-1-1515.

ANALYSIS OF INDIVIDUAL RULES

ARTICLE 1

R12-1-102. 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 radiation devices and radioactive material regulated and described in Title 12 Chapter 1.

3. **Analysis of effectiveness in achieving the objective**

The rule is not effective because it is missing definitions from Article 14 that will apply to both Article 14 and a newly created article 16. In addition, modifications of the definitions based upon updates to title 10 of the Code of Federal Regulations related to compatibility issues between Arizona and the U.S. Nuclear Regulatory Commission.

5. **Status of enforcement of the rule**

The rule is not enforced as written. As an alternative, definitions from Article 14 and from Title 10 and Title 21 of the U.S code of federal regulations are used by professionals working in the field of radiation use and compliance.

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.

R12-1-1501. Requirement for License

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 requirements of licensing for transport of radioactive material to a transportation carrier.

3. **Analysis of effectiveness in achieving the objective**
The rule is not effective because it needs an addition to the rule to meet a compatibility code classification and add verbiage that clarifies that Article 15 does not authorize possession of licensed material outside of the limits set forth for transportation as stated in 10 CFR 71.3.
5. **Status of enforcement of the rule**
The rule is not enforced as written. As an alternative, enforcement is based upon the most current version of 10 CFR 71.3.
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.

R12-1-1503. Transportation of Licensed Material

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 incorporates by reference the regulations for transportation of nuclear material under the jurisdiction of the federal DOT.
3. **Analysis of effectiveness in achieving the objective**
The rule is not effective because it needs update to the incorporated material in 10 CFR 71.5 to meet a compatibility code classification.
5. **Status of enforcement of the rule**
The rule is not enforced as written. As an alternative, enforcement is based upon the most current version of 10 CFR 71.5.
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.

R12-1-1504. Intrastate Transportation and Storage of Radioactive Materials

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 issues a general license to persons transporting nuclear material in accordance with appropriate regulations of the DOT. The rule also requires that any notification required under federal regulations regarding an incident involving radiation during transport be filed with or made to the Agency.

3. **Analysis of effectiveness in achieving the objective**

The rule is not effective because it needs update to the incorporated material in 49 CFR 171 through 180 to meet a compatibility code classification.

5. **Status of enforcement of the rule**

The rule is not enforced as written. As an alternative, enforcement is based upon the most current version of 49 CFR 171 through 180.

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.

R12-1-1505. Storage of Radioactive Material in Transport

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 specific storage requirements for radioactive hazardous material bearing a yellow class II or class III label.

3. **Analysis of effectiveness in achieving the objective**

The rule is not effective because it needs update to the incorporated material in 49 CFR 177.848 to meet a compatibility code classification.

5. Status of enforcement of the rule

The rule is not enforced as written. As an alternative, enforcement is based upon the most current version of 49 CFR 177.848.

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.

R12-1-1506. Preparation of Radioactive Material for Transport

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 specific storage requirements for radioactive hazardous material bearing a yellow class II or class III label.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because it needs update to the incorporated material in 49 CFR 171 through 180, and 39 CFR 111.1 to meet a compatibility code classification.

5. Status of enforcement of the rule

The rule is not enforced as written. As an alternative, enforcement is based upon the most current version of 49 CFR 171 through 180, and 39 CFR 111.1.

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.

R12-1-1507. Packaging Quality Assurance

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 states that a quality assurance program and associated record keeping are required prior to shipping radioactive material. It further requires that the Agency approve the quality assurance program before shipment of a Type B package.
3. **Analysis of effectiveness in achieving the objective**
The rule is not effective because it needs update to the incorporated material in 10 CFR 71 to meet a compatibility code classification.
5. **Status of enforcement of the rule**
The rule is not enforced as written. As an alternative, enforcement is based upon the most current version of 10 CFR 71.
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.

R12-1-1508. Advance Notification of Nuclear Waste Transportation

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 requires notification be made to the Agency prior to shipping or transporting nuclear waste.
3. **Analysis of effectiveness in achieving the objective**
The rule is not effective because it needs update to the incorporated material in 49 CFR 172.202 and 49 CFR 172.203 to meet a compatibility code classification.
5. **Status of enforcement of the rule**

The rule is not enforced as written. As an alternative, enforcement is based upon the most current version of 49 CFR 172.202 and 49 CFR 172.203.

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.

R12-1-1509. General License: Plutonium-Beryllium Special Form Material

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 grants a general license to transport cert types of fissile material if appropriately packaged and under the restrictions listed in the rule.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because it needs update to the incorporated material in 49 CFR 173.417(a) to meet a compatibility code classification.

5. Status of enforcement of the rule

The rule is not enforced as written. As an alternative, enforcement is based upon the most current version of 49 CFR 173.417(a).

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.

R12-1-1510. Packaging

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 packaging requirements and limits the use or possession of radioactive material.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because it needs additional language to address Type “A” packaging to remain in compliance with the Agreement State Status. In addition, an update of the incorporated material to 10 CFR 71, all portions or subdivisions, to meet a compatibility code classification.

5. Status of enforcement of the rule

The rule is not enforced as written. As an alternative, enforcement is based upon the most current version of 10 CFR 71.

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.

R12-1-1511. Air Transport of Plutonium

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 limits in any form the amounts of plutonium that may be shipped by air.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because it needs update to the incorporated material in 10 CFR 71 and 73, all portions or subdivisions, and 49 CFR 107 and 171 through 180 to meet a compatibility code classification.

5. Status of enforcement of the rule

The rule is not enforced as written. As an alternative, enforcement is based upon the most current version of 10 CFR 71 and 73, all portions or subdivisions, and 49 CFR 107 and 171 through 180.

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.

R12-1-1512. Advance Notification of Shipment of Irradiated Reactor Fuel and Nuclear Waste

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 states the general requirement of notifying the Governor or Agency director prior to shipping spent reactor fuel waste.

3. **Analysis of effectiveness in achieving the objective**

The rule is not effective because it needs update to the incorporated material in 10 CFR 71.97 to meet a compatibility code classification.

5. **Status of enforcement of the rule**

The rule is not enforced as written. As an alternative, enforcement is based upon the most current version of 10 CFR 71.97.

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.

R12-1-1513. Opening Instructions

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 states requirement to follow special package opening directions for radioactive material in transport.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because it needs update to the incorporated material in 10 CFR 20.1906(e) to meet a compatibility code classification.

5. Status of enforcement of the rule

The rule is not enforced as written. As an alternative, enforcement is based upon the most current version of 10 CFR 20.1906(e).

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.

R12-1-1515. Exemption for Low-level Radioactive Materials

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 exempts licensees that are transporting exempt quantities or naturally radioactive ore from the requirements of this article.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because it needs update to the incorporated material in 10 CFR 71 to meet a compatibility code classification.

5. Status of enforcement of the rule

The rule is not enforced as written. As an alternative, enforcement is based upon the most current version of 10 CFR 71.

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.

FIVE-YEAR REVIEW
TITLE 12, CHAPTER 1
ARTICLE 3. RADIOACTIVE MATERIAL LICENSING

Introduction:

The rules contained in Article 3 provide the general licensing information used to cover application and qualifications to be issued a license by the Radiation Regulatory Agency. Arizona is an Agreement State by the Document negotiated between the United States Atomic Energy Commission (now United States Nuclear Regulatory Commission) and the Governor of Arizona in March of 1967. In order to remain in agreement, Arizona must adopt regulations related to the control of radioactive material in a manner that is consistent with federal regulations.

1. General and Specific Statutes Authorizing the Rules:

The Radiation Regulatory Agency is responsible for regulating the use of radioactive material in Arizona, and in accordance with A.R.S. §§ 30-651, 30-654(A)(2), (B)(5), (6), (7), (8), (9), (12), (13), 30-657, 30-671, 30-672, and 30-673, the Agency is authorized to establish rules for the protective measures needed to keep exposure to radiation as low as reasonably achievable. In addition, the Agency is authorized to inspect, enforce, impose civil penalties, conduct hearings, and issue notice of violations in accordance with A.R.S. §§ 30-673, 30-681, 30-687, 30-688, 30-689, 32-516, and 32-3233.

2. Objective of the Rules:

ARTICLE 3

- R12-1-301: This rule describes the additional articles that a person would be subject to dependent upon the intended use of radioactive material. It further outlines that an individual's right to own radioactive material is not limited; rather a license is required to possess, use, or transfer the material. It further clarifies that only the U.S. Nuclear Regulatory Commission can license a manufacturer to issue or transfer exempt quantities for radioactive material to individuals in exempt amounts.
- R12-1-302: This rule describes the qualifications that allow possession that is exempt from the article. It lists specific packages or products that may have radioactive material in the product, but that the possession of the product in an unaltered state exempts them from the rules.
- R12-1-303: This rule describes possession exemptions for entities that have material in quantities that do not exceed limits stated in Exhibit A of the article. Specific products that may have radioactive material in exempt amounts are listed for clarification.
- R12-1-304: This rule describes the two types of radioactive material licenses. The types are general and specific and the rule discusses the defined differences between the two types.
- R12-1-305: This rule describes the general license for source material (uranium and/or thorium) and lists the amounts that an entity may possess under the license. Restrictions are listed that set the boundaries of the general license by amount and use.
- R12-1-306: This rule describes general license restrictions for materials that are not source material. It sets the boundaries of the general material license by type and use of the non-source material. It outlines the registration process and refers to the category type for fees. The rule also outlines some of the safety and labeling requirements for some types of general licensed material as well as sets an

exemption from registration of generally licensed material that is in Arizona less than 180 days.

- R12-1-308: This rule describes the method of applying for a specific license to use or possess radioactive material for a specific purpose.
- R12-1-309: This rule lists the general requirements that must be met by an applicant of a specific license. The agency is required by this rule to issue a license if the applicant meets the requirements listed.
- R12-1-310: This rule lists the three classes of a specific broad scope license. The rule describes the license types of possession used by academic and industrial uses including medical classes that are Class A, Class B, and Class C. The specific requirements of each broad scope license class are described in the rule as well as the approval process.
- R12-1-311: This rule lists the license requirements for a specific license to create, form, or manufacture a product or device that contains radioactive material. This rule allows Arizona to license a manufacturer that builds, assembles, or otherwise manufactures a product or device that contains as a portion of the device quantities of radioactive material in exempt amounts. The license is issued because the manufacturer would need to possess amounts that are not exempt in order to create the product.
- R12-1-312: This rule describes the situations where additional requirements or conditions may be added to a specific license. The rule also lists the requirement to allow Agency inspections to any locations that the radioactive material may be stored or that it passed through.
- R12-1-313: This rule restricts the transfer of assignment of a license. The rule also requires that legal reorganizations by bankruptcy require written notice.
- R12-1-314: This rule describes the conditions of expiration of a license.

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- R12-1-315: This rule describes the conditions for renewing a license.
- R12-1-316: This rule lists the requirement to amend a license when information changes.
- R12-1-317: This rule sets the criteria for amending or renewing a license.
- R12-1-318: This rule sets the conditions for the transfer of radioactive material. The rule lists specific verification steps that must be taken to ensure that radioactive material is only transferred to authorized licensees. The rule further stipulates the requirement of proper packaging of radioactive material for transport.
- R12-1-319: This rule sets forth the conditions where a radioactive material license may be modified, revoked, or terminated. It also sets forth the minimum requirements for clean-up to ensure public health and safety.
- R12-1-320: This rule allows the Agency to recognize licenses issued by other Agreement States or the NRC. This allows the temporary use of radioactive material in Arizona based upon the qualifications, intended use, and license of an entity that remains in Arizona 180 days or less. The rule also stipulates under what conditions a federal entity may use radioactive material in Arizona under a NRC license.
- R12-1-322: This rule sets forth the requirement for an emergency plan related to the use of radioactive material. The rule sets up factors that may be used for evaluation of the plan, and requirements for responding to accidental releases. The rule also requires a timeframe for responders to make comments to an emergency plan that is submitted in support of a license application.
- R12-1-323: This rule describes the requirements and conditions for financial assurance. The rule requires financial assurance to guarantee clean up or decontamination after use or accidental release of

radioactive material. The rule also describes the decommissioning procedures to be used upon termination or vacation of a site or facility that used or possessed radioactive material.

R12-1-324: This rule describes when the Agency will notify members of the public about the termination or decommissioning of an area that housed or stored radioactive material. It also lists entities that may be contacted for comments.

R12-1-325: This rule sets the expected time limits for decommissioning a site contaminated by radioactive material.

Exhibit A. This exhibit lists exempt concentrations of nuclides by elemental state of gas or solid. The exhibit also describes the unity rule.

Exhibit B. This exhibit lists the nuclides in microrcurie amounts of activity that are exempt.

Exhibit C. This exhibit lists the limits for Class B and C, broad scope licenses in microrcuries of activity.

Exhibit D. This exhibit lists the amount by activity of a nuclide that requires an emergency plan.

Exhibit E. This exhibit lists the minimum amount of information needed on an application for a license to possess or use radioactive material.

3. Effectiveness of the Rules in Achieving the Objectives:

In general, the rules contained in Article 3 are effective in providing a portion of the regulatory program that meets the requirements for licensing of radioactive materials or sources in Arizona in accordance with the Agreement State document.

4. 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 Article 3.

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

The rules contained in Article 3 are consistent with other relevant Agency rules and statutes.

6. Agency Enforcement of the Rules:

The rules in Article 3 are enforced in accordance with A.R.S. § 30-687 and the procedures in Article 12.

7. Clarity, Conciseness, and Understandability of the Rules:

Generally, the rules contained in Articles 3 are clear, concise and understandable.

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:

- 1) Currently there are approximately 465 licensees in the State of Arizona that use the rules and incorporated material in Article 3.
- 2) No additional economic impact is predicted for the regulated community for the enforcement of these rules that is not already required.
- 3) Exhibits A, B, C, D, and E were last amended in 1999, and no economic impact statement is available showing these exhibits for this review. However, the Agency does not believe that the economic impact has been different than what has been expected for these rules.

1999 Rulemaking:

R12-1-314, R12-1-316, R12-1-317, R12-1-318, and R12-1-

322

2006 Rulemaking:

R12-1-301, R12-1-304, R12-1-308, R12-1-309, R12-1-312,
R12-1-315, R12-1-319, and R12-1-325

2009 Rulemaking:

R12-1-302, R12-1-311, R12-1-313, R12-1-323, and R12-1-
324

2012 Rulemaking:

R12-1-303, R12-1-305, R12-1-306, R12-1-310, and R12-1-
320

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:

The Agency completed all actions for Article 3 from the last five year review.

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:

Agency assessment of the rules contained in Article 3 has determined that

the rules are necessary and required by the Agreement State document signed between the Governor and the United States Atomic Energy Commission (now NRC) in 1967. The Agency believes that the rules contained in Article 3, after amendments consistent with this report, will impose the least burden and costs to the regulated community but will protect the public health and safety from unsafe use of radiation sources. The alternative is to release control of the regulatory program back to the Federal government and increase the fees charged to the businesses and citizens of Arizona to the federal fee table.

12. Stringency of the Rules:

The Agency has determined that the rules in Article 3 are not more stringent than corresponding federal regulations. The rules are reviewed by the NRC for compatibility on a regular basis and each time a federal regulation is amended a RATS-ID is created that lists the verbiage that must be changed by Agreement States in their respective rules.

13. Rules That Are a General License:

The Agency believes that it is exempt from A.R.S. §§ 41-1037 due to paragraph (A)(3) as the issuance of a general permit would not meet the statutory requirement of A.R.S. §§ 30-656 which allows Arizona to be and Agreement State and compatibility of licensing is one of the requirements of the agreement specified in the introduction of this report.

14. Course of Action for Rule Making:

The Agency intends to amend the rules as reflected in this review and a rulemaking will be submitted to the GRRC within one year of the removal of the rulemaking moratorium and its extensions. Since this is currently slated for December 31, 2014, the rules will be submitted by June 2015.

The rulemaking at this time will include the following amendments:

- R12-1-301: Revision of the text to reference a new Article of requirements for licensing (Article 16) is needed. Agreement States were to implement the change by 06/05/2008 in accordance with RATS ID 2007-4.
- R12-1-306: Revision of the text to meet the B category assigned to this rule by the NRC is needed. This rule is significantly the same as 10 CFR 30.15, 30.19, and 30.20. The text of these regulations was recently changed. In addition, 10 CFR 30.22 was recently added and the verbiage of this regulation needs to be added to this rule. Agreement States are to implement the verbiage change by 10/23/2015 in accordance with RATS ID 2012-4. In addition, an update of the incorporated material is needed to reflect the verbiage changes discussed.
- R12-1-308: Revision of the text to meet the C category assigned to this rule by the NRC is needed. This rule is significantly the same as 10 CFR 30.32. The text of these regulations was recently changed. Agreement States are to implement the verbiage change by 10/23/2015 in accordance with RATS ID 2012-4.
- R12-1-309: Revision of the text to reference a new Article of requirements for licensing (Article 16) is needed. Agreement States were to implement the change by 06/05/2008 in accordance with RATS ID 2007-4.
- R12-1-310: Revision of the text to reference a new Article of requirements for licensing (Article 16) is needed. Agreement States were to implement the change by 06/05/2008 in accordance with RATS ID 2007-4.

