NOTICES OF FINAL RULEMAKING

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

NOTICE OF FINAL RULEMAKING

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

PREAMBLE

1. Sections Affected	Rulemaking Action
Article 2	Amend
R12-1-201	Amend
R12-1-202	Amend
R12-1-203	Amend
R12-1-205	Amend
R12-1-206	Amend
R12-1-207	Amend
R12-1-208	Amend
Appendix A	Amend
R12-1-602	Amend
R12-1-603	Amend
R12-1-604	Amend
R12-1-605	Amend
R12-1-606	Amend
R12-1-607	Amend
R12-1-608	Amend
R12-1-609	Amend
R12-1-610	Amend
R12-1-611	Amend
R12-1-613	Amend
R12-1-614	Amend
R12-1-615	Repeal
Appendix A	Amend
Appendix B	Repeal
R12-1-901	Amend
R12-1-902	New Section
R12-1-903	Amend
R12-1-904	Amend
R12-1-905	Amend
R12-1-906	Amend
R12-1-907	Amend
R12-1-908	Amend
R12-1-909	Amend
R12-1-910	Amend
R12-1-911	Amend
Appendix A	New Appendix
R12-1-1201	Amend
R12-1-1202	Amend
R12-1-1205	Amend
R12-1-1206	Repeal
R12-1-1207	Amend
R12-1-1208	Repeal
R12-1-1209	Amend
R12-1-1210	Amend
R12-1-1213	Amend
R12-1-1215	Amend

R12-1-1216	Amend
R12-1-1217	Amend
R12-1-1219	Amend
R12-1-1220	Amend
R12-1-1223	Amend
Table A	Amend
Article 17	Amend
R12-1-1702	Amend
R12-1-1703	Amend
R12-1-1712	Amend
R12-1-1714	Amend
R12-1-1715	Amend
R12-1-1717	Amend
R12-1-1718	Amend
R12-1-1719	Amend
R12-1-1720	Amend
R12-1-1721	Amend
R12-1-1722	Amend
R12-1-1723	Amend
R12-1-1731	Amend
R12-1-1733	Amend
R12-1-1734	Amend
R12-1-1741	Amend
R12-1-1742	Amend
R12-1-1743	Amend
R12-1-1751	Amend

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

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

Implementing statutes: A.R.S. §§ 30-657, 30-671(B), 30-672(H) and (J), 30-673, 30-686, 30-687, 30-688, 32-2842, and 32-2843

3. The effective date of the rules:

November 14, 2003

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

Notice of Rulemaking Docket Opening: 6 A.A.R. 4834, December 29, 2000

Notice of Rulemaking Docket Opening: 7 A.A.R. 4097, September 14, 2001

Notice of Proposed Rulemaking: 7 A.A.R. 5585, December 21, 2001

Notice of Public Information: 8 A.A.R. 2763, June 28, 2002

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

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6. An explanation of the rules, including the agency's reasons for initiating the rules:

Introductory Statement: The majority of the changes are the result of a five-year review of the rules contained in the following Articles: Article 2, completed in February 2000; Article 17, completed in June 2000; Articles 6 and 9, completed in September 2000; and Articles 12, completed in October 2000. The reviews have resulted in significant rule changes.

Article 2: Minor changes are made to Article 2 as a result of the five-year review.

Article 6: A number of definitions are added and deleted to assist the reader to understand the requirements in this Article. Fluoroscopic treatment simulators will be exempted from the requirements effecting other fluoroscopic systems regulated in R12-1-606. Unclear language concerning the holding of animals during veterinary x-rays is amended. Persons holding animals during x-ray procedures will be required to meet all of the safety requirements in R12-1-613. The mammography rules in Article 6 are updated to include

current federal standards. Physicist training requirements in R12-1-615, and procedures and tests for mammography systems in Appendix B are deleted because the most current training standards are listed in the incorporated federal reference.

Article 9: Article 9 is amended to include a list of definitions needed to understand the updates that were added during the previous rulemaking. R12-1-904 is amended to require applicants to provide a staff list to the Agency so that safety concerns associated with inadequate staffing will be addressed before the registration is issued. R12-1-905 is amended to allow the use of accelerator-produced photon radiation to produce x-ray images when performing electron therapy. Training requirements for operators of particle accelerators in R12-1-906 is delineated according to medical or industrial use. The requirement to perform a periodic smear survey in R12-1-911 and maintain an adequate ventilation system in R12-1-912 are deleted because contamination concerns are addressed in Article 4.

Article 12: Article 12 is amended to repeal the "hearing procedures" that conflict with those of the Office of Administrative Hearings. There are new Divisions added to the list under R12-1-1215. Included are laser demonstrations, class II surgical devices, and other nonionizing radiation producing machines. Corresponding additions are being made to the associated administrative time-frames listed in R12-1-1223.

Article 17: R12-1-1734 which regulates particle accelerators used in well logging, is modified because rules regulating their use are located in Article 9. A new rule is added regulating the use of well logging sources in uncased wells. In the past, well logging in uncased holes has been regulated through the use of conditions-of-use in the radioactive material license.

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

None

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

Not applicable

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

The changes proposed for Article 2 should not pose a financial burden on radiation-producing machine users.

The changes proposed for Article 6 should do little to impact the financial status of users of x-ray producing machines in the practice of human and veterinary medicine. The changes to the mammography rules are extensive, however, all of the users should be impacted very little by the proposed changes because Agency inspectors are already insuring that mammographers are meeting the most current FDA standards. The FDA requires that Agency inspectors, who inspect these facilities for the federal government, inspect registrants according to the most current federal standards, even if the standards have not been amended to the Arizona rules.

The changes proposed for Article 9 are made to improve the clarity and understandability of the rules it contains. In many cases unclear language is removed or modified. These changes should have little economic impact on the affected registrants.

The changes proposed for Article 12 will have little economic impact on the licensees and registrants regulated by the Agency. Most of the changes are made to conform to the hearing procedures of the Office of Administrative Hearings. Obviously, the additional workload that may be transferred to their personnel may impact them while decreasing Agency administrative costs. The cost of the hearings has not been determined. Also, there is a potential civil penalty cost associated with each category, should a licensee or registrant fail to meet the rules for use of radiation sources. The monetary values of the civil penalties are thoroughly defined in the existing Article 12.

The changes proposed for Article 17 will result in the following economic impact. The majority of the changes are made to clarify and improve rule language, as a result of a recent five-year review. Amended standards are added to required operating and emergency procedures in R12-1-1722. R12-1-1734 is amended to add a new rule regulating the use of well logging sources in uncased wells. In the past, well logging in uncased holes has been regulated in conditions of use on a radioactive material license. The Agency has not developed methods to reduce the impact of casing well holes on small businesses because casing a hole is required as part of the Agreement Arizona has with the Nuclear Regulatory Commission (NRC), and the fact that well logging licensees working in Arizona are already required to case well holes, as required by license condition for over 10 years. Because casing well holes where radioactive sources are used is a national requirement, there have not been any previous complaints by Arizona licensees. The probable cost to private persons and consumers should be minimal because the actual cost to case a hole would be spread over a large segment of the population using revenue generated by selling the natural resource extracted from the hole. An estimate of costs associated with this rule are provided in the economic impact report filed with the Article 17 rule changes.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules:

The major change to this rule package is the removal of R12-1-209 and Article 14. The rules are deleted because of concern for patient and personnel safety with the proposed change from direct supervision of users of medical lasers and photothermolysis devices, as presented in the proposed rule package, to indirect supervision in the final. The change to indirect supervision came about as a result of discussions at the public hearing held in connection with this rulemaking package. R12-1-209 is included in the withdrawal because nonionizing radiation registration requirements, located in this rule were being moved to Article 14 in the original package. These deletions will be presented in a supplemental rule package that will contain a description of training for use of laser and photothermolysis machines that must be completed by operators functioning under indirect supervision. The training programs under consideration will be discussed and developed by individuals who represent the regulated community and interested regulatory boards. The Agency is unable to provide a date for the supplemental package.

For other changes, see item #11 below for a compilation of each comment received, associated change, if any, and the Agency's response to the comments. Item #11 contains both written and oral comments received by the Agency during the public meeting held on February 27, 2002.

In closing, there are two minor changes that need to be mentioned. R12-1-1716 was deleted from the package because, after further review, it was decided that the proposed changes were not needed. In a second case, it was discovered that R12-1-1721 incorrectly listed a rule that does not exist in the current regulations. Therefore, the proposed changes to the rule were not correct. The correct rule version, in association with minor changes resulting from the most recent five-year review, is listed in the final rulemaking. It is believed the proposed changes are not substantive in nature and do not result in a significant cost to the Agency or the regulated community.

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

The changes between the proposed and final rules in the rule project, Docket Number 0052 are provided below. The changes are based on written and oral comments that were received by the Agency prior to, and in a public meeting held on February 27, 2002. Also, during the meeting, the Agency received suggestions from the Radiation Regulatory Hearing Board. All of the comments are listed below with the Agency's responses. Additionally, it should be noted that the record was reopened on June 4, 2002, to allow the Agency additional time to respond to the numerous initial comments and to allow further comments from interested parties. The record was closed on September 27, 2002.

Because a court reporter was not present during this public hearing, the public hearing record does not always reflect who made a particular comment. The identifying information has been lost in the transcription of the meeting audiotapes. Therefore, the comments will be listed without a person's name. The following is a list of persons who were present during the morning session of the public meeting, or provided written comments regarding this rulemaking:

Roland Wong and Robert Metzger from Radiation Safety Engineering,

Roxanne Cottrel of Affordable Laser Hair Removal,

Kolton Fox, Kim Denton, Maria Dericola, Kem Pettit, C. Jefferson, all representing themselves,

Alex Juarez of A Gentle Solution,

Bill Pavlicek, Ph.D. of the Mayo Clinic,

Subramania Jayaraman of Valley Radiation Oncology,

Hollae Ploof-Mnatzaganias of Le Vanishe Laser Hair Removal and Aesthetic Ctrs.,

Alan Douglas from the Flagstaff Medical Center,

Gary L. Zaharek of the FDA,

Cliff J. Vanell of the Office of Administrative Hearings (OAH),

Members of the Radiation Regulatory Hearing Board,

Agencies that recommended changes,

Arizona State Board of Medical Examiners,

Arizona Medical Association,

Arizona State Board of Nursing (Avisory Opinion),

Arizona State Board of Cosmetology (Position Paper),

Dennis Blaha, M.D. of the Laser Skin and Vein Center,

Arizona Board of Osteopathic Examiners

Thomas E. Garrison, M.D. of Advanced Laser Clinics,

Hale and Dorr LLP, Counselors at Law,

Please note: Many of the attending persons listed above were in attendance for a discussion of the proposed changes to Article 14. Because Article 14 has been dropped from this package, Article 14 comments have also been removed from this package.

Recommended changes received from the public and the Radiation Regulatory Hearing Board:

Format: Comment or criticism, new wording, if applicable, followed by old wording, followed by Agency's response to the comment or criticism.

The following comments were received in written form:

1. **Comment** From Cliff Vanell; As drafted the following are the only rules in Article 12 that supplement the OAH jurisdiction: R12-1-1201, R12-1-1202, R12-1-1205, R12-1-1207(C) through (F) and R12-1-1209 through R12-1-1223 (all as amended)

   Action: Not all of the recommended changes are made. In R12-1-1201 the phrase "unless otherwise provided by law" has not been added, because the Agency Director did not feel it was necessary. R12-1-1202 was amended as recommended, referencing the law that the OAH operates under. However, subsections (D) and (E) are left in at the request of the Agency Director. R12-1-1204 is not repealed as requested for the reason noted above. R12-1-1205 is updated using "administrative law judge." R12-1-1206 is deleted as recommended. R12-1-1207(A) and (B) are deleted as requested. However the change in the language in subsection (C) is not made at the request of the Agency Director. R12-1-1208 is deleted as requested. R12-1-1209 through R12-1-1223 contain numerous minor changes resulting from the most recent five-year review and not resulting from the OAH review.

   Agency response: The Agency appreciates the comments provided by the OAH. Not all of the recommended changes were made because it was felt the Agency would be unable to conduct its business in an efficient manner if all of the recommended rule deletions are made.

2. The following comments were received in a letter from Alan Douglas:

   Comment A: The record retention time-frame in R12-1-905(C)(5) is not consistent with other time-frames in the Agency rules.

   Action: None

   Agency response: The Agency agrees that record retention should be consistent when possible, however, this change may be substantial in nature. It will be held for a future rulemaking so that members of the regulated community will be allowed to comment on the change's effect.

   Comment B: The use of the word "manually" in R12-1-908(C) (in the final version it will be No. 3) is not always appropriate when referencing particle accelerator interlocks.

   Action:

   (Final) ~~**C.**~~3. ~~When~~ If an interlock system connected to an entrance door that provides access to the therapy suite has been tripped, it ~~shall only be~~ is not possible to resume operation of the particle accelerator by ~~manually~~ resetting the interlock switch at the entrance where it had been tripped; ~~controls at the position where the interlock has been tripped, and lastly at the main control console.~~

   (Proposed) **C.** When an interlock system has been tripped, it shall only be possible to resume operation of the particle accelerator by manually resetting the interlock switch at the entrance where it had been tripped. ~~controls at the position where the interlock has been tripped, and lastly at the main control console.~~

   Agency response: The Agency agrees that all interlocks may not require a manual reset, especially on some of the newest therapy equipment.

   Comment C: Not all interlocks can be totally fail-safe, as is required in R12-1-908(E).

   Action:

   (Final) ~~**E.**~~5. If possible, the interlock system is ~~All safety interlocks shall be fail safe~~ fail-safe in design, ~~, i.e., designed~~ so that any defect or component failure in the interlock system prevents operation of the particle accelerator~~.~~ , and

   (Proposed) **E.** All safety interlocks shall be fail safe in design, ~~, i.e., designed~~ so that any defect or component failure in the interlock system prevents operation of the particle accelerator.

   Agency response: The Agency agrees that interlocks on state-of-the-art equipment may not meet the standard in the rule. Therefore, an allowance should be made for the equipment that cannot meet the standard as currently written.

Comment D: The Agency should require that service be performed by properly trained personnel rather than only requiring the maintenance of electrical circuit diagrams in accordance with R12-1-910(D).

Action:

(Final) **D.** ~~Electrical~~ A registrant shall keep current electrical circuit diagrams of a particle ~~the~~ accelerator, and the associated interlock systems, and maintain the diagrams ~~shall be kept current and maintained~~ for inspection by the Agency ~~and available to the operator at each accelerator facility~~.

(Proposed) **D.** Electrical circuit diagrams of a particle ~~the~~ accelerator, and the associated interlock systems, shall be kept current and maintained for inspection by the Agency and available to the operator at the particle ~~each~~ accelerator facility.

Agency response: The recommended change cannot be made because it would result in a substantive change. The request is deferred to a later rulemaking package. A reference will be made to qualified service providers, servicing particle accelerators.

Comment E: The requirement in R12-1-911(A) to have a survey instrument in a particle accelerator facility is unnecessary. There is no radiation hazard after the power is turned off.

Action: None

Agency response: The Agency disagrees. Under some circumstances the machine can store energy in the form of "dark current" that can unexpectedly expose a person to radiation even though the system appears to be off.

Comment F: Because Mr. Douglas believes that a meter is not needed as described in Part E above, the check source required to maintain the meter in R12-1-911(B) is unnecessary.

Action: None

Agency response: As stated above a meter is necessary, and if it is necessary, the operator will need to know it is operating correctly before it is used to evaluate a radiation field. If the registrant has an alternative method for checking a survey meter's operation, it should be provided to the Agency for consideration.

Comment G: The retention period for records in R12-1-911(C)(2) is in conflict with R12-1-905(C)(5).

Action:

(Final) **C.** The registrant shall ~~retain~~ maintain the following records:

1. Radiation ~~Records of any radiation~~ protection surveys required in subsection (B)(2), and ~~an~~ the associated facility description, required in R12-1-202(E), until the registration is terminated.
2. Records of the surveys required in ~~subsection~~ subsections (B)(3) and (B)(4) ~~shall be maintained~~ for three years following the measurement.

(Proposed) **C.** No change

1. Radiation ~~Records of any radiation~~ protection surveys required in subsection (B), and an associated facility description, required in R12-1-202(E), until the registration is terminated.
2. ~~Records of~~ Particle accelerator calibration, spot checks, personnel radiation safety system tests, and ~~periodic~~ radiation protection surveys until the registration is terminated.

Agency response: This comment is greatly appreciated. An older version of the rule was used when creating the rule package. Therefore, the requested change was unnecessary. However, it should be noted that some nonsubstantive changes were made to clarify the language in this subsection.

3. The following comments are provided in writing by Roland Wong and Robert Metzger of Radiation Safety Engineering.

Comment A: The dark room standards listed in R12-1-603(D) are not current.

Action: None

Agency response: Because the suggested change may be substantial, it will be addressed during a future rulemaking project.

Comment B: In R12-1-606(C)(2) insert "per minute" after "5.2 mCi/kg (20 roentgen)"

Action:

(Final) 2. ~~When~~ If provided with optional high-level control, the equipment ~~shall~~ is not operable at any combination of tube potential and current ~~which~~ that will result in an exposure rate in excess of 2.6 ~~μ~~ mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, unless the high-level control is activated, in which case an exposure rate in excess of 5.2 ~~μ~~ mC/kg (20 roentgens) per minute is prohibited ~~shall not be exceeded~~.

(Proposed) 2. When provided with optional high-level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.6 ~~μ~~ mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, unless the high-level control is activated, in which case 5.2 ~~μ~~ mC/kg (20 roentgens) shall not be exceeded.

Agency response: The Agency agrees the correction is needed and will be made as recommended.

Comment C: Cardiac catheterization should be included with surgical procedures as part of the exemption in R12-1-606(E)(2).

Action:

(Final) 2. Except for fluoroscopy performed using portable or mobile C-arm x-ray systems or during surgical procedures or cardiac catheterization, provide protective drapes, or hinged or sliding panels of at least 0.25 millimeters lead equivalent, ~~shall be provided~~ between the patient and fluoroscopist to intercept scattered radiation ~~which~~ that would otherwise reach the fluoroscopist and others near the machine, but not substitute drapes and panels ~~shall not be substituted~~ for a protective apron; and

(Proposed) 2. Except for fluoroscopy performed using portable or mobile C-arm x-ray systems or during surgical procedures, protective drapes, or hinged or sliding panels of at least 0.25 millimeters lead equivalent, shall be provided between the patient and fluoroscopist to intercept scattered radiation which would otherwise reach the fluoroscopist and others near the machine, but drapes and panels shall not be substituted for a protective apron;

Agency response: The Agency believes that a cardiac catheterization is a surgical procedure. To relieve any concern or confusion this surgical procedure will be listed by name in the rule.

Comment D: Lead gloves are not necessary unless a person's hands are in the useful beam. Delete the use of gloves from R12-1-606(H)(4).

Action:

(Final) 4. Ensure that each person whose presence is necessary is in the simulator room during exposure and protected with a lead apron of at least 0.5 mm lead equivalent or a portable shield. Any person who places their hands in the useful x-ray beam shall wear leaded gloves; and.

(Proposed) 4. Only persons whose presence is necessary shall be in the simulator room during exposure and shall be protected with lead aprons of at least 0.5 mm lead equivalent or portable shields, and lead gloves.

Agency response: The Agency disagrees in that this requirement should be deleted from the rule. The requirement will be clarified so that persons not putting their hands in the beam will not be required to wear leaded gloves.

Comment E: The words "step less" in R12-1-607(A)(2)(e) should be "stepless."

Action:

(Final) e. All beam-limiting devices installed after August 8, 1986, on general purpose fixed and mobile radiographic x-ray systems, ~~shall~~ provide ~~step less~~ stepless means of continuous adjustment of the projected radiation field size.

(Proposed) e. All beam limiting devices installed after August 8, 1986, ~~the effective date of this Section,~~ on general purpose fixed and mobile radiographic x-ray systems, shall provide a step less means of continuous adjustment of the projected radiation field size.

Agency response: The Agency agrees, and will make the necessary change.

Comment F: Chest photofluorographic systems regulated in R12-1-609 should be prohibited. They are no longer used and more importantly, are not safe.

Action: None

Agency response: The Agency agrees that this rule should be repealed. Even though there are no users in Arizona at this time, and there has not been for a number of years, the deletion of this rule would be a substantial change from the proposed changes. This rule will be deleted in a future rule package.

Comment G: The sentence in R12-1-610(A)(4) needs to be clarified.

Action:

(Final) 4. ~~A timer shall be provided to terminate the exposure at a preset time interval, present product of current and time, and preset number of pulses, or a preset radiation exposure to the image receptor.~~ Provide a timer to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor;

(Proposed) 4. A timer shall be provided to terminate the exposure at a preset time interval, preset ~~present~~ product of current and time, and preset number of pulses, or a preset radiation exposure to the image receptor.

Agency response: The Agency agrees there is a clarity problem. The rule will be amend as recommended by Mr. Wong.

Comment H: There is text missing in R12-1-613(B)(2). There are phrases needed to clarify R12-1-613(B)(5)(a) and R12-1-613(B)(6), and make them understandable.

Action:

(Final) **B.** Procedures: A registrant shall ensure that:

1. Unless required to restrain an animal, the operator stands at least 1.82 meters (6 feet) away from the useful beam and the animal during a radiographic exposure;
2. An individual other than the operator is not in the x-ray room or area while an exposure is being made, unless the individual's assistance is required;
3. If possible, an animal is held in position during an x-ray exposure using mechanical supporting or restraining devices;
4. An individual holding an animal during an x-ray exposure is:
   a. Wearing protective gloves and an apron of not less than 0.5 millimeter lead equivalent or positioned behind a whole-body protective barrier;
   b. Wearing required personnel monitoring devices; and
   c. Positioned so that no part of the person's body, except hands and arms, will be struck by the useful beam.
5. If an individual holds or supports an animal or a film during an x-ray exposure, the name of the individual is recorded in an x-ray log that contains the animal's name, the type of x-ray procedure, the number of exposures, and the date of the procedure.
6. As a condition of employment an individual is not required to routinely hold or support animals, or hold film during radiation exposures.

(Proposed) **B.** Procedures:

1. Unless required to restrain an animal, the operator shall stand at least 1.82 meters (6 feet) away from the useful beam and the animal during radiographic exposures.
2.
3. Persons other than the operator shall not be in the x-ray room or area while an exposure is being made unless the persons' assistance is required.
4. When an animal must be held in position during an x-ray exposure, mechanical supporting or restraining devices shall be used when techniques permit.
5. A person holding an animal during an x-ray exposure shall:
   a. Wear protective gloves and apron of not less than 0.5 millimeter lead equivalent or whole body protective barriers;
   b. Wear personnel monitoring; and
   c. Be positioned so that no part of the person's body, except hands and arms, will be struck by the useful beam.
6. If a person holds or supports an animal or a film during an x-ray exposure, the name of the person shall be recorded in an x-ray log containing the animal's name, the type of x-ray procedure, and the date of the procedure.
7. As a condition of employment a person shall not be required to routinely hold or support animals, or hold film during radiation exposures.

Agency response: The necessary correction will be made. It appears that nothing was left out of this rule as suggested by Mr. Wong in his first comment concerning R12-1-613. However, the phrases he suggests for the other subsections will aid in the understanding of the rule. The additions will be made as suggested.

Comment I: R12-1-614 should be repealed, with the exception of R12-1-614(C)(1)(b). The requirements are covered under the Federal Mammography Quality Standards Act (MQSA).

