NOTICES OF PROPOSED RULEMAKING

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

NOTICE OF PROPOSED RULEMAKING

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

Editor's Note: The following Notice of Proposed Rulemaking was reviewed per Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 1502.) The Governor's Office authorized the notice to proceed through the rulemaking process on April 2, 2013.

[R13-94]

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R12-1-602	Amend
R12-1-603	Amend
R12-1-605	Amend
R12-1-606	Amend
R12-1-607	Amend
R12-1-608	Amend
R12-1-610	Amend
R12-1-610.01	New Section
R12-1-611	Amend
R12-1-611.01	New Section
R12-1-611.02	New Section
R12-1-612	Amend
R12-1-614	Amend
R12-1-615	Amend

2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):

Authorizing statute: A.R.S. § 30-654(B)(5).

Implementing statutes: A.R.S. §§ 30-651, 30-654, 30-657, 30-671(B), 30-672, 30-673, 30-681, 30-687, 30-688, and 30-689.

3. Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the proposed rule:

Notice of Rulemaking Docket Opening: 19 A.A.R. 895, April 26, 2013

4. The agency's contact person who can answer questions about the rulemaking:

Name: Jerry W. Perkins

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

Telephone: (602) 255-4845, ext. 272

Fax: (602) 437-0705

E-mail: jperkins@azrra.gov

Web site: www.azrra.gov

5. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

This rulemaking package amends and adds several rules to ensure that Arizona radiation compliance addresses recent safety issues related to Computed Tomography (CT) scans and emergent technical advances in equipment, and digital developing techniques that lower the expected radiation dose to the public when used correctly. In some cases, the rules are amended to reduce the regulatory burden on businesses that are already accredited by other entities.

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

None

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

Not applicable

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

There is little or minimal economic impact from any of the proposed rules in this rulemaking. Currently, all registrants pay an annual fee which covers the administrative cost and inspection fees for each facility registration number. This package has no fee increase or new requirements that would markedly change the way businesses operate with radiation safety concerns in mind. The amendments in this rulemaking address recent safety issues related to CT scans and emergent technical advances in equipment, and developing techniques that lower the expected radiation dose to the public when used correctly.

9. The agency's contact person who can answer questions about the economic, small business and consumer impact statement:

Name:	Jerry W. Perkins
Address:	Arizona Radiation Regulatory Agency 4814 S. 40th St. Phoenix, AZ 85040
Telephone:	(602) 255-4845, ext. 272
Fax:	(602) 437-0705
E-mail:	jperkins@azrra.gov
Web site:	www.azrra.gov

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

An oral proceeding at the Agency will be scheduled for 9:00 a.m. on July 18, 2013, at 4814 S. 40th St., Phoenix, AZ. A person may also submit written comments concerning the proposed rules by submitting them no later than 5:00 p.m. July 11, 2013, to the following person:

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

11. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

The Agency believes that it is exempt from A.R.S. §§ 41-1037 due to subsection (A)(2) as the issuance of an alternative type of permit is authorized under the statutory requirement of A.R.S. §§ 30-672 to protect the public health and safety.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

The rule amendments are compatible with existing federal regulations and are not more stringent in sections that have a federal equivalent. Currently the regulation of radiation producing equipment is conducted at the state level and federal regulations only govern the manufacture of radiation producing electronic devices with the exception of mammography screening facilities. Facilities that screen for mammography are dually regulated as an MQSA facility for federal insurance reimbursement as well as under the rules of the Agency. The federal rules governing MQSA are located in 10 CFR 900.12 and are incorporated in the rules of the Agency.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No analysis has been submitted as the regulated community must be in compliance with either federal regulations if accepting Medicare insurance, or if certified as a MQSA mammography facility.

12. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:

Rule	Incorporated Material
R12-1-614(B)(2)	21 CFR 900.12(d)(1), and (e)(1) through (e)(10)
R12-1-615(A)(1)(a)	21 CFR 900.12(a)(1)
R12-1-615(A)(1)(b)	21 CFR 900.12(a)(2)
R12-1-615(A)(1)(c)	21 CFR 900.12(a)(3)

13. The full text of the rules follows:

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

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

Section
R12-1-602. Definitions
R12-1-603. Operational Standards, Shielding, and Darkroom Requirements
R12-1-604. General Procedures
R12-1-605. X-ray Machine Standards
R12-1-606. Fluoroscopic and Fluoroscopic Treatment Simulator Systems
R12-1-607. Additional X-ray Machine Standards, Shielding Requirements, and Procedures, Except Mobile Fluoroscopic, Dental Panoramic, Cephalometric, Dental CT, or ~~and~~ Dental Intraoral Radiographic Systems
R12-1-608. Mobile Diagnostic Radiographic and Mobile Fluoroscopic Systems, Except Dental Panoramic, Cephalometric, Dental CT, or Dental Intraoral Radiographic Systems
R12-1-610. Dental Intraoral Radiographic Systems
R12-1-610.01. Hand-held Intraoral Dental Radiographic Unit Requirements For Use
R12-1-611. Therapeutic X-ray Systems of Less Than 1 MeV
R12-1-611.01. Electronic Brachytherapy
R12-1-611.02. Other Use of Electronically-Produced Radiation to Deliver Therapeutic Radiation Dosage
R12-1-612. ~~Computerized Tomographic~~ Computed Tomography Systems
R12-1-614. Mammography Systems
R12-1-615. ~~Repealed~~ Mammography Personnel