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- R12-1-311: An update to the incorporated material is needed to meet the requirements of RATS ID 2006-3 for nationally tracked source material.
- R12-1-313: Revision of the text to meet the health and safety category assigned to this rule by the NRC is needed. This rule is significantly the same as 10 CFR 30.34. The text of these regulations was recently changed. Agreement States are to implement the verbiage change by 08/06/2015 in accordance with RATS ID 2012-3.
- R12-1-311: An update to the incorporated material is needed to meet the requirements of RATS ID 2008-1 for records of surveys from decommissioning or clean-up of radioactive material.
- R12-1-323: Revision of the text to meet the health and safety category assigned to this rule by the NRC is needed. This rule is significantly the same as 10 CFR 30.35, 40.36, and 70.25. The text of these regulations was recently changed. Agreement States are to implement the change by 2/17/2015 in accordance with RATS ID 2011-1. In addition an update of the incorporated material is needed to reflect the verbiage changes.
- R12-1-324: An update to the term "Indian Nation" to reflect the definition of "Indian Tribe" and "Tribal Official" as referenced in 10 CFR 71.4 is needed for clarification purposes.
- Exhibit E: Revision of the text to meet the C category assigned to this Exhibit is needed. This rule contains information required that is similar to 10 CFR 30.32. Agreement States are to implement the verbiage change by 10/23/2015 in accordance with RATS ID 2012-4.

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

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FIVE-YEAR REVIEW
TITLE 12, CHAPTER 1
ARTICLE 5. SEALED SOURCE INDUSTRIAL RADIOGRAPHY
**ARTICLE 11. INDUSTRIAL USES OF X-RAYS, NOT INCLUDING ANALYTICAL X-
RAY SYSTEMS**

Introduction:

The rules contained in Article 5 provide the general licensing information used to cover application, qualifications, as well as use of radioactive material used for industrial purposes regulated by the Radiation Regulatory Agency. Arizona is an Agreement State by the Document negotiated between the United States Atomic Energy Commission (now United States Nuclear Regulatory Commission) and the Governor of Arizona in March of 1967. In order to remain in agreement, Arizona must adopt regulations related to the control of radioactive material in a manner that is consistent with federal regulations. In addition, the rules contained in Article 11 provide for the registration information used to cover application, qualifications, as well as use of x-ray devices used for industrial purposes regulated by the Radiation Regulatory Agency.

1. General and Specific Statutes Authorizing the Rules:

The Radiation Regulatory Agency is responsible for regulating the use of radioactive material and radiation producing equipment in Arizona, and in accordance with A.R.S. §§ 30-651, 30-654(A)(2), (B)(5), (6), (7), (8), (9), (12), (13), 30-657, 30-657 and 30-672, the Agency is authorized to establish rules for the protective measures needed to keep exposure to

radiation as low as reasonably achievable. In addition, the Agency is authorized to inspect, enforce, impose civil penalties, conduct hearings, and issue notice of violations in accordance with A.R.S. §§ 30-681, 30-687, and 30-688.

2. Objective of the Rules:

ARTICLE 5

- R12-1-501: This rule describes the definitions that apply to article 5 specifically. The definitions are used for clarification of terms used in this article.
- R12-1-502: This rule describes the application review process used by the Agency for industrial use licenses. The rule describes the application, emergency procedure plan, program review, organizational structure, leak testing, and other application requirements. The rule was created to ensure safety checks were made on the leaded shielding of devices at regular intervals. The rule was established to provide a minimum expectation of what materials are required for registration.
- R12-1-503: This rule describes equipment and containment requirements for industrial products containing radioactive material. It also describes labeling requirements used for emergency identification and packaging standards. The rule was created to ensure that NRC approved containment was used to protect public health and safety. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S. NRC.
- R12-1-504: This rule describes the survey meter requirements used to check for radiation leaks in industrial equipment housing radioactive material.
- R12-1-505: This rule describes the requirement and replacement processed

used to test shielding apertures that house source material. In addition, record keeping requirements related to testing are listed.

- R12-1-506: This rule describes the requirement for a quarterly inventory of sealed sources and any device that may contain depleted uranium. The rule also describes the three year record keeping requirement. This rule was created to ensure that radioactive uranium used for shielding is tracked and the location is known for public health and safety. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S. NRC.
- R12-1-507: This rule describes the requirement for a log that describes the use location, user, removal date and return date from storage and the identifying information of a sealed source device. This rule provides a way to track potential use when operators express concern from occupational exposure or when accidents occur. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S. NRC.
- R12-1-508: This rule describes the licensees required actions for surveys, checks, procedures, and record keeping on each of the sealed sources in their possession. The rule was created to ensure minimum safety checks related to leaky shielding is identified as early as possible to avoid radiation illness in operators. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S. NRC.
- R12-1-509: This rule describes the safety requirement of constant surveillance of the source and radiation area when radioactive material is outside of its protective shielding. The rule was created to meet the

health and safety criteria for use of radioactive material in uncontrolled environments. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S. NRC.

R12-1-510: This rule lists the personnel requirements for operating a source and the requirement that each location be listed on the license prior to use. The rule was created to ensure that public members are not at risk from exposure to devices when worksites are not pre-approved and licensed with tie-down information. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S. NRC.

R12-1-511: This rule has been repealed and is used as a place holder.

R12-1-512: This rule describes the radiation safety officer requirement and some of the minimum qualifications that are required for the position. This RSO rule is specific to industrial uses of radioactive material. This rule was created in part as the safety requirement for use of radioactive material. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S. NRC.

R12-1-513: This rule clarifies that the dosimetry rule in Article 4 applies for record keeping. The rule was created to ensure industrial users were aware that record keeping was required for risk assessment. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S. NRC.

R12-1-514: This rule provides the radiation limit at the specified distant for

storage and source changers. The rule was created to ensure public health and safety by limiting the scatter radiation on storage containers in the event that public transport is used for movement of devices. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S. NRC.

R12-1-515: This rule describes the conditions for security measures that are required with mobile and portable containers containing radioactive material. It also describes surveillance requirements of devices when not locked. The reason for the rule is to prevent unauthorized possession by theft or other means of devices containing radioactive material by entities not authorized to possess the material. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S. NRC.

R12-1-516: This rule describes the chain of custody requirement for depleted uranium shielded radionuclides. The reason for the rule is to limit the access an entity has to the type of radioactive material that is shielded by radioactive uranium. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S. NRC.

R12-1-517: This rule describes the posting requirement for temporary job sites that use industrial radiography. The rule was created to inform the general public as well as occupational workers of the presence of radioactive material at a location that does not typically have such a hazard. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S. NRC.

- R12-1-518: This rule sets the restrictions for transportation, clearly labeled storage containers, and security locks for radioactive material in devices considered portable or mobile. The rule was created to protect members of the public that work in transportation from avoidable radiation exposure. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S. NRC.
- R12-1-519: This rule has been repealed and is used as a place holder.
- R12-1-520: This rule has been repealed and is used as a place holder.
- R12-1-521: This rule has been repealed and is used as a place holder.
- R12-1-522: This rule describes the minimum content of emergency procedures required in industrial radiography. In addition, it requires that the procedures be retained for three years and be located on site. The rule was created to ensure that safety plans were developed and available for industrial radiography. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S. NRC.
- R12-1-523: This rule describes the requirements and conditions for additional personnel monitoring for exposure. It requires the use of traditional monitoring devices as well as a pocket dosimeter that may be read immediately and alarming dosimeter that will audibly alert the user of potential risk of exposure. The rule was created to provide multiple failsafe's in recording an acute dose of radiation from an accident in order to alert the occupational user to seek immediate medical attention. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the

U.S. NRC.

- R12-1-524: This rule sets the supervision requirement of an assistant that may be using an industrial source. The rule was created in order to provide a physical presence for occupational workers in the event of an accident. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S. NRC.
- R12-1-525: This rules set the requirement for Agency notification of temporary work sites across the state so that the interests of public health and safety may be regulated. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S. NRC.
- R12-1-526: Reserved.
- R12-1-527: Reserved.
- R12-1-528: Reserved.
- R12-1-529: Reserved.
- R12-1-530: Reserved.
- R12-1-531: This rule depicts the visual security requirements for industrial radiography. The security requirements ensure that public members do not enter the field of exposure. In addition, security is required to ensure that the source material is not absconded by other parties not authorized possession. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S. NRC.
- R12-1-532: This rule repeats the requirements of R12-1-517 for posting requirements. It was inadvertently left in the code when a verbiage change was made to R12-1-517.

- R12-1-533: This rule describes the safety requirement of surveys and the frequency and calibration requirements. In addition it requires the recording of the survey results each day in order to confirm operation of the instrument. The rule was created in order to provide a portion the safety culture required for use of radioactive material. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S. NRC.
- R12-1-534: This rule has been repealed and is used as a place holder.
- R12-1-535: This rule describes the incident notification requirement. The rule describes how and when to report device issues. The rule was created to ensure that exposures were investigated by the Agency and the public was protected from unintentional contamination. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S. NRC.
- R12-1-536: Reserved.
- R12-1-537: Reserved.
- R12-1-538: Reserved.
- R12-1-539: This rule sets the alarm requirements of permanent radiography installations. The rule also set testing requirements of the alarm system and the record keeping requirement. This rule was created to ensure safety systems are routinely tested. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S.
- R12-1-540: This rule sets the requirement of which documents must be maintained at all temporary field locations. The rule was created to ensure that a minimum amount of safety information is available to

workers at temporary locations. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S.

R12-1-541: This rule has been repealed and is used as a place holder.

R12-1-542: This rule has been repealed and is used as a place holder.

Appendix A: This rule has been repealed and is maintained by the Secretary of Sates office for historical purposes.

R12-1-543: This rule describes the training requirements for industrial radiographers. In addition it sets the restrictions of use to trained industrial radiographers when using sealed source devices. It also set the continued training requirements and record maintenance. The rule was developed in an effort to ensure only radiation trained workers use or handle radioactive material for safety reasons. This rule was created to meet the Agreement State requirement of being essentially the same as federal requirements based in part upon compatibility codes listed by the U.S.

Appendix A: This rule sets the requirements institutions that provide radiography certification.

ARTICLE 11

R12-1-1101: This rule has been repealed and is used as a place holder.

R12-1-1102: This rule describes the definitions that apply to article 11 specifically. The definitions are used for clarification of terms used in this article.

R12-1-1103: This rule has been repealed and is used as a place holder.

R12-1-1104: This rule describes the Agency's response to an application. In addition, it clarifies information that is needed specific to industrial use of x-ray radiation. The rule was created to ensure that the minimum information that is need for a registration is understood by

an applicant that if provided the Agency will issue a registration within the allowable timeframes.

R12-1-1105: Reserved.

R12-1-1106: This rule describes the minimum security required for an industrial x-ray unit. The rule was created to provide a mechanism to protect members of the public and other occupational users from accidental exposure of x-ray radiation

R12-1-1107: Reserved.

R12-1-1108: This rule describes the licensees required actions for surveys, checks, procedures, and record keeping on each of the sealed sources in their possession. The rule was created to mimic safety procedures used for other types of radiation radiography in order to remain consistent for procedures.

R12-1-1109: Reserved.

R12-1-1110: This rule describes the requirement for a quarterly inventory of devices. The rule also describes the three year record keeping requirement. The rule was created to ensure consistent monitoring of x-ray equipment occurs to protect the public from unauthorized possession and use of the equipment.

R12-1-1111: Reserved.

R12-1-1112: This rule describes the requirement for a log that describes the use location, user, removal date and return date from storage and the identifying information of an industrial x-ray device. The rule was created to ensure that occupational over exposure could be investigated for cause.

R12-1-1113: Reserved.

R12-1-1114: This rule describes the requirements for visual inspection of the functionality of an industrial x-ray unit. In addition it lists the required record keeping and maintenance records for each x-ray

unit. The rule was created as a portion of the safety program in an effort to prevent use of faulty equipment that may cause undesired radiation exposure to the user or others in proximity of the device.

R12-1-1115: Reserved.

R12-1-1116: This rule describes the safety requirement of constant surveillance of the x-ray unit and radiation area when industrial radiography is being conducted. The rule was created to ensure visual protection of the area to protect the public from accidental exposure.

R12-1-1117: Reserved.

R12-1-1118: This rule describes the requirement of a second individual's presence for safety when conducting industrial x-ray. In addition it requires use locations to be authorized by the registration issued by the Agency.

R12-1-1119: Reserved.

R12-1-1120: This rule describes the radiation safety officer requirement and some of the minimum qualifications that are required for the position. This RSO rule is specific to industrial uses of x-ray devices. The rule was created in order to require a radiation subject expert is available for questions related to using x-ray equipment.

R12-1-1121: Reserved.

R12-1-1122: This rule describes the record maintenance requirements based upon dosimetry requirements. The rule was created so that industrial occupational workers would be aware of the record keeping requirement.

R12-1-1123: Reserved.

R12-1-1124: Reserved.

R12-1-1125: Reserved.

R12-1-1126: This rule describes the worksite posting requirement. The rule was

created as a portion of the protection offered to the public in order to raise awareness of the potential from a hazard that is not permanently in the area.

R12-1-1127: Reserved.

R12-1-1128: This rule describes the minimum content of emergency procedures required in industrial radiography. In addition, it requires that the procedures be retained for three years and be located on site. The rule was created to ensure that occupational workers had access to emergency procedures in the event of an accident.

R12-1-1129: Reserved.

R12-1-1130: This rule describes the requirements and conditions for additional personnel monitoring for exposure. It requires the use of traditional monitoring devices as well as a pocket dosimeter that may be read immediately and alarming dosimeter that will audibly alert the user of potential risk of exposure. The intent of the rule is to provide a failsafe in the event of an acute exposure to alert occupational workers of the need to seek medical attention.

R12-1-1131: Reserved.

R12-1-1132: This rule sets the supervision requirement of an assistant that may be using an industrial source. The rule was created to ensure that an individual had help from another in the event of an emergency or accident.

R12-1-1133: Reserved.

R12-1-1134: This rule describes the safety requirement of surveys and the frequency and calibration requirements. In addition it requires the recording of the survey results each day in order to confirm operation of the instrument. The rule was created in order to ensure that leaks are recognized as soon as possible to protect operators from avoidable exposure.

R12-1-1135: Reserved.

R12-1-1136: This rule describes the additional alarming features required for high radiation areas at permanent work locations. In addition, it describes the testing frequency and the record keeping requirement. The rule was created to ensure that safety equipment works as expected in the event of an accident.

R12-1-1137: Reserved.

R12-1-1138: This rule lists the required documents that must be maintained at the permanent and temporary work locations. The rule was created so that occupational workers would have access to safety documents at the work location.

R12-1-1139: Reserved.

R12-1-1140: This rule sets the conditions that allow a certified cabinet to be exempt from a majority of the rules in this article provided an annual radiation survey is conducted on the unit. It also describes additional surveys and warning devices required for enclosed radiography if not exempted in the first portion of rule.

R12-1-1141: Reserved.

R12-1-1142: This rule describes the minimum additional requirements for baggage units used in close proximity to members of the public. The rule was created to protect members of the public from unintentional exposure to dangerous levels of radiation.

R12-1-1143: Reserved.

R12-1-1144: Reserved.

R12-1-1145: Reserved.

R12-1-1146: This rule describes the training requirements for industrial radiographers. In addition it sets the restrictions of use to trained industrial radiographers when using radiation devices. It also sets the continued training requirements and record maintenance. The

rule was created to ensure that only trained entities operate radiation devices.

Appendix A: This rule sets the requirements institutions that provide radiography certification must meet to be recognized.

3. Effectiveness of the Rules in Achieving the Objectives:

In general, Article 5 and Article 11 rules are effective in achieving their objective of protecting the public health and safety related to the use of radioactive material used in sealed source devices and x-ray radiation. The rules provide a partial regulatory program that sets forth requirements for licensing or registering of radioactive materials, sources, industrial devices and x-ray units in accordance the Agreement State document and the statutory requirements of the Agency.

4. 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 5 and 11.

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

The rules contained in Articles 5 and 11 are consistent with other relevant agency rules posted in A.A.C. Title 12, Chapters 1 and 2. In addition they are consistent with Federal or State statutes specific to the control, possession, or use of radioactive material or electronically produced radiation. Most Federal rules associated with radioactive materials are found in title 10 of the Code of Federal Regulations. The majority of electronic producing radiation device manufacturer regulations can be found under title 21 of the Code of Federal Regulations.

6. Agency Enforcement of the Rules:

The rules in Articles 5 and 11 are enforced in accordance with A.R.S. § 30-687 and the procedures in Article 12. These are the only methods currently available to the Agency for enforcement other than encouraging a safety awareness culture during performance based inspections.

7. Clarity, Conciseness, and Understandability of the Rules:

Generally, the rules contained in Articles 5 and 11 are clear, concise and understandable.

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:

- 1) Currently there are approximately 465 licensees in the State of Arizona that use the rules and incorporated material in Article 5. There are approximately 5,350 registrants that use the rules and incorporated material in Article 11.
- 2) No additional economic impact is predicted for the regulated community for the enforcement of these rules that is not already required.
- 3) R12-1-532 was last amended in 1994, and no economic impact statement is available showing these exhibits for this review. However, the Agency does not believe that the economic impact has been different than what has been expected for these rules.