Agency response: Some of the state requirements are more stringent than the FDA/MQSA standards, for example. Annual mammography inspections are required under the Arizona law, with or without MQSA. Without ARRA's rules, some currently acceptable documentation under MQSA would not be sufficient and require additional paperwork, for example MRTBE Mammography Certification.

Comment J: R12-1-614(A)(4) should be amended to include American College of Radiology (ACR) standards.

Agency response: The state programs were not furnished an updated ACR manual-99; therefore a 1999 manual is not on file. All necessary information can be found in both manuals. Therefore, the Agency does not believe the ACR standards will improve the safety of the existing rules.

Comment K: Mr. Wong proposes another change to R12-1-614(A)(4). The change would be from "measured kVp/100 and measured kVp/100+0.1 millimeters" of aluminum equivalent to "measured kVp/100 and measured kVp/100 +L millimeters "of aluminum equivalent", where L=0.12 for Mo/Mo, L=0.19 for Mo/Rh, L=0.22 for Rh/Rh, L=0.30 for W/Rh target/filtration combinations and L=0.35 for other target/filtration combinations not otherwise specified.

Action: None at this time.

Agency response: The Agency agrees that a change should be considered for this subsection, however, it is believed the change could be substantial in nature, and that the Agency should provide additional public notice and time to comment. Therefore, the suggested change will not be made until the affected rule is reopened in the future.

Comment L: The focal spot performance standard for mammography systems in R12-1-614(A)(5) should be eliminated or should follow federal standards.

Action: No action will be taken.

Agency response: The current standard for focal spots has been in effect in Arizona since June 30, 1997. In the past this standard of operation has been overlooked by physicist consultants. This standard was brought to their attention when older mammography systems did not pass their state inspection. The Agency believes resolution is very important in determining whether a mammography system is able to discern very small breast lesions. The Agency agrees the current standard of 12 line pairs/millimeter is not equivalent to federal standards, but is comparable technically and is not too stringent.

Comment M: The compression paddle standards in R12-1-614(A)(6) should meet the federal MQSA standards.

Action:

(Final) 6. The compression device used with the mammographic unit, unless specifically manufactured otherwise, is ~~shall be~~ parallel to the imaging plane, not varying at any spot by more than 1 centimeter; ~~to adequately immobilize and compress the breast.~~

(Proposed) 6. The compression device used with the mammographic unit shall be parallel to the imaging plane, not varying at any spot by more than 1 centimeter, to adequately immobilize and compress the breast.

Agency response: The Agency agrees that the state rule does not offer the same latitude as the federal standard. A change is made to the rule to allow the use of a paddle that is designed to be used from a position that is not parallel to the breast support surface.

Comment N: The MQSA term "initial power drive" should replace "automatic pressure unit" in R12-1-614(A)(7). These words are not an accurate descriptor of the actual device.

Action:

(Final) 7. The ~~mammographic~~ mammography x-ray system with initial power drive: ~~shall be capable of:~~

(Proposed) 7. The mammographic x-ray system with automatic pressure units shall: ~~shall be capable of:~~

Agency response: The Agency agrees to make the needed change. It is not substantive nature.

Comment O: The film density requirement in R12-1-614(A)(12) will soon be outdated with the new MQSA standard due out in October 2002.

Action: None

Agency response: Because the recommended change is substantial it cannot be made at this time. It is realized that it is important that the Agency mammography standards be maintained at the highest level of safety, however, this change will not be made until the regulated community is properly informed of an impending change to a more strict standard.

Comment P: The most recent version of *Mammography Quality Control Manual* (1999) should be incorporated into R12-1-614(A)(15)(a).

Action: No action will be taken at this time (see Item J above for a similar concern).

Agency response: State Radiation Safety Programs were not furnished an updated 1999 ACR Manual. Therefore, a manual is not on file. All necessary information can be found in both versions of the manual. Therefore, the Agency does not believe the 1999 version of the ACR standards will improve the safety of the existing rules.

Comment Q: The list of test criteria listed in R12-1-614(B)(2)(a) through (i) does not allow for the flexibility of the quality control program prescribed in ACR guidelines and MQSA standards. Making a deviation of these criteria a violation. This rule should be repealed.

Action: None

Agency response: The rules in this subsection will stimulate mammography facilities to make the necessary changes to meet the safety requirements established in the rule. Past Agency experience has demonstrated that if a standard is not in rule, a facility will ignore the needed change or make changes that only cover or hide the actual safety issues. It is the state's responsibility to ensure radiation users meet minimum standards in a proactive manner. Therefore, the Agency believes this rule should remain in effect.

Comment R: The requirements in R12-1-614(B)(2)(i) are not in alignment with the MQSA standards. Also the word "calibration" is not equivalent to the word "survey" that is used in the MQSA standards. It is recommended this proposed rule be deleted because of the cost associated with performing all of the listed tests.

Action:

(Final) i. Annually and whenever indicated for installation, major repairs, parts replacement, or as deemed necessary by a qualified expert when quality control test results indicate a survey is necessary; the survey shall include the following tests: automatic exposure control performance and thickness response; kVp accuracy and reproducibility; system resolution; breast entrance air kerma and automatic exposure control reproducibility; average glandular dose; x-ray field, light field and image receptor alignment; compression paddle alignment; uniformity of screen speed; system artifacts; radiation output; decompression; and beam quality and half value layer.

(Proposed) i. Annually and whenever indicated by installation, major repairs, parts replacement or when other pertinent quality control test results indicate a calibration may be necessary, the following tests shall be performed: automatic exposure control performance and thickness response; kVp accuracy and reproducibility; system resolution; breast entrance air kerma and automatic exposure control reproducibility; average glandular dose; x-ray field/light field/image receptor alignment; compression paddle alignment; uniformity of screen speed; system artifacts; radiation output; decompression; and beam quality and half value layer.

Agency response: In an attempt to eliminate some of the potential unnecessary cost, the requirement is modified to include the consulting physicist in determining whether all elements of the survey should be repeated. Generally the Agency agrees with Mr. Wong's comments. Also, because the term "survey" carries a somewhat different definition in three Agency rules, a more appropriate definition is needed for this rule.

Comment S: The traditional term "radiograph," as used in Number 13 (as proposed M) of Appendix A, located at the end of Article 6, does not take into account modern technology. The term "medical image" allows for images that are created electronically.

Action:

(Final) 13. ~~13.~~**M.** A description of the procedures for ~~the~~ retention or disposition of the radiographic images ~~radiographs~~ and other records pertaining to the x-ray examination ~~examinations~~.

(Proposed) 13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examination ~~examinations~~.

Agency response: The Agency agrees with this finding. The change will be made as suggested.

4. The following changes are being made at the recommendation of the Agency staff, but were not received in writing.

   Concern: New rules referencing TENORM in Article 12 should be deleted with the withdrawal of new Article 11, which contained proposed rules regulating Technically Enhanced Naturally Occurring Radioactive Material (TENORM), from RMP-054.

   Action: TENORM will be removed from the Division list in R12-1-1215(A), which lists radioactive material licensees and from Table A in R12-1-1223, which lists time-frames for Agency actions involving the licensees.

   Agency response: These rules will be added at a latter date when and if TENORM regulations are added, as was originally proposed in RMP-054.

5. The following comments were received in a letter from William Pavlicek, Ph.D.

   Comment A: Why is the scale drawing of an x-ray room necessary, as requested in R12-1-202(A)? The production of this information is quite expensive and may result in an economic impact. Also what safety value will this information have if the applicant has 30 days after the x-ray's first use to get all registration materials to the Agency.

   Agency response: The Agency disagrees with the idea that there is additional cost resulting from the request in R12-1-202(A). Because an architect is already involved in building the facility, the registrant would simply make copies of the information associated with the build-out and provide it to the Agency with the application.

   The safety value of this information may vary depending on scope of operation the x-ray facility. That is why some x-ray facilities have been exempted from the requirement to provide detailed facility descriptions, while the particle accelerators, which are considerably more hazardous, must provide the information and be inspected by the Agency before treating the first patient.

   Comment B: Does the registration of service providers in R12-1-203(A) encompass in-house service engineers and physicists? This rule is not written very clearly and could be of considerable cost to many medical institutions in Arizona.

   Agency response: The intent of this rule is to require only private separate companies that offer their services as a business, to apply for registration. The Agency believes the rule is clearly written and will make no clarification changes at this time.

   Comment C: The definition of "fluoroscopic system" in R12-1-602 should be broadened to include all of the purposes for this type of x-ray examination.

   Agency response: The Agency agrees there should be a change made to this definition. See comment B under Dr. Pavliceks oral comments for additional information concerning this issue.

   Comment D: The word "dedicated" or phrase "engineered to" should be added to the definition of mammographic x-ray system.

   Agency response: The Agency agrees. The change is made to the definition in question under Dr. Pavlicek's oral comment section for additional information concerning this issue.

   Comment E: The definition of "screen" in R12-1-602, is not appropriate for the radiation use industry.

   Agency action: The definition has been expanded as recommended. See Dr. Pavliceks comments under the oral presentation section of this report.

   Comment F: The definition of "Spot film" in R12-1-602 should be modified to include the fact these images are made to improve visualization by arresting motion and to document medical observations. In some cases, a film may not be created.

   Action:

   (Final) "Spot check" ~~means an abbreviated calibration procedure which is performed to assure that a previous calibration continues to be valid.~~ means an abbreviated calibration procedure which is performed to assure that a previous calibration continues to be valid. Also, a spot film may be taken to improve visualization by arresting motion and to document medical observations. Note that in some cases, a film may not be created.

   (Proposed) "Spot check" means an abbreviated calibration procedure which is performed to assure that a previous calibration continues to be valid.

   Agency response: The Agency agrees to make the necessary change to expand the definition.

Comment G: The incorporated standard in R12-1-603(C)(2) does not agree with the standards that exist in Article 4. This standard predates the current standard. (500 mrem vs the current accepted exposure to the general public of 100 mrem)

Action:

(Final) 2. ~~The required~~ A registrant shall ensure that attenuation ~~of~~ provided by a protective ~~barriers shall be as determined in accordance with~~ barrier meets or exceeds the level of protection established in the National Council on Radiation Protection Report No. 49, "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies Up To 10 MeV", September 15, 1976 edition, published by the National Council on Radiation Protection and Measurement, Inc., which is incorporated ~~herein~~ by reference and on file with the Agency ~~the Office of Secretary of State~~. This incorporation by reference contains no future editions or amendments. Each registrant shall use this incorporated reference to provide sufficient shielding to prevent public exposure in excess of the limits in R12-1-416.

(Proposed) 2. The required attenuation of protective barriers shall be as determined in accordance with the National Council on Radiation Protection Report No. 49, "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies Up To 10 MeV", September 15, 1976 Edition, published by the National council on Radiation Protection and Measurement, Inc., which is incorporated ~~herein~~ by reference and on file with the Agency and the Office of Secretary of State. This incorporation contains no future editions or amendments.

Agency response: The Agency greatly appreciates this information that was overlooked in regard to this reference. The Agency has required licensees and registrants to meet the public limit in Article 4 since about 1994, when the NRC 10 CFR 20 public limit was incorporated into the Arizona rules. The amendment of this rule will finally clarify the need to follow the Article 4 standard and not the acrimonious standard in the reference.

Comment H: There is concern for the Agency's ability to make determinations concerning the use of x-rays to screen patients for disease, as described in R12-1-604(A)(3)(c).

Action: None

Agency response: This rule is not new. The rule is only amended to clarify existing language that has existed in this rule for a number of years. Also, it should be noted that the Agency is prevented from approving screening procedures other than mammography by MRTBE law, and by the fact that all rule changes must be approved by the Radiation Regulatory Hearing Board, which has as members, two physicians, one each representing the diagnostic radiology and nuclear medicine community.

Comment I: The log that is required in R12-1-607(D)(5) is a duplication of efforts when compared to other existing regulations. Also, the rule fails to require information that is reasonably helpful in a determination of the patient dose or exposure.

Action:

(Final) 5. Provide documentation of the patient's identity, the x-ray examination performed, the date it was performed, number of projections (if applicable), and a method of identifying the individual who performed the examination, for Agency review. The registrant shall maintain the documentation for three years from the date the examination is performed.

(Proposed) 5. A log containing a record of patient identification, the x-ray procedure performed, the date it was performed, number of views, and initials of the individual performing the procedure shall be maintained for Agency review. The log shall be maintained for three years from the date the procedure is performed.

Agency response: The alternate language proposed by Dr. Pavlicek has been incorporated as recommended.

Comment J: The following changes shall be made in regard to R12-1-614(A).

1. In No. 10 the receptor agreement with the radiation field should agree with ACR standards (2% for the accuracy of the receptor agreement the radiation field as per the ACR).
2. In No. 12 the word "constant" should be removed from the first line.
3. In No. 15a the 1999 edition should be referenced.

Action:

(Final) 10. The collimation ~~Collimation shall be~~ provided ~~which shall limit~~ limits the useful beam to ~~such that the x-ray field at the plane of~~ the image receptor so that the beam does not extend beyond any edge of the image receptor at any designated source to image receptor distance ~~except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may~~

~~not extend beyond this edge by more than 2 percent of the source to image receptor distance;~~ by more than 2% of the source to image receptor distance;

(Proposed) 10. The collimation ~~Collimation shall be~~ provided ~~which~~ shall limit the useful beam to ~~such that the x-ray field at the plane of~~ the image receptor so that the beam does not extend beyond any edge of the image receptor at any designated source to image receptor distance by more than 1% of the source to image distance with the exception of the chest wall edge, which shall not extend beyond the image receptor by more than 2% of the source to image distance. ~~except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the source to image receptor distance;~~

(Final) 12. ~~Mammographic~~ Mammography x-ray systems operating with automatic exposure control ~~shall be~~ are capable of maintaining a ~~constant~~ film density ~~to~~ within +/- 0.30 optical density units over the clinical range of kVp used ~~clinically used kVps~~, for a breast having an equivalent phantom thicknesses from 2 ~~of 2 centimeters~~ to 6 centimeters. If~~, or if~~ the film density cannot be maintained to within +/- 0.30 of the average kVp used ~~of clinically used kVp settings~~ and phantom thickness from 2 to 6 centimeters cannot be maintained by the automatic exposure control, a technique chart ~~shall be developed~~ is used that alters kVp and density control settings as a function of breast thickness and density. If a technique chart is used, the operator shall maintain ~~which maintains~~ the film density ~~within~~ at +/- 0.30 optical density units.~~;~~

(Proposed) 12. Mammographic x-ray systems operating with automatic exposure control shall be capable of maintaining a constant film density to within +/- 0.15 ~~0.30~~ optical density units over the clinical range of kVp used ~~clinically used kVps~~, for a breast having an equivalent phantom thicknesses from 2 ~~of 2 centimeters~~ to 6 centimeters. If~~, or if~~ the film density cannot be maintained to within +/- 0.15 ~~0.30~~ of the average kVp used ~~of clinically used kVp settings~~ and phantom thickness from 2 to 6 centimeters cannot be maintained by the automatic exposure control, a technique chart shall be developed that alters kVp and density control settings as a function of breast thickness and density. If a technique chart is used ~~which maintains~~ the film density shall be maintained within +/- 0.15 ~~0.30~~ optical density units.~~;~~

(Final) a. Meets the minimum mammography film standards for phantom performance in "Mammography Quality Control", 1992 edition, published by the American College of Radiology, which is incorporated by reference~~, and~~ on file with the Agency ~~and the Office of Secretary of State, containing no future editions or amendments~~ and contains no future editions or amendments ~~, for accreditation on the standard mammography film in use at the facility~~; or

(Proposed) a. Meet the minimum mammography film standards for phantom performance ~~standards of the~~ in "Mammography Quality Control," 1992 Edition, published by the American College of Radiology, incorporated ~~herein~~ by reference and on file with the Agency and the ~~at the~~ Office of Secretary of State. This incorporation by reference contains no future editions or amendments. ~~, for accreditation on the standard mammography film in use at the facility~~; or

Agency response: The Agency agrees and will make the necessary changes as noted, with the exception of the incorporating the 1999 ACR manual.

Comment K: The following comments are made in reference to R12-1-614(B)(2), (2)(c), and (2)(i). In subsection (2) there is a typographical error. In subsection (2)(c) the word "monthly" should be removed. In subsection (2)(i) the requirements in this rule should be separated.

Action: None

Agency response: The typographical error could not be determined from his comment. A reason was not given as to why the monthly requirement should be removed. Therefore, the requirement will remain. The suggested separation is unnecessary because the Agency believes there is enough similarity in the requirements to keep them together in the same rule. The language is clear and understandable.

Comment L: Again, Dr. Pavlicek expresses his concern for the Agency authorizing the screening of persons for hidden diseases. This comment is in regard to the informational criteria listed in Appendix A at the end of Article 6. This appendix is referenced when applying the requirements in R12-1-604(A)(3)(c). He goes on to list a number of items that should be included in the requested information gathered when reviewing a proposed screening procedure.

Action: None

Agency response: The Agency does not understand the concern for this rule which has been in effect for quite some time. The reader should review the comments listed above in response to his first comments concerning R12-1-604. Also, it is believed the suggested additions would result in a substantive change to the existing rule. Therefore, his recommendations will be considered during a future rulemaking. Finally, the Agency is well aware of the radiation exposure associated

with CT examinations. If a CT is performed in accordance with a prescription from a licensed practitioner, it is not performed for screening purposes.

The following comments were received during the oral preceding held on February 27, 2002. In some cases a comment was given to the Board that was previously addressed in writing to the Agency. In those cases, the reader will be directed to the appropriate section under the commenter's name in the written comment section of this report.

1. The following comments were presented by Alan Douglas:

Comment A: The reference in R12-1-904(H) is somewhat old. The standards may not be applicable today with the improved therapy technology.

Action: The 1986 publication of *Radiation Oncology in Integrated Cancer Management* will be referenced in the rule. A more current version is being completed at this time and will be added in future rulemaking.

Agency response: The Agency agrees. The most current, available document will be referenced in a future rulemaking to avoid a substantial change in this package.

Comment B: There is an inconsistency in record retention time-frame for "spot check" records required in R12-1-905(C)(5).

Agency response: This comment was responded to above under 2(A) in the Written Comment Section.

Comment C: There is some confusion as to which interlock systems are addressed in R12-1-908(3). Not all interlock systems can be reset easily.

Action:

(Final) 3. ~~When~~ If an interlock system connected to an entrance door that provides access to the therapy suite has been tripped, it ~~shall only be~~ is not possible to resume operation of the particle accelerator by manually resetting the interlock switch at the entrance where it had been tripped; ~~controls at the position where the interlock has been tripped~~, ~~and lastly at the main control console.~~

(Proposed) **C.** When an interlock system has been tripped, it shall only be possible to resume operation of the particle accelerator by manually resetting the interlock switch at the entrance where it had been tripped. ~~controls at the position where the interlock has been tripped~~, ~~and lastly at the main control console.~~

Agency response: The interlocks of concern are located only at the entrance to the therapy room. They protect personnel entering the room when the accelerator is radiating patients. Language is being added to clarify this concern.

Comment D: An interlock cannot be "fail-safe" as is stated in R12-1-908(E); only an interlock system can be "fail-safe."

Action: The term "system" will be inserted where needed in the rule.

Agency response: The term "system" will be added to clarify the intent of the rule. The interlock system must be redundant and be fail-safe.

2. The following comments were presented to the Board by Roland Wong:

Comment A: The dark room procedures and standards require changes to meet current standards.

Agency response: No change will be made at this time because this portion of the rule is slated for amendment in a future rulemaking as noted in the written comment section of this report

Comment B: R12-1-609 should be repealed. These pieces of equipment are outdated and unsafe.

Agency response: The Agency agrees. As noted in the written section above. However, this rule cannot be repealed at this time because the change to the proposed rule would be substantial.

Comment C: The mammography rules contained in R12-1-614 are a duplication of effort when compared to federal standards.

Agency response: The Agency agrees, as noted above under the written comment section of Mr. Wong. The rule will be amended as proposed and not repealed because the Agency has a specific law that it operates under that requires the Agency to develop the mammography regulations.

Mr. Wong proposed numerous changes to R12-1-614 that are addressed under Mr. Wong's written comment section above.

3. The following comments are provided to the Board by Bill Pavlicek of the Mayo Clinic:

Comment A: The regulatory time-frames should be as consistent as possible. Specifically R12-1-206 requires certain actions to occur in 15 days when the remaining requirements in Article 2 shall be performed in 30 days. Amend R12-1-206 to agree with the rest of Article 2.

Action: No action will be taken at this time because the rule will be corrected in a future rulemaking.

Agency response: The Agency agrees that the amendment request is sensible. The change will be made as part of a later rulemaking, involving R12-1-206(A) and (B).

Comment B: The definition of "fluoroscopic system" in R12-1-602 should include a reference to visualization of internal structures (also see his comments under written comments).

Action:

(Final) "Fluoroscopic system" means a radiographic x-ray system used to directly visualize internal structure, the motion of internal structures, and fluids in real time, or near real-time, to aid in the treatment or diagnosis of disease, or the performance of other medical procedures.

(Proposed) "Fluoroscopic system" means a radiographic x-ray system used to directly visualize the motion of internal structures and fluids to aid in the diagnosis of disease.

Agency response: The Agency agrees, and will make the necessary change.

Comment C: The definition of "mammographic x-ray system" in R12-1-602 does not portray the specificity of the equipment used to image human breasts.

Action:

(Final) "Mammographic x-ray system" means an x-ray system that is specifically engineered to image human breasts.

(Proposed) "Mammographic x-ray system" means an x-ray system used to image human breasts.

Agency response: The Agency agrees, and will make the necessary change.

Comment D: The definition of "screen" does not include modern technology that includes screens that contain a phosphor.

Action:

(Final) "Screen" or "intensifying screen" means a device that converts the energy of the x-ray beam into visible light that interacts with the radiographic film, forming a latent image, or contains photostimulable phosphor plates that upon exposure, emit visible or nonvisible light to create an image.

(Proposed) "Screen" means a device that converts the energy of the x-ray beam into visible light that interacts with the radiographic film, forming the latent image. More commonly called an "intensifying screen."

Agency response: The Agency agrees, and will make the necessary change.

Comment E: R12-1-614(D) should contain a rule requiring storage of mammography films after a mammography center closes.

Action:

(Final) **D.** Mammography films and reports. A registrant shall:

1. Maintain films and reports for a minimum of five years. In those cases where no subsequent mammography procedures are performed, the registrant shall maintain films and associated reports for 10 years. If the mammography facility is closed, the registrant shall make arrangements for storage of the films and associated reports for five years after the closure.
2. Make films and reports available for comparison upon request for temporary or permanent transfer to other mammography facilities.

(Proposed) **D.** Mammography films and reports shall be:

1. Maintained for a minimum of five years. In those cases where no subsequent mammography procedures are performed, the films and reports shall be maintained for 10 years; and
2. Available for comparison upon request for temporary or permanent transfer to other mammography facilities.

Agency response: The additional language is added as requested. The change is made because it is believed the addition of this requirement is not substantive. The original intent was to ensure that patient histories are available for a reasonable period of time. The Agency failed to take into account a

facility that closes and disposes of the patient records prematurely. The intent of the rule remains the same.

Comment F: The training and experience requirement for physicists in R12-1-614(C)(1)(c)(iv) and (v) is clearly stated. Which category of physicist needs to meet the requirements in these two subsections?