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

R12-1-602. Definitions

The following definitions apply in this Article, unless the context otherwise requires:

"Accessible surface" No change
"Added filter" No change
"Aluminum equivalent" No change
"Annual" means annually within two months of the anniversary due date as determined by the original installation date, inspection date, survey date, or a reset date created by conducting a full survey before the anniversary date has arrived.
"Assembler" No change
"Attenuation block" No change
"Automatic exposure control" means a device that automatically controls one or more technique factors in order to obtain, at a preselected location or locations, a required quantity of radiation.

"Barrier" No change
"Beam axis" No change
"Beam-limiting device" No change
"C-arm x-ray system" No change
"Changeable filter" No change
"Cinefluorography" No change
"Coefficient of variation" No change
"Collimator" No change
"Compression device" No change
"Computed tomography" No change
"Contact therapy system" No change
"Control panel" No change
"Cooling curve" No change
"CT gantry" No change
"Dead-man switch" No change
"Diagnostic source assembly" No change
"Diagnostic x-ray system" No change
"Direct scattered radiation" No change
"Electronic brachytherapy" means a method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage.
"Entrance exposure rate" No change
"Equipment" No change
"Filter" No change
"Fluoroscopic imaging assembly" No change
"Fluoroscopic system" No change
"Focal spot" No change
"General purpose radiographic x-ray system" No change
"Gonadal shield" No change
"Grid" No change
"Half-value layer" or "HVL" No change
"Healing arts radiography" No change
"Healing arts screening" No change
"Image intensifier" No change
"Image receptor" No change
"Inherent filtration" No change
"Kilovolts peak" or "kVp" No change
"Lateral fluoroscope" means the x-ray tube and image receptor combination in a biplane system dedicated to the lateral projection. It consists of the lateral x-ray tube housing assembly and the lateral image receptor that are fixed in position relative to the table with the x-ray beam axis parallel to the plane of the table.
"Lead equivalent" No change
"Leakage radiation" No change
"Leakage technique factors" No change
"mA" No change
"Mammographic x-ray system" No change
"mAs" No change
"Mobile equipment" No change
"Peak tube potential" No change
"Phantom" No change
"Phototimer" No change
"Portable equipment" No change
"Primary protective barrier" No change
"Protective apron" No change
"Protective barrier" No change
"Protective glove" No change
"Radiologic physicist" means an individual who:
Is certified by the American Board of Radiology, American Board of Medical Physics, or the American Board of Health Physics;
Possesses documentation of state approval;
Holds a master's degree or higher in a physical science; and

Meets the training and certification requirements in ~~R12-1-614(C)(1)(c)~~ R12-1-615(A)(1)(c).

"Scattered radiation"	No change
"Screen" or "intensifying screen"	No change
"Secondary protective barrier"	No change
"Shutter"	No change
"Source"	No change
"Source-to-image receptor distance" or "SID"	No change
"Spot check"	No change
"Stationary equipment"	No change
"Stray radiation"	No change
"System"	No change
"Technique chart"	No change
"Technique factors"	No change
"Treatment simulator"	No change
"Tube"	No change
"Tube housing assembly"	No change
"Tube rating chart"	No change
"Useful beam"	No change
"Visible area"	No change

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

"Hand-held" means x-ray equipment designed to be held by an operator while being used.

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

"Portable" means x-ray equipment designed to be hand-carried, but used with a cord or delayed timer system that allows the operator to be six feet or more away from the useful beam.

"Stationary" means x-ray equipment installed in a fixed location.

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

"X-ray system"	No change
"X-ray tube"	No change

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

A. No change

B. A registrant shall direct the operation of x-ray machines under the registrant's control and 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" using equipment under the registrant's control, unless the individual possesses ~~a valid~~, and displays in the primary employer's facility, an official certificate issued by, or is exempt from, the Medical Radiologic Technology Board of Examiners that contains an original signature of its Director or designee. A copy of the certificate shall be posted at any secondary employment location with documentation that verifies that the employer has physically seen the official certificate and has annotated on the copy the location where the official certificate may be viewed by Agency staff.
2. The registrant shall maintain records documenting compliance with subsection (B)(1) for each individual practicing "Healing Arts Radiography" using equipment under the registrant's control ~~practicing "Healing Arts Radiography."~~
3. No change

C. Shielding

1. No change
2. No change
3. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
4. A registrant shall also meet the structural shielding requirements in R12-1-607(C), if the x-ray system in question is not a mobile fluoroscopic unit, dental panoramic, cephalometric, dental CT, or intraoral radiographic system.