2001 Rulemaking:
R12-1-531

2003 Rulemaking:

R12-1-514, and R12-1-535,

2004 (July and December) Rulemakings:

R12-1-502, R12-1-503, R12-1-504, R12-1-505, R12-1-506,
R12-1-507, R12-1-508, R12-1-509, R12-1-510, R12-1-512,
R12-1-513, R12-1-515, R12-1-516, R12-1-517, R12-1-518,
R12-1-522, R12-1-523, R12-1-524, R12-1-525, R12-1-533,
R12-1-539, R12-1-540, R12-1-543, Appendix A, R12-1-
1104, R12-1-1106, R12-1-1108, R12-1-1110, R12-1-1112,
R12-1-1114, R12-1-1116, R12-1-1118, R12-1-1120, R12-1-
1122, R12-1-1126, R12-1-1128, R12-1-1130, R12-1-1132,
R12-1-1134, R12-1-1136, R12-1-1138, R12-1-1146, and
Appendix A

2005 Rulemaking:

R12-1-1101, and R12-1-1140

2006 Rulemaking:

R12-1-501

2009 Rulemaking:

R12-1-1142

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 Agency has reconsidered actions for Articles 5 and 11 from the last five year review filed in 2008. In line with the Agencies understanding of the Executive memorandum and extension orders causing a rule moratorium effective January 22, 2009 through and including the date of this report, the Agency did not proceed with any rulemaking not absolutely required for health and safety unless authorized by the Governors office. The rules in Article 5 did not have changes required by the U.S. NRC that were due for implementation prior to this report and the incorporated material issue continues to be listed as federal regulations change annually. The previous 5 year report was written without a working knowledge of x-ray radiation. The suggested changes in Article 11 have been reconsidered as a burden to the regulated community and reduction of the requirements in this Article is currently the focus of the Agency in order to lessen or ease the regulatory burden while achieving the same regulatory objective of protecting the public for health and safety from the effects of radiation.

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:

Agency assessment of the rules contained in Article 5 has determined that the rules are necessary and required by the Agreement State document signed between the Governor and the United States Atomic Energy Commission (now NRC) in 1967. The Agency believes that the rules contained in Article 5, after amendments consistent with this report, will impose the least burden and costs to the regulated community but will protect the public health and safety from unsafe use of radiation sources. The alternative is to release control of the regulatory program back to the

Federal government and increase the fees charged to the businesses and citizens of Arizona to the federal fee table. Agency assessment of the rules contained in Article 11 has determined that the rules are necessary and required by § 30-654(B)(1). In order to meet the statutory requirement of protecting the health and safety of the public from unnecessary exposure for radiation, the regulation of devices is included in the objectives of the Agency. The Agency believes that the rules contained in Article 11, after amendments consistent with this report, will impose the least burden and costs to the regulated community but will protect the public health and safety from unsafe use of industrial x-ray devices.

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

The Agency has determined that the rules in Article 5 are not more stringent than corresponding federal regulations. The rules are reviewed by the NRC for compatibility on a regular basis and each time a federal regulation is amended a RATS-ID is created that lists the verbiage that must be changed by Agreement States in their respective rules. The rules in Article 11 do not have a federal equivalent, but a national body represented by Radiation Programs Directors for each state, the NRC, the EPA, the FDA, the DOD, the DOE, and other parties interested in radiation protection programs have developed suggested state regulations (SSR). The purpose of the SSR is to guide rulemakers in the intent of safety regulations related to radiation in an effort to create an atmosphere of regulation that is predominately similar in each state in order to ensure businesses and the public have a basic understanding on what is regulated for safe use of radiation. The basic content of the SSR's include registration of equipment, training of users and radiation safety officers, and use of industrial x-ray equipment. These regulations are also

provided to the U.S. NRC for comment, but as is common for x-ray equivalent regulations they suggested the following:

“We believe these regulatory requirements are important, however, given that "Part F" is outside of NRC's regulatory authority, we did not conduct a review of the final regulation. As is our practice, NRC does not provide federal concurrence on Suggested State Regulations which are not within NRC regulatory jurisdiction”.

Example Letter dated Jan 13, 2010 by Robert J. Lewis, Director

13. Rules That Are a General License:

The Agency believes that it is exempt from A.R.S. §§ 41-1037 due to paragraph (A)(3) as the issuance of a general permit would not meet the statutory requirement of A.R.S. §§ 30-656 which allows Arizona to be an Agreement State and compatibility of licensing is one of the requirements of the agreement specified in the introduction of this report for Article 5. The Agency believes that it is 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 to protect the public health and safety for the rules included in Article 11.

14. Course of Action for Rule Making:

The Agency intends to amend the rules as reflected in this review and a rulemaking will be submitted to the GRRC within one year of the removal of the rulemaking moratorium and its extensions. Since this is currently slated for December 31, 2014, the rules will be submitted by December 2015. The rulemaking at this time will include the following amendments:

R12-1-501: Revision of the definitions is needed to add additional terms found in the federal code 10 CFR 34.3 specific to industrial

radiography and security. These include “Exposure Head”, “Offshore platform radiography”, and “Radiation Safety Officer for industrial radiography”.

R12-1-502: Revision of the text to meet the security requirements assigned to this rule by the NRC is needed. This rule must be written to essentially match the verbiage in 10 CFR 34.13 upon the passage of part 37 of 10 CFR and updates required by RATS-ID 2011-1, 2011-2, 2012-1, 2012-2, 2012-3, 2013-1, and additional compatibility requirements added by the U.S. NRC each year during the next five year period.

R12-1-503: Revision of the text to meet the requirements assigned to this rule by the NRC is needed. This rule must be written to essentially match the verbiage in 10 CFR 34.20 upon the passage of part 37 of 10 CFR and updates required by RATS-ID 2011-1, 2011-2, 2012-1, 2012-2, 2012-3, 2013-1, and additional compatibility requirements added by the U.S. NRC each year during the next five year period. In addition an update to incorporated material 10 CFR 71 is needed to the current year of 2013.

R12-1-510: Revision of the text to meet the requirements assigned to this rule by the NRC is needed. This rule must be written to essentially match the verbiage in 10 CFR 34.41 upon the passage of part 37 of 10 CFR and updates required by RATS-ID 2011-1, 2011-2, 2012-1, 2012-2, 2012-3, 2013-1, and additional compatibility requirements added by the U.S. NRC each year during the next five year period. An addition to include lay-barge, offshore, and underwater radiography is needed.

R12-1-518: Revision of the text to meet the requirements assigned to this rule by the NRC is needed. This rule must be written to essentially match the verbiage in 10 CFR 34.35 upon the passage of part 37 of 10 CFR and updates required by RATS-ID 2011-1, 2011-2, 2012-1, 2012-

2, 2012-3, 2013-1, and additional compatibility requirements added by the U.S. NRC each year during the next five year period. An update to incorporated material is needed.

R12-1-522: Revision of the text to meet the requirements assigned to this rule by the NRC is needed. This rule must be written to essentially match the verbiage in 10 CFR 34.45 upon the passage of part 37 of 10 CFR and updates required by RATS-ID 2011-1, 2011-2, 2012-1, 2012-2, 2012-3, 2013-1, and additional compatibility requirements added by the U.S. NRC each year during the next five year period. An update to incorporated material is needed.

R12-1-532: This rule should be repealed as it is a duplicate of R12-1-517.

R12-1-540: Revision of the text to meet the requirements assigned to this rule by the NRC is needed. This rule must be written to essentially match the verbiage in 10 CFR 34.89 upon the passage of part 37 of 10 CFR and updates required by RATS-ID 2011-1, 2011-2, 2012-1, 2012-2, 2012-3, 2013-1, and additional compatibility requirements added by the U.S. NRC each year during the next five year period. An update to incorporated material is needed.

R12-1-543: Revision of the text to meet the requirements assigned to this rule by the NRC is needed. This rule must be written to essentially match the verbiage in 10 CFR 34.79, 34.43 and subpart E upon the passage of part 37 of 10 CFR and updates required by RATS-ID 2011-1, 2011-2, 2012-1, 2012-2, 2012-3, 2013-1, and additional compatibility requirements added by the U.S. NRC each year during the next five year period. An update to incorporated material is needed.

R12-1-1102: Revision of the definitions is needed to add additional terms to include “baggage unit”, “open-beam industrial radiography”, “package unit”, and “specimen unit”. There is not federal equivalent

regulatory program for x-ray device usage. The terms are used in the regulated community and definitions are needed to ensure appropriate understanding of applicable rules and a separation of types of units used in different industries.

R12-1-1104: Revision of the text to clarify that radiographers and radiographers assistant training is only required for open-beam industrial radiography. In addition, several requirements that are more appropriate to radioactive material and not x-ray need to be removed from this rule including (B), (C), (D), (E), (F), and (H). The change is being made to reduce regulation of units that do not have the same safety concerns as open-beam units.

R12-1-1110: Revision of the inventory requirement to clarify that only open-beam units require a quarterly inventory. The change is being made to reduce regulation of units that do not have the same safety concerns as open-beam units.

R12-1-1116: Revision of the surveillance requirement to clarify that only open-beam units require this safety measure. The change is being made to reduce regulation of units that do not have the same safety concerns as open-beam units.

R12-1-1120: Revision of the RSO requirement to exempt those with "specimen units" and security forces using "package units" from the training requirements. The change is being made to reduce regulation of units that do not have the same safety concerns as open-beam units. Safeguards inherent in the unit make additional safety training unnecessary.

R-12-1-1122 Repeal of this rule is needed as it is a repeat of R12-1-405.

R-12-1-1126 A clarification to this rule that only R12-1-429 (A),(B), and (C) applies. In addition, removal R12-1-1-430 verbiage re-instating exemption language is required. Posting requirements were written for

radio-isotope radiation and x-ray units cease radiation production when not powered.

R-12-1-1130 A clarification to this rule that the requirement only applies to open-beam radiography except package units is required. The change is being made to reduce regulation of units that do not have the same safety concerns as open-beam units.

R-12-1-1134 A clarification to this rule that removes (B) and (C) is required. The change is being made to reduce regulation of units that do not have the same safety concerns as open-beam units.

R-12-1-1136 Repeal of this rule as it is repeated in R12-1-1140 (C) is required. The change is being made to reduce regulation of units that do not have the same safety concerns as open-beam units.

R-12-1-1142 Clarification of this rule to remove “at airlines, railroads, bus terminals, package inspection facilities, or similar facilities” and replace it with verbiage similar to “near pedestrian traffic or with public access” is needed.

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

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FIVE-YEAR REVIEW
TITLE 12, CHAPTER 2
RADIATION REGULATORY AGENCY MEDICAL RADIOLOGIC TECHNOLOGY
BOARD OF EXAMINERS

Introduction:

The Agency is responsible for regulating professions and occupations as they relate radiologic technologists in Arizona, and in accordance with A.R.S. §§ 32-2801 to 32-2804, 32-2811 to 32-2819, 32-2821 to 32-2825 and 32-2841; the Agency is authorized to establish rules for the certification and licensure of qualified technologists in various fields related to the safe and healthy practice of radiation exposure to humans.

Chapter 2 is used by a program under the direction of the Radiation Regulatory Agency in order to qualify, test, and issue certification to radiological technologists in a variety of modalities.

1. General and Specific Statutes Authorizing the Rules:

Medical Radiologic Technology Board of Examiners (MRTBE) is responsible for certifying and ensuring educational minimums of technologists using radiation on humans, and in accordance with the rulemaking authority in A.R.S. §§ 30-652, 30-654(B), 32-2803, 32-2815 32-2819 (B).

2. Objective of the Rules:

ARTICLE 1

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R12-2-101. Definitions

This rule provides the definitions used throughout Chapter 2. The definitions are used for clarification of terms used in this Chapter.

R12-2-102. Certificate Granting Bodies

This rule describes that MRTBE shall maintain a list of any approved national certifying bodies recognized by the State of Arizona.

R12-2-103. Communications

This rule informs the public to contact MRTBE for information on rules and other technologist matters.

R12-2-104. Approval of Radiologic Technology Schools

This rule describes the steps an institution must take to be approved as an instructional facility in medical radiological technology in the State.

ARTICLE 2

R12-2-201. Applications

This rule describes the minimum requirements to apply for certification to be a technologist in Arizona.

R12-2-202. Qualifications

This rule describes under which qualifications a certificate will be issued by the Board. Additionally, the rule describes the examination requirement for individuals that have not practiced for three or more years.

R12-2-203. Examination Failures

This rule requires retraining upon three failures of the certification exam.

R12-2-204. Prohibitions and Limitations

This rule describes certain restrictions that apply to certified practical technologists.

R12-2-205. Certificate Expiration

This rule describes under what circumstances a certification will expire in Arizona

R12-2-206. Fees

This rule lists the renewal fee for certification of \$60.00.

R12-2-207. Changes of Name or Address; Duplicate Certificates

This rule describes the steps a certified technologist would take to address legal name changes or loss of an original certificate.

ARTICLE 3

R12-2-301. Licensing Time-frames

This rule describes notification procedures with incoming applications as well as anticipated time-frames for issuing either a certificate or a denial of certification. The rule also describes the application abandonment criteria and time frame.

ARTICLE 4

R12-2-401. Course Time-frames

This rule lists the minimum hour requirements for a course to become a practical radiological technologist.

R12-2-402. Clinical Training

This rule describes how clinical rotations are defined and what may be used to meet minimum exams and maximum modality timeframes.

R12-2-403. Equipment and Facilities

This rule describes the needs of an institution that trains practical technologists and describes the need to register and maintain equipment according to the rules of Title 12, Chapter 1 if in possession of an energized lab.

R12-2-404. Program Administration

This rule describes the administrative makeup of a teaching institution and the minimum requirements of specific personnel.

R12-2-405. Didactic Training

This rule describes the minimum hours needed in specific subjects of education for a practical technologist.

R12-2-406. School Approval

This rule describes the steps needed to open a practical technologist school.

ARTICLE 5

R12-2-501. Definitions

This rule lists the terms and definitions used in Article 5 for nuclear medicine.

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R12-2-502. Use of Title

This rule lists which individuals may use the nuclear medicine technologist title.

R12-2-503. Display of Certificate

This rule describes the requirement to prove certification in nuclear medicine technology.

R12-2-504. Application for Approval of a Nuclear Medicine Technology School

This rule describes the application process for schools that wish to teach nuclear medicine technology.

R12-2-505. Standards for Nuclear Medicine Technology Schools; Approved Nuclear Medicine Technology Schools

This rule describes the specific items needed to be an approved school in nuclear medicine technology.

R12-2-506. Certification and Grandfather Provisions

This rule describes the circumstance where an individual would be allowed to practice nuclear medicine technology with a temporary certification and the time frames for passing the Boards examination.

ARTICLE 6

R12-2-601. Definitions

This rule lists the terms and definitions used in Article 6 for “Practical technologist in bone densitometry”.

R12-2-602. Recognized Certificate-granting Bodies

This rule lists the requirement for the Board to keep a list of acceptable certificate issuing bodies for practical technologists in bone densitometry.

R12-2-603. Limitation

This rule lists the limitation on the scope of practice of a practical technologist in bone densitometry.

R12-2-604. Education

This rule lists the minimum education hour requirements for practical technologists in bone densitometry.

R12-2-605. Qualified Instructors

This rule lists the requirement of the Board to maintain a list of qualified instructors in practical technology in bone densitometry.

3. Effectiveness of the Rules in Achieving the Objectives:

In general, Chapter 2 has limited effectiveness in achieving the objective of protecting the public health and safety related to the certification of technologists in radiation. The rules provide an out-of-date application of statutes that does not incorporate changes to the industry such as digital imaging, new handheld units, and modalities separations such as CT technologists as a stand-alone certification, the scope of practice for many modalities, or addition of the Radiologist Assistant certification added by Laws 2008, Ch. 228.

4. 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 Chapter 2.

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

The rules contained in Chapter 2 are mostly consistent with other relevant agency rules posted in A.A.C. Title 12, Chapter 1. Some inconsistencies include but are not limited to the lack of rules as required by the Radiologist Assistant certification added by Laws 2008, Ch. 228, the lack of a scope of practice for computed tomography and radiologic technologists as it relates to the Medicare Improvements for Patients and Providers Act (MIPPA) partially listed in the provisions of 42 CFR 486.104, and the requirement of certified therapy technologists used in x-ray therapy in Title 12, Chapter 1, Article 6 that does not have current rules in Chapter 2. In addition the rules are inconsistent with State requirements found in A.R.S. § 32-2841 and Federal requirements for mammographic technologist certification found in 21 CFR 900.12 as rules

for mammography technologists are not in the chapter. The listed rules in Chapter 2 will need corrections to provide scope of practice standards, ensuring that these standards are consistent with federal requirements and Arizona statutes. Continuing education rules will be added through the rulemaking proposed in this report, consistent with A.R.S. § 32-2815(D), which requires the Board to establish minimum continuing education requirements for specified classes of technologists by rule.

6. Agency Enforcement of the Rules:

The rules in Chapter 2 are enforced in accordance with A.R.S. §32-2802, 32-2804, 32-2812, 32-2813, 32-2814, 32-2815, 32-2816, 32-2819, 32-2821, 32-2825, and 32-2841.