Action:

(Final) ... or

i. Be certified by the American Board of Radiology, American Board of Medical Physics, or the American Board of Health Physics;

ii. Possess documentation of state approval;

iii. Hold a master's degree or higher in a physical science;

iv. Have, upon initial employment as a radiologic physicist, experience conducting at least one mammography facility survey and evaluating at least 10 mammography units;

v. Have, after completing the experience requirements in subsection (C)(1)(c)(iv), continuing experience surveying two mammography facilities and evaluating six mammography units during the preceding two years; and

(Proposed) ... or

i. Be certified by the American Board of Radiology, American Board of Medical Physics, or the American Board of Health Physics;

ii. Possess documentation of state approval;

iii. Hold a master's degree or higher in a physical science;

iv. Have initial experience of conducting, as a minimum, one mammographic facility survey and the evaluation of 10 mammographic units;

v. Have continuing experience of surveying, as a minimum, two mammography facilities and evaluation of six mammography units during the preceding two years; and

vi. Have completed 15 hours of continuing medical education credits in mammography during the preceding three years.

Agency response: The Agency agrees there may be some confusion as to which group of physicists should be affected by the proposed rules. There is an intent to separate new from experienced physicists.

Comment G: The new requirement concerning the staffing of a machine therapy program in R12-1-904(G) is not clearly written, and the reference is somewhat outdated.

Action:

(Final) **G.** At the time of application for registration or when a therapy program is expanded to multiple sites, each applicant or registrant shall provide the Agency with a description of the quality management program, a listing of the professional staff assigned to the facility, and the expected ratio of patient workload to staff member for programs involving multiple therapy sites. If the staffing ratio exceeds the recommended levels in Radiation Oncology in Integrated Cancer Management, 1986 edition, published in November 1986 by the Inter-Society Council for Radiation Therapy, which is incorporated by reference and on file with the Agency, the applicant shall provide to the Agency for approval the justification for the larger ratio and the safety considerations that have been addressed in establishing the program. This incorporation contains no future additions or amendments.

(Proposed) **G.** At the time of application for registration or when a therapy program is expanded to multiple sites, each applicant or registrant shall provide a description of the radiation therapy program. As a minimum the description shall describe the staffing of professional personnel at each facility, or expected ratio of patient workload to staff member for programs involving multiple therapy sites. If the staffing ratio exceeds the recommended levels in Radiation Oncology in Integrated Cancer Management, 1986 Edition, published in November 1986 by the Inter-Society Council for Radiation Therapy, incorporated by reference and on file with the Agency and the Secretary of State, the applicant shall provide to the Agency for approval the justification for the larger ratio and the safety considerations that have been addressed in establishing the program. This incorporation contains no future additions or amendments.

Agency response: The Agency agrees there is some confusion created by the wording of this new rule. Also, the reference should be to the quality management program not radiation therapy program.

Comment H: Because many of the transcribed sections are not well documented, this comment section in the transcript cannot be understood, the Agency will not respond to it at this time. The subject deals with the reporting of incidents (injuries from radiation) for all sources of radiation, as is the case for tanning injuries.

4. The following rules were deleted from the proposed changes because it was determined the proposed change(s) were not necessary following additional review: R12-1-912, R12-1-1214, R12-1-1218, and R12-1-1716.

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

Rules in Article 17 must be compatible with the Nuclear Regulatory Commission regulations. The Agency is bound to these considerations by the Agreement between the federal government and the state of Arizona.

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

Rule	Incorporation
R12-1-614(B)(2)	21 CFR 900.12
R12-1-614(C)(1)(a)	21 CFR 900.12
R12-1-614(C)(1)(b)	21 CFR 900.12
R12-1-614(C)(1)(c)	21 CFR 900.12
R12-1-904(H)	*Radiation Oncology in Integrated Cancer Management*, published by the Inter-Society Council for Radiation Therapy - 1986

14. Were the rules previously adopted as emergency rules?

No

15. The full text of the rules follows:

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

ARTICLE 2. ~~RADIATION MACHINE FACILITY REGISTRATION OR LICENSING, INSTALLATION AND SERVICE REGISTRATION, AND MAMMOGRAPHIC FACILITY CERTIFICATION~~ REGISTRATION, INSTALLATION, AND SERVICE OF IONIZING RADIATION-PRODUCING MACHINES; AND CERTIFICATION OF MAMMOGRAPHY FACILITIES

Section

R12-1-201. Exemptions

R12-1-202. Application for Registration~~, Certification, and Licensing of Ionizing and Nonionizing Radiation Machine Facilities;~~ of Ionizing Radiation Producing Machines ~~: Notification~~

R12-1-203. Application for ~~registration of servicing and installation~~ Registration of Servicing and Installation

R12-1-205. Expiration of Notice of Registration or Certification

R12-1-206. Assembly, Installation, Removal from Service, and Transfer

R12-1-207. Reciprocal Recognition of Out-of-state Radiation Machines

R12-1-208. Certification of Mammography Facilities ~~Mammographic Certification Requirements~~

Appendix A. Application Information

ARTICLE 6. USE OF X-RAYS IN THE HEALING ARTS

Section

R12-1-602. Definitions

R12-1-603. ~~General Safety Provisions~~ Operational Standards, Shielding, and Darkroom Requirements

R12-1-604. General Procedures ~~Procedural Requirements~~

R12-1-605. X-ray Machine Standards ~~General Equipment Requirements~~

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

R12-1-607. Additional X-ray Machine Standards, Shielding Requirements, and Procedures, Except ~~Diagnostic Radiographic Systems Other Than~~ Fluoroscopic ~~, or~~ and Dental Intraoral Radiographic Systems

R12-1-608. ~~Special Requirements for~~ Mobile Diagnostic Radiographic Systems ~~Equipment~~, Except Dental Intraoral Radiographic Systems

R12-1-609. ~~Special Requirements for~~ Chest Photofluorographic Systems

R12-1-610. Dental Intraoral Radiographic Systems

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

R12-1-613. Veterinary Medicine Radiographic Systems

ARTICLE 9. PARTICLE ACCELERATORS

ARTICLE 12. ADMINISTRATIVE PROVISIONS

ARTICLE 17. ~~RADIATION SAFETY REQUIREMENTS FOR~~ WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

R12-1-1734. Use of a Sealed Source in a Well Without a Surface Casing and Particle ~~accelerators~~ Accelerators
R12-1-1741. Radiation ~~surveys~~ Surveys
R12-1-1742. Documents and Records Required at Field Stations
R12-1-1743. Documents and Records Required at Temporary Job Sites
R12-1-1751. Notification of Incidents, Abandonment, and Lost Sources

ARTICLE 2. ~~RADIATION MACHINE FACILITY REGISTRATION OR LICENSING, INSTALLATION AND SERVICE REGISTRATION, AND MAMMOGRAPHIC FACILITY CERTIFICATION~~
REGISTRATION, INSTALLATION, AND SERVICE OF IONIZING RADIATION-PRODUCING MACHINES; AND CERTIFICATION OF MAMMOGRAPHY FACILITIES

R12-1-201. Exemptions

A. Electronic equipment that produces X-radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this Article, ~~providing~~ provided that an exposure rate, from any accessible surface, averaged over an area of 10 square centimeters (1.55 in.^{2}) does not exceed ~~129 nC/kg~~ 129μC/kg per hour (0.5 milliroentgen per hour) at 5 cm (2.0 in.) ~~from any accessible surface of such equipment~~. The production, testing, or factory servicing of electronic equipment that produces X-radiation incident to its operation is not ~~such equipment shall not be~~ exempt.

B. Radiation machines in storage or in transit to or from storage ~~while in transit or storage incident thereto~~ are exempt from the requirements of this Article.

C. No change

~~**D.** The following nonionizing radiation machines are exempt from the registration requirement prescribed in this Article:~~

~~1. Radiofrequency emitting devices which are designed and marketed as consumer products, including but not limited to, microwave ovens, citizen band and amateur radio transmitters, and remote control transmitters used in toys and garage door openers;~~

~~2. Radiofrequency devices where the radiofrequency power input to the radiating element does not exceed 7 watts, provided the emission frequency of such devices does not exceed 1 Gigahertz;~~

~~3. All certified Class I, Class II, Class IIa, and Class IIIa laser products, except for those that allow access to Class IIIb or Class IV laser radiation during servicing, are exempted from these rules, provided that the laser product is maintained as a certified Class I, Class II, Class IIa, or Class IIIa laser product throughout its useful life;~~

~~4. Lasers in storage, during shipment or sale, provided the such lasers are inoperable or not operated.~~

R12-1-202. Application for Registration~~, Certification, and Licensing of Ionizing and Nonionizing Radiation Machine Facilities;~~ of Ionizing Radiation Producing Machines ~~: Notification~~

A. No change

B. A person ~~Possessing~~ possessing a nonexempt radiation machine shall apply for registration of the machine with the Agency within 30 days after its installation. The person applying for registration of a radiation-producing machine shall use the application forms provided by the Agency. The applicant shall provide the information identified in Appendix A of this Article.

~~**C.** The registrant shall notify the Agency within 30 days of any change to the information contained in the notice of registration and, when appropriate, certification issued pursuant to R12-1-208.~~

~~**D.**~~**C.** In addition to the application form or forms, the applicant shall remit the appropriate registration or licensing fee in R12-1-1306 and ~~such~~ provide other information ~~as may be~~ required ~~to comply with~~ by R12-1-208.

~~**E.D.** With the application form for registration of a radiation machine, except~~ Each applicant that applies for registration of a stationary x-ray system, with the exception of applicants from bone densitometry, cabinet radiography, podiatry, dental, bone mineral analyzer and mammography facilities, ~~the applicant~~ shall provide a scale drawing of the room in which ~~a stationary~~ the x-ray system is located, or provide measurements from the radiation source to the surrounding barrier surfaces. The drawing shall denote the type of materials and the thickness (or lead equivalence) of each barrier of the room (walls, ceilings, floors, doors, windows). The drawing shall also denote the type and frequency of occupancy in adjacent areas, including those above and below the x-ray room of concern (e.g., hallways, offices, parking lots, and lavatories). Estimates of workload shall also be provided with the drawing.

~~**F.**~~**E.** An applicant proposing to use a particle accelerator for medical purposes shall not use the particle accelerator until the Agency inspection required in R12-1-914 has been completed.

R12-1-203. Application for ~~registration of servicing and installation~~ Registration of Servicing and Installation

A. Each person who is engaged in the business of installing or offering to install radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this state shall apply for registration ~~of such services with the Agency within 30 days following the effective date of this Article~~. ~~Subsequent applications~~ If registration is required, any subsequent application shall be submitted ~~prior to~~ before furnishing or offering to furnish any radiation machine service or installation ~~such services~~.

B. Application for registration shall be completed on forms furnished by the Agency and shall contain all information required by A.R.S. § 30-672.01.

R12-1-205. Expiration of Notice of Registration or Certification

A Notice of Registration, or ~~certification~~ certificate issued according ~~pursuant~~ to R12-1-208, ~~shall expire~~ expires at the end of the day on the date stated in the Notice of Registration or certificate ~~therein~~ unless ~~a~~ the registrant or certificate holder, not less than 30 days prior to the expiration of the ~~registrant's or certificate holder's existing~~ Notice of Registration or ~~certification~~ certificate, ~~has filed an~~ files a complete application ~~in proper form~~ for renewal. If a timely application for renewal ~~has been~~ is filed, the ~~existing~~ Notice of Registration or ~~certification~~ certificate does ~~shall~~ not expire until the application status ~~has been~~ is finally determined by the Agency.

R12-1-206. Assembly, Installation, Removal from Service, and Transfer

A. A ~~Any~~ person who assembles, or installs ionizing radiation machines in this state shall notify the Agency in writing within 15 days of:
1. No change
2. No change
3. The date each machine was assembled~~,~~ or installed, or the first clinical procedure is performed.

B. No change

C. In the case of diagnostic x-ray systems ~~which~~ that contain certified components, an assembler shall submit to the Agency a copy of the assembler's report (FDA Report No. 2579) prepared in compliance with requirements in 21 CFR 1020.30(d), 2000 Edition, published April 1, 2000 by the Office of the Federal Register, National Archives and Records Administration, incorporated by reference and on file with the Agency ~~and the Office of the Secretary of State~~, containing no future editions or amendments, within 15 days following completion of the assembly. The report shall suffice in lieu of any other report by the assembler, ~~when~~ if it contains the information required in subsection (A)(2).

D. No change

R12-1-207. Reciprocal Recognition of Out-of-state Radiation Machines

A. ~~When~~ If any radiation machine is to be brought into the state~~,~~ for temporary use, the person proposing to bring the radiation ~~such~~ machine into the state shall ~~give~~ provide written notice to the Agency at least ~~3~~ three working days before the radiation ~~such~~ machine is to be used in the state. The notice shall include the type of radiation machine; the nature, duration, and scope of use; and the exact location where the radiation machine is to be used. If, for a specific case, the three working-day period would impose an undue hardship, the person may upon application to the Agency, obtain permission to proceed sooner.

B. In addition, the owner of the radiation machine and the person possessing the machine while in the state shall:
1. Comply with all applicable rules of the Agency, ~~and upon request:~~
2. ~~Supply~~ Upon request, supply the Agency with a copy of the machine's registration and ~~such~~ other information ~~necessary to insure~~ regarding the safe operation of a machine while it is in the state; and
3. ~~Have available at the jobsite while in the state:~~ Upon request, supply the Agency with the work authorization from the Agency, machine registration, operating~~/~~ and emergency procedures, utilization log, survey instrument and associated calibration record, and training records for all users.

C. A ~~No~~ radiation machine shall not be operated within the state on a temporary basis in excess of 180 ~~calender~~ calendar days per year.

R12-1-208. Certification of Mammography Facilities ~~Mammographic Certification Requirements~~

~~Facilities required to be certified pursuant~~ An applicant seeking certification of a facility according to A.R.S. ~~30-672.J.~~ § 30-672(J) shall:
1. Provide evidence with the application ~~evidence~~ that a quality assurance program ~~is~~ has been established and is in use for the items listed in Appendix B of ~~Article 6 in this Chapter~~ 12 A.A.C. 1, Article 6,
2. Provide evidence with the application that physicians reading mammographic images have the ~~with the application evidence that all physicians reading the mammographic images have the~~ training and experience required in A.R.S. § 32-2842(A) ~~32-2842.A~~; and,
3. Provide evidence with the application that physicians reading mammographic images have met the minimum criteria established by their respective licensing boards, as required in A.R.S. § 32-2842(C). ~~Require that all physicians reading mammographic images provide evidence that they meet the requirements of A.R.S. § 32-2842.C.~~

Appendix A. Application Information

An application shall contain the following information as required in R12-1-202(B), before a registration ~~or license~~ will be issued. The Agency shall provide an application form to an applicant with a guide, if available, or shall assist the applicant to ensure that only correct information is provided ~~in~~ on the application.

Name and mailing address of applicant	Use location
Person responsible for radiation safety program	Telephone number
Type of facility	Facility subtype
Legal structure and ownership	Signature of certifying agent

Radiation machine information	Equipment identifiers
Shielding information	Scale drawing, if applicable
Equipment operator instructions and restrictions	Physicist name and training, if applicable
Classification of professional in charge	
Record of calibration for therapy units	Type of request: amendment, new, or renewal
Protection survey results, if applicable	
Type of industrial radiography program, if applicable	
Radiation Safety Officer name, if applicable	Contact person
~~Laser class and type, if applicable~~	Appropriate fee listed in Article 13 schedule
Other ~~licensing and~~ registration requirements listed in Articles 2, 6, 8, ~~9, and 14~~ and 9	

ARTICLE 6. USE OF X-RAYS IN THE HEALING ARTS

R12-1-602. Definitions

The following definitions apply in this Article:

~~1.~~ "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

~~2.~~ "Added filter" means the filter added to the inherent filtration.

~~3.~~ "Aluminum equivalent" means the thickness of aluminum (type 1100 alloy) ~~affording the same~~ that affords equivalent attenuation, under specified conditions, as the material in question. (The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0. 12 percent copper~~.~~).

~~4.~~ "Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem.

~~5.~~ "Attenuation block" means a block or stack, having dimensions 20 cm by 20 cm by 3.8 cm (7.9 inches by 7.9 inches by 1.5 inches) of type 1100 aluminum alloy or other materials ~~having~~ that afford equivalent attenuation.

~~6.~~ "Automatic exposure control" means a device ~~which~~ that automatically controls one or more technique factors in order to obtain at a preselected location or locations a required quantity of radiation ~~(See "Phototimer")~~.

~~7.~~ "Barrier" (See "Protective barrier")

~~8.~~ "Beam ~~Axis~~ axis" means a line from the source through the ~~centers~~ center of the x-ray ~~fields~~ field.

~~9.~~ "Beam-limiting device" means a device ~~which~~ that provides a means to restrict the dimensions of the x-ray field.

"C-arm x-ray system" means an x-ray system that has the image receptor and x-ray tube housing assembly connected by a common mechanical support system to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

~~10.~~ "Changeable ~~filters~~ filter" means any filter, exclusive of inherent filtration, which can be removed from the useful beam ~~through any~~ by an electronic, mechanical, or physical process.

"Cinefluorography" means fluorography that uses a movie camera to record fluorograph images on film for later playback.

~~11.~~ "Coefficient of variation" means the ratio of the standard deviation to the mean value of a population of observations.

"Collimator" means an adjustable device, generally made of lead, that is fixed to an x-ray tube housing to intercept or collimate the useful beam and, if not made of lead, has a lead equivalency of not less than that of the tube housing assembly.

"Compression device" means a device used to bring object structures closer to the image plane of a radiograph and make a part of the human body a more uniform thickness so the optical density of the radiograph will be more uniform.

"Computed tomography" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data. For purposes of these rules this term has the same meaning as "CT".

~~12.~~ "Contact therapy system" means that the x-ray tube port is put in contact with or within 5 centimeters (2 inches) of the surface being treated.

~~13.~~ "Control panel" means that part of the x-ray ~~control upon which are mounted the~~ machine where switches, knobs, push-buttons, ~~and~~ or other hardware necessary for manually setting the technique factors are located.

"Cooling curve" means the graphical relationship between heat units stored and cooling time.

"CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structure, frame, and cover which hold or enclose these components.

~~14.~~ "Dead-man switch" means a switch ~~so~~ constructed so that a ~~circuit closing~~ circuit-closing contact can be maintained only by continuous pressure on the switch by the operator.

~~15.~~ "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

~~16. "Diagnostic-type protective tube housing" means an x-ray tube housing so constructed that the leakage radiation measured at the distance of 1 meter from the source cannot exceed 25.8 µC/kg (100 mR) in 1 hour when the tube is operated at its maximum continuous rated current for the maximum rated tube potential.~~

"Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of a human or animal body for the purpose of diagnosis or visualization.

~~17.~~ "Direct scattered radiation" means ~~that~~ scattered radiation ~~which~~ that has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").

~~18.~~ "Entrance exposure rate" means the roentgens per unit time at the point where the center of the useful beam enters the patient.

~~19.~~ "Equipment" (See "X-ray equipment")

~~20.~~ "Filter" means material placed in the useful beam to absorb ~~preferentially selected radiations~~ undesirable radiation.

~~21.~~ "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor or receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material ~~providing~~ that provides a linkage between the image receptor and diagnostic source assembly.

"Fluoroscopic system" means a radiographic x-ray system used to directly visualize internal structure, the motion of internal structures, and fluids in real time, or near real-time, to aid in the treatment or diagnosis of disease, or the performance of other medical procedures.

~~22.~~ "Focal spot" means ~~the area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates~~ the region of the anode target in an x-ray tube where electrons from the cathode interact to produce x-rays.

~~23. "Full beam detector" means a radiation detector of such size that the total cross section of the maximum size useful beam is intercepted.~~

~~24.~~ "General purpose radiographic x-ray system" means any radiographic x-ray system ~~whic~~h that, by design, is not limited to radiographic examination of a specific anatomical region.

~~25.~~ "Gonadal shield" means a protective barrier for the testes or ovaries.

"Grid" means a device used to improve the image detail in a radiograph by reducing the intensity of x-ray scatter radiation exiting the film side of the patient.

~~26.~~ "Half-value layer (HVL)" means the thickness of a specified material ~~which~~ that attenuates the beam of radiation to an ~~extent such that the~~ exposure rate ~~intensity is reduced to~~ that is one-half of its original value. In this definition, the contribution of ~~all~~ any scattered radiation, other than ~~any~~ that which ~~might be~~ is present initially in the beam ~~concerned~~, is ~~deemed to be~~ excluded.

~~27.~~ "Healing ~~Arts Radiography~~ arts radiography" means the practice of applying x-radiation to human patients for diagnostic or therapeutic purposes at the direction of a licensed practitioner. Healing arts radiography includes ~~any or all of the following acts~~:

~~a.~~ Positioning the x-ray beam with respect to the patient;

~~b.~~ Anatomical positioning of the patient;

~~c.~~ Selecting exposure factors; or

~~d.~~ Initiating the exposure.

"Healing arts screening" means the application of radiation from an x-ray machine to a human for the detection or evaluation of health indications when the tests are not specifically and individually ordered by a licensed practitioner.

"Image intensifier" means an electronic device, installed in an x-ray system housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher intensity.

~~28.~~ "Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformation.

~~29.~~ "Inherent filtration" means the filtration of ~~permanently in~~ the useful beam by permanently installed components of the tube housing assembly. ~~; it includes the window of the x-ray tube and any permanent tube or source enclosure.~~

30. ~~"Interlock" means a device for precluding access to a high radiation area by automatically reducing the exposure rate upon entry by personnel.~~

31. "Kilovolts peak (kVp)" (See "Peak tube potential")

32. "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

33. "Leakage radiation" means all radiation emanating from ~~coming from within~~ the tube housing except the useful beam and radiation produced when the exposure switch or timer is not activated.

34. "Leakage technique factors" means the technique factors associated with the diagnostic source ~~tube housing~~ assembly ~~which~~ that are used in measuring leakage radiation. ~~They are defined as follows:~~ Included are:

   a. For capacitor energy storage equipment, the maximum-rated peak tube potential and the ~~maximum rated~~ maximum-rated number of exposures in an hour for operation at the ~~maximum rated~~ maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (mAs) or the minimum obtainable from the unit, whichever is larger~~.~~;

   b. For field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and maximum-rated ~~maximum rated~~ number of x-ray pulses in an hour for operation at the ~~maximum rated~~ maximum-rated peak tube potential~~.~~; and

   c. For all other source assemblies ~~equipment~~, the maximum-rated peak tube potential and maximum-rated ~~maximum rated~~ continuous tube current for the ~~maximum rated~~ maximum-rated peak tube potential.

35. "mA" means milliampere.

"Mammographic x-ray system" means an x-ray system that is specifically engineered to image human breasts.

36. "mAs" means milliampere second.

37. "Mobile equipment"~~.~~ (See "X-ray equipment"~~.~~)

38. "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

39. "Phantom" means a volume of material ~~behaving~~ that behaves in a manner similar to tissue with respect to the attenuation and scattering of radiation. (i.e. "Breast phantom" means an artificial test object ~~which~~ that simulates the average composition of, and various structures in the breast.)

40. "Phototimer" (See automatic exposure control) ~~means a method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s) that is/are part of an electronic circuit which controls the duration of the time the tube is activated.~~

41. "Portable equipment" (See X-ray equipment")

42. "Primary protective barrier" (See "Protective barrier")

43. "Protective apron" means an apron made of radiation, absorbing ~~materials~~ material used to reduce radiation exposure.