D. Film Processing and Darkroom Requirements. A registrant shall:

1. Ensure that the darkroom is light-tight and use proper safe-lighting~~, so~~ such that any film type in use ~~is~~ exposed in a cassette to x-ray radiation sufficient to produce an optical density from 1 to 2 when processed~~,~~ shall not suffer an increase in density greater than 0.1 (0.05 for mammography) when ~~the film is~~ exposed in the darkroom for two minutes~~, and exposure will not produce an increase in optical density greater than 0.1 (0.05 for mammography).~~ with all

safe-lights illuminated. (A processor with a daylight loader satisfies this requirement.);
2. No change
3. No change
4. No change
5. No change
6. No change
7. Ensure that film processing solutions are prepared and maintained in accordance with the directions of the manufacturer; ~~and~~
8. No change
9. Follow manufacturer's recommendations for cleaning or inspection of computed radiography (CR) cassettes, but not less than annually;
10. Follow manufacturer's recommendations for preventive maintenance on digital radiography panels or cassettes, but not less than annually; and
11. Maintain documentation that demonstrates that requirements of this subsection are being met for three years for agency review from the date of inspection.

R12-1-605. X-ray Machine Standards

A. No change
B. No change
C. Beam quality.
1. The registrant shall prevent the useful beam half-value layer (HVL) for diagnostic x-ray given x-ray tube potential 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 that is not listed in Table I, the registrant shall use linear interpolation or extrapolation to make the determination.

Table I

Design operating range (kilovolts peak)	*Measured potential (kilovolts peak)*	*Half-value layer (millimeters of aluminum)* *Dental Intraoral Units manufactured after December 1, 1980*	*Medical X-ray Units manufactured before June 10, 2006 and Dental Intraoral Units manufactured on or before December 1, 1980*	*Medical X-ray Units manufactured on or after June 10, 2006*
Below 51	30	~~0.3~~ 1.5	0.3	0.3
	40	~~0.4~~ 1.5	0.4	0.4
	50	~~0.5~~ 1.5	0.5	0.5
51 to 70	51	~~1.2~~ 1.5	1.2	1.3
	60	~~1.3~~ 1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

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

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

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

A. No change

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

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

C. No change
1. No change
2. No change
   a. No change
   b. No change
3. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
   f. For a ~~lateral-type~~ lateral fluoroscope, measure the exposure rate 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. No change
1. No change
2. No change
3. No change
4. No change

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

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

G. No change

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

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

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

d. No change
e. No change
3. No change

B. No change
1. No change
2. No change
3. No change
4. No change
a. A device (usually a ~~milliammeter~~ milliamp meter) that will give a positive indication during radiation production; and
b. No change

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

D. No change
1. No change
2. No change
3. No change
4. No change
a. No change
b. No change
c. No change
d. No change
e. No change
5. Provide documentation ~~in the order specified~~ of the following items:
a. No change
b. No change
c. No change
d. The number of projections (if applicable), or on-time, or dose factors depending upon the unit; and
e. No change
6. No change

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

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

B. No change

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

R12-1-610. Dental Intraoral Radiographic Systems

A. No change
1. No change
2. No change
3. No change
4. No change
5. No change
6. No change
7. No change
8. No change
a. No change
b. No change
9. Use technique factors, where deviation of measured ~~or~~ values from indicated values for kVp and exposure time do not exceed the limits specified by the manufacturer. In the absence of the manufacturer's specifications, the deviation

shall not exceed plus or minus 10 percent of the indicated value for kVp and plus or minus 20 percent for exposure time duration.

10. For a digital system that uses an electronic sensor, use digital radiography techniques that permit reducing x-ray beam on-time to 25 percent of the exposure time required for "D" speed film or lower, reducing radiation to the patient by the same rate.
11. For a computed radiography (imaging plate (IP) made of photostimulable phosphor) system that uses an imaging plate, use radiography techniques that permit reducing x-ray beam on-time to 50 percent of the exposure time required for "D" speed film or lower, reducing radiation to the patient by the same rate.

B. No change

1. Provide dental installations with primary and secondary barriers to ensure compliance with the personnel exposure requirements in Article 4 of this Chapter; (Note: In many cases, structural materials of ordinary walls suffice as a protective barrier without addition of special shielding material.)
2. No change
3. No change
4. No change
5. No change

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

C. No change

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

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

A. Registrants are subject to the following requirements for Intraoral dental radiographic units designed to be operated as a hand-held unit:

1. For all uses:
   a. Operators of hand-held intraoral dental radiographic units shall be specifically trained to operate such equipment.
   b. A hand-held intraoral dental radiographic unit shall be held without any motion during a patient examination. A tube stand may be utilized to immobilize a hand-held intraoral dental radiographic unit during patient examination.
   c. The operator shall ensure there are no bystanders within a radius of at least six feet from the patient being examined with a hand-held intraoral radiographic unit.
2. Additional requirements for operatories in permanent facilities:
   a. Hand-held intraoral dental radiographic units shall be used for patient examinations in dental operatories that meet the structural shielding requirements specified by the Agency or by a qualified health or medical physicist.
   b. Hand-held intraoral dental radiographic units shall not be used for patient examinations in hallways and waiting rooms.