7. Clarity, Conciseness, and Understandability of the Rules:

Generally, the rules contained in Chapter 2 are clear, concise, and understandable. Clarity issues are a result of missing or implied rules related to scope of practice issues and the absence of Radiology Assistant rules required by A.R.S. §32-2819.

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:

- 1) Currently there are approximately 5,300 registrants and 8,000 certified technologists that use the rules in Chapter 2.
- 2) No additional economic impact is predicted for the regulated community for the enforcement of these rules that is not already required.
- 3) The Agency does not believe that the economic impact has been different than what has been expected for these rules.

1998 Rulemaking:

R12-2-301,

1999 Rulemaking:

R12-2-102, R12-2-103, R12-2-104, R12-2-201, R12-2-202,
R12-2-203, R12-2-204, R12-2-205, R12-2-206, R12-2-207,
R12-2-402, R12-2-403, R12-2-404, R12-2-405, R12-2-406,

2004 Rulemaking:

R12-2-101, R12-2-401, R12-2-501, R12-2-502, R12-2-503,
R12-2-504, R12-2-505, R12-2-506, R12-2-601, R12-2-602,
R12-2-603, R12-2-604, R12-2-605

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 Agency has reconsidered actions for Chapter 2 from the 2009 report in part because of the moratorium on rulemaking for the majority of that interval. The proposed actions will be unnecessary or incorporated into the modernization and restructuring of the Chapter to meet the current needs of the profession upon approval to proceed from the Governor's office. Proposed changes have been sent to the Governor's office with a request for an over-ride of the existing moratorium. At this time neither approval to proceed nor rejection of action has taken place.

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:

Agency assessment of the rules contained in Chapter 2 has determined that the rules are necessary and required by State Statutes. The Agency believes that the rules contained in Chapter 2, after amendments consistent with this report, will impose the least burden and costs to the regulated community but will protect the public health and safety by ensuring qualified and trained professionals are certified in the application or radiation by the Agency.

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

The Agency has determined that the rules in Chapter 2 are not more stringent than corresponding federal regulations where they exist. However, the rules in Chapter 2 do not fully meet the current requirements in 21 CFR 900.12 and 42 CFR 486.104 for inspection programs operated under federal contract or at the federal level for Medicare and Medicaid reimbursement by accredited organizations approved under MIPPA.

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:

None of the rules reviewed were adopted after July 29, 2010 and therefore complies with A.R.S. § 41-1037. To the extent that the rules require issuance of a regulatory certificate, approval, or permit, the authorization is arguably a "general permit" under A.R.S. § 41-1001(10) and therefore complies with A.R.S. § 41-1037.

14. Course of Action for Rule Making:

The Agency plans to amend or repeal but one all of the existing rules, submitting them to the Council after approval to proceed is received from the Governor's Office or, if the rulemaking moratorium ends as scheduled on December 31, 2014, by June 2015. The rulemaking at this time will include the following amendments:

R12-2-101. Several additional definitions are required to meet the changes in Chapter 2 that are proposed as well as to move definitions from each Article to a single section in Article 1. Additional terms include ARRT, ASCP, ASRT, ACR, Authorized user, Board, Bone Density Radiologic Technologist, Brachytherapy, CBRPA, Computed Tomography Technologist, Diagnostic dosage, Direct supervision, Electronic brachytherapy, general supervision, Healing arts radiography, Immediate supervision, ISCD, Licensed practitioner, Medical event, medical use, MRI Technologist, MRI image, NMTCB, Nonionizing radiation, Nuclear Medicine Technologist, Qualified instructor, Radiologist Assistant, radionuclide, Radiopharmaceutical, Radiopharmaceutical agent,

R12-2-102. A clarification is needed for this rule to include "all fields and specialties".

R12-2-104. The title and form of this rule will be changed to include information on licensing time frames. The rule will also include reply to application response times and Board actions on ineligible or abandoned applications.

Article 2 This Article title and rules will be modified to list requirements for schools and training programs for radiologic technologies

- R12-2-201. The rule will be stricken and replaced with information on Radiologic Technology and Radiation Therapy qualifications.
- R12-2-202. The rule will be stricken and replaced with information on Practical Radiologic Technology qualifications. The rule will include school approval requirements for practical technology.
- R12-2-203. The rule will be stricken and replaced with information on Practical Technologist in Bone Densitometry & Podiatry qualifications.
- R12-2-204. The rule will be stricken and replaced with information on Nuclear Medicine qualifications.
- R12-2-205. The rule will be stricken and replaced with information on Bone Densitometry qualifications.
- R12-2-206. The rule will be stricken and replaced with information on Mammography qualifications.
- R12-2-207. The rule will be stricken and replaced with information on Computerized Tomography & Magnetic Resonance Technology qualifications.
- R12-2-208. This new rule will be added with information on Radiologist Assistant qualifications in order to meet statutory requirements and the 2009 report.
- Article 3 This Article title and rules will be repurposed to list the application and certification of Radiologic Technologists requirements.
- R12-2-301. The rule will be stricken and replaced with information on application requirements.
- R12-2-302. The rule will be added with information on qualification requirements listed by statute.
- R12-2-303. The rule will be added to the Article with information on fee requirements for applications and certifications.
- R12-2-304. The rule will be added to the Article with information on renewal timeframes and penalties for renewing an expired certificate.

- R12-2-305. The rule will be added to the Article with information on requirements for posting the certificate at employment sites. It will also contain replacement certificate criteria.
- Article 4 This Article title and rules will be repurposed to list the scope of practice incorporations for each type of profession certified by MRTBE
- R12-2-401. The rule will be stricken and replaced with information on the scope of practice for Radiologic Technology, Mammography, and Radiation Therapy Technology.
- R12-2-402. The rule will be stricken and replaced with information on the scope of practice for Practical Radiologic Technology.
- R12-2-403. The rule will be stricken and replaced with information on the scope of practice for Nuclear Medicine Technology.
- R12-2-404. The rule will be stricken and replaced with information on the scope of practice for Bone Density Technology.
- R12-2-405. The rule will be stricken and replaced with information on the scope of practice for Computerized Tomography and Magnetic Resonance Technology.
- R12-2-406. The rule will be stricken and replaced with information on the scope of practice for Radiologist Assistants.
- Article 5 This Article will be repealed.
- Article 6 This Article will be repealed.

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

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Five-year Review
ARRA MRTBE
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FIVE-YEAR REVIEW
TITLE 12, CHAPTER 1
ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING
RADIATION

Introduction:

The rules contained in Article 4 provide the occupational exposure limits regulated by the Radiation Regulatory Agency. Arizona is an Agreement State by the Document negotiated between the United States Atomic Energy Commission (now United States Nuclear Regulatory Commission) and the Governor of Arizona in March of 1967. In order to remain in agreement, Arizona must adopt regulations related to the control of radioactive material in a manner that is consistent with federal regulations.

1. General and Specific Statutes Authorizing the Rules:

The Radiation Regulatory Agency is responsible for regulating the use of radioactive material and radiation producing equipment in Arizona, and in accordance with A.R.S. §§ 30-651, 30-654(A)(2),(B)(2), (B)(5), (6), (7), (8), (9), (12), (13), 30-657, and 30-672, the Agency is authorized to establish rules for the protective measures needed to keep exposure to radiation as low as reasonably achievable. In addition, the Agency is authorized to inspect, enforce, impose civil penalties, conduct hearings, and issue notice of violations in accordance with A.R.S. §§ 30-681, 30-687, and 30-688.

2. Objective of the Rules:

ARTICLE 4

- R12-1-401: This rule gives the purpose of standards described in Article 4.
R12-1-402: This rule provides the scope, describing persons affected by Article 4.
R12-1-403: This rule provides the definitions of terms specific to Article 4 unless the

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ARRA

Last revised June 13, 2014 @ 11:00 am

context of the rule implies otherwise.

- R12-1-404: This rule describes the requirement of Standard International (SI) units in all records required by this Article. It further sets the requirement for distinction by type among the quantities recorded for this Article.
- R12-1-405: This rule describes the types and forms of records that are allowable during retention periods.
- R12-1-406: This rule describes the implementation of license or registration conditions that are more restrictive and the timeframe for the restriction.
- R12-1-407: This rule sets the requirements for radiation protection programs. In addition, it lists specific registration and license classes that are exempt from record requirements of the rule.
- R12-1-408: This rule sets the occupational dose limits for adult individuals except for planned special exposures as authorized in R12-1-413.
- R12-1-409: This rule lists the summation expectations that a licensee or registrant will follow to show compliance with occupational dose limits.
- R12-1-410: This rule lists determination factors used to calculate dose reports from airborne radioactive material.
- R12-1-411: This rule lists the methods for determining the internal dose received by occupational workers.
- R12-1-412: This rule lists the requirements for obtaining prior exposure values for individuals as well as the need to reduce exposure values if lifetime records cannot be secured in order to remain in compliance with limits set in other rules in the Article.
- R12-1-413: This rule lists the methods for authorizing a planned radiation exposure over the adult limits specified earlier in the Article with the restrictions and record requirements for the exposure.
- R12-1-414: This rule lists the annual dose limits for minor occupational workers.
- R12-1-415: This rule lists the dose limits for an embryo or fetus.
- R12-1-416: This rule lists the annual dose limits for members of the public and the restrictions to public places that must be evaluated for this limit. It also

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includes the exception for equipment manufactured before August 10, 1994 but retains the Agency's right to impose additional restrictions.

- R12-1-417: This rule lists the methods of testing required for sealed sources of radioactive material.
- R12-1-418: This rule provides the requirements for surveys and the additional requirement to process dosimetry with an authorized entity for radiation and radioactive material.
- R12-1-419: This rule describes the requirements for individual monitoring of internal and external contamination and dose from exposure.
- R12-1-420: This rule describes the conditions that need to be met in controlling a high radiation area including the minimum safety devices that are needed.
- R12-1-421: This rule describes the conditions that need to be met in controlling a very-high radiation area including the limited access features not previously required.
- R12-1-422: This rule describes the conditions that need to be met in controlling an irradiator area. This rule is added to remain compliant with the agreement status, but the state does not have a license at this time that meets the needs of this rule.
- R12-1-423: This rule requires process or engineering controls for reducing radioactive concentrations in the air.
- R12-1-424: This rule describes other alternatives for limiting intake of radioactivity from the air.
- R12-1-425: This rule describes the requirements for authorizing respiratory units to be used to control radiation intake.
- R12-1-426: This rule requires that radiation sources be securely stored when left in unrestricted areas.
- R12-1-427: This rule describes the requirements related to the control of radiation sources not stored or in a restricted area by visual contact.
- R12-1-428: This rule describes the signage requirements for radiation areas.
- R12-1-429: This rule describes the posting requirements for radiation areas.

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- R12-1-430: This rule describes the exceptions to posting requirements for radiation areas.
- R12-1-431: This rule describes the labeling requirements on packages that contain radioactive material.
- R12-1-432: This rule provides the exceptions to the labeling requirements listed in R12-1-431.
- R12-1-433: This rule describes the procedures for receiving and opening packages containing radioactive material.
- R12-1-434: This rule describes the general requirements for licensed waste material.
- R12-1-435: This rule provides list of the information needed to seek approval to dispose of licensed radioactive material and to describe the general requirements for licensed waste material.
- R12-1-436: This rule describes the conditions that shall be met before disposing of radioactive material in a sanitation sewer.
- R12-1-437: This rule describes the conditions that shall be met before disposing of radioactive material by incineration.
- R12-1-438: This rule describes requirements related to disposal of specific types of waste.
- R12-1-438.01: This rule describes requirements related to certain radioactive material not previously covered in the rules.
- R12-1-439: This rule describes the requirements relating to transfer of radioactive waste listed on manifests to land disposal facilities.
- R12-1-440: This rule affirms that nothing in the listed rules relieves the licensees from following other local, state and federal rules and regulations.
- R12-1-441: This rule describes the requirements for maintaining records of disposal of licensed material.
- R12-1-442: This rule allows for inspection of wastes shipped from Arizona.
- R12-1-443: This rule lists the required steps for notification of a missing, lost or stolen radioactive source.
- R12-1-444: This rule describes the requirements for reporting exposures that exceed

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dose limits to the Agency.

R12-1-445: This rule describes the timeframes for notification and reporting of listed incidents to the Agency.

R12-1-446: This rule lists the dose notification requirements.

R12-1-447: This rule describes the general requirements of a licensee and of the Agency before and after a licensee vacates a facility.

R12-1-448: This rule lists the reporting requirements for medical events that are related to radiation doses.

R12-1-449: This rule lists the calibration requirements of instruments used to show compliance with recording dose.

R12-1-450: This rule describes the use restrictions for a sealed source by the licensee.

R12-1-451: This rule describes requirements relating to the termination of a radioactive material license by a licensee.

R12-1-452: This rule describes the radiological criteria for termination of a license by a licensee.

R12-1-453: This rule describes notification and reporting requirements related to an individual exposure to radiation in excess of allowable limits.

R12-1-454: This rule lists the federal requirement to register certain radioactive material on the national tracked source database.

R12-1-455: This rule describes the security requirements for portable gauges.

Appendix A: This appendix describes assigned protection factors for respirators.

Appendix B: This appendix describes annual limits of intake (ALI) and derived air concentrations (DAC) of radionuclides for occupational exposure; effluent concentrations; concentrations for release to sanitary sewerage.

Appendix C: This appendix describes quantities of licensed or registered material requiring labeling.

Appendix D: This appendix describes classification and characteristics of low-level radioactive waste.

Appendix E: This appendix describes quantities for use with decommissioning forms.

3. Effectiveness of the Rules in Achieving the Objectives:

In general, Article 4 rules are effective in achieving their objective of protecting the public health and safety related to limiting the occupational dose received from radiation. The rules in Article 4 provide the requirements for measuring, determining, and achieving doses by occupational workers and members of the public as low as reasonably achievable, in accordance the Agreement State document and the statutory requirements of the Agency.

4. 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 Article 4.

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

The rules contained in Article 4 are consistent with other relevant agency rules posted in title 12. In addition they are consistent with Federal and State statutes specific to the control, possession, or use of radioactive material or electronically produced radiation in relation to occupational exposure.

6. Agency Enforcement of the Rules:

The rules in Article 4 are enforced in accordance with A.R.S. § 30-687 and the procedures in Article 12. These are the only methods currently available to the Agency for enforcement other than encouraging a safety awareness culture during performance based inspections.

7. Clarity, Conciseness, and Understandability of the Rules:

Generally, the rules contained in Article 4 are clear, concise and understandable.

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:

1) Currently there are approximately 5,750 registrants or licensees in the State of Arizona that use the rules and incorporated material in Article 4.

2) R12-1-414, Appendix C, D, and Appendix E were last amended in 1994, and no economic impact statement is available from that rulemaking for these rules. However, R12-1-414 specifically restates the federal restriction that radiation workers under the age of 18 are restricted to a dose a dose limit of 10% of that of an adult. Currently Arizona does not have registered or licensed radiation workers under the age of 18, but the rule is stated in the event that a registrant or licensee hires underage employees so that they are aware of the greater restriction of exposure for health reasons. No economic impact is predicted over the existing need to monitor these individuals similar to the monitoring already required for radiation workers in general. The listed Appendices are reference tables for calculation and are provided as reference material. No economic impact is predicted for the regulated community.

3) The economic impact of the rules has been as was predicted in the last EIS for the following rules:

2001 Rulemaking:

R12-1-401, R12-1-402, R12-1-404, R12-1-406, R12-1-409,
R12-1-410, R12-1-411, R12-1-417, R12-1-420,
R12-1-421, R12-1-426, R12-1-427, R12-1-428, R12-1-429,
R12-1-436, R12-1-437, R12-1-442

2003 Rulemaking:

R12-1-423, Appendix A

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2004 Rulemakings

R12-1-407, R12-1-416, R12-1-424, R12-1-425, R12-1-444, R12-1-445,
R12-1-450, R12-1-451, R12-1-452

2006 Rulemaking

R12-1-405, R12-1-412, R12-1-413, R12-1-415,
R12-1-418, R12-1-430, R12-1-433, R12-1-441,
R12-1-453

2007 Rulemaking

R12-1-455

2009 Rulemaking

R12-1-403, R12-1-419, R12-1-422, R12-1-431, R12-1-432,
R12-1-435, R12-1-440, R12-1-443, R12-1-447, R12-1-448, R12-1-449,
R12-1-454

2013 Rulemaking

R12-1-408, R12-1-434, R12-1-438, R12-1-438.01, R12-1-439,
R12-1-446, and Appendix B

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 recommended change to R12-1-408(C), and R12-1-439, were completed as

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described in final rulemaking effective March 8, 2014 as a portion of mandated changes requested by the NRC. The remaining actions from the prior report are still outstanding due to the moratorium that remains in effect. No additional requests have been made by the NRC to amend dose limits and the Agency has priorities in other areas so it has not requested an over-ride to the moratorium as a public health and safety criteria has not been determined for the rule amendment from the prior report that is greater than current efforts involving rulemaking.