44. "Protective barrier" means a barrier of radiation- absorbing ~~material(s)~~ material used to reduce radiation exposure.

   a. "Primary protective barrier" means the material, excluding filters, placed in the useful beam~~, for protective purposes, to reduce the radiation exposure~~.

   b. "Secondary protective barrier" means the material which attenuates stray radiation ~~means a barrier sufficient to attenuate the stray radiation to the required degree~~.

45. "Protective glove" means a glove made of radiation-absorbing ~~materials~~ material used to reduce radiation exposure.

46. "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction. (See ~~also~~ "Direct scattered radiation"~~.~~)

"Screen" or "intensifying screen" means a device that converts the energy of the x-ray beam into visible light that interacts with the radiographic film, forming a latent image, or contains photostimulable phosphor plates that upon exposure, emit visible or nonvisible light to create an image.

47. "Secondary protective barrier"~~.~~ (See "Protective barrier~~.~~)

48. "Shutter" (See collimator) ~~means an adjustable device, generally of lead, fixed to an x-ray tube housing to intercept or collimate the useful beam and which has a lead equivalency not less than that of the tube housing assembly~~.

49. "Source" means the focal spot of the x-ray tube.

50. "Source-image receptor distance (SID)" means the distance from the source to the center of the input surface of the image receptor.

51. "Spot check" ~~means an abbreviated calibration procedure which is performed to assure that a previous calibration continues to be valid.~~ means an abbreviated calibration procedure which is performed to assure that a previous calibration continues to be valid. Also, a spot film may be taken to improve visualization by arresting motion and to doc-

ument medical observations. Note that in some cases, a film may not be created.

~~52.~~ "Stationary equipment"~~.~~ (See X-ray equipment"~~.~~)

~~53.~~ "Stray radiation" means the sum of leakage and scattered radiation.

"System"- (See x-ray system)

~~54. "Therapeutic-type protective tube housing" means:~~

~~a. For x-ray therapy equipment not capable of operating at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that the leakage radiation at a distance of one meter from the sources does not exceed 258 µC/kg (one roentgen) in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential.~~

~~b. For x-ray therapy equipment capable of operating at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that the leakage radiation at a distance of one meter from the source does not exceed 0.1 percent of the useful beam dose rate at one meter from the source for any of its operating conditions.~~

"Technique chart" means a tabulation of technique factors.

"Technique factors" means the following conditions of operation:

For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of x-ray pulses;

For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and number of x-ray pulses in mAs;

For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current, exposure time in mAs, when the scan time and exposure time are equivalent; and

For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

"Treatment simulator" means a diagnostic x-ray system that duplicates a medical particle accelerator or other teletherapy in terms of its geometrical, mechanical, and optical qualities; the main function of which, is to display radiation treatment fields so that the target volume may be accurately included in the area of irradiation without delivering excess radiation to surrounding normal tissue.

"Tube" means x-ray tube unless otherwise specified.

"Tube housing assembly" means the tube housing with the tube installed. It includes high-voltage or filament transformers and other elements contained within the tube housing.

"Tube rating chart" means the set of curves that specify the rated limits of operation of the tube in terms of the technique factors.

~~55.~~ "Useful beam" means the radiation emanating from the ~~which passes through the~~ tube housing port or the radiation head and passing through ~~and~~ the aperture of the beam-limiting device when the exposure controls are in a mode that causes the system to produce radiation ~~switch or timer is activated~~.

~~56. "Virtual source" means a point from which radiation appears to originate.~~

"Visible area" means that portion of the input surface on the image receptor over which incident x-ray photons are producing a visible image.

~~57.~~ "X-ray equipment" means an x-ray system, subsystem, or component described further by the following terms:

~~a.~~ Mobile means x-ray equipment mounted on a permanent base with wheels ~~and/or~~ casters for moving while completely assembled.

~~b.~~ Portable means x-ray equipment designed to be hand-carried.

~~c.~~ Stationary means x-ray equipment ~~which is~~ installed in a fixed location.

~~d.~~ Transportable mobile means x-ray equipment installed in a vehicle or trailer.

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes, at minimum, an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components that function with the system are considered integral parts of the system.

"X-ray tube" means any electron tube that is designed for the conversion of electrical energy into x-ray energy. For purposes of the rules contained in 12 A.A.C. 1, this term is synonymous with "tube."

R12-1-603. ~~General Safety Provisions~~ Operational Standards, Shielding, and Darkroom Requirements

A. A ~~No~~ person shall not make, sell, lease, transfer, lend, or install x-ray equipment or the supplies used in connection with the ~~such~~ equipment unless the ~~such~~ supplies and equipment, when properly placed in operation and properly used, ~~will meet~~ meets the requirements of ~~these rules~~ 12 A.A.C. 1. ~~This includes responsibility for the delivery of cones or collimator, filters, adequate timers, and fluoroscopic shutter (where applicable).~~

B. ~~The~~ A registrant shall ~~be responsible for directing~~ direct the operation of x-ray machines under the registrant's control and ~~assuring~~ assure that all of the following provisions are met in the operation of x-ray machines:

1. The registrant shall not permit any individual to engage in the practice of ~~"healing arts radiography"~~ "Healing Arts Radiography" using equipment under the registrant's control, unless the individual possesses a valid certificate issued by, or is exempt from, the Medical Radiologic Technology Board of Examiners~~, pursuant to A.R.S. § 32-2800~~.
2. The registrant shall maintain records documenting compliance with subsection (B)(1) ~~above~~ for each individual using equipment under the registrant's ~~registrants'~~ control practicing "Healing Arts Radiography."
3. The registrant shall provide safety rules to each individual operating x-ray equipment under the registrant's ~~his~~ control, including any restrictions in operating procedures necessary for the safe use of the equipment and require that the operator demonstrate familiarity with ~~these rules~~ 12 A.A.C. 1.

C. No change

1. Each registrant shall provide each installation ~~shall be provided~~ with ~~such~~ primary and secondary protective barriers ~~as~~ that are necessary to assure compliance with 12 A.A.C. 1, Article 4 ~~of this Chapter~~.
2. ~~The required~~ A registrant shall ensure that attenuation ~~of~~ provided by a protective ~~barriers shall be as determined in accordance with~~ barrier meets or exceeds the level of protection established in the National Council on Radiation Protection Report No. 49, "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies Up To 10 MeV," September 15, 1976 Edition edition, published by the National Council on Radiation Protection and Measurement, Inc., which is incorporated ~~herein~~ by reference and on file with the Agency ~~the Office of Secretary of State~~. This incorporation by reference contains no future editions or amendments. Each registrant shall use this incorporated reference to provide sufficient shielding to prevent public exposure in excess of the limits in R12-1-416.
3. ~~Protective barriers shall meet these additional provisions.~~ A registrant shall:
   a. ~~Lead barriers shall be mounted in such a manner that they will not sag or cold-flow because of their own weight and shall be protected against mechanical damage.~~ Mount each lead barrier so that the barrier will not sag or cold flow because of its own weight and protect the barrier from damage;
   b. ~~Joints between different kinds of protective materials shall be so designed that the overall protection of the barrier is not impaired.~~ Use barriers designed so that joints between different ends of protective material do not impair the overall protection of the barriers;
   c. ~~Joints at the floor and ceiling shall be so designed that the overall protection is not impaired~~ Use barriers designed so that joints at the floor and ceiling do not impair the overall protection of the barriers;
   d. ~~Windows, window frames, doors, and door frames shall have the same lead equivalent as that required of the adjacent wall~~ Use windows, window frames, doors, and door frames that have the same lead equivalence required in the adjacent walls; and
   e. ~~Holes in protective barriers shall be covered so that overall attenuation is not impaired~~ Cover holes in protective barriers so that overall attenuation is not impaired.
4. A registrant shall also meet the structural shielding requirements in R12-1-607(C), if the x-ray system in question is not fluoroscopic or intraoral.

D. Darkroom Requirements. A registrant shall:

1. ~~The~~ Use a darkroom ~~shall be~~ that is light-tight as determined ~~using 1~~ under one of the following formulas:
   a. No change
   b. No change
2. ~~A~~ Use a thermometer and timer operable and appropriate to the type of film processing ~~shall be in use~~ in the darkroom~~.~~ ; ~~Film shall be developed in accordance with the manufacturer's instructions;~~ and
3. Develop film according to the manufacturer's instructions.

R12-1-604. General Procedures ~~Procedural Requirements~~

A. The registrant shall ensure the following procedural requirements are met in the operation of x-ray equipment:

1. No change
2. Except for patients who cannot be moved out of the room, only the individuals required for the radiological procedure or in training may be present in the room during radiographic exposure, and all the following requirements ~~shall~~ apply:
   a. No change
   b. No change
   c. No change

d. ~~When~~ If a portion of the body of any staff or ancillary personnel is potentially subjected to stray radiation ~~which~~ that could result in that individual receiving 10% ~~one-quarter~~ of the maximum permissible dose as defined in Article 4 of this Chapter, the registrant shall provide additional protective devices ~~may be required~~ as specified by the Agency.

3. ~~Persons~~ An individual shall not be exposed to the useful beam except for a healing arts purpose authorized by a licensed practitioner of the healing arts. ~~Specifically prohibited are~~ The following acts are prohibited:
   a. Exposure of an individual without meeting the required healing art requirements and ~~proper prescription~~ without a valid directive from a licensed practioner;
   b. Exposure of an individual for training, demonstration, or other non-healing arts purpose;
   c. Exposure of an individual for the purpose of healing arts screening, except as authorized ~~pursuant to Appendix A of this~~ by the Agency after submitting to the Agency the information listed in Appendix A of this Article. If any information submitted to the Agency ~~becomes invalid or outdated, the Agency shall be immediately notified~~ changes, the registrant shall immediately notify the Agency of the changes.
4. No change

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

R12-1-605. X-ray Machine Standards ~~General Equipment Requirements~~

A. ~~The~~ A registrant shall prevent leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source assembly ~~shall not exceed~~ from exceeding 25.8 μC/kg (100 milliroentgens) in one hour when the x-ray tube is operated at its leakage technique factors. ~~Compliance shall be determined~~ The Agency shall determine compliance by obtaining measurements averaged over an area of 100 square centimeters (15.5 square inches) with no linear dimension greater than 20 centimeters (7.9 inches).

B. The registrant shall prevent radiation emitted by a component other than the diagnostic source assembly ~~shall not exceed~~ from exceeding 516 nC/kg (2 milliroentgens) in one hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. ~~Compliance shall be determined~~ The Agency shall determine compliance by obtaining measurements averaged over an area of 100 square centimeters (15.5 square inches) with no linear dimension greater than 20 centimeters (7.9 inches).

C. Beam quality.
1. The registrant shall prevent the useful beam half-value layer (HVL) for diagnostic x-ray given x-ray tube potential ~~shall not be less than~~ from falling below the values shown in Table I. If it is necessary to determine the half-value layer at an x-ray tube potential ~~which~~ that is not listed in Table I, the registrant shall use linear interpolation or extrapolation ~~may be made~~ to make the determination.

Table I

Design operating range (kilovolts peak)	*Measured potential (kilovolts peak)*	*Half-value layer (millimeters of aluminum)*
Below 51	30	0.3
	40	0.4
	50	0.5
51 to 70	51	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

2. ~~The above HVL criteria will be considered to have been met if it can be demonstrated~~ If the registrant demonstrates that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table II, the registrant is considered to have met the criteria in subsection (C)(1).

Table II - Filtration Required vs. Operating Voltage

Operating Voltage (kVp)	*Total Filtration (inherent plus added) (millimeters aluminum equivalent)*
Below 51	0.5 millimeters
51 - 70	1.5 millimeters
Above 70	2.5 millimeters

3. ~~Beryllium~~ The registrant shall use beryllium window tubes ~~shall~~ that have a minimum of 0.5 mm aluminum equivalent filtration permanently mounted in the useful beam.
4. For capacitor energy storage equipment, the Agency shall determine compliance ~~shall be determined~~ with the maximum quantity of charge per exposure.
5. ~~The required minimal~~ When determining the minimum aluminum equivalent filtration ~~shall~~ The registrant shall include the filtration contributed by all materials ~~which~~ that are always present between the focal spot of the tube and the patient (for example, a tabletop when the tube is mounted "under the table" and inherent filtration of the tube).

D. Multiple tubes. ~~Where~~ If two or more radiographic tubes are controlled by one exposure switch, the operator shall clearly indicate which tube or tubes ~~which~~ have been selected ~~shall be clearly indicated prior to~~ before initiation of the exposure, activating one light ~~. This indication shall be both~~ on the x-ray control panel and a second light at or near the tube housing assembly, ~~which has~~ each indicating the tube or tubes that have been selected.

E. Mechanical support of tube head. The registrant shall adjust the tube housing assembly supports ~~shall be adjusted such~~ so that the tube housing assembly will remain stable during an exposure, unless the tube housing movement is a designed function of the x-ray system.

F. Exposure reproducibility. The coefficient of variation shall not exceed 0.10 when all technique factors are held constant. This requirement ~~shall be deemed to have been met~~ is satisfied if the value of the average exposure (E) is greater than or equal to five times the difference between the maximum exposure (Emax) and minimum exposure (Emin) when four exposures are made at identical technique factors, [$E \geq 5(Emax - Emin)$].

~~**G.** Film processing equipment shall be utilized in accordance with the manufacturer's specifications and recommendations.~~

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

A. Useful beam limitation. A registrant shall:
1. ~~Beam-limiting~~ Provide beam-limiting devices ~~shall be provided which~~ that restrict the entire cross-section of the useful beam to less than the area of the primary barrier at any Source-to-Image Receptor Distance (SID).
2. ~~The~~ Ensure that the x-ray field size produced by fluoroscopic systems without image intensification ~~shall~~ does not extend beyond the visible area of the image receptor at any SID~~.~~ ;
3. ~~The~~ Ensure that the x-ray field size produced by fluoroscopic systems with image intensification and automatic shutter control ~~shall~~ does not exceed the diameter of the image receptor at any SID~~.~~;
4. ~~The~~ Ensure that the x-ray field size produced by fluoroscopic systems with image intensification and manual shutter control ~~shall~~ does not exceed the diameter of the image receptor with the fluoroscopic imaging assembly positioned at the maximum usable distance above the table top~~.~~; and
5. ~~The~~ Ensure that the x-ray field size produced by fluoroscopic systems with image intensification and manual shutter control, where the fluoroscopic tube is above the table top, ~~shall~~ does not exceed the diameter of the image receptor with the shutters open to the fullest extent, and at the maximum SID ~~"SID"~~ which the fluoroscopic tube is capable of producing radiation.

B. Fluoroscopic primary protective barrier. A registrant shall
1. ~~The~~ Provide the fluoroscopic imaging assembly ~~shall be provided~~ with a primary protective barrier ~~which~~ that always intercepts the entire cross-section of the useful beam at any SID.
2. ~~The~~ Ensure that the fluoroscopic tube ~~shall not be~~ is not capable of producing radiation unless the primary protective barrier is in a position to intercept the entire cross-section of the useful beam.
3. ~~Fluoroscopic~~ Ensure that fluoroscopic radiation production ~~shall~~ automatically ~~terminate when~~ terminates if the primary protective barrier is removed from the useful beam.
4. ~~The~~ Ensure that the fluoroscopic primary protective barrier ~~shall meet~~ meets the following requirements for attenuation of the useful beam~~.~~:
   a. For equipment installed before November 15, 1967, the required lead equivalent of the barrier ~~shall~~ is not ~~be~~ less than 1.5 millimeters for ~~up to~~ fluoroscopes that produce less than 100 kVp, 1.8 millimeters for fluoroscopes that produce from ~~greater than~~ 100 kVp ~~and less than~~ up to 125 kVp, and 2.0 millimeters for fluoroscopes that pro-

duce 125 or more kVp ~~or greater~~. (For conventional fluoroscopes, these requirements may be assumed to have been met if the exposure rate measured at the viewing surface of the fluorescent screen does not exceed 12.9 µC/kg (50 milliroentgens) per hour with the screen in the primary beam of the fluoroscope without a patient, under normal operating conditions.) For equipment installed or reinstalled ~~thereafter~~, the required lead equivalent of the barrier ~~shall not be less than~~ is 2.0 millimeters for up to 125 kVp or ~~shall not be less than~~ 2.7 millimeters for 125 or more kVp ~~or greater~~.

b. For fluoroscopic systems ~~utilizing~~ that use image intensification, the exposure rate, due to transmission through the primary protective barrier, ~~shall~~ does not exceed 516 nC/kg (2 milliroentgens) per hour at 10 centimeters (4 inches) from any accessible surface of the fluoroscopic imaging assembly, beyond the plane of the image receptor for each 258µC /kg (1 roentgen) per minute of entrance exposure rate.

c. Compliance with ~~subsection~~ subsections (B)(4)(a) and (b) ~~shall be~~ is determined with the image receptor positioned 35.5 centimeters (14 inches) from the panel or table top, at normal operating technical factors and with the attenuation block in the useful beam for systems with image intensification.

C. Entrance exposure rate limits. A registrant shall ensure that:

1. The exposure rate, measured at the point where the center of the useful beam enters the patient ~~shall~~ does not exceed 2.6 ~~µC~~ mC/kg (10 roentgens) per minute at any combination of tube potential and current, except during recording of flu oroscopic images or ~~when~~ if provided with optional high-level control.
2. ~~When~~ If provided with optional high-level control, the equipment ~~shall~~ is not ~~be~~ operable at any combination of tube potential and current ~~which~~ that will result in an exposure rate in excess of 2.6 ~~µC~~ mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, unless the high-level control is activated, in which case an exposure rate in excess of 5.2 ~~µC~~ mC/kg (20 roentgens) per minute is prohibited ~~shall not be exceeded~~.
   a. Special means of activation of high-level controls, such as additional pressure applied continuously by the operator, ~~shall be~~ are required to avoid accidental use.
   b. A continuous signal audible to the fluoroscopist ~~shall~~ is required to indicate that the high-level control is being employed.
3. ~~Compliance with~~ The Agency shall determine compliance with subsections (C)(1) and (C)(2) ~~Paragraph (C)(1) and (C)(2) above shall be determined~~ as follows:
   a. ~~Movable~~ Remove grids and compression devices ~~shall be removed~~ from the useful beam during the measurement; ~~and~~
   b. If the source is below the table, measure the exposure rate ~~shall be measured~~ 1 centimeter above the table top or cradle; and
   c. If the source is above the table, measure the exposure rate ~~shall be measured at~~ 30 centimeters (11.8 inches) above the table top with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement; ~~or~~
   d. ~~In~~ For fluoroscopy involving a mobile C-arm x-ray system ~~a mobile C-arm type of fluoroscope~~, measure the exposure rate ~~shall be measured at~~ 30 centimeters (11.8 inches) from the input surface of the fluoroscopic imaging assembly~~.~~:
   e. ~~In~~ For fluoroscopy involving a C-arm x-ray system ~~a C-arm type fluoroscope~~, measure the exposure rate ~~shall be measured~~ 30 centimeters (11.8 ~~5.9~~ inches) from the input surface of the fluoroscope imaging assembly, with the x-ray source positioned at any available SID, provided that the end of the beam-limiting device or spacer is not closer than 30 centimeters (11.8 ~~5.9~~ inches) from the input surface of the fluoroscopic image assembly~~.~~; and
   f. ~~In~~ For a lateral-type fluoroscope, measure the exposure rate ~~shall be measured at a point~~ 15 centimeters (5.9 inches) from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters (5.9 inches) to the centerline of the x-ray table.

D. The registrant shall ensure that the source-to-skin distance ~~shall not be~~ is not less than:

1. 38 centimeters (15 inches) on stationary fluoroscopes installed after ~~the effective date of this Section~~ January 2, 1996;
2. 35.5 centimeters (14 inches) on stationary fluoroscopes which are in operation ~~prior to the effective date of this Section,~~ before January 2, 1996;
3. No change
4. 20 centimeters (8 inches) for image-intensified fluoroscopes used for a specific surgical application. The registrant shall follow any precautionary measures in the users operating manual.

E. Each fluoroscopic system installation ~~shall be~~ is subject to all of the following requirements for the control of stray radiation~~:~~ . A registrant shall:

1. ~~A~~ Provide a shielding device of at least 0.25 millimeter lead equivalent ~~shall be provided~~ for covering the Bucky-slot during fluoroscopy;
2. Except for fluoroscopy performed using portable or mobile C-arm x-ray systems or during surgical procedures or cardiac catheterization, provide protective drapes, or hinged or sliding panels of at least 0.25 millimeters lead equivalent,

~~shall be provided~~ between the patient and fluoroscopist to intercept scattered radiation ~~which~~ that would otherwise reach the fluoroscopist and others near the machine, but not substitute drapes and panels ~~shall not be substituted~~ for a protective apron; and

3. ~~Protective~~ Ensure that protective aprons of at least 0.25 millimeter lead equivalent ~~shall be~~ are worn in the fluoroscopy room by each person, except the patient, whose body is likely to be exposed to 50 µSv/hr (5 mR/hr) or more.

F. Exposure control. A registrant shall:

1. ~~Activation~~ Ensure that activation of the fluoroscopic tube ~~shall be~~ is controlled by a "dead-man" switch; ~~"deadman type" exposure switch(s)~~.
2. ~~A~~ Provide a manual reset cumulative timing device, which is activated only during production of radiation in the fluoroscopic mode, ~~shall be provided and shall~~ to indicate elapsed time by an audible signal or terminate production of radiation~~.~~;
3. ~~A~~ Provide a device ~~shall be provided~~ for exposure control in the "spot film" mode ~~which~~ that terminates exposure either automatically, or after a preset time interval, preset number of pulses, preset product of current and time, or preset exposure~~.~~ ; and
4. ~~During fluoroscopy and cinefluorography,~~ Ensure that the x-ray tube potential and current ~~shall be~~ are continuously indicated.

G. ~~Systems utilized~~ A registrant shall provide systems used for mobile fluoroscopy ~~shall be provided~~ with image intensification.

H. Fluoroscopic treatment simulators. Simulators are exempt from subsections (A) through (G). A registrant shall:

1. Use a beam limiting device that restricts the beam to the area of clinical interest.
2. Include and label devices for settings or physical factors, such as kVp, mA, or exposure time on the control panel;
3. Ensure that the fluoroscopic exposure switch or switches are of the "deadman" type;
4. Ensure that each person whose presence is necessary is in the simulator room during exposure and protected with a lead apron of at least 0.5 mm lead equivalent or a portable shield. Any person who places their hands in the useful x-ray beam shall wear leaded gloves; and
5. Ensure that the operator stands behind a barrier and is able to observe the patient during simulator exposures.

R12-1-607. Additional X-ray Machine Standards, Shielding Requirements, and Procedures, Except ~~Diagnostic Radiographic Systems Other Than~~ Fluoroscopic~~, or~~ and Dental Intraoral Radiographic Systems

A. Useful beam limitation. A registrant shall:

1. ~~Means shall be provided~~ Provide a means to restrict the useful beam to the area of clinical interest for any combination of SID and image receptor size employed.
2. ~~Beam-limiting~~ Ensure that beam-limiting devices ~~shall~~ meet the following ~~appropriate~~ requirements:
   a. Devices ~~which~~ that project a circular radiation field ~~shall~~ restrict the diameter of the useful beam, not to exceed the diagonal dimension of the image receptor by greater than 2% of the SID;
   b. Devices ~~which~~ that project a rectangular or square radiation field ~~shall~~ restrict the useful beam to the longitudinal and transverse dimensions of the image receptor to within 2% of the SID;
   c. Beam limiting devices that do not ~~incorporating~~ incorporate light beams to define the projected radiation field ~~shall be~~ are clearly labeled, indicating the SID and image receptor size at which each ~~such~~ device complies with the applicable requirements of subsection (A)(2)(a) or (b) ~~subparagraph (a) or (b) above~~;
   d. Adjustable beam-limiting devices installed after July 31, 1971, ~~shall~~ incorporate light beams to define the projected dimensions of the useful beam and ~~shall~~ provide an average illumination of not less than 100 lux (9 footcandles) at 1 meter (3.3 feet) or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field; and
   e. All beam-limiting devices installed, on general purpose fixed and mobile radiographic systems, ~~shall~~ provide ~~step-less~~ stepless means of continuous adjustment of the projected radiation field size.
3. ~~Means shall be provided~~ Provide a means to align the center of the radiation field to the center of the image receptor to within 2% of the SID.