B. Hand-held units may only be used in a manner as specified on the registration issued by the Agency.

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

A. No change

1. Leakage radiation. ~~A registrant shall ensure that:~~ When the x-ray tube is operated at its maximum rated tube current for the maximum kVp, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified:
   a. ~~Contact therapy systems. Leakage radiation does not exceed 25.8 microcoulombs per kilogram (100 milliroentgens) per hour at 5 centimeters (2 inches) from the surface of the tube housing assembly.~~ 5-50 kVp Systems. The leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly shall not exceed 1 mGy (100 mrad) in any one hour.
   b. ~~0-150 kVp systems. Systems that are manufactured or installed before January 2, 1996, have a leakage radiation that does not exceed 258 microcoulombs per kilogram (1 roentgen) in one hour at 1 meter (3.3 feet) from the source.~~ Greater than 50 kVp and less than 1MeV Systems. The leakage air kerma rate measured at a distance of 1 meter from the target in any direction shall not exceed 1 centigray (1 rad) in any 1 hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters (100 cm2). In addition, the air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly shall not exceed 30 centigray (30 rad) per hour.

~~c. 0-150 kVp systems. Systems that are manufactured on or after January 2, 1996, have a leakage radiation that does not exceed 25.8 microcoulombs per kilogram (100 milliroentgens) in one hour at 1 meter from the source.~~
~~d. Above 150 kVp. The leakage radiation 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. A registrant shall ensure that fixed diaphragms or cones used for limiting the useful beam provide the same or higher degree of ~~protection~~ attenuation as required for the tube housing assembly.
3. No change
   a. No change
   b. ~~Adjustable beam-limiting devices installed before the effective date of this Section, 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.~~ When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.
4. No change
   a. No change
   b. For equipment installed after January 1, 2011, an interlock system prevents irradiation if the proper filter is not in place;
   c. The air kerma rate escaping from the filter slot shall not exceed 1 centiGray (1 rad) per hour at one (1) meter under any operating conditions; and
   ~~b.~~d. Each filter is marked regarding its material of construction and its thickness or wedge angle for wedge filters.~~; and~~
   ~~c. It 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 if the operator is at the control panel, either by display at the control panel or by direct observation.~~
5. X-ray tube immobilization. A registrant shall ensure that the tube housing assembly is capable of being immobilized during stationary treatments and the x-ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture.
6. No change
7. No change
   a. Provide a timer 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. No change
   c. No change
   d. No change
   e. No change
   f. 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
11. No change
    a. No change
    b. No change
12. No change

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

b. No change
c. No change
d. No change

C. No change
1. No change
2. The person conducting the survey reports the ~~person's~~ survey findings in writing to the individual in charge of the facility and maintains a copy of the survey report for inspection by the Agency.
3. No change

D. No change
1. The calibration of ~~an~~ a therapeutic x-ray system includes, but is not limited to, the following determinations:
   a. No change
   b. No change
   c. No change
   d. No change
2. The calibration of an x-ray system is performed at intervals not to exceed ~~12 months~~ annually and after any change or replacement of components that could cause a change in the radiation output;
3. No change
4. No change
5. Records of calibration performed under subsection (D)(3) are maintained for at least ~~two~~ three years after completion of the calibration and are made available for inspection by the Agency; and
6. No change

E. Spot checks. A registrant shall ensure that spot checks are performed on therapeutic x-ray systems capable of operation at greater than 150 kVp. The registrant shall ensure that spot checks meet the following requirements:
1. The spot-check procedures are in writing and have been developed by a qualified expert ~~person~~;
2. No change
3. No change
4. No change
5. No change

F. Operating procedures. A registrant shall ensure that:
1. No change
2. No change
3. No change
4. No change

G. Electronic Brachytherapy units are exempt from the requirements of this Section.

R12-1-611.01. Electronic Brachytherapy

A. Electronic brachytherapy devices shall be subject to the requirements of this Section, and shall be exempt from the requirements of R12-1-611.
1. An electronic brachytherapy device that does not meet the requirements of this Section shall not be used for irradiation of patients; and
2. An electronic brachytherapy device shall only be utilized for human use applications specifically approved by the U.S. Food and Drug Administration (FDA), unless participating in a research study approved by the registrant's Institutional Review Board (IRB).

B. Each facility location authorized to use an electronic brachytherapy device in accordance with this Section shall possess appropriately calibrated portable monitoring equipment. At a minimum, such equipment shall include a portable survey instrument capable of measuring dose rates over the range 10 μSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument or instruments shall be operable and calibrated before first use, at intervals not to exceed 12 months, and after survey instrument repairs.

C. Facility Design Requirements for Electronic Brachytherapy Devices. In addition to shielding adequate to meet requirements of R12-1-603(C), the treatment room shall meet the following design requirements:
1. If applicable, provision shall be made to prevent simultaneous operation of more than one therapeutic radiation machine in a treatment room.
2. Access to the treatment room shall be controlled by a door at each entrance.
3. Each treatment room shall have provisions to permit continuous oral communication and visual observation of the patient from the treatment control panel during irradiation. The electronic brachytherapy device shall not be used for patient irradiation unless the patient can be observed.
4. For electronic brachytherapy devices capable of operating below 150 kVp, radiation shielding for the staff in the treatment room shall be available, either as a portable shield or as localized shielded material around the treatment site.