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:

Agency assessment of the rules contained in Article 4 has determined that the rules are necessary and required by the Agreement State document signed between the Governor and the United States Atomic Energy Commission (now NRC) in 1967. The Agency believes that the rules contained in Article 4, after amendments consistent with this report, will impose the least burden and costs to the regulated community but will protect the public health and safety from unsafe use of radiation sources. The alternative is to release control of the regulatory program back to the Federal government and increase the fees charged to the businesses and citizens of Arizona to the federal fee table.

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

The Agency has determined that the rules in Article 4 are not more stringent than corresponding federal regulations. The rules are reviewed by the NRC for compatibility on a regular basis and each time a federal regulation is amended a RATS-ID is created that lists the verbiage that must be changed by Agreement States in their respective rules. The Agency has updated many of the rules to a more recent version of the federal code in order to remain as consistent as practical with federal regulatory changes that have occurred in the past five years.

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 Article 4 promotes standards and limits but does not issue a registration or license.

14. Course of Action for Rule Making:

The Agency plans to amend the existing rules, submitting them to the Council if the rulemaking moratorium ends as scheduled on December 31, 2014, by June 2015. The rulemaking at this time will include the following amendments:

ARTICLE 4

R12-1-404: A verbiage clarification to the rule will require registrants and licensees to keep records on site and will be added in the next rulemaking action.

R12-1-405 (D) A deletion of duplicate rule. R12-1-405(D) is a repeat of information contained in R12-1-404(B) and should be deleted during the next rulemaking action involving Article 4.

R12-1-407: Consideration will be given to the possibility of moving computed tomography units to an E1 class to be investigated during next rulemaking action.

R12-1-416: Updates to incorporated material

R12-1-418: Updates to incorporated material

R12-1-419: A verbiage clarification for TODE needs to be corrected to match the definition previously given at the beginning of the chapter.

R12-1-423: This rule should be re-written for clarity.

R12-1-424: This rule should be re-written for clarity.

R12-1-425: Updates to incorporated material needed. In addition, the NRC requests additional requirements as stated in § 20.1703(c), (g), and (h) be added in the next rulemaking action.

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R12-1-433: Updates to incorporated material

R12-1-444: Updates to incorporated material

Although Arizona does not have a low level waste disposal facility at this time, if the legislative branch were to adopt a proposed plan and application prior to the next five year review of Article 4, an additional appendix for requirements for transfer would also need to be developed to remain in compliance with NRC guidelines and our agreement State status.

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

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FIVE-YEAR REVIEW
TITLE 12, CHAPTER 1
ARTICLE 17. WIRELINE SERVICE OPERATIONS AND SUBSURFACE
TRACER STUDIES

Introduction:

The rules contained in Article 17 provide the usage rules for wireline studies conducted in Arizona using radioactive material regulated by the Radiation Regulatory Agency. Arizona is an Agreement State by the Document negotiated between the United States Atomic Energy Commission (now United States Nuclear Regulatory Commission) and the Governor of Arizona in March of 1967. In order to remain in agreement, Arizona must adopt regulations related to the control of radioactive material in a manner that is consistent with federal regulations.

1. General and Specific Statutes Authorizing the Rules:

The Radiation Regulatory Agency is responsible for regulating the use of radioactive material and radiation producing equipment in Arizona, and in accordance with A.R.S. §§ 30-651, 30-654(A)(2),(B)(2), (B)(5), (6), (7), (8), (9), (12), (13), 30-657, and 30-672, the Agency is authorized to establish rules for the protective measures needed to keep exposure to radiation as low as reasonably achievable. In addition, the Agency is authorized to inspect, enforce, impose civil penalties, conduct hearings, and issue notice of violations in accordance with A.R.S. §§ 30-681, 30-687, and 30-688.

2. Objective of the Rules:

ARTICLE 17

R12-1-1701: This rule provides two definitions specific to this article for energy compensation source and tritium neutron generator target source.

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- R12-1-1702: This rule provides the requirements for identifying the responsible party to comply with recovery or abandonment processes in well logging of source material. This rule sets the agreement standards for identifying the responsible party for the recovery, monitoring, decontamination, and abandonment expectations on lost or disconnected well logging sources.
- R12-1-1703: This rule stipulates that those who transport source material must do so in a manner that meets safety requirements in Article 4 and the transportation requirements in Article 15.
- R12-1-1712: This rule describes the safety and security precautions to be used when storing or transporting source material that is used in a manner consistent with Article 17.
- R12-1-1713: This rule describes the securing of containers containing radioactive material used in a manner consistent with Article 17 for transport.
- R12-1-1714: This rule sets the requirements and specifies detection capabilities for radiation survey meters for material used in a manner consistent with Article 17. The rule also lists the calibration and record keeping requirements for calibration.
- R12-1-1715: This rule describes the testing and test frequency for sealed sources as well as the types of sources exempt from leak testing that is used in in a manner consistent with Article 17. The rule also lists requirements for removing a source from service.
- R12-1-1716: This rule provides the inventory requirements for licensed material used in in a manner consistent with Article 17.
- R12-1-1717: This rule lists the utilization log requirements for licensed material used in in a manner consistent with Article 17.
- R12-1-1718: This rule states the minimum specification for the design of a sealed source used for well logging and the requirements for package specifications of the source before use of material in well logging applications.
- R12-1-1719: This rule lists the labeling requirements for well logging equipment that

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- contains radioactive material.
- R12-1-1720: This rule provides inspection and maintenance requirements and restricts opening or tampering with sealed sources in source holders or logging tools.
- R12-1-1721: This rule lists the minimum training requirements for those acting as supervisors for logging operations using source material in a manner consistent with Article 17.
- R12-1-1722: This rule lists the requirements for operating and emergency procedures that protect individuals from radiation in excess of the dose limits when using source material or tools containing radioactive material.
- R12-1-1723: This rule lists the personnel monitoring requirements for supervisors and logging assistants using source material.
- R12-1-1724: This rule lists the requirements for controlling contamination in the event that a sealed source ruptures or leaks.
- R12-1-1725: This rule provides the requirements governing use of depleted uranium bars for well logging.
- R12-1-1726: This rule lists the conditions for use of an energy compensation source in a tool or component.
- R12-1-1727: This rule lists the conditions for use of a neutron generator in well logging applications.
- R12-1-1728: This rule describes the conditions that need to be met in order to use a sealed source in a well without a surface casing.
- R12-1-1731: This rule lists the requirement for the supervisor to remain on site during well logging, and under what circumstances the supervisor may leave a job site.
- R12-1-1732: This rule describes requirements to use remote handling tools for source material.
- R12-1-1733: This rule describes the requirements for gloves and protective clothing; a restriction against injecting material into potable water aquifers, and a requirement regarding disposal of source material.

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R12-1-1734: This rule lists specific restrictions on well logging without a surface casing and the use of particle accelerators.

R12-1-1741: This rule describes the requirements related surveying a job site for radiation levels and maintaining the survey records.

R12-1-1742: This rule describes the documentation that must be available at all field stations for well logging.

R12-1-1743: This rule describes the documentation that must be available at temporary job sites for well logging.

R12-1-1751: This rule describes the notification requirements for incidents, lost sources, and abandoned sources.

3. Effectiveness of the Rules in Achieving the Objectives:

In general, Article 17 rules are effective in achieving their objective of protecting the public health and safety related to limiting the occupational dose received from radiation. The rules in Article 17 provide the requirements for well logging activities, in accordance the Agreement State document, and the statutory requirements of the Agency.

4. 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 Article 17.

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

The rules contained in Article 17 are consistent with other relevant agency rules posted in title 12. In addition they are consistent with Federal and State statutes specific to the control, possession, or use of radioactive material used in wireline operations and tracer studies.

6. Agency Enforcement of the Rules:

The rules in Article 17 are enforced in accordance with A.R.S. § 30-687 and the procedures in Article 12. These are the only methods currently available to the Agency for enforcement other than encouraging a safety awareness culture during performance based inspections.

7. Clarity, Conciseness, and Understandability of the Rules:

Generally, the rules contained in Article 17 are clear, concise and understandable.

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:

1) Currently there may be one eligible licensee in the State of Arizona that uses the rules and incorporated material in Article 17.

2) R12-1-1732 was last amended in 1990, and no economic impact statement is available from that rulemaking for these rules. However, R12-1-1732 specifically states the requirement that tools rather than bare hands be used whenever possible for higher energy handling of radioactive material. Currently Arizona has one licensee but maintains the rules to meet agreement state requirements of compatibility with the federal program. No economic impact is predicted for the regulated community other than the cost of the tools which are estimated to be less costly than the damage to life and body of the operator if contact with this radioactive material were to occur.

3) The economic impact of the rules has been as was predicted in the last EIS for the following rules:

2003 Rulemaking:

R12-1-1703, R12-1-1712, R12-1-1714, R12-1-1717, R12-1-1719, R12-1-1722, R12-1-1731, R12-1-1733, R12-1-1734, R12-1-1741

2004 Rulemaking:

R12-1-1701, R12-1-1702, R12-1-1715, R12-1-1716, R12-1-1718, R12-1-1720, R12-1-1721, R12-1-1723, R12-1-1724, R12-1-1725, R12-1-1726, R12-1-1727, R12-1-1728, R12-1-1742, R12-1-1743, R12-1-1751

2009 Rulemaking

R12-1-1713

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:

No actions were recommended in the last five year review. No additional requests have been made by the NRC to amend the existing rules.

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:

Agency assessment of the rules contained in Article 17 has determined that the rules are necessary and required by the Agreement State document signed between the Governor and the United States Atomic Energy Commission (now NRC) in 1967. The Agency believes that the rules contained in Article 4, after amendments consistent with this report, will impose the least burden and costs to

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the regulated community but will protect the public health and safety from unsafe use of radiation sources. The alternative is to release control of the regulatory program back to the Federal government and increase the fees charged to the businesses and citizens of Arizona to the federal fee table.

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

The Agency has determined that the rules in Article 17 are not more stringent than corresponding federal regulations enforced by the NRC contained in 10 CFR part 39. The rules are reviewed by the NRC for compatibility on a regular basis and each time a federal regulation is amended a RATS-ID is created that lists the verbiage that must be changed by Agreement States in their respective rules. The Agency has not had a need to update the rules to meet the requirements of the Agreement State requirements to a more recent version of the federal code in order to remain as consistent as practical with federal regulatory changes as no changes have occurred in the past five years.

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 Article 17 promotes standards and limits but does not issue a registration or license.

14. Course of Action for Rule Making:

The Agency does not plan to amend the existing rules unless there is a change to the federal code that requires amendment for continued agreement. Security changes that will be adopted in the next few years will cover some of the rules that relate to 10 CFR Part 39, but will be contained in a new Article as a self-contained requirement and to apply the security measures to multiple articles in Title 12, Chapter 1.

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

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FIVE-YEAR REVIEW
TITLE 12, CHAPTER 1
ARTICLE 2. REGISTRATION, INSTALLATION, AND SERVICE OF
IONIZING RADIATION-PRODUCING MACHINES; AND
CERTIFICATION OF MAMMOGRAPHY FACILITIES

Introduction:

The rules contained in Article 2 provide the registration and exemption requirements for x-ray producing devices in Arizona by the Radiation Regulatory Agency. The rules were created to remain in compliance with statutory requirements and to protect the health and safety of the citizens in the state from unnecessary or unauthorized exposure from x-ray devices.

1. General and Specific Statutes Authorizing the Rules:

The Radiation Regulatory Agency is responsible for regulating the use of radiation producing equipment in Arizona, and in accordance with A.R.S. §§ 30-651, 30-652(C)(1), 30-654(A)(2), (B)(5), (9), (13), (17), (18), 30-657(A), 30-671(B), 30-672, 30-672.01, and 30-673, , the Agency is authorized to establish rules for the protective measures needed to keep exposure to radiation as low as reasonably achievable. In addition, the Agency is authorized to inspect, enforce, impose civil penalties, conduct hearings, and issue notice of violations in accordance with A.R.S. §§ 30-655, 30-681, 30-687, and 30-688.

2. Objective of the Rules:

ARTICLE 2

R12-1-201: This rule provides exemption from registration of radiation producing equipment criteria specific to this article. This rule also lists the criteria

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where service providers are not exempted from the Article. The purpose of the rule is to exempt certain sources of radiation from the need to register as there is not a measured impact to the health and safety of the public.

- R12-1-202: This rule provides the restrictions for use as well as the requirements for registering of radiation producing machines including the need to pay annual fees, and provide shielding diagrams. In addition, the rule includes a general restriction against the use of particle accelerators for medical purposes until the initial State inspection is completed. The purpose of the rule is to register certain sources of radiation as there is a requirement of the Agency to protect the public health and safety from harmful radiation to the extent practical.
- R12-1-203: This rule states the requirement for service providers who install, sell or service x-ray machines in Arizona to be registered with the Agency. The purpose of the rule is to track or assist in locating service providers as required in A.R.S 30-672.01.
- R12-1-204: This rule describes the requirement of the Agency to issue a registration as well as offering a point of clarity that all units at a single facility will be registered on one Notice of Registration. The purpose of the rule is to issue a registration that allows the operation of certain sources of radiation.
- R12-1-205: This rule describes conditions for expiration of a Notice of Registration and under what condition an exemption of expiration is in effect during the renewal process. The purpose of the rule is to continue the registration that allows the operation of certain sources of radiation until such time as a renewal can be issued.
- R12-1-206: This rule sets the requirements of notification that a service provider must meet. The rule also specifies that service providers may not install, sell, or service an x-ray unit unless when it is placed into operation it meets the

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rules of the Agency. The purpose of the rule is to tract to the extent possible the installation of radiation producing equipment that is installed in Arizona to follow-up on unregistered activities in order to protect the public from harmful radiation.

R12-1-207: This rule describes the conditions that possessors and owners must adhere to when operating a radiation machine in Arizona on a temporary basis. The purpose of the rule is to issue a temporary reciprocity approval in order to honor registrations from other states for equipment that is used less than 180 days in Arizona to reduce the costs of business that could occur if equipment had to be registered in multiple states.

R12-1-208: This rule lists the requirements that must be met to certify a mammography facility in Arizona. Requirements include the establishment of a quality assurance program, the need to use a physician who meets the training and experience criteria listed in Statue, and providing evidence that physicians meet the continuing education requirements set by their respective boards. The purpose of the rule is to issue a registration as required by A.R.S.

R12-1-209: This rule states the notification requirement when changes to the information on a registration occur. The rule also lists notification requirements when a registrant no longer possesses a specific x-ray unit. The purpose of the rule is to ensure a registration is accurate and all devices are controlled and inventoried by those authorized to possess them.

Appendix A: This appendix lists the required information for a registration request. The purpose of the rule is to provide a list of the majority of the information that is found on the current registration forms.

3. Effectiveness of the Rules in Achieving the Objectives:

In general, Article 2 rules are effective in achieving their objective of registering

x-ray service providers, mammography facilities and x-ray devices to protect the public health and safety. The rules in Article 2 provide the requirements for registration in accordance with the statutory requirements of the Agency.

4. 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 Article 2.

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

The rules contained in Article 2 are consistent with other relevant agency rules posted in title 12. In addition they are consistent with Federal and State statutes specific to the control, possession, or use of radiation producing equipment.

6. Agency Enforcement of the Rules:

The rules in Article 2 are enforced in accordance with A.R.S. § 30-687 and the procedures in Article 12. These are the only methods currently available to the Agency for enforcement other than encouraging a safety awareness culture during performance based inspections.

7. Clarity, Conciseness, and Understandability of the Rules:

Generally, the rules contained in Article 2 are clear, concise and understandable.

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:

- 1) Currently there are approximately 155 mammographic facilities and 5,400 other x-ray registrants in the State of Arizona that use the rules and

incorporated material in Article 2.

2) R12-1-204 was last amended in 1997, and no economic impact statement is available from that rulemaking for these rules. However, no economic impact is predicted for the regulated community from allowing the use of equipment when a renewal for has been submitted in a timely fashion.

3) The economic impact of the rules has been as was predicted in the last EIS for the following rules:

2003 Rulemaking:

R12-1-202, R12-1-208

2005 Rulemaking:

R12-1-209

2009 Rulemaking

R12-1-201, R12-1-203, R12-1-205, R12-1-206, R12-1-207, Appendix A

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:

No actions were recommended in the last 5 year review.

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:

Agency assessment of the rules contained in Article 2 has determined that the rules are necessary and required by State Statute. The Agency believes that the rules contained in Article 2, after amendments consistent with this report, will impose the least burden and costs to the regulated community but will protect the public health and safety from unsafe use of radiation sources.

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

The Agency has determined that the rules in Article 2 are not more stringent than corresponding federal regulations where applicable.

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 2 is 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 and 3--672.01 to protect the public health and safety.

14. Course of Action for Rule Making:

The Agency plans to amend the existing rules, submitting them to the Council once the rulemaking moratorium ends provided it is not continued or the legislative branch does not pass an additional restriction on rulemaking. The rulemaking at that time will include the following amendments:

ARTICLE 2

R12-1-201: Additional subsections are needed to this rule. The first is to clarify that providers of radiation machines for mobile services are not exempt from registration to subsection (C). The second is to add a new

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exemption to financial institutions that take possession of radiation machines as a result of foreclosure, bankruptcy, or other default of payment if they document that the unit is not in operation and possession is for the sole purpose of selling, leasing, or transferring the equipment to an entity that can be registered.