B. Radiation exposure control. A registrant shall:

1. ~~A means shall be provided~~ Provide a means to terminate the exposure at a preset time interval, preset product of current and time, preset number of pulses, or a preset exposure to the image receptor. ~~It shall not be~~ The registrant shall ensure that it is not possible to make an exposure when the exposure control device is set to a "zero" or "off" position if either position is provided.
2. ~~The~~ Ensure that the exposure switch ~~shall meet the requirements of~~ is a "dead-man" switch ~~"deadman type switch"~~, and except for those used ~~in~~ with "spot-film" devices in fluoroscopy, ~~shall be so~~ is arranged so that it cannot be conveniently operated outside a shielded area.
3. Provide x-ray systems ~~Systems provided~~ with automatic exposure control, which indicates ~~shall indicate~~ at the control panel when this mode is selected, and a visual ~~and/or~~ and audible signal, ~~shall indicate~~ which indicates termination of the exposure.

4. ~~The~~ Use a control panel ~~shall include~~ that includes:
   a. A device (usually a milliammeter) ~~which~~ that will give a positive indication during radiation production; and
   b. Control setting indicators ~~Indicators labeled control settings~~ or meters ~~indicating~~ that indicate the appropriate technical factors: kVp, mAs mA, or exposure time~~, or mass~~, and any special mode selected for the exposure.

C. Structural shielding. A registrant shall:
1. ~~All~~ Ensure that all wall, floor and ceiling areas struck by the useful beam ~~shall~~ have primary protective barriers. Primary protective barriers in walls shall extend from the finished floor to a minimum height of 2.13 meters (7 feet) ~~seven feet.~~ ;
2. ~~Secondary~~ Ensure that secondary protective barriers ~~shall be~~ are provided in all wall, floor, and ceiling areas ~~not having~~ that do not have primary protective barriers or where the primary protective barrier requirements are lower than the secondary barrier requirements~~.~~;
3. ~~The~~ Ensure that the operator's station ~~at the control shall be~~ is behind a protective barrier sufficient to ~~assure~~ ensure compliance with R12-1-408, R12-1-414, and R12-1-416, and the operator is able to communicate with the patient from the operator's station. ~~Provision shall be made for the operator to communicate with the patient from the operator's station.~~
4. ~~A~~ Provide a window of transparent material equal in attenuation to that required by the adjacent barrier, or a mirror system, ~~shall be provided and shall be~~ that is large enough and ~~so~~ placed so that the operator can see the patient during exposure without having to leave the protected area.

D. Operating procedures. A registrant shall:
1. Use mechanical supporting or restraining devices, if ~~When~~ a patient must be held in position for radiography~~, mechanical supporting or restraining devices should be used~~. If the patient must be held by an individual, the registrant shall ensure that the individual ~~shall be~~ is protected with appropriate shielding devices, such as protective gloves and apron, and ~~shall be so~~ is positioned so that no part of the body of the individual holding the patient is ~~will be~~ struck by the useful beam~~.~~;
2. ~~Only~~ Ensure that only individuals required for the radiographic procedure ~~shall be~~ are in the radiographic room during exposure, and, except for the patient, all ~~such persons shall be~~ these individuals are equipped with ~~appropriate~~ protective devices~~.~~;
3. ~~The~~ Restrict the useful beam ~~shall be restricted~~ to the clinical area of interest~~.~~;
4. ~~A~~ Provide a chart ~~shall be provided~~ in the vicinity of the diagnostic x-ray system's control panel ~~which~~ that specifies, for all routine examinations performed with the system, the following information:
   a. Patient's anatomical size ~~versus~~ and technique factors ~~to be utilized~~;
   b. Type and size of the film or film screen combination ~~to be used~~;
   c. Type and focal distance of the grid ~~to be used~~, if any;
   d. X-ray source-to-image receptor distance ~~to be used~~; and
   e. Type and location ~~of placement~~ of gonad shielding ~~to be used~~.
5. Provide documentation of the patient's identity, the x-ray examination performed, the date it is performed, number of projections (if applicable), and a method of identifying the individual who performed the examination, for Agency review. The registrant shall maintain the documentation for three years from the date the examination is performed.

R12-1-608. ~~Special Requirements for~~ Mobile Diagnostic Radiographic Systems ~~Equipment~~, Except Dental Intraoral Radiographic Systems

A. No change
1. No change
2. A registrant shall provide a ~~dead-man type of exposure~~ "dead-man" switch ~~shall be provided~~, together with an electrical cord of sufficient length so that the operator can stand out of the useful beam and at least 1.82 meters (6 feet) from the patient during all x-ray exposures
3. A registrant shall ensure that a cone, spacer frame, or inherent provision ~~shall be~~ is made so that the equipment is not operated at source-skin distances of less than 20.3 centimeters (8 inches).

B. Structural shielding. ~~When~~ If a mobile unit is used routinely in one location, it ~~shall be~~ is considered a fixed installation subject to the shielding requirements ~~specified~~ in R12-1-603(C), and R12-1-607(C).

C. No change
1. No change
2. ~~Personnel monitoring shall be~~ An individual who operates a mobile x-ray system shall comply with R12-1-419(B). ~~required for all individuals operating mobile x-ray equipment.~~

R12-1-609. ~~Special Requirements for~~ Chest Photofluorographic Systems

A. No change
1. No change
2. No change

B. No change

C. Operating procedures
1. All provisions of R12-1-607(D) apply.
2. All individuals except the patient being examined shall be in shielded positions during exposures.
3. Personnel monitoring shall be worn by persons operating photofluorographic systems in accordance with R12-1-419(B) ~~required for all individuals operating the equipment~~.

R12-1-610. Dental Intraoral Radiographic Systems

A. Equipment. A registrant shall:
1. ~~The~~ Use a protective tube housing ~~shall be~~ of diagnostic type.
2. ~~Diaphragms~~ Use diaphragms or cones ~~shall be used~~ for restricting the useful beam and ~~shall~~ to provide the same degree of protection as the housing. The diameter of the useful beam at the end of the cone or spacer frame shall not be more than 7.6 centimeters (3 inches) for intraoral radiography.
3. ~~A~~ Ensure that a cone or spacer frame ~~shall provide~~ provides a source-to-skin distance of not less than 17.8 centimeters (7 inches) with apparatus operating above 50 kVp or 10 centimeters (4 inches) with apparatus operating at 50 kVp or below for intraoral radiography~~.~~:
4. ~~A timer shall be provided to terminate the exposure at a preset time interval, present product of current and time, and preset number of pulses, or a preset radiation exposure to the image receptor~~. Provide a timer to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor;
5. ~~It shall~~ Ensure that it is not ~~be~~ possible to make an exposure ~~when~~ if the timer is set to the "zero" or "off" position~~.~~;
6. ~~The~~ Ensure that the tube head ~~shall remain~~ remains stationary ~~when~~ if placed in the exposure position~~.~~;
7. ~~The~~ Ensure that the exposure initiating device ~~shall meet the requirements of~~ is a "dead-man" ~~type~~ switch~~.~~; and
8. ~~The~~ Use a control panel ~~shall include~~ that includes:
   a. A device ~~(usually a milliammeter) which~~ that will give positive indication during radiation production; and
   b. Indicators, labeled control settings, or meters, indicating the appropriate technical factors: kVp, mA, or exposure time, ~~or mass,~~ and any special mode selected for the exposure.

B. Structural shielding. The registrant shall:
1. ~~Dental~~ Provide dental installations ~~shall be provided~~ with ~~such~~ primary and secondary barriers ~~primary barriers and/or secondary protective barriers as are necessary~~ to ~~assure~~ ensure compliance with the personnel exposure requirements in Article 4 of this Chapter~~.~~;
2. Install primary protective ~~When dental x-ray units are installed in adjacent rooms or areas, protective~~ barriers ~~shall be provided~~ between ~~the~~ rooms or areas~~.~~ if dental x-ray units are used in adjacent rooms or areas;
3. ~~Each~~ Provide each installation ~~shall be provided~~ with a protective barrier for the operator or ~~shall be so arranged~~ arrange the installation so that the operator can stand at least 1.82 meters (6 feet) from the patient and well away from the useful beam~~.~~;
4. ~~The~~ Arrange the operator's position ~~shall be arranged~~ to allow visual contact with the patient during exposure~~.~~; and
5. ~~Structural shielding. When~~ Comply with fixed installation requirements, if a mobile unit is used routinely in one location~~, it shall be considered a fixed installation~~.

   Note: In many cases structural materials of ordinary walls suffice as a protective barrier without addition of special shielding material.

C. No change
1. ~~Neither the dentist nor assistants~~ A dentist or other persons shall not hold patients or films during exposure. ~~, nor shall any individual be regularly used for this service~~. Only persons required for the radiographic procedure ~~shall be~~ are allowed in the radiographic room during exposures.
2. An ~~During each exposure, the~~ operator shall stand at least 1.82 meters (6 feet) from the patient or behind a protective barrier during each exposure.
3. ~~Only~~ An operator shall ensure that only the patient ~~shall be~~ is in the useful beam.
4. The licensed practitioner or other person shall not hold the ~~Neither the~~ tube housing or ~~nor~~ the cone ~~shall be hand-held~~ during the exposure.
5. A registrant shall not perform dental fluoroscopy without an image intensifier. ~~Fluoroscopy without image intensification shall not be used in dental examinations.~~

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

A. No change
1. Leakage radiation. A registrant shall ensure that:
   a. Contact therapy systems. Leakage radiation ~~shall~~ does not exceed 25.8 µC/kg (100 milliroentgens) per hour at 5 centimeters (2 inches) from the surface of the tube housing assembly.
   b. 0-150 kVp systems. Systems ~~which~~ that are manufactured or installed ~~prior to~~ before January 2, 1996 ~~the effective date of this Section shall~~ have a leakage radiation ~~which~~ that does not exceed 258 nC/kg (1 roentgen) in 1 hour at 1 meter (3.3 feet) from the source.

c. 0-150 kVp systems. Systems ~~which~~ that are manufactured on or after ~~the effective date of this Section~~ January 2, 1996, ~~shall~~ have a leakage radiation ~~which~~ that does not exceed 25.8 µC/kg (100 milliroentgens) in one hour at 1 meter from the source.

d. ~~151-999 kVp systems~~ Above 150 kVp. The leakage radiation ~~shall~~ does not exceed 258 nC/kg (1 roentgen) in one hour at 1 meter (3.3 feet) from the source except systems that operate in excess of 500 kVp may have a leakage radiation at 1 meter from the source equivalent to the exposure within one hour of the useful beam at 1 meter (3.3 feet) from the source multiplied by a factor of 0.001.

2. Permanent beam limiting devices. ~~Permanent~~ A registrant shall ensure that fixed diaphragms or cones used for limiting the useful beam ~~shall~~ provide the same or higher degree of protection as required ~~by~~ for the tube housing assembly.
3. Removable and adjustable beam-limiting devices. A registrant shall ensure that:
   a. Removable and adjustable beam-limiting devices ~~shall~~, for the portion of the useful beam to be blocked by these devices, transmit not more than ~~1~~ one percent of the original x-ray beam at the maximum kilovoltage and maximum treatment filter~~.~~; and
   b. Adjustable beam-limiting devices installed before the effective date of this Section ~~shall~~, for the portion of the x-ray beam to be blocked by these devices, transmit not more than 5~~%~~ percent of the useful x-ray beam at maximum kilovoltage and maximum treatment filter.
4. Filter system. ~~The~~ A registrant shall ensure that the filter system ~~shall be so~~ is designed so that:
   a. Filters cannot be accidentally displaced from the useful beam at any possible tube orientation;
   b. Each filter is marked ~~as to~~ regarding its material of construction and its thickness or wedge angle for wedge filters; and
   c. It ~~shall be~~ is possible for the operator to determine the presence or absence of each filter and the orientation of each wedge filter in the useful beam ~~when~~ if the operator is at the control panel, either by display at the control panel or by direct observation.
5. X-ray tube immobilization. ~~The~~ A registrant shall ensure that the tube housing assembly ~~shall be~~ is capable of being immobilized during stationary treatments.
6. Focal spot marking. ~~The~~ A registrant shall ensure that the tube housing assembly ~~shall be so~~ is marked so that it is possible to determine the location of the focal spot to within 5 millimeters, and ~~such~~ the marking ~~shall be~~ is readily accessible for use during calibration procedures.
7. Therapy treatment timers ~~shall meet the following requirements:~~. A registrant shall:
   a. ~~A~~ Provide a timer ~~shall be provided which~~ that has a display at the treatment control panel. The timer shall be graduated in minutes and fractions of minutes. The timer shall have a preset time selector and an elapsed time indicator~~.~~;
   b. ~~The~~ Ensure that the timer ~~shall be~~ is a cumulative timer ~~which~~ that activates with the radiation~~,~~ ~~and~~ retains its reading after irradiation is interrupted or terminated~~.~~ , and requires the operator ~~After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary~~ to reset the preset time selector after irradiation is terminated and before irradiation can be reinitiated;~~.~~
   c. ~~The~~ Ensure that the timer ~~shall terminate~~ terminates irradiation when a preselected time has elapsed~~.~~;
   d. ~~The~~ Ensure that the timer ~~shall permit~~ permits accurate presetting and determination of exposure times as short as 1 second~~.~~;
   e. ~~The~~ Ensure that the timer ~~shall~~ does not permit an exposure if set at 0~~.~~ ; and
   f. ~~The~~ Ensure that the timer ~~shall~~ does not activate until the shutter is opened ~~when~~ if irradiation is controlled by a shutter mechanism.
8. Control panel functions. ~~The control panel, in~~ In addition to the displays required in other provisions of this Section, ~~shall have~~ a registrant shall ensure that a control panel has:
   a. No change
   b. No change
   c. No change
   d. No change
   e. A locking device ~~which~~ that will prevent unauthorized use of the x-ray system; and
   f. For x-ray equipment installed after ~~the effective date of this Section~~ January 2, 1996, a positive display of specific filters in the beam.
9. Multiple tubes. ~~When a~~ If one control panel ~~may~~ is used to energize more than one x-ray tube a registrant shall ensure that:
   a. It ~~shall be~~ is possible to activate only one x-ray tube during any time interval;
   b. There ~~shall be~~ is an indication at the control panel ~~identifying~~ that identifies which x-ray tube is energized; and
   c. There ~~shall be~~ is an indication at the tube housing assembly when that tube is energized.
10. Source-to-patient distance. ~~There shall be~~ A registrant shall ensure that there is a means of determining the source-to-patient distance to within 1 centimeter.

11. Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds, a registrant shall ensure that the entire useful beam ~~shall be~~ is automatically attenuated by a shutter ~~having~~ with a lead equivalency not less than that of the tube housing assembly. In addition the registrant shall ensure that:
    a. After the unit is at operating parameters, the operator controls the shutter ~~shall be controlled~~ electrically ~~by the operator~~ from the control panel; and
    b. An indication of shutter position ~~shall appear~~ appears at the control panel.
12. Low filtration x-ray tubes. ~~Each~~ A registrant shall ensure that each x-ray system equipped with a beryllium or other low-filtration window ~~shall be~~ is clearly labeled as low-filtration equipment on ~~as such upon~~ the tube housing assembly and at the control panel.

B. Facility design requirements. In addition to shielding necessary to meet the requirements of Article 4 of this Chapter, a registrant shall ensure that ~~the treatment room shall meet all the following design requirements~~:
1. Warning lights. ~~Treatment~~ A treatment room to which access is possible through more than one entrance ~~shall be provided with~~ has a warning ~~lights~~ light, in a readily observable position near the outside of ~~all~~ any access doors, which will indicate when the useful beam is "on."
2. Voice communication. ~~Provision shall be made for 2-way~~ Two-way oral communication is possible between the patient and the operator at the control panel; ~~however,~~ or where excessive noise levels make oral communication impractical, ~~other~~ another effective method ~~methods~~ of communication ~~shall be used~~.
3. Viewing systems. Windows, mirrors, ~~or~~ closed-circuit television, or an equivalent system, ~~shall be provided to permit~~ permits continuous observation of the patient during irradiation and ~~shall be so~~ is located so that the operator can observe the patient from the control panel. ~~When~~ If the primary viewing system is by electronic means (for example, television), the registrant shall have an alternate viewing system ~~shall be available~~ for use in the event of electronic failure.
4. ~~Additional requirement~~ Systems above 150kVp. ~~Treatment~~ For treatment rooms ~~which~~ that contain an x-ray system capable of operating above 150 kVp ~~shall meet the following additional requirements~~ a registrant shall ensure that:
    a. All necessary shielding, except for any beam interceptor, ~~shall be~~ is provided by fixed barriers;
    b. The control panel ~~shall be~~ is within a protective booth equipped with an interlocked door, or located outside the treatment rooms;
    c. All doors of the treatment room ~~shall be~~ are electrically connected to the control panel ~~such~~ so that x-ray production cannot occur unless all doors are closed; and
    d. Opening of any door ~~of~~ to the treatment room during exposure ~~shall result~~ results in automatic termination of x-ray production or reduction of radiation levels to an average of no more than 516 nC/kg (2 milliroentgens) per hour and a maximum of 2.6 µC/kg (10 milliroentgens) per hour at a distance of 1 meter (3.3 feet) from the target in any direction~~., and restoration of After such shut-off or reduction, it shall be possible to restore~~ the machine to full operation is possible only from the control panel after the termination or reduction.

C. Surveys. A registrant shall ensure that:
1. All facilities, both new and existing, or not previously surveyed, ~~shall have a survey made prior~~ are surveyed before ~~to~~ being put into service for the treatment of patients by, or under the direction of, a person trained and experienced in the principles of radiation protection~~., and perform additional Additional~~ surveys ~~shall be made~~ of a facility after any change in the facility or a facility's equipment ~~which~~ that might cause a significant increase in radiation hazard, ~~prior to~~ before being put into service for the treatment of patients.
2. The person conducting the survey ~~shall report~~ reports the person's findings in writing to the individual in charge of the facility and maintains a copy of the report ~~shall be maintained by the registrant~~ for inspection by the Agency.
3. The installation ~~shall be~~ is operated in compliance with any limitations indicated by the protection survey required by subsection ~~paragraph~~ (C)(1) ~~above~~.

D. Calibrations. A registrant shall ensure that:
1. The calibration of ~~the~~ an x-ray system ~~shall include~~ includes, but is not ~~be~~ limited to, the following determinations:
    a. No change
    b. No change
    c. The degree of congruence between the radiation field and the field indicated by the localizing device if ~~such~~ a localizing device is ~~present~~ used; and
    d. An evaluation of the uniformity of the radiation field symmetry for the field sizes used and any dependence upon source housing assembly orientation~~.~~;
2. The calibration of an x-ray system ~~shall be~~ is performed at intervals not to exceed 12 months and after any change or replacement of components ~~which~~ that could cause a change in the radiation output~~.~~ ;
3. The calibration of the radiation output of the x-ray system ~~shall be~~ is performed by, or under the direction of, a person trained and experienced in performing calibrations, who is physically present at the facility during ~~such~~ calibration~~.~~;
4. Calibration of the radiation output of an x-ray system ~~shall be~~ is performed with a calibrated instrument. The registrant shall ensure that calibration of ~~such~~ the instrument ~~shall be~~ is directly traceable to the National Institute of Standards and Technology (NIST) and ~~shall have~~ that the instrument has been calibrated within the preceding 24 months~~.~~;

5. Records of calibration performed ~~pursuant to~~ under subsection (D)(3) ~~above shall be~~ are maintained ~~by the registrant~~ for at least two years after completion of the calibration and ~~shall be~~ are made available for inspection by the Agency~~.~~ ; and
6. A copy of the most recent calibration ~~shall be~~ is available for use by the operator at the control panel.

E. Spot checks. ~~Spot~~ A registrant shall ensure that spot checks ~~shall be~~ are performed on x-ray systems capable of operation at greater than 150 kVp. The registrant shall ensure that ~~Such~~ spot checks ~~shall~~ meet the following requirements:
1. The spot-check procedures ~~shall be~~ are in writing and ~~shall~~ have been developed by a qualified person;
2. The measurements taken during the spot checks ~~shall~~ demonstrate the degree of consistency of the operating characteristics ~~which~~ that can affect the radiation output of the x-ray system;
3. The written ~~spot check~~ spot-check procedure ~~shall specify~~ specifies the frequency of the ~~at which such~~ tests or measurements, made at intervals not to exceed monthly;
4. The ~~spot check~~ spot-check procedure ~~shall note~~ identifies conditions ~~which shall~~ that require recalibration of the system in accordance with subsection (D)(l); and
5. Records of spot-check measurements performed as required by subsection (E)(3) ~~above shall be~~ are maintained, available for inspection by the Agency, for three years following the ~~such~~ measurements.

F. Operating procedures. A registrant shall ensure that:
1. Therapeutic x-ray systems ~~shall~~ are not ~~be~~ left unattended unless the system is secured according to subsection ~~in accordance with subparagraph~~ (A)(8)(e) ~~above.~~;
2. ~~When~~ If a patient must be held in position for radiation therapy, mechanical supporting or restraining devices ~~shall be~~ are used~~.~~;
3. The tube housing assembly ~~shall~~ is not ~~be~~ held by an individual during exposures~~.~~; and
4. At 150 kVp or more the patient is the only person ~~No individual other than the patient shall be~~ in the treatment room during production of radiation. At less than 150 kVp an ~~unless such~~ individual may be in the room with patient, provided the individual is protected by a barrier sufficient to meet the requirements of Article 4 of this Chapter. ~~No individual other than the patient, shall be in the treatment room while radiation is being produced when the kVp exceeds 150.~~

R12-1-613. Veterinary Medicine Radiographic Systems

A. Equipment. A registrant shall ensure that:
1. ~~Prior to the effective date of these rules~~ Before January 2, 1996, the total filtration permanently in the useful beam ~~shall~~ is not ~~be~~ less than 1.5 millimeters aluminum-equivalent for equipment operating at up to 70 kVp and 2.0 millimeters aluminum-equivalent for ~~machines~~ equipment operating in excess of 70 kVp~~.~~;
2. A device ~~shall be~~ is provided to terminate the exposure after a preset time or exposure~~.~~;
3. ~~A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least 6 feet from the animal during all x-ray exposures.~~ Each radiographic system has a "dead-man" exposure switch with an electrical cord of sufficient length to allow the operator to stand at least 1.82 meters (six feet) away from the useful beam during x-ray exposures.