5. For electronic brachytherapy devices capable of operating at or greater than 150 kVp, the facility must meet the requirements of R12-1-611(B)(4).

D. Reserved

E. Control Panel Functions. The control panel, in addition to the displays required by other provisions in this Section, shall:
1. Provide an indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;
2. Provide an indication of whether x-rays are being produced;
3. Provide a means for indicating electronic brachytherapy source potential and current;
4. Provide the means for terminating an exposure at any time; and
5. Include an access control (locking) device that will prevent unauthorized use of the electronic brachytherapy device.

F. Timer. A suitable irradiation control device (timer) shall be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor.
1. A timer shall be provided at the treatment control panel. The timer shall indicate the planned setting and the time elapsed or remaining;
2. The timer shall not permit an exposure if set at zero;
3. The timer shall be a cumulative device that activates with an indication of "BEAM-ON" that retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be re-initiated, it shall be necessary to reset the elapsed time indicator;
4. The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system has not previously terminated irradiation.
5. The timer shall permit setting of exposure times as short as 0.1 second; and
6. The timer shall be accurate to within one percent of the selected value or 0.1 second, whichever is greater.

G. Qualified Medical Physicist Support.
1. The services of a Qualified Medical Physicist shall be required in facilities having electronic brachytherapy devices. The Qualified Medical Physicist shall be responsible for:
   a. Evaluation of the output from the electronic brachytherapy source;
   b. Generation of the necessary dosimetric information;
   c. Supervision and review of treatment calculations prior to initial treatment of any treatment site;
   d. Establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in subsection (K);
   e. Consultation with the authorized user in treatment planning, as needed; and
   f. Performing calculations/assessments regarding patient treatments that may constitute a medical event.
2. If the Qualified Medical Physicist is not a full-time employee of the registrant, then the operating procedures required by subsection (H) shall also specifically address how the Qualified Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Qualified Medical Physicist can be contacted.

H. Operating Procedures.
1. Only individuals approved by the authorized user, Radiation Safety Officer, or Qualified Medical Physicist shall be present in the treatment room during treatment;
2. Electronic brachytherapy devices shall not be made available for medical use unless the requirements of subsections (A), (I), and (J) have been met;
3. The electronic brachytherapy device shall be inoperable, either by hardware or password, when unattended by qualified staff or service personnel;
4. During operation, the electronic brachytherapy device operator shall monitor the position of all persons in the treatment room, and all persons entering the treatment room, to prevent entering persons from unshielded exposure from the treatment beam;
5. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used;
6. Written procedures shall be developed, implemented, and maintained for responding to an abnormal situation. These procedures shall include:
   a. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions; and
   b. The names and telephone numbers of the authorized users, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.
7. A copy of the current operating and emergency procedures shall be physically located at the electronic brachytherapy device control console;
8. Instructions shall be maintained with the electronic brachytherapy device control console to inform the operator of the names and telephone numbers of the authorized users, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally; and
9. The Radiation Safety Officer, or the Radiation Safety Officer's designee, and an authorized user shall be notified

immediately if the patient has a medical emergency, suffers injury or dies. The Radiation Safety Officer or the Qualified Medical Physicist shall inform the manufacturer of the event.

I. Safety Precautions for Electronic Brachytherapy Devices.

1. An individual other than the person being treated shall wear personnel monitoring devices;
2. An authorized user and a Qualified Medical Physicist shall be physically present during the initiation of all patient treatments involving the electronic brachytherapy device;
3. A Qualified Medical Physicist and either an authorized user or a physician or a certified therapy technologist (CTT) by the Arizona Medical Radiological Technology Board of Examiners, under the supervision of an authorized user, who has been trained in the operation and emergency response for the electronic brachytherapy device, shall be physically present during continuation of all patient treatments involving the electronic brachytherapy device;
4. When shielding is required by subsection (C)(4), surveys shall be conducted to ensure that the requirements of R12-1-408, R12-1-414, and R12-1-416 are met. Alternatively, a Qualified Medical Physicist shall designate shield locations sufficient to meet the requirements of R12-1-603(C) and R12-1-607(C) for any individual, other than the patient, in the treatment room; and
5. All personnel in the treatment room are required to remain behind shielding during treatment. A Qualified Medical Physicist shall approve any deviation from this requirement and shall designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.