R12-1-202: A clarification to the verbiage of this rule in subsection (B) is needed to ensure that facilities that are new or new to possession of electronic radiation device use are referred to by this rule. Simplification of the drawing requirements in subsection (D) are needed in this rule. In addition, a new subsection to the rule to include the prohibition of therapy equipment until a registration is issued is included to meet the requirements of R12-1-611, 611.01, and 611.02.

R12-1-203: Simplification to remove redundant statutory language is needed for this rule to promote ease of understanding.

R12-1-204: Removal of subsection (B) is needed to update this rule as mammography facilities require a separate registration to meet federal requirements.

R12-1-206: Updates to the number of days for notice to 30 is needed to make this rule consistent with similar notification rules in the Article. Clarification of required information is needed to meet the needs of current forms such as the removal of kVp and mA information previously requested and the addition of a reference to R12-1-203 in subsection (D). In addition, an update to the incorporated material is needed.

R12-1-207: A clarification to this rule is needed to strengthen the understanding that this rule only applies to equipment that is registered in another state; unregistered equipment must meet registration requirements prior to use.

R12-1-208: This rule must be corrected to remove the reference to a portion of Statute §32-2842 that has been removed. In addition, the

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Appendix referenced in this rule needs to be corrected to reference Appendix A instead of the current listing of Appendix B.

R12-1-209: Updates to the number of days for notice to 30 is needed to make this rule consistent with similar notification rules in the Article.

Appendix A: This appendix should be re-written for clarity.

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

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Five-year Review of Article 9
ARRA
Revised July 7, 2015 per request GRRC

FIVE-YEAR-REVIEW REPORT
TITLE 12. NATURAL RESOURCES
CHAPTER 1. RADIATION REGULATORY AGENCY

ARTICLE 9. PARTICLE ACCELERATORS

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FIVE-YEAR-REVIEW SUMMARY

The rules contained in Article 9 provide standards for registration, shielding, operation, and quality control requirements for protection against ionizing radiation from particle accelerators. These rules were developed to meet standards as set forth by the federal Food and Drug Administration in Title 21, CFR part 1020 as well as Part I of the Suggested State Regulations for Control of Radiation as presented by Conference of Radiation Control Program Directors (CRCPD). The rules were created to remain in compliance with statutory requirements and to protect the health and safety of the citizens in the state from unnecessary or unauthorized exposure from therapeutic x-ray devices.

Article 9

R12-1-914 was adopted in 2001 and has not been amended. R12-1-903, R12-1-908, R12-1-909 914 were last amended in 2003. R12-1-901 was last amended in 2007. R12-1-902, R12-1-905, R12-1-906, R12-1-907, R12-1-910, R12-1-911, R12-1-913, and Appendix A were last amended in 2009.

Exhibit 1

R12-1-914 was last amended in 2001, and no economic impact statement is available from that rulemaking for these rules. However, no economic impact is predicted for the regulated community from inspecting prior to use for entities that plan in advance for this process. 12-1-903, R12-1-908, R12-1-909 914 was last amended in 2003, and no economic impact statement is available from that rulemaking for these rules. However, no economic impact is predicted for the regulated community from inspecting prior to use for entities that plan in advance for this process.

Prior communication with GRRC staff indicated that these EIS statements were already on file and did not need to be submitted again historically.

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ARTICLE 9. PARTICLE ACCELERATORS

- R12-1-901. Purpose and Scope
- R12-1-902. Definitions
- R12-1-903. General Registration Requirements
- R12-1-904. Registration of Particle Accelerators Used in the Practice of Medicine
- R12-1-905. Medical Particle Accelerator Equipment, Facility and Shielding, and Spot Checks
- R12-1-906. Limitations
- R12-1-907. Shielding and Safety Design
- R12-1-908. Particle Accelerator Controls and Interlock Systems
- R12-1-909. Warning Systems
- R12-1-910. Operating Procedures
- R12-1-911. Radiation Surveys
- R12-1-912. Repealed
- R12-1-913. Misadministration
- R12-1-914. Initial Inspections of Particle Accelerators Used in the Practice of Medicine
- Appendix A. Quality Control Program

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), 30-654(B)(18), 30-657(A), 30-671(B), 30-672, 30-672.01, and 30-673. Any specific authority is stated in the applicable rule.

4. 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 Article 9.

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

The rules contained in Article 9 are consistent with other relevant agency rules posted in title 12. There are not federal statutes and rules specific to the control, possession, or use of radiation producing equipment described in Article 9 as the regulatory authority is held at the state level.

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 90 accelerator registrants in the State of Arizona that use the rules and incorporated material in Article 9. Analysis of the economic impact statement for the rules created or last amended is attached as Exhibit 1.

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:

No actions were completed from the last 5 year review as rulemaking moratoriums were in place during the entire five year period and other actions took priority or met with the requirements available at the time to be granted approval to proceed.

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

The Agency has determined that the rules in Article 9 are not more stringent than corresponding federal regulations as there is no corresponding federal law that regulates the use of radiation machines described in these rules.

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:

None of the rules in article 9 were adopted or amended after July 29th, 2010. However, the Agency believes that the registrations issued by Article 9 is 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 to protect the public health and safety.

14. Course of Action for Rule Making:

The Agency would like to amend the existing rules; however it is the opinion of the Agency that prior executive orders along with the current rulemaking moratorium issued by executive order and new legislation prohibit these changes. The rulemaking that is needed include the following amendments or adoptions:

R12-1-902: Definitions need to be updated to include emergent technology terms (IMRT, VMAT, SRS, SBRT, MCC etc.)

R12-1-903: The training and experience required to register an accelerator should be further defined to meet the training as described in R12-1-711. This clarification should be added to the rule. In addition, 903(B)(3) needs the number “1” removed as a typographical error and subsection bullet of the rule to be lined up under the subsection 3 for clarification of the rule items.

R12-1-904: This rules needs to be amended to reflect ASTRO staffing requirements to meet accreditation and minimum safety standards.

R12-1-910: This rule states the minimum operational procedures for accelerators. A clarification to 910(E) is needed to include an additional numbered item stating “unless the bypass is for calibration and testing only”.

R12-1-913: This rule lists reporting requirements for therapeutic “misadministration” of radiation that needs the term to be updated to “medical event” and clarified to match the requirements similar to R12-1-611.01(Q), (R), and (S).

In addition, the adoption of several new rules in this article is needed to reflect emergent technology and advances in the manufacture of radiation treatment equipment. Some of these include rules that enforce preventative maintenance checks to prevent injury and death. In addition, consideration of a certification recognition rule for nationally recognized dosimetrists will need to be added.

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:

R12-1-901, R12-1-905 through R12-1-909, R12-1-911, R12-1-912, R12-1-914, and Appendix A.

6. Status of enforcement of the rule

The following rules are enforced as written:

R12-1-901, R12-1-905 through R12-1-909, R12-1-911, R12-1-912, R12-1-914, and Appendix A.

7. Analysis of clarity, conciseness, and understandability

The following rules are clear, concise, and understandable:

R12-1-901, R12-1-905 through R12-1-909, R12-1-911, R12-1-912, R12-1-914, and Appendix A.

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:

R12-1-901, R12-1-905 through R12-1-909, R12-1-911, R12-1-912, R12-1-914, and Appendix A.

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

R12-1-902, R12-1-903, R12-1-904, R12-1-910, and R12-1-913.

ARTICLE 1. RETIREMENT SYSTEM; DEFINED BENEFIT PLAN

R12-1-901. Purpose and Scope

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, and 30-673.

2. **Objective**

The objective of the rule is to provide notice to the public of the scope and purpose of the rules in Article 9.

R12-1-902. 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), 30-654(B)(18), 30-657(A), 30-671(B), 30-672, 30-672.01, and 30-673.

2. **Objective**

This rule provides the definitions specific for clarification in for this Article. The purpose of this rule is to provide definitions specific to accelerators to ensure general understanding of terms used in the Article.

3. **Analysis of effectiveness in achieving the objective**

The rule is not effective because several terms used in accelerator therapy are missing from this section.

6. **Status of enforcement of the rule**

The rule is not enforced as written because it is missing several terms. As an alternative, enforcement is by conditions listed in the issued registration for the facility.

7. **Analysis of clarity, conciseness, and understandability**

The rule is not clear, concise, or understandable because it is missing terms 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. The agency did not complete the proposed course of action as it is the opinion of the Agency that prior executive orders along with the current rulemaking moratorium issued

by executive order and new legislation prohibited these changes and staff priorities were for other projects.

R12-1-903. General Registration Requirements

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, and 30-673.

2. Objective

This rule stipulates the general registration requirements specific to particle accelerators. The purpose of this rule is to ensure that registrations are restricted to facilities that have qualified operators, adequate shielding, and an assigned radiation safety office in order to protect public health and safety.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because a clarification should be added to the rule. The training and experience required to register an accelerator should be further defined to meet the training as described in R12-1-711. In addition, 903(B)(3) needs the number “1” removed as a typographical error and subsection bullet of the rule to be lined up under the subsection 3 for clarification of the rule items.

6. Status of enforcement of the rule

The rule is not enforced as written because a clarification should be added to the rule. The training and experience required to register an accelerator should be further defined to meet the training as described in R12-1-711. In addition, 903(B)(3) needs the number “1” removed as a typographical error and subsection bullet of the rule to be lined up under the subsection 3 for clarification of the rule items. Acceptance to act as an authorized user is determined based upon the training and experience described in R12-1-711 and forms for registration include this information and reference.

7. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable because a clarification should be added to the rule. The training and experience required to register an accelerator should be further defined to meet the training as described in R12-1-711. In addition, 903(B)(3) needs the number “1” removed as a typographical error and subsection bullet of the rule

to be lined up under the subsection 3 for clarification of the rule items, 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. The agency did not complete the proposed course of action as it is the opinion of the Agency that prior executive orders along with the current rulemaking moratorium issued by executive order and new legislation prohibited these changes and staff priorities were for other projects.

R12-1-904. Registration of Particle Accelerators Used in the Practice of Medicine

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, and 30-673.

2. Objective

This rule describes additional registration requirements for accelerator registrants doing human research, authorized users and their board certification, quality management programs, calibration requirements, and staffing ratios. The purpose of this rule is to further list specific registration criteria for medical facility accelerator registrations.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because it needs to be amended to reflect the American Society for Radiation Oncology (ASTRO) staffing requirements to meet accreditation and minimum safety standards.

6. Status of enforcement of the rule

The rule is not enforced as written because it needs to be amended to reflect the American Society for Radiation Oncology (ASTRO) staffing requirements to meet accreditation and minimum safety standards. As an alternative, enforcement is by conditions listed in the issued registration for the facility.

7. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable because it needs to be amended to reflect the American Society for Radiation Oncology (ASTRO) staffing requirements to meet accreditation and minimum safety standards, and thereby does not fulfill its objective.

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

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, and 30-673.

2. Objective

This rule describes the equipment standards, facility shielding requirements, calibration procedures, and patient operating restrictions. The purpose of this rule is to provide regulatory guidance on the frequency, types, and what equipment to use to ensure that the energy from these high powered accelerators is being produced as desired before the device is used to treat humans.

R12-1-906. Limitations

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, and 30-673.

2. Objective

This rule sets the limits under which an individual may operate an accelerator. The purpose of this rule is to provide additional limits the registered activities in an accelerator facility to ensure that safety measures are followed and that the individuals accountable for safety have the managerial authority to cease operations to protect the public health and safety.

R12-1-907. Shielding and Safety Design

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, and 30-673.

2. Objective

This rule describes shielding requirements and documentation standards for shielding. The purpose of this rule is to ensure that adequate shielding is placed into operation and

tested prior to full operations by authorized and trained individuals and that the plans are reviewed at the Agency.

R12-1-908. Particle Accelerator Controls and Interlock 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), 30-654(B)(18), 30-657(A), 30-671(B), 30-672, 30-672.01, and 30-673.

2. Objective

This rule describes labeling, control panel, and interlock requirements. The purpose of this rule is to list the requirements for to check the workings and displays for entry point safety systems that are designed to protect public health and safety.

R12-1-909. Warning 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), 30-654(B)(18), 30-657(A), 30-671(B), 30-672, 30-672.01, and 30-673.

2. Objective

This rule describes the warning light, auditory alarms, and signage requirements for accelerators. The purpose of this rule is to ensure that auditory and visual warnings are equipped and used in accelerator facilities.

R12-1-910. Operating Procedures

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, and 30-673.

2. Objective

This rule states the minimum operational procedures for accelerators. The purpose of this rule to ensure that important information is maintained at the control area for use of the operators and available for inspection in the event of an audit.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because a clarification to 910(E) is needed to include an additional numbered item stating “unless the bypass is for calibration and testing only”.

6. Status of enforcement of the rule

The rule is not enforced as written because a clarification to 910(E) is needed to include an additional numbered item stating “unless the bypass is for calibration and testing only”.

7. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable because a clarification to 910(E) is needed to include an additional numbered item stating “unless the bypass is for calibration and testing only”, 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. The agency did not complete the proposed course of action as it is the opinion of the Agency that prior executive orders along with the current rulemaking moratorium issued by executive order and new legislation prohibited these changes and staff priorities were for other projects.

R12-1-911. Radiation 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), 30-654(B)(18), 30-657(A), 30-671(B), 30-672, 30-672.01, and 30-673.

2. Objective

This rule lists the survey meter and testing requirements as well as documentation timeframes. The purpose of this rule is to regulate the requirement of surveys to detect radiation levels that may accumulate from workload on undesired surfaces. This check is a portion of the radiation safety program designed to promote as low as reasonable achievable (ALARA).

R12-1-913. Misadministration

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, and 30-673.

2. Objective

This rule lists reporting requirements for therapeutic misadministration of radiation. The purpose of this rule is to describe the reporting requirements of a medical event. It lists the circumstances and timeframes for various reports.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because it needs to be updated to “medical event” and clarified to match the requirements similar to R12-1-611.01(Q), (R), and (S).

6. Status of enforcement of the rule

The rule is not enforced as written it needs to be updated to “medical event” and clarified to match the requirements similar to R12-1-611.01(Q), (R), and (S). As an alternative, enforcement is by conditions listed in the issued registration for the facility.

7. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable it needs to be updated to “medical event” and clarified to match the requirements similar to R12-1-611.01(Q), (R), and (S) and thereby does not fulfill its objective.

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

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, and 30-673. Specific: §30-681.

2. Objective

This rule lists the requirement for the Agency to conduct an initial inspection prior to accelerator being used on humans. The purpose of this rule is to ensure that a regulatory authority reviews or spot-checks the shielding of a new installation prior to use on humans to protect the public health and safety of the citizens of Arizona.

Appendix A. Quality Control Program

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, and 30-673.

2. Objective

This rule lists the minimum quality control tests required for accelerators. The purpose of this appendix is to list the outline of the minimum factors required to be addressed in a quality control program.

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ARRA
Revised October 20, 2015

FIVE-YEAR-REVIEW REPORT
TITLE 12. NATURAL RESOURCES
CHAPTER 1. RADIATION REGULATORY AGENCY

ARTICLE 6. USE OF X-RAYS IN THE HEALING ARTS,
ARTICLE 12. ADMINISTRATIVE PROVISIONS,
ARTICLE 14. REGISTRATION OF NONIONIZING RADIATION SOURCES
AND STANDARDS FOR PROTECTION AGAINST NONIONIZING
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6.	CURRENT RULES	Exhibit 2
7.	ENABLING AND RELATED STATUTES	Exhibit 3

FIVE-YEAR-REVIEW SUMMARY

The rules contained in Article 6 provide standards for registration, shielding, operation, and quality control requirements for protection against ionizing radiation from medical x-ray units. These rules were developed to meet standards as set forth by the federal Food and Drug Administration in Title 21 CFR part 1020 as well as Part F of the Suggested State Regulations (SSR's) for control of radiation as presented by the Conference of Radiation Control Program Directors (CRCPD).

The rules contained in Article 12 provide standards for administration of Title 12, Chapter 1 of the rules for the Radiation Regulatory Agency. They are required by A.R.S. §30-685, 30-686, 30-687, 30-688, and 30-689; and consistent with Part A of the SSR's for control of radiation as presented by the CRCPD.

The rules contained in Article 14 provide standards for registration, shielding, operation, and quality control requirements for protection against nonionizing radiation from radiation devices. These rules were developed to meet standards as set forth by the federal Food and Drug Administration in Title 21 CFR and with Parts AA and BB 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 6

R12-1-613 and Appendix A were last amended in 2003. R12-1-609 was last amended in 2004. R12-1-604 was last amended in 2009. R12-1-602, R12-1-603, R12-1-605, R12-1-606, R12-1-607, R12-1-608, R12-1-610, R12-1-610.01, R12-1-611, R12-1-611.01, R12-1-611.02, R12-1-612, R12-1-614 and R12-1-615 were last amended in 2014.