~~**B.** Appropriate shielding shall be employed such as protective gloves and apron, and the animal positioned so that no part of the occupationally exposed person's body will not be struck by the useful beam. Persons exposed to ionizing radiation for this purpose shall be monitored~~

B. Procedures: A registrant shall ensure that:
1. Unless required to restrain an animal, the operator stands at least 1.82 meters (6 feet) away from the useful beam and the animal during a radiographic exposure;
2. An individual other than the operator is not in the x-ray room or area while an exposure is being made, unless the individual's assistance is required;
3. If possible, an animal is held in position during an x-ray exposure using mechanical supporting or restraining devices;
4. An individual holding an animal during an x-ray exposure is:
   a. Wearing protective gloves and an apron of not less than 0.5 millimeter lead equivalent or positioned behind a whole-body protective barrier;
   b. Wearing required personnel monitoring devices; and
   c. Positioned so that no part of the person's body, except hands and arms, will be struck by the useful beam;
5. If an individual holds or supports an animal or a film during an x-ray exposure, the name of the individual is recorded in an x-ray log that contains the animal's name, the type of x-ray procedure, the number of exposures, and the date of the procedure; and
6. As a condition of employment an individual is not required to routinely hold or support animals, or hold film during radiation exposures.

~~**C.** Operating procedures.~~
~~1. The operator shall stand well away from the tube housing and the animal during radiographic exposures. Provisions shall be made so that the operator will not be required to stand in the useful beam. Hand-held fluoroscopic screens shall not be used. The tube housing shall not be held by the operator. No individual other than the operator shall be in~~

~~the x-ray room while exposures are being made unless such individual's assistance is required.~~

~~2. In any application in which the operator or other assisting individual is not located behind a protective barrier, clothing consisting of a protective apron and gloves having a lead-equivalent of not less than 0.5 millimeters shall be worn by the operator and any other individual in the room during exposures.~~

~~3. No individual shall be regularly employed to hold or support animals or hold film during radiation exposures. Occupationally exposed individuals shall not perform this service except in where cases in which no other method is available and that person shall be provided with a personnel monitoring device.~~

~~4. If an individual must support an animal or a film during an x-ray exposure, the name of the individual holding the animal shall be recorded in an x-ray log containing the animal's name, the type of examination, and the date the examination was performed.~~

R12-1-614. Mammography ~~Mammographic Systems~~

A. Equipment. A registrant shall ensure that:

1. Only radiation machines specifically designed for mammography examinations ~~shall be~~ are used~~.~~;
2. The film processor used in the registrant's facility ~~shall be~~ is maintained in accordance with the film processor's and film manufacturer's recommendations~~.~~;
3. Each facility ~~shall have~~ has an image development system onsite unless the Agency has approved an alternate system~~.~~;
4. ~~When~~ If used with screen-film image receptors, and the contribution to filtration made by the compression device is included, the useful beam ~~shall have~~ has a half-value layer between the values of: "measured kVp/100 and measured kVp/100 + 0.1 millimeters" of aluminum equivalent~~.~~;
5. The combination of focal spot size, source-to-image distance and magnification ~~shall produce~~ produces a radiograph with a resolution of at least 12 line pairs per millimeter at an object-to-image receptor distance of 4.5 ~~five~~ centimeters; or the standards in Table 3-3 of the American Associates of Physicists in Medicine, Report No. 29, August 1990 edition, published by the American Institute of Physics, Inc., which is incorporated by reference, ~~and~~ on file with ~~the Department~~ the Agency ~~the Office of Secretary of State~~, ~~containing no future editions or amendments are followed~~ and contains no future editions or amendments;~~.~~
6. The compression device used with the mammographic unit, unless specifically manufactured otherwise, is ~~shall be~~ parallel to the imaging plane, not varying at any spot by more than 1 centimeter; ~~to adequately immobilize and compress the breast.~~
7. The ~~mammographic~~ mammography x-ray system with initial power drive: ~~shall be capable of:~~
   a. Has compression paddles compatible with each size of image receptor;
   ~~a.~~b. Is capable of compressing ~~For automatic pressure units only, compressing~~ the breast with a force of at least 25 pounds, ~~and~~ but not more than 47 ~~40~~ pounds, and maintaining the compression for at least three seconds; and
   ~~b.~~c. Is used in a manner so that the ~~The~~ chest wall edge of the compression device ~~paddle~~ is ~~shall be~~ aligned just beyond the chest wall edge of the image receptor so ~~such~~ that the chest wall edge of the compression device ~~paddle~~ does not appear on the image receptor. ~~in the mammogram:~~;
8. A ~~mammographic~~ mammography x-ray system ~~utilizing~~ using screen-film image receptors ~~shall have~~ has:
   a. ~~The capability of using anti-scatter grids which are specifically designed for mammography, integral to the x-ray system, and are available for all image receptor sizes;~~ At least two different sizes of moving anti-scatter grids, including one for each size of image receptor utilized; and
   b. ~~The capability of automatic~~ Automatic exposure control~~.~~;
9. All ~~mammographic~~ mammography x-ray systems ~~shall~~ indicate, or provide ~~the~~ a means of determining, the mAs resulting from each exposure made with automatic exposure control~~.~~;
10. The collimation ~~Collimation shall be~~ provided ~~which shall limit~~ limits the useful beam to ~~such that the x-ray field at the plane of~~ the image receptor so that the beam does not extend beyond any edge of the image receptor at any designated source to image receptor distance ~~except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the source to image receptor distance;~~ by more than 2% of the source to image receptor distance;
11. The accuracy of the indicated kVp ~~shall be~~ is within ±2kVp~~.~~;
12. ~~Mammographic~~ Mammography x-ray systems operating with automatic exposure control ~~shall be~~ are capable of maintaining a ~~constant~~ film density ~~to~~ within ± 0.30 optical density units over the clinical range of kVp used ~~clinically used kVps~~, for a breast having an equivalent phantom thicknesses from 2 ~~of 2 centimeters~~ to 6 centimeters. If~~, or if~~ the film density cannot be maintained to within ± 0.30 of the average kVp used ~~of clinically used kVp settings~~ and phantom thickness from 2 to 6 centimeters cannot be maintained by the automatic exposure control, a technique chart ~~shall be developed~~ is used that alters kVp and density control settings as a function of breast thickness and density. If a technique chart is used, the operator shall maintain ~~which maintains~~ the film density ~~within~~ at ± 0.30 optical density units.~~:~~

13. At a kVp of 28, the ~~mammographic~~ mammography x-ray system ~~shall be~~ is capable of generating at least 2.0 µC/kg/ mAs (8 mR/ mAs) and at least 200 µC/kg/second (800 mR/second), measured at a point 4.5 centimeters above the surface of the patient support device when the source-to-image receptor distance is at its maximum~~.~~;
14. Cassettes ~~shall~~ are not ~~be~~ used for mammography if one or more areas of greater than 1 cm^2 ~~square centimeter or 2 or more areas of less than 1square centimeter~~ of poor screen-film contact are seen when tested, using a 40 mesh screen test;
15. Mammography image quality ~~acceptable to operate a mammographic x-ray system shall~~:
    a. ~~Meet~~ Meets the minimum mammography film standards for phantom performance in "Mammography Quality Control," 1992 edition, published by the American College of Radiology, which is incorporated by reference, ~~and~~ on file with the Agency ~~and the Office of Secretary of State~~, ~~containing no future editions or amendments~~ and contains no future editions or amendments ~~, for accreditation on the standard mammography film in use at the facility~~; or
    b. Is sufficient to demonstrate in the image produced the presence of at least 4 fibers, 3 speck groups, and 3 masses that include a ~~Shall be of a quality to observe the image of a~~ 0.75 millimeter fiber, a 0.32 millimeter speck group, and a 0.75 millimeter mass ~~from an image made utilizing~~ , using a Radiation Measurements Inc. (RMI), Model 156 phantom or its equivalent~~.~~;
16. The mean glandular dose for one cranio-caudal view of a 4.2 centimeter (1.8 inch) compressed breast, composed of 50 percent adipose ~~/~~ and 50 percent glandular tissue, ~~shall~~ does not exceed 300 millirads (3 milligray)~~.~~ ~~for screen-film image receptor; and,~~; and
17. ~~Mammography units shall be calibrated when equipment is first installed, after any major changes or replacement of parts and at least annually and when quality assurance tests indicate calibration is needed.~~ A radiologic physicist who meets the requirements in R12-1-614(C)(1)(c) evaluates the operation of a mammography x-ray system:
    a. When first installed and annually thereafter;
    b. Following any major change in equipment or replacement of parts; and
    c. When quality assurance tests indicate calibration is necessary.

B. Operating Procedures. A registrant shall ensure that:

~~1.~~ ~~Each facility shall have a quality assurance testing program for the items listed in Appendix B. The procedures shall describe each test, the acceptable results, and corrective actions when required. Records of the quality assurance testing program shall be maintained for Agency inspection.~~

~~2.~~ ~~Each facility shall have an radiologic physicist as defined in R12-1-615 review all the test results for those tests specified in Paragraph 2 above. The radiologic physicist shall make recommendations as necessary for the facility to comply with these rules.~~

1. Each mammography facility has a quality assurance program, and that the quality assurance program includes performance and documentation of the quality control tests in subsection (B)(2), conducted at the required time intervals, with test results that fall within the specified limits or corrective action taken if results fall outside of the specified limits. A radiologic physicist, as defined in R12-1-614(C)(1)(c), shall review the program and make any recommendations necessary for the facility to comply with this Section;
2. The quality assurance program meets the requirements contained in 21 CFR 900.12(d)(1); (e)(1); (e)(2)(i),(ii), and (iii); (e)(3); (e)(4), (e)(5)(i), (ii), (iii)(A), (iv), (v), (vi), (vii)(B) and (C), (viii), (ix), (x), and (xi); (e)(8)(ii); (e)(9)(ii); and (e)(10), 2001 edition, published April 1, 2001, which is incorporated by reference, on file with the Agency, and contains no future editions or amendments; or meets the following requirements:
    a. Daily sensitometric and densitometric evaluation of the image processing system demonstrates that Base + Fog < +0.03 optical density of operating level, Mid Density +/-0.15 optical density of operating level, and Density Difference +/-0.15 optical density of operating level;
    b. Weekly phantom image quality evaluations demonstrate the visualization of at least four fibers, three speck groups, and three masses with a background of >1.20 optical density of operating level, not varying by +/-0.20 optical density of operating level;
    c. Monthly technique chart evaluations demonstrate updates for all equipment changes and that all examinations are being performed according to a physicist's density control recommendation;
    d. Quarterly fixer retention evaluations demonstrate an acceptable limit of </= 5.0 micrograms per square centimeter;
    e. Quarterly repeat analysis demonstrates an acceptable limit of < 2% increase in repeats;
    f. Semiannual darkroom fog evaluations meet the limit of </= 0.05 optical density of fog, using the 2 minute exposed film method;
    g. Semiannual screen film contact evaluations meet the limit of < 1.0 centimeter squared area of poor contact, using a 40 mesh screen on all clinically-used screens;
    h. Semiannual compression force evaluations meet the limit of >/= 25 pounds (111 Newtons) and < 47 pounds (209 Newtons); and

i. Annually and whenever indicated for installation, major repairs, parts replacement, or as deemed necessary by a qualified expert when quality control test results indicate a survey is necessary; the survey shall include the following tests: automatic exposure control performance and thickness response; kVp accuracy and reproducibility; system resolution; breast entrance air kerma and automatic exposure control reproducibility; average glandular dose; x-ray field, light field and image receptor alignment; compression paddle alignment; uniformity of screen speed; system artifacts; radiation output; decompression; and beam quality and half value layer.

C. Personnel.

1. Each registrant shall require personnel who perform mammography, which includes the production and interpretation of mammograms and related quality assurance activities, to meet the following requirements:
   a. An interpreting physician shall meet the requirements of 21 CFR 900.12(a)(1)(i) and (ii)(A) and (B), 2001 edition, published April 1, 2001, which is incorporated by reference, on file with the Agency, and contains no future editions or amendments; or:
      i. Be licensed under A.R.S. Title 32, Chapters 13 or 17;
      ii. Have initially completed 40 hours of medical education credits in mammography;
      iii. Be certified by the American Board of Radiology or the American Osteopathic Board of Radiology or be approved by the Arizona Board of Medical Examiners or the Arizona Board of Osteopathic Examiners as qualified to read and interpret mammogram images;
      iv. Have interpreted or reviewed an average of 300 mammograms per year during the preceding two years or have completed a radiology residency that included mammogram image interpretation; and
      v. Have completed 15 hours of continuing medical education credits in mammography during the preceding three years.
   b. A mammography technologist shall meet the requirements of 21 CFR 900.12(a)(2)(i)(B), (ii), and (iii), 2001 edition, published April 1, 2001, which is incorporated by reference, on file with the Agency, and contains no future editions or amendments; or:
      i. Possess a valid mammographic technologist certificate issued by the Medical Radiologic Technology Board of Examiners, as required in A.R.S. § 32-2841, or be pursuing mammography certification by training under the direct supervision of a technologist who possesses a valid mammographic certificate, and
      ii. Have completed 15 hours of continuing medical education credits in mammography during the preceding three years.
   c. A radiologic physicist shall meet the requirements in 21 CFR 900.12(a)(3)(i) and (iii), and 21 CFR 900.12(a)(4), 2001 edition, published April 1, 2001, which is incorporated by reference and on file with the Agency, and contains no future editions or amendments; or
      i. Be certified by the American Board of Radiology, American Board of Medical Physics, or the American Board of Health Physics;
      ii. Possess documentation of state approval;
      iii. Hold a master's degree or higher in a physical science;
      iv. Have, upon initial employment as a radiologic physicist, experience conducting, at least one mammography facility survey and evaluating at least 10 mammography units;
      v. Have, after completing the experience requirements in subsection (C)(1)(c)(iv), continuing experience surveying two mammography facilities and evaluating six mammography units during the preceding two years; and
2. Each registrant shall maintain records documenting the requirements in subsection (C)(1) for three years from the date the requirement is met and make the records available for Agency inspection.

D. Mammography films and reports. A registrant shall:

1. Maintain films and reports for a minimum of five years. In those cases where no subsequent mammography procedures are performed, the registrant shall maintain films and associated reports for 10 years. If the mammography facility is closed, the registrant shall make arrangements for storage of the films and associated reports for five years after the closure; and
2. Make films and reports available for comparison upon request for temporary or permanent transfer to other mammography facilities.

R12-1-615. ~~Radiologic Physicist Training~~ Repealed

~~The radiologic physicist utilized to provide the services required by R12-1-614(B)(2) shall:~~

~~1. Be certified by the American Board of Radiology or the American Board of Medical Physicists in:~~
   ~~a. Diagnostic Radiological Physics; or,~~
   ~~b. Radiological Physics; or,~~
~~2. Hold a Master's or Doctor's degree in physics, biophysics, radiological physics, health physics, or be certified by the American Board of Health Physics and have completed 1 year of full time training in diagnostic radiological physics and 2 years of full time work experience under the supervision of a diagnostic x-ray physicist in supporting a mammography facility.~~

Appendix A. ~~Information to be Submitted by Persons Proposing to Conduct Healing Arts Screening Other Than Mammography~~ Information Submitted to the Agency According to R12-1-604(A)(3)(c)

~~Persons requesting that the Agency approve a healing arts screening program shall submit the following information and evaluation:~~

~~1.~~**A.** Name and address of the applicant and, ~~where~~ if applicable, the ~~names~~ name and ~~addresses~~ address of any person within ~~agents within~~ this state that is authorized to act on behalf of the applicant;~~.~~

~~2.~~**B.** Disease or conditions to be diagnosed using the proposed ~~for which the~~ x-ray ~~examinations are to be used in diagnoses.~~ examination;

~~3.~~**C.** A detailed description of ~~the~~ each x-ray examination that will be used in the diagnosis; ~~examinations to be used in diagnoses.~~

~~4.~~**D.** A description ~~Description~~ of the population to be examined in the screening program, ~~that is,~~ using characteristics such as age, sex, physical condition, and other ~~appropriate~~ descriptive information~~.~~;

~~5.~~**E.** An evaluation of any known alternative diagnostic modalities ~~alternate methods~~ not involving ionizing radiation ~~which~~ that could achieve the same diagnosis as a ~~goals for the~~ screening program and why these modalities have not been chosen; ~~methods are not used instead of the x-ray examinations.~~

~~6.~~**F.** An evaluation by a qualified expert of the x-ray equipment used in the screening program, ~~of the x-ray system or system(s) to be used in the screening program~~. ~~The evaluation by the qualified expert shall~~ which demonstrates that the x-ray equipment satisfies the ~~show that such system(s) do satisfy all~~ requirements of ~~these rules~~ this Article.

~~7.~~**G.** A description of the ~~diagnostic film~~ quality control program~~.~~;

~~8.~~**H.** A copy of the technique chart for the planned x-ray examination ~~procedures to be used.~~;

~~9.~~**I.** The qualifications of each individual who will be operating the x-ray equipment; ~~system or systems.~~

~~10.~~**J.** The qualifications of the individual who will be supervising ~~the operators~~ each operator of the x-ray equipment; ~~system or systems.~~

~~11.~~**K.** The name and address of the individual who will interpret ~~the radiograph or radiographs~~ each radiographic image;

~~12.~~**L.** A description of the planned procedures for ~~to be used in~~ advising a screened individual ~~the individuals~~ and the screened individual's physician of the screening procedure results, ~~screened and their private practitioners of the healing arts, of the results of the screening procedure~~ and the need for further medical care, and ~~any further medical needs indicated.~~

~~13.~~**M.** A description of the procedures for ~~the~~ retention or disposition of the radiographic images ~~radiographs~~ and other records pertaining to the x-ray examination ~~examinations~~.

Appendix B. ~~Procedures and Tests for Mammography Systems~~ Repealed

~~I. Procedures.~~
- ~~a. Description of the x-ray examinations to be performed~~
- ~~b. Description of the use of grids~~
- ~~c. Description of the use of compression devices~~
- ~~d. Description of any tests to be performed by the operator prior to the initial examinations~~
- ~~e. Description of patient acceptance criteria (for self referral screen only)~~
- ~~f. Description of image development procedures~~

~~II. Quality Control~~
- ~~a. Daily tests on the film processor using sensitometry and densitometry procedures.~~
- ~~b. Monthly tests:~~
  - ~~1. Availability of technique charts~~
  - ~~2. Image quality with a phantom~~
- ~~c. Quarterly test: Retake analysis~~
- ~~d. Annual tests:~~
  - ~~1. Exposure timer accuracy~~
  - ~~2. Linearity of the mA stations~~
  - ~~3. Skin entrance exposure~~
  - ~~4. Exposure timer reproducibility~~
  - ~~5. Half Value Layer~~
  - ~~6. AEC, kVp, and thickness response~~
  - ~~7. AEC reproducibility~~
  - ~~8. Beam alignment, where appropriate~~
  - ~~9. Average glandular dose~~

ARTICLE 9. PARTICLE ACCELERATORS

R12-1-901. Purpose and Scope

A. No change

B. In addition to the requirements of this Article, all registrants are subject to the requirements of Articles 1, 2, 4, and 10. Registrants engaged in industrial radiographic operations are subject to the requirements of Article 5, and registrants engaged in the healing arts are subject to the requirements of Article 6 of ~~these Rules~~ this Chapter. Registrants ~~engaged in the use of~~ using a particle accelerator for the production of radioactive material are subject to the requirements of Article 3, and if the radioactive material is used for medical purposes, Article 7.

R12-1-902. ~~Repealed~~ Definitions

"Added filter" (See Article 6)

"Arc therapy" means radiation therapy that uses electrons to treat large, superficial volumes that follow curved surfaces, as in postmastectomy patients.

"Beam-limiting device" (See Article 6)

"Beam-monitoring system" means a system of devices that will monitor the useful beam during irradiation and terminate irradiation when a preselected number of monitor units has been accumulated.

"Control panel" (See Article 6)

"Full beam detector" means a radiation detector of such size that the total cross-section of the maximum size useful beam is intercepted.

"Gantry" means that part of a linear accelerator that supports the radiation source so that it can rotate about a horizontal axis.

"Interlock" (See Article 1).

"Isocenter" means the point of intersection of the collimator axis and the axis of rotation of the gantry.

"Monitor unit" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

"Moving beam therapy" means radiation therapy in which there is displacement of the useful beam relative to the patient. Moving beam therapy includes arc therapy, skip therapy, and rotational beam therapy.

"Rotational beam therapy" means radiation therapy that is administered to a patient from a radiation source that rotates around the patient's body or the patient is rotated while the beam is held fixed.

"Skip therapy" means rotational beam therapy that is administered in a way that maximizes the dose to an area of interest and minimizes the dose to surrounding healthy tissue.

"Spot check" (See Article 6)

Stationary beam therapy" means radiation therapy that involves a beam from a radiation source that is aimed at the patient from different directions. The distance of the source from the isocenter remains constant irrespective of the beam direction.

"Virtual source" means a point from which radiation appears to originate.

R12-1-903. General Registration Requirements ~~for the Issuance of a Registration for Particle Accelerators~~

A. No change

B. No change

1. The applicant is qualified by training and experience to use the accelerator for the purpose in the application submitted to the Agency under Article 2 ~~requested according to this Article, and Articles 4, and 10, of these rules to minimize danger to public health or property~~;
2. The applicant's proposed equipment, facilities, and operating and emergency procedures are adequate to protect public health ~~and minimize danger to public health and minimize danger to public health and safety or property~~;
3. The ~~issuance of the registration will not be inimical to the health and safety of the public, and the~~ applicant satisfies any other applicable ~~special~~ requirements ~~requirement~~ in this Section; and ~~R12-1-904;~~
4. The applicant has appointed a radiation safety officer.
5. ~~The applicant's staff has substantial experience in the use of particle accelerators for the intended uses; and~~
6. ~~The applicant has an adequate training program for particle accelerator operators.~~

R12-1-904. ~~Special~~ Registration of Particle Accelerators Used in the Practice of Medicine ~~Requirements for Medical Use of Particle Accelerators~~

A. No change

B. No change

C. No change

1. No change
   a. No change
   b. No change
   c. No change

d. No change
2. No change
   a. No change
      i. No change
      ii. No change
      iii. No change
      iv. No change
   b. No change
      i. No change
      ii. No change
      iii. No change
      iv. No change
      v. No change
   c. No change
      i. No change
      ii. No change
      iii. No change
      iv. No change

D. No change

E. Each registrant ~~licensee~~ shall establish and maintain a written quality management program to provide high confidence the radiation produced by the particle accelerator will be administered as directed by an authorized user. The quality management program shall include written policies and procedures to meet the specific patient safety objectives established by the Radiation Safety Officer or Radiation Safety Committee~~;~~ if applicable, and at minimum, contain a quality control program that addresses the tests and checks listed in Appendix A.

F. Each particle accelerator shall be calibrated by ~~an~~ a qualified expert meeting the training and experience qualifications in R12-1-716(G).

G. At the time of application for registration or when a therapy program is expanded to multiple sites, each applicant or registrant shall provide the Agency with a description of the quality management program, a listing of the professional staff assigned to the facility, and the expected ratio of patient workload to staff member for programs involving multiple therapy sites. If the staffing ratio exceeds the recommended levels in Radiation Oncology in Integrated Cancer Management, 1986 edition, published in November 1986 by the Inter-Society Council for Radiation Therapy, which is incorporated by reference and on file with the Agency, the applicant shall provide to the Agency for approval the justification for the larger ratio and the safety considerations that have been addressed in establishing the program. This incorporation contains no future additions or amendments.