J. Electronic Brachytherapy Source Calibration Measurements.

1. Calibration of the electronic brachytherapy source output shall be performed by, or under the direct supervision of, a Qualified Medical Physicist. If the control console is integral to the electronic brachytherapy device, the required procedures shall be kept where the operator is located during electronic brachytherapy device operation.
2. Calibration of the electronic brachytherapy source output shall be made for each electronic brachytherapy source, or after any repair affecting the x-ray beam generation, or when indicated by the electronic brachytherapy source quality assurance checks;
3. Calibration of the electronic brachytherapy source output shall utilize a dosimetry system appropriate for the energy output of the unit and calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration;
4. Calibration of the electronic brachytherapy source output shall include, as applicable, determination of:
   a. The output within two percent of the expected value, if applicable, or determination of the output if there is no expected value;
   b. Timer accuracy and linearity over the typical range of use;
   c. Proper operation of back-up exposure control devices;
   d. Evaluation that the relative dose distribution about the source is within five percent of that expected; and
   e. Source positioning accuracy to within one millimeter within the applicator;
5. Calibration of the x-ray source output required shall be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of a calibration protocol published by a national professional association, the manufacturer's calibration protocol shall be followed.
6. The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include: the date of the calibration; the manufacturer's name, model number and serial number for the electronic brachytherapy device and a unique identifier for it's electronic brachytherapy source; the model numbers and serial numbers of the instrument(s) used to calibrate the electronic brachytherapy device; and the name and signature of the Qualified Medical Physicist responsible for performing the calibration.

K. Periodic and Day-of-Use Quality Assurance Checks for Electronic Brachytherapy Devices.

1. Quality assurance checks shall be performed on each electronic brachytherapy device:
   a. At the beginning of each day of use;
   b. Each time the device is moved to a new room or site; and
   c. After each x-ray tube installation.
2. The registrant shall perform periodic quality assurance checks required in accordance with procedures established by the Qualified Medical Physicist;
3. To satisfy the requirements of this subsection, radiation output quality assurance checks shall include at a minimum:
   a. Verification that output of the electronic brachytherapy source falls within three percent of expected values, as appropriate for the device, as determined by:
      i. Output as a function of time, or
      ii. Output as a function of setting on a monitor chamber.
   b. Verification of the consistency of the dose distribution to within three percent, observed at the source calibration required by R12-1-611.01(I); and

c. Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within one millimeter; and

4. The registrant shall use a dosimetry system that has been intercompared within the previous 12 months with the dosimetry system described in this Section to make the quality assurance checks required in R12-1-611.01(J)(3);
5. The registrant shall review the results of each radiation output quality assurance check to ensure that:
   a. An authorized user and Qualified Medical Physicist is immediately notified if any parameter is not within its acceptable tolerance, and the electronic brachytherapy device is not used until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances;
   b. If all radiation output quality assurance check parameters appear to be within their acceptable range, the acceptable quality assurance check shall be reviewed and signed by either the authorized user or Qualified Medical Physicist within two days of the check. In addition, the Qualified Medical Physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 30 days.
6. To satisfy the requirements of R12-1-611.01(K)(1), safety device quality assurance checks shall, at a minimum, assure:
   a. Proper operation of radiation exposure indicator lights on the electronic brachytherapy device and on the control console;
   b. Proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;
   c. Proper operation of radiation monitors, if applicable;
   d. The integrity of all cables, catheters or parts of the device that carry high voltages; and
   e. Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.
7. If the results of the safety device quality assurance checks required in R12-1-611.01(K)(6) indicate the malfunction of any system, a registrant shall secure the control console in the OFF position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning system.
8. The registrant shall maintain a record of each quality assurance check required by R12-1-611.01 in a legible form for three years.
   a. The record shall include the date of the quality assurance check; the manufacturer's name, model number and serial number for the electronic brachytherapy device; the name and signature of the individual who performed the periodic quality assurance check and the name and signature of the Qualified Medical Physicist who reviewed the quality assurance check;
   b. For radiation output quality assurance checks required by R12-1-611.01(K)(3), the record shall also include the unique identifier for the electronic brachytherapy source and the manufacturer's name; model number and serial number for the instrument or instruments used to measure the radiation output of the electronic brachytherapy device.

L. Therapy-related Computer Systems. The registrant shall perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of an acceptance testing protocol published by a national professional association, the manufacturer’s acceptance testing protocol shall be followed.

1. Acceptance testing shall be performed by, or under the direct supervision of a Qualified Medical Physicist. At a minimum, the acceptance testing shall include, as applicable, verification of:
   a. The source-specific input parameters required by the dose calculation algorithm;
   b. The accuracy of dose, dwell time, and treatment time calculations at representative points;
   c. The accuracy of isodose plots and graphic displays;
   d. The accuracy of the software used to determine radiation source positions from radiographic images; and
   e. If the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.
2. The position indicators in the applicator shall be compared to the actual position of the source or planned dwell positions, as appropriate, at the time of commissioning.
3. Prior to each patient treatment regimen, the parameters for the treatment shall be evaluated for correctness and approved by the authorized user and the Qualified Medical Physicist through means independent of that used for the determination of the parameters.