Article 12

R12-1-1203 and R12-1-1204 was adopted in 1996 and not amended. R12-1-1211, R12-1-1212, R12-1-1214, R12-1-1218, and R12-1-1222 were adopted in 1999 and not amended. R12-1-1201, R12-1-1202, R12-1-1205, R12-1-1207, R12-1-1209, R12-1-1210, R12-1-1213, R12-1-1216, R12-1-1217, R12-1-1219, R12-1-1220, and R12-1-1223 were last amended in 2003. R12-1-1215 and Table A were last amended in 2015.

Article 14

R12-1-1402, R12-1-1403, R12-1-1404, R12-1-1405, R12-1-1406, R12-1-1407, R12-1-1408, R12-1-1409, R12-1-1410, R12-1-1412, R12-1-1413, R12-1-1414, R12-1-1415, R12-1-1416, R12-1-1418, R12-1-1421, R12-1-1422, R12-1-1423, R12-1-1425, R12-1-1426, R12-1-1427, R12-1-1429, R12-1-1433, R12-1-1434, R12-1-1435, R12-1-1436, R12-1-1437, R12-1-1440, R12-1-1441, R12-1-1442, R12-1-1443, R12-1-1444, Appendix A, Appendix B, Appendix C, and Appendix D were last amended in 2005. R12-1-1401 was last amended in 2009. R12-1-1438, R12-1-1438.01, R12-1-1439, were last amended in 2010.

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 6. USE OF X-RAYS IN THE HEALING ARTS

R12-1-601. Repealed

R12-1-602. Definitions

R12-1-603. Operational Standards, Shielding, and Darkroom Requirements

R12-1-604. General Procedures

R12-1-605. X-ray Machine Standards

R12-1-606. Fluoroscopic and Fluoroscopic Treatment Simulator Systems

R12-1-607. Additional X-ray Machine Standards, Shielding Requirements, and Procedures, Except Mobile Fluoroscopic, Dental Panoramic, Cephalometric, Dental CT, or Dental Intraoral Radiographic Systems

R12-1-608. Mobile Diagnostic Radiographic and Mobile Fluoroscopic Systems, Except Dental Panoramic, Cephalometric, Dental CT, or Dental Intraoral Radiographic Systems

R12-1-609. Chest Photofluorographic Systems

R12-1-610. Dental Intraoral Radiographic Systems

R12-1-610.01. Hand-held Intraoral Dental Radiographic Unit Requirements For Use

R12-1-611. Therapeutic X-ray Systems of Less Than 1 MeV

R12-1-611.01. Electronic Brachytherapy to Deliver Interstitial and Intracavity Therapeutic Radiation Dosage

R12-1-611.02. Other Use of Electronically-Produced Radiation to Deliver Superficial Therapeutic Radiation Dosage

R12-1-612. Computed Tomography Systems

R12-1-613. Veterinary Medicine Radiographic Systems

R12-1-614. Mammography Systems

R12-1-615. Mammography Personnel

Appendix A. Information Submitted to the Agency According to R12-1-604(A)(3)(c)

Appendix B. Repealed

ARTICLE 12. ADMINISTRATIVE PROVISIONS

- R12-1-1201. Timeliness
- R12-1-1202. Administrative Hearings
- R12-1-1203. Procedures for Rulemaking Public Hearings
- R12-1-1204. Initiation of Administrative Hearings
- R12-1-1205. Intervention in Administrative Hearings; Director as a Party
- R12-1-1206. Repealed
- R12-1-1207. Rehearing or Review
- R12-1-1208. Repealed
- R12-1-1209. Notice of Violation
- R12-1-1210. Response to Notice of Violation
- R12-1-1211. Initial Orders
- R12-1-1212. Request for Hearing in Response to an Initial Order
- R12-1-1213. Severity Levels of Violations
- R12-1-1214. Mitigating Factors
- R12-1-1215. License and Registration Divisions
- R12-1-1216. Civil Penalties
- R12-1-1217. Augmentation of Civil Penalties
- R12-1-1218. Payment of Civil Penalties
- R12-1-1219. Additional Sanctions-Show Cause
- R12-1-1220. Escalated Enforcement
- R12-1-1221. Reserved
- R12-1-1222. Enforcement Conferences
- R12-1-1223. Registration and Licensing Time-frames
- Table A. Registration and Licensing Time-frames

ARTICLE 14. REGISTRATION OF NONIONIZING RADIATION SOURCES AND STANDARDS FOR PROTECTION AGAINST NONIONIZING RADIATION

- R12-1-1401. Registration of Nonionizing Radiation Sources and Service Providers
- R12-1-1402. Definitions
- R12-1-1403. General Safety Provisions and Exemptions

R12-1-1404. Radio Frequency Equipment

R12-1-1405. Radio Frequency Radiation: Maximum Permissible Exposure

R12-1-1406. Radio Frequency Hazard Caution Signs, Symbols, Labeling, and Posting

R12-1-1407. Microwave Ovens

R12-1-1408. Reporting of Radio Frequency Radiation Incidents

R12-1-1409. Medical Surveillance for Workers Who May Be Exposed to Radio Frequency Radiation

R12-1-1410. Radio Frequency Compliance Measurements

R12-1-1411. Repealed

R12-1-1412. Tanning Operations

R12-1-1413. Tanning Equipment Standards

R12-1-1414. Tanning Equipment Operators

R12-1-1415. Tanning Facility Warning Signs

R12-1-1416. Reporting of Tanning Injuries

R12-1-1417. Repealed

R12-1-1418. High Intensity Mercury Vapor Discharge (HID) Lamps

R12-1-1419. Reserved

R12-1-1420. Reserved

R12-1-1421. Laser Safety

R12-1-1422. Laser Protective Devices

R12-1-1423. Laser Prohibitions

R12-1-1424. Repealed

R12-1-1425. Laser Product Classification

R12-1-1426. Laser and Collateral Radiation Exposure Limits

R12-1-1427. Laser Caution Signs, Symbols, and Labels

R12-1-1428. Repealed

R12-1-1429. Posting of Laser Facilities

R12-1-1430. Repealed

R12-1-1431. Repealed

R12-1-1432. Repealed

R12-1-1433. Laser Use Areas that are Controlled

R12-1-1434. Laser Safety Officer (LSO)
R12-1-1435. Laser Protective Eyewear
R12-1-1436. Reporting Laser Incidents
R12-1-1437. Special Lasers
R12-1-1438. Hair Reduction and Other Cosmetic Procedures Using Laser and Intense Pulsed Light
R12-1-1438.01. Certification and Revocation of Laser Technician Certificate
R12-1-1439. Laser and IPL Laser Technician and Laser Safety Training Programs
R12-1-1440. Medical Lasers
R12-1-1441. Laser Light Shows and Demonstrations
R12-1-1442. Measurements and Calculations to Determine MPE Limits for Lasers
R12-1-1443. Laser Compliance Measurement Instruments
R12-1-1444. Laser Classification Measurements
Appendix A. Radio Frequency Devices (Include, but are not limited to, the following)
Appendix B. Application Information
Appendix C. Hair Removal and Other Cosmetic Laser or IPL Operator Training Program
Appendix D. Laser Operator and Laser Safety Officer Training

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), 30-654(B)(18), 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 6 are consistent with other relevant agency rules posted in Title 12. There are not federal statutes and regulations specific to the control, possession, or use of radiation producing equipment described in Article 6 as the regulatory authority is held at the state level with the exception of the R12-1-614 and R12-1-615.

Three rules in Article 12 are not consistent with Arizona Statutes as expressed in the previous 5 year report. Modification is pending approval to correct Article 12 after approval or denial of existing packages in the Governor's office out of respect for the moratorium and the existing priorities of other Agency rulemakings. These consistency issues will be addressed in the specific rules during that portion of the report.

The rules in Article 14 are not consistent with some of the scopes of practice in other agencies that have authority to issue practice licenses such as the Acupuncture Board of Examiners and the Board of Physical Therapy, The State Board of Nursing, and other therapy regulated boards that the Agency may not be fully aware of. These areas will be addressed in future rulemaking that seeks to better differentiate human application of nonionizing energy compared to industrial uses. The current endeavor seeks to re-write Article 14 as industrial use only and create a human application Article with three minor subdivisions (medical, cosmetic, therapy) that address various scope issues.

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 6, and 12. The Agency has received criticism on the rules in Article 14. Specifically many industries such as acupuncture, physical therapy, occupational therapy, and dermatology feel that the classifications and breakout of nonionizing uses in Article 14 are inadequate. Two stakeholder meetings have been conducted to solicit feedback on potential modifications. In addition, management of the Agency has spoken to the acupuncture board and the physical therapy board on possible solutions.

Also, the Agency has been made aware of an issue in the cosmetic or Medspa environment as the verbiage in the law has created an issue with the rules that is not easily resolved without legislative actions. This issue is that most of these cosmetic facilities have an electronic nonionizing unit with interchangeable heads or attachments. These heads are typically a laser device, an IPL device, and an RF device. As the law is written, technician may only use the laser or IPL attachments and a medical practitioner is required to use the RF device head. The rules in Article 14 cannot combine these technologies until the statutes related to cosmetic use of nonionizing radiation are modified or corrected.

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 6; 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 12; and 1600 technicians certified as cosmetic laser techs as well as 1,500 nonionizing facilities using the rules and incorporated material in Article 14. 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 6, 12, and 14 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 Article 6, 12, and 14 except as expressed below.

Administrative rules made in 1996 (R12-1-1203 and R12-1-1204) refer to internal Agency processes and little or no economic impact has occurred within the Agency. It is likely that there is little to no economic impact on the regulated community with the exception of travel expenses incurred for those that attend public hearings or may request an administrative hearing. It is the Agency 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.

The rules last amended in 1999 (R12-1-1211, R12-1-1212, R12-1-1214, R12-1-1218, and R12-1-1222) are 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 \$72,322 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 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 6 were completed in a rulemaking in 2014. No actions were completed from the last 5 year review as rulemaking for Articles 12 and 14 as progress in this area was suspended until the new governor could take office and pending the outcome of the Agency Sunset Audit to

ensure that as many recommendations as practical can be included in the request to proceed.

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

The Agency has determined that the rules in Article 6, 12, and 14 are not more stringent than corresponding federal regulations. As a point of clarification, although some federal performance standards are incorporated by reference in the rules, there is no corresponding federal law that regulates the use of radiation machines described in Articles 6 and 14, and Article 12 is specific to Arizona laws and rules for administrative provisions.

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 14 and the certifications under R12-1-1438.01 and R12-1-1439 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 6 or 12 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 to proceed following two additional pending requests (the second of which has some modifications listed in this report) and the completion of the sunset audit recommendations as previously stated. The Agency is currently writing the draft proposal for our assigned Policy Advisor in the Governor's office for submission but was asked to hold for the outcome of the Committee of Reference hearing On November 4th as additional statutory language may impact how the portions related to laser techs is addressed (possibility of chapter 2 compared to chapter one). We anticipate the request to be submitted as soon as we know the legislative plan for the Agency. It is believed

that the Governor's office will likely support the rulemaking in the early portion of 2016, following the passage of the existing RMP-0078 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 2016. The rulemaking that is needed includes the following amendments or adoptions:

ARTICLE 6

None

ARTICLE 12

R12-1-1204: A re-write of the rule to more closely match ARS 41-1092.03 (A)(4) and (B).

R12-1-1205: A re-write of the rule to more closely match ARS 41-1092.03 (B).

R12-1-1212: A re-write of the rule to more closely match ARS 41-1092.03 (B).

R12-1-1215: The modification of the heading of this rule to read “Certification, License, and Registration Divisions” is needed. The addition of a certified laser technician schools to (A)(3) and a correction of the heading to include certificates is needed. The addition of certified laser technicians and certified laser technician schools to (D) as item 5 and a correction of the title to include certificates is needed unless the agency moves this certification program to the MRTBE board in which case it will be listed as an amendment under Title 12, Chapter 2.

Table A: The table needs to be updated to account for the time frame requirements listed in R12-1-1438.01(G) and R12-1-1439(B) unless the agency moves this certification program to the MRTBE board in which case it will be listed as an amendment under Title 12, Chapter 2.

ARTICLE 14

The rules under Article 14 are currently being investigated for a possible rewrite to differentiate the industrial application uses of nonionizing

radiation from the application of nonionizing radiation on humans. In order to accomplish this task, the Agency has conducted stakeholder meetings to retain some portion of Article 14 that applies to industrial uses. Those rules that apply to the application of nonionizing radiation on humans would be moved to a new article and subdivided into three primary applications: medical, cosmetic, and therapeutic. Several issues are present in the current Article related to statutory language of 32-516, 32-3231, and 32-3233 that creates the need for some nonionizing applications for the use of cosmetic lasers and IPL devices to be regulated in two different manners for the same unit because of the attachment heads not considered. In addition occupations have demonstrably difficult issues related to meeting the regulatory requirements listed in these rules such as dermatologists that use ultra violet light to treat jaundice but must meet the regulatory requirements listed as a tanning bed because of the limited and antiquated framework of the rules. Other examples include the scope of practice for light, laser, and other nonionizing therapy in the real world that must be pigeon holed in to the rules for cosmetic or medical, neither of which is appropriate for that occupation. The suggested amendments in this portion of the report are suggested as guidance until further legislative actions and rulemaking opportunities transpire. It is likely that these suggested amendments would be unnecessary following the proposed correction of the Statutes.

R12-1-1401: A clarification that amended registration information will need to be submitted to the Agency on Agency supplied forms is needed.

R12-1-1402: Clarification of some definitions on supervision may be needed as well as a definition of a prescribing health care professional may be needed. There are multiple other incorporations by reference related to the Code of Federal Regulations that will also need to be updated either in Article 14 or in

Article 1 or Article 16 depending upon where each definition with an incorporated reference is relocated.

- R12-1-1403: This rule needs an update to list that cosmetic uses of lasers and IPL requires an individual working under their scope of practice or a certification to be a laser technician as issued by this Agency.
- R12-1-1404: An update to the incorporated material to IEEE Std C95.1-2005 is needed.
- R12-1-1405: An update to the incorporated material to IEEE Std C95.1-2005 is needed.
- R12-1-1407: An update to the incorporated material to April 1, 2015 is needed.
- R12-1-1410: An update to the incorporated material to IEEE Std C95.1-2005 is needed.
- R12-1-1413: An update to the incorporated material to April 1, 2015 is needed.
- R12-1-1418: An update to the incorporated material to April 1, 2015 is needed.
- R12-1-1422: An update to the incorporated material to April 1, 2015 is needed.
- R12-1-1425: An update to the incorporated material to April 1, 2015 is needed.
- R12-1-1426: An update to the incorporated material to ANSI Standard Z136.1 (2014) and the CFR's to April 1, 2015 is needed.
- R12-1-1427: An update to ANSI Standard Z136.1 (2014) is needed as well as an update to the incorporated material to April 1, 2015 is needed.
- R12-1-1429: An update to ANSI Standard Z136.1 (2014) is needed.
- R12-1-1436: The editor's note no longer makes sense in the rule and should be removed.
- R12-1-1438: An update to the incorporated material to April 1, 2015 is needed.
- R12-1-1438.01: Removal of the time frame requirements when it can be

added to Article 12 is anticipated unless the program is moved under MRTBE and then the amendment will occur in Chapter 2.

R12-1-1439: Removal of the time frame requirements when it can be added to Article 12 is anticipated unless the program is moved under MRTBE and then the amendment will occur in Chapter 2.

R12-1-1441: An update to the incorporated material to April 1, 2015 is needed.

R12-1-1442: An update to ANSI Standard Z136.1 (2014) is needed.

R12-1-1444: An update to the incorporated material to April 1, 2015 is needed.

Appendix B: An update to the minimum amount of information needed to apply for registration is needed.

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:

R12-1-602 through R12-1-615, and Appendix A; R12-1-1201 through R12-1-1203, R12-1-1207 through R12-1-1211, R12-1-1213 through R12-1-1214, R12-1-1216 through R12-1-1223; R12-1-1406, R12-1-1408, R12-1-1409, R12-1-1412, R12-1-1415, R12-1-1416, R12-1-1421, R12-1-1423, R12-1-1433 through R12-1-1435, R12-1-1437, R12-1-1440, R12-1-1443, and Appendix A, C, and D.

5. **Status of enforcement of the rule**

The following rules are enforced as written:

R12-1-602 through R12-1-615, and Appendix A; R12-1-1201 through R12-1-1203, R12-1-1207 through R12-1-1211, R12-1-1213 through R12-1-1214, R12-1-1216 through R12-1-1223; R12-1-1406, R12-1-1408, R12-1-1409, R12-1-1412, R12-1-1415, R12-1-1416, R12-1-1421, R12-1-1423, R12-1-1433 through R12-1-1435, R12-1-1437, R12-1-1440, R12-1-1443, and Appendix A, C, and D.

6. **Analysis of clarity, conciseness, and understandability**

The following rules are clear, concise, and understandable:

R12-1-602 through R12-1-615, and Appendix A; R12-1-1201 through R12-1-1203, R12-1-1207 through R12-1-1211, R12-1-1213 through R12-1-1214, R12-1-1216 through R12-1-1223; R12-1-1406, R12-1-1408, R12-1-1409, R12-1-1412, R12-1-1415, R12-1-1416, R12-1-1421, R12-1-1423, R12-1-1433 through R12-1-1435, R12-1-1437, R12-1-1440, R12-1-1443, and Appendix A, C, and D.