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

A. No change
1. No change
   a. No change
   b. No change
   c. No change
   d. No change
2. No change
3. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
   f. No change
4. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
      i. No change
      ii. No change
      iii. No change
   f. No change

g. No change
i. No change
ii. No change
iii. No change
iv. No change
v. No change
5. No change
a. No change
b. No change
c. No change
d. No change
e. No change
f. No change
i. No change
ii. No change
6. No change
a. No change
b. No change
c. ~~An interlock system shall be provided to prevent irradiation with x-rays when electron applicators are fitted and irradiation with electrons when accessories specific for x-ray therapy are fitted; and~~ An interlock system shall be available and in operating condition on a therapy machine, and shall be used to prevent unwanted x-ray or electron irradiation when preparing for, or performing radiation therapy procedures. The interlock system need not be available for use, if the therapy machine is only used to make an image of an inanimate object; and
d. No change
7. No change
a. No change
b. No change
c. No change
d. No change
8. No change
a. No change
b. No change
c. No change
d. No change
e. No change
f. No change
9. No change
a. No change
b. No change
c. No change
10. No change

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

v. No change
e. No change
f. No change
i. No change
ii. No change
iii. No change

C. No change
1. No change
2. No change
3. No change
4. No change
5. Records of spot checks shall be maintained available for inspection by the Agency for two years following the spot check measurements. Records of spot checks not performed by a qualified expert shall be signed by a qualified expert within 15 days of the spot check.

D. No change
1. No change
2. No change

R12-1-906. Limitations

~~**A.** No registrant shall permit any person to act as a particle accelerator operator until such person:~~
~~1. Has been instructed in radiation safety and shall have demonstrated an understanding thereof;~~
~~2. Has received copies of and instruction in this Article and the applicable requirements of Articles 4 and 10, pertinent registration conditions and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and~~
~~3. Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed in his assignment.~~

A. A registrant shall not permit an individual to act as:
1. A particle accelerator operator of any type unless the individual:
a. Has received copies of and instruction in this Article and the registrant's operating and emergency procedures,
b. Demonstrates an understanding of the material, and
c. Has demonstrated competence in the use the particle accelerator, related equipment, and survey instruments that will be employed during the operation of the particle accelerator;
2. A medical particle accelerator operator unless the individual is certified as required in A.R.S. § 32-2811 or the operator meets the requirements in R12-1-603(B); or
3. An industrial particle accelerator operator unless the individual has been instructed in radiation safety.

B. A registrant shall provide either ~~Both~~ the Radiation Safety Committee or ~~and~~ the Radiation Safety Officer ~~shall have~~ with the authority to terminate ~~the~~ operations at a particle accelerator facility if ~~such action is deemed~~ this is necessary to protect ~~health and/or minimize danger to public~~ health and safety or property.

C. If equipment is capable of both stationary and moving beam therapy, the registrant shall ensure that:
1. Irradiation is not possible unless either stationary or moving beam therapy has been selected at the control panel,
2. An interlock is provided to ensure that the machine will operate only in the mode that has been selected,
3. An interlock is provided that terminates irradiation if the gantry fails to move properly during moving beam therapy,
4. A means is provided to prevent movement during stationary therapy, and
5. The mode of operation is displayed at the control panel.

R12-1-907. Shielding and Safety Design ~~Requirements~~

A. A person experienced in the principles of radiation protection and installation design shall be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation. The registrant shall provide a copy of the installation radiation survey to the Agency before an Agency inspection conducted according to R12-1-904(G).

B. The registrant shall shield ~~provide~~ each particle accelerator installation with the primary and secondary protective barriers ~~that are~~ necessary to comply ~~assure compliance~~ with R12-1-408 and R12-1-416.

R12-1-908. Particle ~~accelerator controls~~ Accelerator Controls and ~~interlock systems~~ Interlock Systems

A registrant shall ensure that:
~~**A.**~~1. Instrumentation, readouts and controls on the particle accelerator control panel are ~~console shall be~~ clearly identified and easily discernible~~.~~;
~~**B.**~~2. All entrances into the area ~~a target room~~ that contains the particle accelerator room, target room, or other high radiation area~~.~~ ~~shall be~~ are provided with interlocks that shut down the machine if an entrance door is opened; ~~under conditions of barrier penetration.~~

~~C.~~3. ~~When~~ If an interlock system connected to an entrance door that provides access to the therapy suite has been tripped, it ~~shall only be~~ is not possible to resume operation of the particle accelerator by ~~manually~~ resetting the interlock switch at the entrance where it had been tripped; ~~controls at the position where the interlock has been tripped~~, ~~and lastly at the main control console.~~

~~D.~~4. Each safety interlock ~~shall be~~ is on a circuit ~~which shall allow its operation~~ that allows it to operate independently of all other safety interlocks~~.~~;

~~E.~~5. If possible, the interlock system is ~~All safety interlocks shall be~~ ~~fail safe~~ fail-safe in design, ~~fail safe, i.e., designed~~ so that any defect or component failure in the interlock system prevents operation of the particle accelerator~~.~~; and

~~F.~~6. A scram button or other emergency power cutoff switch ~~shall be~~ is located and easily identifiable in the area that contains the particle accelerator ~~all high radiation areas~~. The registrant shall ensure that the scram button ~~Such a cutoff switch~~ prevents persons from restarting the particle accelerator ~~shall include a manual reset so that the accelerator cannot be restarted from~~ at the accelerator control panel ~~console~~ without resetting the button or switch ~~cutoff switch~~.

R12-1-909. Warning Systems ~~Devices~~

A registrant shall ensure that:

~~A.~~1. High radiation areas and entrances to the high radiation areas in medical facilities are equipped with a continuously-operating warning light system that operates when, and only when, radiation is produced; ~~All areas, except those in medical facilities, designated as high radiation areas, and entrances to the areas shall be equipped with easily observable flashing or rotating warning light system that operates when, and only when, radiation is being produced. Medical facilities shall be equipped with a continuously operating warning light system.~~

2. High radiation areas and entrances to the high radiation areas in nonmedical facilities are equipped with an easily-observable flashing or rotating warning light system that operates when, and only when, radiation is produced;

~~B.~~3. High radiation areas associated with nonmedical particle accelerators ~~except in facilities designed for human exposure, each high radiation area shall~~ have an audible warning device ~~which shall be~~ that is activated for 15 seconds ~~prior to the~~ before creation of the high radiation area~~. The~~ ; and the warning device ~~shall be~~ is clearly discernible in all high radiation areas and all radiation areas~~.~~ ; and

~~C.~~4. High radiation areas associated with any particle accelerator are posted according to ~~Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with~~ R12-1-428 and R12-1-429.

R12-1-910. Operating Procedures ~~procedures~~

A. A registrant shall secure from use a particle accelerator when it is not being used ~~Particle accelerators, when not in operation, shall be secured~~ to prevent unauthorized use.

B. A particle accelerator operator shall use the switch on the control panel ~~Only a switch on the accelerator control console shall be routinely used~~ to turn the accelerator beam on and off during normal operations. The safety interlock system ~~shall not~~ may be used to turn off the accelerator beam in emergencies ~~except in an emergency~~.

C. ~~All~~ A registrant shall ensure that all safety and warning systems ~~devices~~, including interlocks, are tested ~~shall be checked~~ for proper operation ~~operability~~ at intervals not to exceed three months~~. Results~~ , and maintain results of each test ~~such tests shall be maintained~~ for Agency inspection for at least three years from the date of the test. ~~at the accelerator facility.~~

D. ~~Electrical~~ A registrant shall keep current electrical circuit diagrams of a particle ~~the~~ accelerator~~,~~ and the associated interlock systems, and maintain the diagrams ~~shall be kept current and maintained~~ for inspection by the Agency ~~and available to the operator at each accelerator facility~~.

E. By-pass of an interlock~~, If for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be~~ is prohibited unless the by-pass is:

1. Authorized in writing by the Radiation Safety Committee ~~and/~~or Radiation Safety Officer;
2. Recorded in a permanent log with a notice of the by-pass posted at any affected interlock and at the control panel, ~~and a notice posted at the interlock(s) so bypassed and at the accelerator control console;~~ and
3. No change

F. ~~A~~ A registrant shall maintain a copy of the current operating and emergency procedures ~~shall be maintained~~ at the particle accelerator control panel.

R12-1-911. Radiation Surveys

A. No change

B. No change

1. Check the operation of the portable survey instrument required in subsection (A), using a known radiation source, before each ~~prior to~~ ~~its~~ use;
2. No change
3. ~~Perform surveys to determine the amount of airborne particulate radioactivity present in areas of airborne hazards in particle accelerator facilities of greater than 30 Mev;~~ For particle accelerator facilities greater than 30 Mev, establish a program of radiation protection surveys that will evaluate the airborne radiation hazards, and ensure that the particulate radioactivity present in the accelerator facility will not result in personnel exposure that exceeds the limits in Article 4; and

~~4. Perform periodic smear surveys to determine the degree of contamination in target and adjoining areas when the conditions described in subsection (B)(3) exist;~~

~~5.~~4. Perform radiation protection surveys, including smear surveys of the particle accelerator facility, as prescribed in the written procedures established by the Radiation Safety Officer of the particle accelerator facility and approved by the Agency at the time of application for registration.

C. The registrant shall ~~retain~~ maintain the following records

1. Radiation ~~Records of any radiation~~ protection surveys required in subsection (B)(2), and ~~an~~ the associated facility description, required in R12-1-202(E), until the registration is terminated~~.~~; and
2. Records of the surveys required in ~~subsection~~ subsections (B)(3) and (B)(4) ~~shall be maintained~~ for three years following the measurement.

Appendix A. Quality Control Program

A. Mechanical Tests
1. Patient support assembly motions
2. Gantry angle indicators
3. Optical distance indicators
4. Alignment lights
5. Congruence of radiation beam and light field
6. Accuracy of field size indicators
7. Mechanical isocenter- gantry and collimator
8. Mechanical interlocks

B. Radiation Beam Tests
1. Machine operating parameters
2. Dose per monitor unit for x-ray and electron beams
3. Dose per degree for moving beam therapy
4. Radiation isocenter
5. Flatness and symmetry
6. Wedge transmission factors
7. Shadow tray transmission factors
8. Energy check on central axis
9. Radiation output versus field size

C. Control Panel Checks
1. Radiation "ON" condition
2. Indicator lamp check
3. Computer control of accelerator
4. Interlock display
5. Digital display
6. Analog display
7. Status display
8. Reset display

D. Facility Checks
1. Patient audio-visual communication
2. Entrance door interlock
3. Warning lights
4. Emergency off button

E. Dose Output Check
1. Each registrant shall use the services of a third party qualified expert or third party TLD system to verify the accelerator's radiation output every two years.
2. If the output check is not within +/- 5% of the calibrated output, the accelerator shall be recalibrated and the discrepancy investigated.
3. Records of output checks shall be maintained for three years

F. Patient Dosimetry Calculation Checks
1. Calculation of patient treatment times
2. Computer calculation of patient treatment times

ARTICLE 12. ADMINISTRATIVE PROVISIONS

R12-1-1201. ~~Criteria for Determining~~ Timeliness

A. No change

B. No change

R12-1-1202. Administrative Hearings ~~Hearing Procedures~~

A. All hearings shall be governed by Title 41, Chapter 6, Article 10. ~~Hearings on the appeal of notices of violation, orders of the Director, or the appeal of proposed licensing or registration actions by the Agency shall be held before the Radiation Regulatory Hearing Board or a hearing officer appointed by the Board.~~

1. ~~If a hearing is held before the Board or if a hearing officer has not been appointed, the Chairperson of the Board or another person designated by the Chairperson shall act as the hearing officer.~~
2. ~~If the Chairperson determines that the hearing is to be held before an appointed hearing officer, the Chairperson shall confer with the hearing officer, the Agency's designated assistant Attorney General, and the licensee or registrant in establishing the time and place of the hearing. The Chairperson shall also confer with the members of the Board before establishing the time and place of a hearing to be held before the Board itself.~~

~~**B.** Except where statutes or provisions of this Chapter applicable to hearings before the Board specify otherwise, all hearings shall be governed by the Administrative Procedure Act, A.R.S. §§ 41-1061 through 41-1066. In the absence of other authority, the Arizona Rules of Civil Procedure shall be followed to the extent practicable.~~

~~**C.** The hearing officer shall rule on all motions, hold prehearing or other conferences for purposes of clarifying procedural steps or legal or factual issues, conduct the hearing, grant continuances, and otherwise rule on procedural matters and regulate the course and manner of the hearing.~~

~~**D.**~~**B.** If the Radiation Regulatory Hearing Board is conducting a hearing, all ~~All~~ motions and rulings shall be in writing, except those made during the hearing may be oral. The Board shall ensure that any agreements reached during a conference are ~~The results of all conferences shall be~~ incorporated in the record, and that all hearings are recorded. ~~All hearings shall be recorded.~~

~~**E.**~~**C.** If it is necessary for an administrative law judge ~~that the hearing officer~~ or the Board to visit the site of an alleged violation or activity that is regulated ~~to be licensed~~ by the Agency in order to supplement testimonial or documentary evidence presented at the hearing, the party that proposed the visit shall enter the purpose of the visit and all pertinent observations ~~shall be entered~~ into the record.

~~**F.** A person may be represented by counsel at any proceeding.~~

~~**G.** All testimony shall be under oath or affirmation.~~

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

A. Any person may submit a timely motion to intervene in a proceeding ~~when~~ if an unconditional right to intervene is granted by law or ~~when~~ the applicant claims an interest to any property or transaction affected by the proceeding.

B. A motion to intervene shall be in writing and shall state the reason why the applicant should be allowed to intervene. If the applicant claims an interest in property or in a transaction affected by the proceeding, the applicant ~~must show~~ shall demonstrate that the result of the proceeding may as a practical matter impair or impede protection of that interest.

C. ~~The motion shall be served upon the hearing officer or the Director~~ The applicant shall serve the motion upon the administrative law judge or the Board, as appropriate, and the Director as a party at least five working days before the hearing. An ~~No~~ application for leave to intervene shall not be granted, if by doing so, the issues will be unduly broadened.

D. ~~When~~ If two or more persons have substantially ~~like~~ similar positions, the ~~hearing officer~~ administrative law judge may declare them a class of interested persons for purposes of the hearing. The members of a class shall designate one person to be spokesperson for the class. More than one class may be established for a hearing.

E. The Director is party to all administrative hearings.

R12-1-1206. ~~Decisions of the Hearing Officer and the Board in Administrative Hearings~~ Repealed

~~**A.** As soon as is practical after the conclusion of an administrative hearing, the hearing officer shall prepare and circulate written findings of fact and conclusions of law and a recommended decision. Each of the parties shall be given 15 calendar days within which to respond.~~

~~**B.** The hearing officer may revise or supplement the original findings, conclusions, and recommended decision in light of responses made or may submit the findings, conclusions, recommended decisions, and a copy of all responses to the Board along with a legible or audible copy of the record and all documentary evidence admitted.~~

~~**C.** A copy of any revised or supplemental findings, conclusions, or recommended decision shall be given to all parties.~~

~~**D.** The Board shall render a decision as promptly as possible but not later than 90 calendar days following receipt of the hearing officer's submittal.~~

R12-1-1207. ~~Rehearings and Reviews of Decisions in Administrative Hearings~~ Rehearing or Review

~~**A.** Any party who is aggrieved by a decision of the Board may file with the Board, not later than 15 working days after issuance of the decision, a written motion for rehearing or review of the decision specifying the particular grounds therefor. A motion for rehearing may be amended at any time before it is ruled upon by the Board.~~

~~**B.** A response to a motion for rehearing may be filed by any other party within 10 working days after service of the motion or amended motion. The Board may require filing of written briefs upon the issues raised in the motion and may provide for oral argument.~~

~~C.~~**A.** The Board may grant a ~~A~~ rehearing or review of a ~~the~~ decision ~~may be granted~~ for any of the following reasons, ~~causes~~ materially affecting ~~the moving~~ a party's rights:

1. Irregularity in the administrative proceedings ~~of the Board or its hearing officer or the prevailing party,~~ or any order or abuse of discretion, ~~whereby the moving~~ that deprived a party ~~was deprived~~ of a fair hearing;
2. Misconduct of the Board, an administrative law judge, ~~or its hearing officer~~ or the prevailing party;
3. Accident or surprise ~~which~~ that could not have been prevented by ordinary prudence;
4. Newly discovered material evidence ~~which~~ that could not, with reasonable diligence have been discovered and produced at the original hearing;
5. Excessive or insufficient penalties;
6. Error in the admission or rejection of evidence or other errors of law occurring at the administrative hearing or during the progress of the proceedings;
7. That the decision is not justified by the evidence or is contrary to law.

~~D.~~**B.** The Board may affirm or modify a ~~the~~ decision or grant a rehearing to all or any of the parties and on all or part of the issues for any of the reasons listed in subsection (A) ~~set forth above~~. An order modifying a decision or granting a rehearing shall specify with particularity the ground or grounds for the order. ~~on which the rehearing is granted, and~~ ~~the~~ A rehearing shall cover only the subject matters ~~so~~ specified in the order.

~~E.~~**C.** No later than 15 working days after the date on the decision the Board may, on its own initiative, order a rehearing or review of its decision for any reason for which it might have granted a rehearing on motion of a party. ~~Not later than 15 working days after a decision is rendered the Board may on its own initiative order a rehearing or review of its decision for any reason for which it might have granted a rehearing on motion of a party.~~ After giving the parties notice and an opportunity to be heard on the matter, the Board may grant a motion for rehearing or review for a reason not stated in the motion. ~~In either case, the order granting such a rehearing shall specify the grounds therefor.~~

~~F.~~**D.** ~~When~~ If a motion for rehearing or review is based upon affidavits, they shall be served with the motion. An opposing party may, within 30 calendar days after ~~such~~ service, serve opposing affidavits. This period of time ~~, which period~~ may be extended by the Board ~~for an additional period~~ if good cause is shown or a written stipulation is received from both parties. The Board may permit reply affidavits.

R12-1-1208. ~~Judicial Review~~ Repealed

~~Any application for judicial review shall be made within the time limit specified in A.R.S. § 12-904.~~

R12-1-1209. Notice of Violation

A. No change

B. No change

1. No change
2. The particular statute, rule, or registration or license condition violated; and
3. No change

C. No change

R12-1-1210. Response to Notice of Violation

A. Except as provided in subsection (D), within 30 calendar days of the date of the notice, or ~~other~~ longer time period specified in the notice, the person charged with the violation shall submit a written response ~~which~~ that includes a description of:

1. No change
2. The actions ~~which~~ that are proposed ~~to be taken~~ and the date when full compliance is expected to be achieved; and
3. No change

B. No change

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

C. If the Agency does not receive an adequate and timely response ~~is not received~~ to the notice, the Director shall issue an initial order conditionally imposing any or all sanctions and civil penalties proposed in the notice of violation. If no civil penalty was proposed, the initial order may impose the base civil penalty listed ~~scheduled~~ in R12-1-1216.

D. No change

R12-1-1213. Severity Levels of Violations

A. No change

1. No change
   a. Radiation exposure to a person ~~An individual exposure~~,
   b. No change
   c. No change

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

B. No change
1. No change
   a. Radiation exposure to a person ~~An individual exposure~~,
   b. No change
   c. No change
2. No change
3. No change
4. No change

C. No change
1. No change
   a. Radiation exposure to a person ~~An individual exposure~~,
   b. No change
   c. No change
2. No change
3. No change
4. No change
5. No change
6. No change
7. No change

D. No change
1. No change
2. No change
3. Failure to maintain records of mammography quality control tests required in R12-1-614. ~~listed in Appendix B of 12 A.A.C.1, Article 6.~~
4. No change

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

R12-1-1215. License and Registration Divisions

A. No change
1. Division I licenses and registrations:
   Broad Academic Class A
   Broad Academic Class B
   Broad Academic Class C
   Broad Industrial Class A
   Broad Medical
   Class C Laser Facility
   Distribution
   Fixed Gauge Class A
   Industrial Radiography Class A
   Low Level Radioactive Waste Disposal Site
   Major Accelerator Facility
   Medical Materials Class A
   Medical Teletherapy
   NORM Commercial Disposal Site
   Nuclear Laundry
   Nuclear Pharmacy
   ~~NORM Commercial Disposal Site~~
   Open Field Irradiator
   Secondary Uranium Recovery
   Waste Processor Class A

Well Logging
X-Ray Machine Class A
2. No change
3. Division III licenses and registrations:
Class A Laser Facility
Class A Industrial Radiofrequency Facility
Depleted Uranium
Gas Chromatograph
General Depleted Uranium
General Industrial
General Medical
General Veterinary Medicine
Health Physics Class B
Laboratory
Leak Detector
Limited Industrial
Medical Materials Class C
Other Ionizing Radiation Machine
Other Nonionizing Radiation Machine
Portable Gauge
Possession Only
Radioactive waste transfer-for-disposal
Reciprocal
Unclassified
Veterinary Medicine
X-ray Machine Class C

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

R12-1-1216. ~~Base Schedule of~~ Civil Penalties

A. No change
1. No change
a. No change
b. No change
c. No change
2. No change
a. No change
b. No change
c. No change
3. No change
a. No change
b. No change
c. No change
4. No change
a. No change
b. No change
c. No change
5. No change
a. No change
b. No change
c. No change

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

C. No change
1. No change
2. No change

R12-1-1217. Augmentation of Civil Penalties

A. A continuing violation ~~is~~, for the purposes of calculating the proposed civil penalty, is considered a separate violation for each day it continues. The second (or successive) day of a continuing violation is not considered a repeat violation of the violation occurring on the first day.

B. If a second severity level I violation is committed within five years, the Agency shall increase the base ~~scheduled~~ civil penalty by 100%, provided the registration or license is not revoked under R12-1-1219.

C. If a second severity level II violation is committed within a period of five years, the Agency shall increase the base ~~scheduled~~ civil penalty by 50%, provided the registration or license is not revoked under R12-1-1219.

D. If a severity level III violation is repeated within five years, the Agency shall increase the base ~~scheduled~~ civil penalty by 50%. If the same severity level III violation is repeated a second time within five years, the base ~~scheduled~~ civil penalty shall be increased by 100%, provided the registration or license is not revoked under R12-1-1219.

E. If a severity level IV violation is repeated within five years, the Agency shall propose the base ~~scheduled~~ civil penalty.
1. If the same violation occurs three times within five years, the Agency shall increase the base ~~scheduled~~ civil penalty by 50%.
2. If the same violation occurs four times within five years, the Agency shall increase the base ~~scheduled~~ civil penalty by 100%, provided the registration or license is not revoked under R12-1-1219.

F. If more than three severity level V violations are observed during two consecutive inspections, the Agency shall impose a civil penalty for each violation. The base civil penalty for each violation is the base ~~scheduled~~ civil penalty assessed for a severity level V violation. If the inspection shows repetition of a violation the base civil penalty for each repeat violation is the base ~~scheduled~~ civil penalty assessed for a severity level IV violation. Subsection (E) does not apply to penalties under this subsection.

G. No change

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

I. No change

R12-1-1219. Additional Sanctions-Show Cause

A. If a severity level I violation is repeated or if any second severity level I violation is committed within 10 years, the Agency shall require the registrant or licensee to show cause why the registration or license should not be suspended or revoked.

B. If any second severity level II violation is committed within five years, or if a severity level II violation involving radioactive effluent releases, excessive radiation levels, or radiation overexposure to an individual is committed within five years of a similar severity level I violation, the Agency shall require the registrant or licensee to show cause why the registration or license should not be suspended or revoked.

C. If repeated or different severity level III violations are committed on three separate occasions within any five year period, the Agency may require the registrant or licensee to show cause why the registration or license should not be suspended or revoked.

R12-1-1220. Escalated Enforcement

A. The Director may issue an order to suspend, revoke, or modify a registration or license, or impound a radiation source for:
1. No change
2. No change
   a. No change
   b. No change
   c. No change

B. The Director may issue an order impounding the radiation source or suspending, revoking, or modifying the registration or license upon determining that conditions exist which cause a potential for a severity level I or severity level II violation.