M. Training for e-brachytherapy Authorized Users.

1. The registrant for any therapeutic radiation machine subject to this Section shall require the authorized user to be a physician who is certified in:
   a. Radiation oncology or therapeutic radiology by the American Board of Radiology or Radiology (combined diagnostic and therapeutic radiology program) by the American Board of Radiology prior to 1976; or
   b. Radiation oncology by the American Osteopathic Board of Radiology; or
   c. Radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of

the Royal College of Radiology"; or
d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
2. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.
a. To satisfy the requirement for instruction, the classroom and laboratory training shall include:
i. Radiation physics and instrumentation;
ii. Radiation protection;
iii. Mathematics pertaining to the use and measurement of ionization radiation; and
iv. Radiation biology.
b. To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include:
i. Review of the full calibration measurements and periodic quality assurance checks;
ii. Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings;
iii. Using administrative controls to prevent medical events as described in R12-1-444;
iv. Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and
v. Checking and using radiation survey meters.
c. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:
i. Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;
ii. Selecting proper dose and how it is to be administered;
iii. Calculating the therapeutic radiation machine doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses and treatment plans as warranted by patients' reaction to radiation; and
iv. Post-administration follow-up and review of case histories.
3. Notwithstanding the requirements of this subsection, the registrant for any therapeutic radiation machine subject to this Section may also submit the training of the prospective authorized user physician for Agency review on a case-by-case basis if the training includes substantially equivalent training as that listed in subsection (M)(2) and the training includes dosimetry calculation training and experience.
4. A physician shall not act as an authorized user until such time as said physician's training has been reviewed and approved by the Agency.

N. Training for Qualified Medical Physicist. The registrant for any therapeutic radiation machine subject to this Section shall require the Qualified Medical Physicist to:
1. Be certified with the Agency, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and
2. Be certified by the American Board of Radiology in:
a. Therapeutic radiological physics; or
b. Roentgen-ray and gamma-ray physics; or
c. X-ray and radium physics; or
d. Radiological physics; or
3. Be certified by the American Board of Medical Physics in Radiation Oncology Physics; or
4. Be certified by the Canadian College of Medical Physics; or
5. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university, and have completed one year of full time training in medical physics and an additional year of full time work experience under the supervision of a Qualified Medical Physicist at a medical institution. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy external beam radiation therapy (photons and electrons with energies greater than or equal to one MV/one MeV). To meet this requirement, the individual shall have performed the tasks listed in this Section under the supervision of a Qualified Medical Physicist during the year of work experience.

O. Qualifications of Operators. Individuals who will be operating a therapeutic radiation machine for medical use shall be certified by the Agency as a certified therapy technologist by the Arizona Medical Radiological Technology Board of Examiners.

P. Additional training requirements.
1. A registrant shall provide instruction, initially and at least annually, to all individuals who operate the electronic

brachytherapy device, as appropriate to the individual's assigned duties, in the operating procedures identified in R12-1-611.01(H). If the interval between patients exceeds one year, retraining of the individuals shall be provided.

2. In addition to the requirements of R12-1-611.01(M) for therapeutic radiation machine authorized users and R12-1-611.01(N) for Qualified Medical Physicists, these individuals shall also receive device-specific instruction initially from the manufacturer, and annually from either the manufacturer or other qualified trainer. The training shall be of a duration recommended by a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of any training protocol recommended by a national professional association, the manufacturer's training protocol shall be followed. The training shall include, but not be limited to:
   a. Device-specific radiation safety requirements;
   b. Device operation;
   c. Clinical use for the types of use approved by the FDA;
   d. Emergency procedures, including an emergency drill; and
   e. The registrant's Quality Assurance Program.
3. A registrant shall retain a record of individuals receiving manufacturers instruction for three years. The record shall include a list of the topics covered, the date of the instruction, the names of the attendees, and the names of the individuals who provided the instruction.

Q. Mobile Electronic Brachytherapy Service. A registrant providing mobile electronic brachytherapy service shall, at a minimum:

1. Check all survey instruments before medical use at each address of use or on each day of use, whichever is more restrictive;
2. Account for the electronic brachytherapy x-ray tube in the electronic brachytherapy device before departure from the client's address; and
3. Perform, at each location on each day of use, all of the required quality assurance checks specified in this Section to assure proper operation of the device.

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

A person shall not utilize any device which is designed to electrically generate a source of ionizing radiation to deliver therapeutic radiation dosage, and which is not appropriately regulated under any existing category of therapeutic radiation machine, until:

1. The applicant or registrant has, at a minimum, provided the Agency with:
   a. A detailed description of the device and its intended application or applications;
   b. Facility design requirements, including shielding and access control;
   c. Documentation of appropriate training for authorized user physicians and qualified medical physicists;
   d. Methodology for measurement of dosages to be administered to patients or human research subjects;
   e. Documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for radiation safety;
   f. Radiation safety precautions and instructions; and
   g. Other information requested by the Agency in its review of the application; and
2. The applicant or registrant has received written approval from the Agency to utilize the device in accordance with the regulations and specific conditions the Agency considers necessary for the medical use of the device; and
3. Submitted the application information and forms required by Article 2.

R12-1-612. ~~Computerized Tomographic~~ Computed Tomography Systems

A. Definitions:

1. "CT" means ~~computerized~~ computed tomography.
2. "CT conditions of operation" means all selectable parameters governing the operation of a CT including~~, but not limited to,~~ nominal tomographic section thickness, and technique factors.
3. No change
4. "CTDI vol" means a value in units of miligray (mGy) used to trigger a notification when the value would likely be exceeded by a prescribed scan.