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

The Agency completed the rule amendments listed in the previous five year report for Article 6. The amended rules in Article 6 are effective in meeting their objectives.

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:

R12-1-602 through R12-1-615, and Appendix A; R12-1-1201 through R12-1-1203, R12-1-1207 through R12-1-1211, R12-1-1213 through R12-1-1214, R12-1-1216 through R12-1-1223; R12-1-1406, R12-1-1408, R12-1-1409, R12-1-1412, R12-1-1415, R12-1-1416, R12-1-1421, R12-1-1423, R12-1-1433 through R12-1-1435, R12-1-1437, R12-1-1440, R12-1-1443, and Appendix A, C, and D.

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

R12-1-1204, R12-1-1205, R12-1-1212, R12-1-1215, Table A, and the separation of Article 14 into two Articles as described in this report or the alternative of amending R12-1-1401, R12-1-1402, R12-1-1403, R12-1-1404, R12-1-1405, R12-1-1407, R12-1-1410, R12-1-1413, R12-1-1414, R12-1-1418, R12-1-1422, R12-1-1425, R12-1-1426, R12-1-1427, R12-1-1429, R12-1-1436, R12-1-1438, R12-1-1438.01, R12-1-1439, R12-1-1441, R12-1-1442, R12-1-1444, and Appendix B.

ANALYSIS OF INDIVIDUAL RULES

ARTICLE 12

R12-1-1204. Initiation of Administrative Hearings

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 standards for initiating a hearing based upon agency action including citations, registration actions, or licensing requirements.

3. **Analysis of effectiveness in achieving the objective**

The rule is not effective because it different from the statutory language of ARS 41-1092.03 (A)(4) and (B) as amended.

5. **Status of enforcement of the rule**

The rule is not enforced as written. As an alternative, enforcement is by ARS 41-1092.03 as amended.

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.

R12-1-1205. Intervention in Administrative Hearings; Director as a Party

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 standards for intervening in a proceeding based upon law or interest.

3. **Analysis of effectiveness in achieving the objective**

The rule is not effective because it different from the statutory language of ARS 41-1092.03 (B) as amended.

5. Status of enforcement of the rule

The rule is not enforced as written. As an alternative, enforcement is by ARS 41-1092.03 as amended.

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.

R12-1-1212. Request for Hearing in Response to an Initial Order

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 discusses the standards used to request a hearing in response to an initial order issued by the Agency.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because it different from the statutory language of ARS 41-1092.03 (B) as amended.

5. Status of enforcement of the rule

The rule is not enforced as written. As an alternative, enforcement is by ARS 41-1092.03 as amended.

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.

R12-1-1215. License and Registration Divisions

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 provides the standards used to classify the severity level of a violation.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because it does not address the certified laser technician classification as well as the registered laser technician school program..

5. Status of enforcement of the rule

The rule is not enforced as written. As an alternative, enforcement of the missing items are enforced in the specific rules for certified laser technicians and schools in Article 14 as well as by A.R.S. §§32-516 and 32-3233.

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.

Table A. Registration and Licensing Time-frames

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 provides the standards used to classify the severity level of a violation.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because it does not address the certified laser technician classification as well as the registered laser technician school program..

5. Status of enforcement of the rule

The rule is not enforced as written. As an alternative, enforcement of the missing items are enforced in the specific rules for certified laser technicians and schools in Article 14 as well as by A.R.S. §§32-516 and 32-3233.

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 14. REGISTRATION OF NONIONIZING RADIATION SOURCES AND STANDARDS FOR PROTECTION AGAINST NONIONIZING RADIATION

R12-1-1401. Registration of Nonionizing Radiation Sources and Service Providers

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, 32-516, and 32-3233..

2. **Objective**

This rule provides registration instructions for non-ionizing radiation units and service providers.

3. **Analysis of effectiveness in achieving the objective**

The rule is not effective because a clarification should be added to the rule as described previously in this report related to potentially modifying the Article in its entirety.

5. **Status of enforcement of the rule**

The rule is not enforced as written because a clarification should be added to the rule as to additional items required in alternative places in Article 14 or in §32-516, and 32-3233.

6. **Analysis of clarity, conciseness, and understandability**

The rule is not clear, concise, or understandable because a clarification should be added to the rule.

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

No.

R12-1-1402. 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), 30-654(B)(18), 30-657(A), 30-671(B), 30-672, 30-672.01, 30-673, 32-516, and 32-3233..

2. Objective

This rule provides the definitions specific to this Article.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because additional definitions as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. Status of enforcement of the rule

The rule is not enforced as written because a clarification should be added to the rule as to additional items required in alternative places in Article 14 or in §32-516, and 32-3233.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable because additional definitions as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

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

No.

R12-1-1403. General Safety Provisions and Exemptions

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, 32-516, and 32-3233..

2. Objective

This rule sets the safety provisions used when utilizing non-ionizing radiation units. It also allows the agency to consider waiving compliance.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because needs an update to state that cosmetic uses of lasers and intense pulse light device (IPL) requires an individual working under their scope of practice or a certification to be a laser technician as issued by this Agency, as well as

restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. Status of enforcement of the rule

The rule is not enforced as written because needs an update to state that cosmetic uses of lasers and intense pulse light device (IPL) requires an individual working under their scope of practice or a certification to be a laser technician as issued by this Agency, as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable because needs an update to state that cosmetic uses of lasers and intense pulse light device (IPL) requires an individual working under their scope of practice or a certification to be a laser technician as issued by this Agency, as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

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

No.

R12-1-1404. Radio Frequency Equipment

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.

2. Objective

This rule lists the standards of use for radio frequency equipment.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because an update to the incorporated material from the 1999 version to the 2005 version is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. Status of enforcement of the rule

The rule is not enforced as written because an update to the incorporated material from the 1999 version to the 2005 version is needed as well as restructuring as described

previously in this report related to potentially modifying the Article in its entirety is needed.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable because an update to the incorporated material from the 1999 version to the 2005 version is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

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

No action was proposed.

R12-1-1405. Radio Frequency Radiation: Maximum Permissible Exposure

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, 32-516, and 32-3233.

2. Objective

This rule lists the permissible exposure standards of use for radio frequency equipment.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because an update to the incorporated material from the 1999 version to the 2005 version is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. Status of enforcement of the rule

The rule is not enforced as written because an update to the incorporated material from the 1999 version to the 2005 version is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable because an update to the incorporated material from the 1999 version to the 2005 version is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

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

No.

R12-1-1407. Microwave Ovens

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.

2. **Objective**

This rule lists the standards of use for microwave ovens.

3. **Analysis of effectiveness in achieving the objective**

The rule is not effective because an update to the incorporated material from the 2004 version to the April 1, 2015 version is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. **Status of enforcement of the rule**

The rule is not enforced as written because an update to the incorporated material from the 2004 version to the April 1, 2015 version is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

6. **Analysis of clarity, conciseness, and understandability**

The rule is not clear, concise, or understandable because an update to the incorporated material from the 2004 version to the April 1, 2015 version is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

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

No.

R12-1-1410. Radio Frequency Compliance Measurements

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, and 30-673.

2. Objective

This rule lists the compliance measurements for radio frequency equipment.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because an update to the incorporated material to the IEEE Std C95.1-2005 is needed as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. Status of enforcement of the rule

The rule is not enforced as written because an update to the incorporated material to the IEEE Std C95.1-2005 is needed as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable because an update to the incorporated material to the IEEE Std C95.1-2005 is needed as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

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

No.

R12-1-1413. Tanning Equipment Standards

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, and 30-673.

2. Objective

This rule describes the standards for tanning facility equipment.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because an update to the incorporated material is needed, addition of FDA approved labeling information is needed, as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. **Status of enforcement of the rule**

The rule is not enforced as written because an update to the incorporated material is needed, addition of FDA approved labeling information is needed, as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

6. **Analysis of clarity, conciseness, and understandability**

The rule is not clear, concise, or understandable because an update to the incorporated material is needed, addition of FDA approved labeling information is needed, as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

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

No.

R12-1-1414. Tanning Equipment Operators

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, and 30-673.

2. **Objective**

This rule describes the standards for tanning facility operators.

3. **Analysis of effectiveness in achieving the objective**

The rule is not effective because an update to the incorporated material is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. **Status of enforcement of the rule**

The rule is not enforced as written because an update to the incorporated material is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

6. **Analysis of clarity, conciseness, and understandability**

The rule is not clear, concise, or understandable because an update to the incorporated material is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

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

No.

R12-1-1418. High Intensity Mercury Vapor Discharge (HID) Lamps

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, and 30-673.

2. Objective

This rule describes under what condition a mercury vapor discharge lamp must be registered.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because an update to the incorporated material is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. Status of enforcement of the rule

The rule is not enforced as written because an update to the incorporated material is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable because an update to the incorporated material is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

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

No.

R12-1-1422. Laser Protective Devices

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, 32-516, and 32-3233..

2. Objective

This rule sets the standards for laser protection requirements for facilities using laser equipment.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because an update to the incorporated material is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. Status of enforcement of the rule

The rule is not enforced as written because an update to the incorporated material is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable because an update to the incorporated material is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

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

No.

R12-1-1425. Laser Product Classification

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, 32-516, and 32-3233.

2. Objective

This rule sets the standards for classification of laser equipment.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because an update to the incorporated material is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. Status of enforcement of the rule

The rule is not enforced as written because an update to the incorporated material is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable because an update to the incorporated material is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

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

No.

R12-1-1426. Laser and Collateral Radiation Exposure Limits

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, 32-516, and 32-3233.

2. Objective

This rule describes the exposure limits when using lasers.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because an update to the incorporated material is needed including an update to ANSI Standard Z136.1 (2014) as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. Status of enforcement of the rule

The rule is not enforced as written because an update to the incorporated material is needed including an update to ANSI Standard Z136.1 (2014) as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

6. **Analysis of clarity, conciseness, and understandability**

The rule is not clear, concise, or understandable because an update to the incorporated material is needed including an update to ANSI Standard Z136.1 (2014) as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

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

No.

R12-1-1427. Laser Caution Signs, Symbols, and Labels

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, 32-516, and 32-3233.

2. **Objective**

This rule describes the caution sign requirements when using lasers.

3. **Analysis of effectiveness in achieving the objective**

The rule is not effective because an update to the incorporated material is needed including an update to ANSI Standard Z136.1 (2014) as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. **Status of enforcement of the rule**

The rule is not enforced as written because an update to the incorporated material is needed including an update to ANSI Standard Z136.1 (2014) as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

6. **Analysis of clarity, conciseness, and understandability**

The rule is not clear, concise, or understandable because an update to the incorporated material is needed including an update to ANSI Standard Z136.1 (2014) as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

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

No.

R12-1-1429. Posting of Laser Facilities

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, 32-516, and 32-3233.

2. Objective

This rule describes the posting requirements when using lasers.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because an update to ANSI Standard Z136.1 (2014) as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. Status of enforcement of the rule

The rule is not enforced as written because an update to ANSI Standard Z136.1 (2014) as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable because an update to ANSI Standard Z136.1 (2014) as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

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

No.

R12-1-1436. Reporting Laser Incidents

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, 32-516, and 32-3233.

2. Objective

This rule describes incident reporting standards for laser use.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because the editor's note is no longer needed; modification to meet medical event criteria similar to rules already in Chapter 1 as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. Status of enforcement of the rule

The rule is not enforced as written because the editor's note is no longer needed; modification to meet medical event criteria similar to rules already in Chapter 1 as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable because the editor's note is no longer needed; modification to meet medical event criteria similar to rules already in Chapter 1 as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

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

No.

R12-1-1438. Hair Reduction and Other Cosmetic Procedures Using Laser and Intense Pulsed Light

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, 32-516, and 32-3233.

2. Objective

This rule describes the cosmetic procedure use of lasers and IPL devices.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because an update from the 2010 to the April 1, 2015 version of the incorporated material is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. **Status of enforcement of the rule**

The rule is not enforced as written because an update from the 2010 to the April 1, 2015 version of the incorporated material is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

6. **Analysis of clarity, conciseness, and understandability**

The rule is not clear, concise, or understandable because an update from the 2010 to the April 1, 2015 version of the incorporated material is needed as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

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

No action was proposed.

R12-1-1438.01.Certification and Revocation of Laser Technician Certificate

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, 32-516, and 32-3233.

2. **Objective**

This rule describes the certification requirements for laser technicians.

3. **Analysis of effectiveness in achieving the objective**

The rule is not effective because additional definitions as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. **Status of enforcement of the rule**

The rule is not enforced as written because the timeliness requirements for this rule should be moved to Article 12 or Chapter 2 depending upon the sunset audit.

6. **Analysis of clarity, conciseness, and understandability**

The rule is not clear, concise, or understandable because the timeliness requirements for this rule should be moved to Article 12 or Chapter 2 depending upon the sunset audit.

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

No.

R12-1-1439. Laser and IPL Laser Technician and Laser Safety Training Programs

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, 32-516, and 32-3233.

2. Objective

This rule describes training programs certification for laser training programs.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because additional definitions as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. Status of enforcement of the rule

The rule is not enforced as written because the timeliness requirements for this rule should be moved to Article 12 or Chapter 2 depending upon the sunset audit.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable because the timeliness requirements for this rule should be moved to Article 12 or Chapter 2 depending upon the sunset audit.

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

No.

R12-1-1441. Laser Light Shows and Demonstrations

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, and 30-673.

2. Objective

This rule describes the posting requirements when using lasers.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because updates to the incorporated material as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. Status of enforcement of the rule

The rule is not enforced as written because updates to the incorporated material as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable because updates to the incorporated material as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

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

No.

R12-1-1442. Measurements and Calculations to Determine MPE Limits for Lasers

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, and 30-673.

2. Objective

This rule describes minimum standards for maximum permissible exposure (MPE) limits.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because an update to ANSI Standard Z136.1 (2014) as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. Status of enforcement of the rule

The rule is not enforced as written because an update to ANSI Standard Z136.1 (2014) as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable because an update to ANSI Standard Z136.1 (2014) as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

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

No.

R12-1-1444. Laser Classification Measurements

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, and 30-673.

2. **Objective**

This rule describes the laser areas used to measure accessible emissions.

3. **Analysis of effectiveness in achieving the objective**

The rule is not effective because updates to the incorporated material as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. **Status of enforcement of the rule**

The rule is not enforced as written because updates to the incorporated material as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

6. **Analysis of clarity, conciseness, and understandability**

The rule is not clear, concise, or understandable because updates to the incorporated material as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

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

No.

Appendix B. Application Information

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, 32-516, and 32-3233.

2. Objective

This appendix lists facility registration application information.

3. Analysis of effectiveness in achieving the objective

The rule is not effective because an update to the minimum amount of information, clarification that an LSO is a sub group of an RSO and modification to meet existing forms as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

5. Status of enforcement of the rule

The rule is not enforced as written because an update to the minimum amount of information, clarification that an LSO is a sub group of an RSO and modification to meet existing forms as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

6. Analysis of clarity, conciseness, and understandability

The rule is not clear, concise, or understandable because an update to the minimum amount of information, clarification that an LSO is a sub group of an RSO and modification to meet existing forms as well as restructuring as described previously in this report related to potentially modifying the Article in its entirety is needed.

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

N/A.

Five-year Review of Article 8, & 10
ARRA
October 24, 2016

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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7.	ENABLING AND RELATED STATUTES	Exhibit 3

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, 30-672 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

R12-1-801. Scope

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

R12-1-806. Operating Requirements

R12-1-807. Surveys

R12-1-808. Posting

R12-1-809. Training

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

R12-1-1002. Posting Notices for Workers

R12-1-1003. Instruction for Workers

R12-1-1004. Notifications and Reports to Individuals

R12-1-1005. Licensee, Registrant, and Worker Representation
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 beam 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.

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ARTICLE 7. MEDICAL USES OF RADIOACTIVE MATERIAL
ARTICLE 13. LICENSE AND REGISTRATION FEES

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1. FIVE-YEAR REVIEW SUMMARY
2. INFORMATION THAT IS IDENTICAL FOR ALL RULES
3. INFORMATION THAT IS IDENTICAL WITHIN GROUPS OF RULES
4. ANALYSIS OF INDIVIDUAL RULES
5. ECONOMIC IMPACT STATEMENT (EIS)
6. CURRENT RULES
7. ENABLING AND RELATED STATUTES

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

- R12-1-701. License Required
- R12-1-702. Definitions
- R12-1-703. License for Medical Use of Radioactive Material
- R12-1-704. Provisions for the Protection of Human Research Subjects
- R12-1-705. Authority and Responsibilities for the Radiation Protection Program
- R12-1-706. Supervision
- R12-1-707. Written Directives
- R12-1-708. Procedures for Administrations Requiring a Written Directive
- R12-1-709. Sealed Sources or Devices for Medical Use
- R12-1-710. Radiation Safety Officer Training
- R12-1-711. Authorized Medical Physicist Training
- R12-1-712. Authorized Nuclear Pharmacist Training
- R12-1-713. Determination of Prescribed Dosages, and Possession, Use, and Calibration of Instruments
- R12-1-714. Authorization for Calibration, Transmission, and Reference

Sources

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

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Sources

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

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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

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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. 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 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 GRRRC 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.

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- 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

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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

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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:

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