C. No change

D. An order to impound a radiation source, or an order to suspend, revoke, or modify a registration or a license shall remain in effect until the order is suspended or modified by the Board according to A.R.S. § 30-688.

R12-1-1223. Registration and Licensing Time-frames

The Agency shall perform an administrative completeness review and substantive review of an application for a new or renewal license or registration; or an amendment to a license or registration within the time-frames ~~provided~~ in Table A. The Agency shall review an application for an amendment to an existing license or registration ~~which~~ that changes the license category listed in R12-1-1306, using the time-frames specified for the requested category.

Table A. Registration and Licensing Time-frames

REGISTRATION AND LICENSING TIME-FRAMES

License or Registration category in R12-1-1306	Administrative Completeness Review Time-frame, in days	Substantive Review Time-frame, in days	Overall Time-frame, in days
A1	90	30	120
A2	90	30	120
A3	90	30	120
A4	60	30	90
B1	90	30	120
B2	90	30	120
B3	90	30	120
B4	90	30	120
B5	90	30	120
B6	40	20	60
C1	60	30	90
C2	60	30	90
C3	60	30	90
C4	60	30	90
C5	60	30	90
C6	60	30	90
C7	60	30	90
C8	90	30	120
C9	60	30	90
C10	40	20	60
C11	90	30	120
C12	90	30	120
C13	90	30	120
C14	90	30	120
C15	90	30	120
C16	90	30	120
C17	90	30	120
D1	90	30	120
D2	90	30	120
D3	90	30	120
D4	40	20	60
D5	40	20	60
D6	90	30	120
D7	40	20	60
D8	60	30	90
D9	90	30	120
D10	90	30	120
D11	1095	365	1460
D12	730	180	910
D13	365	90	455
D14	90	30	120
D15	40	20	60
D16	20	10	30
D17	40	20	60
D18	90	30	120
D19	365	120	485
E1	40	20	60
E2	40	20	60
E3	40	20	60
E4	40	20	60

E5	90	30	120
E6	90	30	120
~~E6~~F1	40	20	60
~~E7~~F2	40	20	60
~~E8~~F3	40	20	60
~~E9~~F4	40	20	60
~~E10~~F5	20	10	30
~~E11~~F6	40	20	60
F7	40	20	60
~~E12~~F8	40	20	60
~~E13~~	~~40~~	~~20~~	~~60~~
~~E14~~F9	40	20	60
~~E15~~F10	40	20	60
~~E16~~F11	40	20	60
~~E17~~F12	90	30	120

Footnote: "administrative completeness review time-frame," "substantive review time-frame," and "overall time-frame" are defined in A.R.S. § 41-1072.

ARTICLE 17. ~~RADIATION SAFETY REQUIREMENTS FOR~~ WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

R12-1-1702. ~~Required written agreement~~ Written Agreement

A. Before beginning operation of a wireline service a ~~No~~ licensee shall enter into a written agreement with the well operator, well owner, drilling contractor, or land owner. At minimum the agreement shall contain the following provisions: ~~perform wireline service operations with a sealed source unless, prior to commencement of the operation, the licensee has a written agreement with the well operator, well owner, drilling contractor, or land owner that:~~

1. If a sealed source is lodged downhole each party shall:
   a. Cooperate in making a reasonable effort to recover the sealed source; and
   b. Unless other provision is made, bear an equal responsibility for recovery costs; ~~In the event a sealed source is lodged downhole, a reasonable effort at recovery will be made; and~~
2. If in the opinion of the licensee, the recovery effort could rupture the source; the parties shall not attempt to recover the source ~~No person will be permitted to attempt recovery of the source in any manner which, in the opinion of the licensee, could rupture the source; and~~
3. ~~If the job site, equipment or personnel are contaminated with radioactive material, such equipment or personnel must be decontaminated before release from the site, and the job site must be decontaminated before release for unrestricted use; and~~ If the job site is contaminated with radioactive material from a leaking source, the parties shall ensure that it is decontaminated before release for unrestricted use, and that equipment and personnel are decontaminated before release from the job site;
4. If the licensee determines that the sealed source should be abandoned ~~In the event a decision is made to abandon the sealed source~~ downhole, ~~the requirements of~~ the parties shall comply with R12-1-1751(C) and the applicable laws implemented by ~~of the rules of~~ the Oil and Gas Conservation Commission, ~~or~~ the Department of Water Resources, and the Department of Environmental Quality. ~~, as appropriate, shall be met.~~

B. ~~A~~ The licensee shall maintain a copy of the agreement ~~must be maintained~~ at the field station during logging operations. The licensee shall retain a copy of the written agreement for three years after completion of the well logging operation.

R12-1-1703. Limits on ~~levels~~ Levels of ~~radiation~~ Radiation

A person in possession of any source ~~Sources~~ of radiation shall ~~be used, stored and transported~~ transport the source according to ~~in such a manner that the transportation requirements of~~ 12 A.A.C. 1, Article 15, and use or store the source in a manner that is consistent with the dose limits in 12 A.A.C. 1, Article 4. ~~limitation requirements of Article 4 of this Chapter are met~~.

R12-1-1712. Storage ~~precautions~~ Precautions

A. A person storing or transporting a ~~Each~~ source of radiation~~, except accelerators,~~ shall ~~be provided with~~ place the source in an approved ~~a~~ storage container, ~~or~~ transport container, or both ~~combination thereof~~. The container or combination of containers shall ~~be provided with~~ have a lock, or tamper-proof seal for calibration sources, to prevent unauthorized removal of the source and exposure to radiation ~~of, or exposure to, the source of radiation~~.

B. ~~Sources of radiation shall be stored~~ A person storing or transporting a source of radiation shall store the source in a manner ~~which~~ that will minimize danger from explosion or fire.

R12-1-1714. Radiation ~~survey instruments~~ Survey Instruments

A. ~~The~~ A licensee shall maintain at each field station and temporary job site ~~keep~~ a calibrated and operable radiation survey instrument capable of detecting beta and gamma radiation ~~at each field station and temporary job site to make the radiation surveys as required by this Article and by Article 4 of this Chapter~~. The licensee shall ensure that the

1. ~~To satisfy this requirement, the~~ radiation survey instrument ~~shall be~~ is capable of measuring 1.0 microsievert (0.1 millirem) per hour through 500 microsievert (50 millirem) per hour.
2. ~~Survey instruments acquired before the effective date of this rule and capable of measuring 1.0 microsievert through at least 200 microsieverts (20 millirem) per hour may be used to satisfy this requirement until July 14, 1992.~~

B. ~~The licensee shall have available additional calibrated and operable radiation detection instruments sensitive enough to detect the low radiation and contamination levels that could be encountered if a sealed source ruptured. The licensee may own the instruments or may establish a procedure to obtain them quickly from a second party.~~ A licensee shall ensure that additional calibrated and operable radiation detection instruments are available as needed and that the instruments are sensitive enough to detect the low radiation and contamination levels that could be encountered if a sealed source is ruptured.

C. ~~Each radiation survey instrument required by subsection (A) shall be calibrated:~~ A licensee shall ensure that the radiation survey instrument required in subsection (A) is calibrated:

1. At intervals not to exceed six months and after each instrument servicing;
2. At energies comparable to the ~~energy~~ energies of the radiation ~~from the~~ sources used;
3. For linear scale instruments, at two points located approximately 1/3 and 2/3 of full-scale on each scale or for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and
4. No change

D. ~~Calibration~~ A licensee shall retain calibration records ~~shall be retained~~ for a period of three years from the date of calibration.

R12-1-1715. Leak Testing of Sealed Sources

A licensee shall test each sealed source ~~containing~~ that contains radioactive material for leakage according to ~~in accordance with the provisions of~~ R12-1-417. Records of the leak tests shall be retained for a period of three years from the date of the test, and a copy shall accompany the source to job sites.

R12-1-1717. Utilization ~~records~~ Records

Each licensee shall maintain ~~current~~ records of use ~~which shall be retained~~ for three years from the date of the recorded event, that contain ~~showing~~ the following information for each source of radiation:

1. Make, model number, and ~~a~~ serial number or a description of each source of radiation used;
2. The identity of the well-logging supervisor or the field unit to ~~whom~~ which the source is assigned;
3. Locations ~~where used~~ and dates of use; and
4. In the case of tracer materials and radioactive markers, ~~the utilization record shall indicate~~ the radionuclide and activity ~~used~~ undertaken in a particular well.

R12-1-1718. Design, ~~performance and certification criteria for sealed sources used in downhole operations~~ Performance, and Certification Criteria for Sealed Sources Used in Downhole Operations

A. ~~Each~~ Except for a sealed source that contains ~~, except those containing~~ radioactive material in gaseous form, a licensee shall use a sealed source ~~used in~~ for downhole operations after July 14, 1989, that is certified ~~shall be certified~~ by the manufacturer ~~to meet the following minimum criteria~~ as meeting minimum criteria, specifically that each source:

1. ~~Be of doubly encapsulated construction~~ Is doubly encapsulated;
2. ~~Contain radioactive material whose chemical and physical forms are as insoluble and nondispersible as practical~~ Contains radioactive material of a chemical and physical form that is as insoluble and nondispersible as practical; and
3. Has been individually pressure tested to at least 170 meganewtons per square meter (24,656 pounds per square inch absolute) without failure.

B. ~~For sealed sources, except those containing radioactive material in gaseous form, used in downhole operations after July 14, 1989, a prototype shall have been tested and found to maintain its integrity after each of the following tests~~ Except for a sealed source that contains radioactive material in gaseous form, a license shall use a sealed source only if the prototype maintains its integrity after each of the following tests:

1. ~~The prototype source shall be held at a temperature of -40 degrees Celsius (C) for 20 minutes, then at 600 degrees C for one hour, and then be subjected to a thermal shock by dropping the temperature from 600 degrees C to 20 degrees C within 15 seconds~~ Thermal shock, generated by first holding the source at a temperature of -40 degrees Celsius (C) for 20 minutes, then holding the source at a temperature of 600 degrees C for one hour, and finally dropping the temperature from 600 degrees C to 20 degrees C in 15 seconds.
2. ~~A five-kilogram steel hammer, 2.5 centimeters in diameter, shall be dropped from a height of one meter onto the prototype source as a test of impact resistance~~ Heavy impact, generated by a five kilogram steel hammer 2.5 centimeters in diameter, dropped from a height of 1 meter onto the source.

3. ~~The prototype source shall be subjected to vibration at a frequency of from 25 Hz to 500 Hz and at an amplitude of five g for 30 minutes.~~ Vibration, generated by varying frequency from 25 Hz to 500 Hz and maintaining an amplitude of 49 m/sec^2 (5g) for 30 minutes.
4. ~~A one-gram hammer with a 0.3 centimeter diameter pin attached shall be dropped from a height of one meter such that the end of the pin strikes the prototype source~~ Focused impact, generated by a 1 gram hammer with a 0.3 centimeter diameter pin, dropped from a height of 1 meter onto the source, so that the end of the pin strikes the source.

C. A licensee shall retain certification ~~Certification~~ documents~~ shall be retained~~ for a period of three years after source disposal. If the source is abandoned downhole, the licensee shall retain certification documents indefinitely~~ shall be retained permanently~~.

R12-1-1719. Labeling

A. A licensee shall mark each ~~Each~~ source, source holder, or logging tool ~~containing~~ that contains radioactive material ~~shall bear~~ with a durable, legible, and clearly visible marking or label, consisting at minimum of ~~which has, as a minimum~~, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

DANGER (or: CAUTION)
RADIOACTIVE

This labeling is required for each ~~shall be on the smallest~~ component transported as a separate piece of equipment regardless of size.

B. A licensee shall permanently attach to each ~~Each~~ transport container a durable, legible, and a clearly visible label consisting at minimum, of ~~shall have permanently attached to it a durable, legible, and clearly visible label which has, as a minimum,~~ the standard radiation caution symbol and the following wording:

DANGER (or: CAUTION)
RADIOACTIVE
NOTIFY CIVIL AUTHORITIES (or name of company)

R12-1-1720. Inspection and ~~maintenance~~ Maintenance

A. At intervals not to exceed six months, each ~~Each~~ licensee shall conduct~~, at intervals not to exceed six months,~~ a program of inspection and maintenance of holders, logging tools, source handling tools, storage containers, transport containers, and injection tools to assure proper labeling and physical condition. ~~Records~~ A licensee shall retain records of inspection and maintenance ~~shall be retained~~ for a period of three years.

B. If an ~~any~~ inspection conducted according to subsection (A) ~~pursuant to R12-1-1720(A)~~ reveals damage to labeling or components critical to radiation safety, the licensee shall remove the device ~~shall be removed~~ from service until repairs have been made.

C. ~~The repair, opening, or modification of any sealed source shall be performed only by persons specifically authorized to do so by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State~~ Only persons specifically authorized by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State may repair, open, or modify a sealed source that contains radioactive material.

R12-1-1721. Training Requirements

A. A licensee shall not permit any individual to act as a logging supervisor as defined in Article 1 until ~~such~~ the individual has:

1. Received, in a course recognized by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State~~, or a Licensing State~~ instruction in the following subjects and demonstrated an understanding ~~thereof~~ of:
   a. ~~Fundamentals~~ The fundamentals of radiation safety
      i. No change
      ii. No change
      iii. No change
         (1) No change
         (2) No change
      iv. No change
      v. No change
         (1) No change
         (2) No change
         (3) Shielding
   b. No change
      i. No change
         (1) No change
         (2) No change
         (3) No change
      ii. No change
      iii. No change

c. No change
i. No change
ii. No change
iii. No change
iv. No change
d. No change
e. No change
f. No change

2. ~~Read and received instruction in~~ Received, read, and demonstrated an understanding of the rules contained in this Article and the applicable Sections of Articles 1, 4, 10, and 15 of this Chapter or their equivalent, conditions of appropriate license or certificate of registration, and the licensee's operating and emergency procedures~~, and demonstrated an understanding thereof~~; and
3. No change

B. A licensee shall not permit ~~any~~ an individual to assist in the handling of sources of radiation until ~~such~~ the individual has:
1. Read or received, and demonstrated an understanding of instruction in the licensee's operating and emergency procedures ~~and demonstrated an understanding thereof~~; and
2. Demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments ~~which~~ that will be used on the job.

C. No change

R12-1-1722. Operating and ~~emergency procedures~~ Emergency Procedures

Each licensee shall develop ~~The licensee's~~ operating and emergency procedures ~~shall include instructions in at least~~ on the following subjects:
1. Procedures designed to prevent individuals from being exposed to radiation in excess of the limits in Article 4 of this Chapter. This subject includes:
   a. Use of a sealed source in a well without a surface casing for the purposes of protecting a fresh water aquifer, as appropriate;
   b. Methods employed to minimize exposure from inhalation or ingestion of licensed tracer materials; and
   c. Methods for minimizing exposure of individuals in the event of an accident; ~~Handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in Article 4 of this Chapter;~~
2. Use of remote handling tools for manipulating a radioactive sealed source or tracer;
~~2.~~3. Methods and occasions for conducting a radiation ~~surveys~~ survey;
~~3.~~4. Methods and occasions for locking and securing ~~sources~~ a source of radiation;
~~4.~~5. Personnel monitoring and the use of personnel monitoring equipment;
~~5.~~6. Transportation of a source to a temporary job ~~sites~~ site or ~~and~~ field ~~stations~~ station, including ~~the~~ packaging and placing ~~of sources~~ the source of radiation in ~~vehicles~~ a vehicle, placarding ~~of vehicles~~ the vehicle, and securing ~~sources~~ the source of radiation during transportation;
~~6. Minimizing exposure of individuals in the event of an accident~~;
7. Procedure for notifying ~~proper personnel in the event of~~ the Agency if there is an accident;
8. No change
9. No change
10. Procedure ~~to be followed in the event a~~ required if a sealed source is:
    a. Lost or lodged downhole; or
    b. Ruptured, including safeguards to prevent job site and personnel contamination, inhalation; and ingestion ~~lost or lodged downhole;~~
11. Procedures ~~to be used~~ required for picking up, receiving, and opening packages ~~containing~~ that contain radioactive material; and
12. Procedures ~~to be used~~ required for site and equipment surveys and decontamination following tracer studies.

R12-1-1723. Personnel Monitoring

A. A licensee shall not permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each ~~such~~ individual wears either a film badge or a thermoluminescent dosimeter (TLD). Each film badge or TLD shall be assigned to and worn by only one individual.

B. ~~Where~~ If necessary in order to aid in determining the extent of an individual's exposure to concentrations of radioactive material, the licensee shall provide bioassay for individuals conducting tracer studies.

C. ~~Personnel~~ The licensee shall maintain personnel monitoring records ~~shall be maintained~~ according to ~~in accordance with~~ R12-1-419(C).

R12-1-1731. Security

~~During each logging or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized or unnecessary entry into a restricted area, as defined in Article 1 of this Chapter.~~

A. A logging supervisor shall be physically present at a temporary job site whenever licensed material is being handled or is not stored and locked in a vehicle or storage place. The logging supervisor may leave the job site to obtain assistance if a source becomes lodged in a well.

B. During well logging, except when a radiation source is below ground or in a shipping or storage container, the logging supervisor or other individual designated by the logging supervisor shall maintain direct surveillance of the operation to prevent unauthorized entry into a restricted area, as defined in R12-1-102.

R12-1-1733. Subsurface ~~tracer studies~~ Tracer Studies

A. ~~Protective~~ Any person who handles radioactive tracer material shall wear protective gloves and other appropriate protective clothing and equipment ~~shall be used by all personnel handling radioactive tracer material~~. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.

B. A ~~No~~ licensee shall not inject ~~cause the injection of~~ radioactive material into potable aquifers without ~~prior written authorization from~~ authority granted in a radioactive material license issued by the Agency.

C. A licensee shall dispose of tracer study waste contaminated with radioactive material in accordance with R12-1-434.

R12-1-1734. Use of a Sealed Source in a Well Without a Surface Casing and Particle ~~accelerators~~ Accelerators

A. A licensee or registrant may use a sealed source in a well without a surface casing to protect a fresh water aquifer if the licensee follows the correct procedure for reducing the probability that the source will become lodged in the well.

B. A licensee or registrant shall not begin well logging operations in a well without a surface casing unless the Agency has approved the licensee's procedure for logging in an uncased hole.

C. ~~No~~ A licensee or registrant shall not permit above-ground testing of a particle ~~accelerators~~ accelerator, designed for use in well-logging, which results in the production of radiation, ~~except in areas or facilities~~ unless the area or facility affected is controlled or shielded ~~so that the~~ in a manner consistent with applicable requirements ~~of~~ in Article 4 of this Chapter~~, as applicable, are met~~.

R12-1-1741. Radiation ~~surveys~~ Surveys

A. ~~Radiation surveys~~ A licensee shall perform and make a record of a radiation survey using instruments or calculations of radiation levels ~~shall be made and recorded for~~ in each area where radioactive ~~materials are~~ material is stored.

B. ~~Radiation surveys~~ A licensee shall make and record a radiation survey using instruments or calculations of radiation levels ~~shall be made and recorded for the radiation levels~~ in occupied positions and on the exterior of each vehicle used to transport radioactive material. ~~Such surveys or calculations~~ The survey or calculation shall include each source of radiation or combination of sources to be transported in the vehicle.

C. After removal of the sealed source from the logging tool and before departing the job site, a licensee shall ensure that the logging tool detector ~~shall be~~ is energized, or a survey meter is used to ~~used, to assure that~~ test the logging tool ~~is free of~~ for contamination. The licensee shall record the test for contamination.

D. ~~Radiation~~ The licensee shall make and record each survey ~~surveys using instruments shall be made and recorded~~ using an appropriate survey instrument for the radionuclide being used, at the job site or wellhead for each tracer operation, except those using Hydrogen-3, Carbon-14 and Sulfur-35. ~~These surveys~~ Each survey shall include measurements of radiation levels before and after ~~the~~ each tracer operation.

E. Records of surveys conducted according to subsections ~~required pursuant to R12-1-1741~~(A) through (D) shall include the ~~dates~~ date of each survey, the identification of ~~individuals~~ each individual making the survey, ~~the~~ identification of each survey ~~instruments~~ instrument used, each radiation ~~measurements~~ measurement in millirem or microsievert per hour, and an exact description of the location of the survey. ~~Records~~ A licensee shall retain records of a survey ~~of these surveys shall be retained~~ for three years after completion of the survey.

R12-1-1742. Documents and Records Required at Field Stations

Each licensee utilizing a field station shall have the following documents and records available for the specific devices and sources used at the field station:

1. Appropriate license~~, certificate of registration,~~ or equivalent document;
2. No change
3. Applicable rules ~~regulations~~;
4. ~~Records~~ Record of the latest survey instrument ~~calibrations~~ calibration required by ~~pursuant to~~ R12-1-1714;
5. ~~Records~~ Record of the latest leak test performed according to ~~test results pursuant to~~ R12-1-1715;
6. Inventories of sealed sources required by ~~pursuant to~~ R12-1-1716;
7. Utilization records required by ~~pursuant to~~ R12-1-1717;
8. Records of inspection and maintenance required by ~~pursuant to~~ R12-1-1720; and
9. Survey records required by ~~pursuant to~~ R12-1-1741.

R12-1-1743. Documents and Records Required at Temporary Job Sites

Each licensee ~~conducting~~ that conducts operations at a temporary job site shall have the following documents and records available at that site:

1. No change
2. Survey records required by ~~pursuant to~~ R12-1-1741 for the period of operation at the site;
3. No change
4. ~~When~~ If operating in Arizona under reciprocity, a copy of the current out-of-state license, certificate of registration, or equivalent documents; and Agency authorization to enter the state to perform operations governed by this Article.

R12-1-1751. Notification of Incidents, Abandonment, and Lost Sources

A. ~~Notification~~ A licensee shall provide notice of incidents and sources lost in situations other than downhole logging operations ~~shall be made~~ according to ~~in accordance with appropriate provisions of~~ Article 4 of this Chapter.

B. ~~Whenever~~ If a sealed source or device ~~containing~~ that contains radioactive material is lodged in a well hole the licensee shall notify the Agency of the planned procedures for recovery ~~prior to~~ before attempting recovery and shall:

1. No change
2. No change

C. ~~When~~ If it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall:

1. Advise the well operator of the Agency rules ~~regulations of the Agency~~ regarding abandonment and an appropriate method of abandonment, which ~~shall include~~ includes:
   a. ~~The immobilization~~ Immobilizing and sealing in place ~~of~~ the radioactive source with a cement plug;
   b. ~~The setting of~~ Setting a whipstock or other deflection device; and
   c. ~~The mounting of~~ Mounting a permanent identification plaque at the surface of the well ~~containing the appropriate~~ that provides information required by ~~R12-1-1751(D)~~ subsection (D) ~~below~~
2. No change
3. File a written report with the Agency within 30 days of the abandonment~~,~~ that contains ~~setting forth~~ the following information:
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
   f. No change
   g. No change
   h. No change

D. ~~Whenever~~ If a sealed source ~~containing~~ that contains radioactive material is abandoned downhole, the licensee shall provide a permanent plaque for posting the well or well-bore. This plaque shall:

1. No change
2. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
   f. No change
   g. No change
   h. No change

E. The licensee shall immediately notify the Agency by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or adjacent to an underground potable water source. ~~Such~~ The notice shall designate the well location and ~~shall~~ describe the magnitude and extent of loss of radioactive material, assess the consequences of ~~such~~ the loss, and explain efforts planned or being taken to mitigate these consequences.