~~4.~~5. "CTN" means CT number, the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

~~5.~~6. "Dose profile" means the dose as a function of position along a line.

7. "DLP" means the dose length product expressed as a value in units of miligray per centimeter (mGy - cm) used to trigger a notification when the value would likely be exceeded by a prescribed scan.

~~6.~~8. "Elemental area" means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted.

~~7.~~9. "Multiple tomogram system" means a CT system that obtains x-ray transmissions data simultaneously during a single scan to produce more than one tomogram.

~~8.~~10. "Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross section volume over which x-ray transmission data are collected.
~~9.~~11. "Reference plane" means a plane that is displaced from and parallel to the tomographic plane.
~~10.~~12. "Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

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

C. No change
1. No change
   a. No change
   b. No change
2. No change
   a. No change
   b. No change
3. No change
   a. No change
   b. No change
   c. No change
4. No change
5. No change
6. No change
7. No change.
8. No change

D. No change
1. No change
2. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. A written or electronic log that contains the information required in R12-1-607(D)(5) as well as an entry in the record of any displayed values for the exam from either a CTDI vol or DLP measurement for each patient exam completed on equipment manufactured on or after January 1, 2011.
3. No change

E. No change
1. Incorporates the use of a CT performance phantom ~~that indicates:~~ that is compatible with an approved accreditation program approved by the Medicare Improvements for Patients and Providers Act (MIPPA) or supplied by or approved for use by the manufacturer of the unit.
   ~~a. Contrast scale,~~
   ~~b. Nominal tomographic section thickness,~~
   ~~c. Resolution capability of the system for low and high contrast objects, and~~
   ~~d. The mean CTN for water or other reference materials.~~
2. Is followed in the evaluation of the CT's operation, that the interval between tests does not exceed those set forth in the application for accreditation or quarterly if not accredited by an organization approved by Medicare Improvements for Patients and Providers Act (MIPPA) ~~two months~~, and that system conditions are specified by the registrant's qualified expert.
3. No change
4. No change
5. Requires that any Alerts and Notification settings using CTDI vol or DLP are reviewed against preloaded techniques in the system and any missing fields are reviewed with the staff radiologist and noted in the annual report.

~~5.~~6. Requires the quality control test procedure and records of quality control tests performed be maintained for three years for Agency inspection.

F. No change
1. No change
2. No change
   a. No change
   b. No change
   c. A complete evaluation of a CT unit, performed before the annual due date shall clearly list if the new survey

changes the annual due date for the unit. It shall be clearly noted on all documentation for the next three years that the survey has established a new annual due date based upon the date of the new survey.

3. No change
   a. No change
   b. No change
4. CT dosimetry phantoms used in determining radiation output are compatible with an approved accreditation program approved by the Medicare Improvements for Patients and Providers Act (MIPPA) or supplied by or approved for use by the manufacturer of the unit ~~meet the requirements specified by the CT manufacturer or a qualified expert who is responsible for maintaining proper operation~~; and
   a. No change
   b. No change
5. No change

G. CT units designated for simulator use, veterinary use, dental use, podiatry use, and non-diagnostic use on humans ~~conjunctive use in a positron emission tomography (PET) unit~~ are exempt from the annual requirements in ~~subsection~~ subsections (E) and (F) provided an initial evaluation is conducted by a qualified expert and the output does not exceed the manufacturers specified limits. The initial evaluation shall be maintained for Agency review.

R12-1-614. Mammography Systems

A. No change
1. No change
2. No change
3. No change
4. No change
5. No change
6. No change
7. No change
   a. No change
   b. Is capable of compressing the breast with a force of at least 25 pounds, but not more than ~~47~~ 45 pounds, and maintaining the compression for at least three seconds; and
   c. No change
8. No change
   a. No change
   b. No change
9. No change
10. No change
11. No change
12. No change
13. No change
14. No change
15. No change
16. No change
17. A radiologic physicist who meets the requirements in ~~R12-1-614(C)(1)(c)~~ R12-1-615(A)(1)(c) evaluates the operation of a mammographic x-ray system:
    a. No change
    b. No change
    c. No change

B. No change
1. Each mammographic 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. Test results shall fall within the specified limits in subsection (B)(2) or the registrant shall take corrective action and maintain documentation that the results are within specified limits before performing or processing any further examinations using the system that failed. A radiologic physicist, as defined in ~~R12-1-614(C)(1)(c)~~ R12-1-615(A)(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 federal requirements (Contained in 21 CFR 900.12(d)(1), and (e)(1) through (e)(10), revised April 1, ~~2008~~ 2013, incorporated by reference and available under R12-1-101. This incorporated material contains no future editions or amendments.); or the following requirements:
   a. No change
   b. No change
   c. No change

d. No change
e. No change
f. No change
g. No change
h. No change
i. No change
   i. No change
   ii. No change
   iii. No change
   iv. No change
   v. No change
   vi. No change
   vii. No change
   viii. No change
   ix. No change
   x. No change
   xi. No change
   xii. No change
j. For systems with image receptor modalities other than screen film~~, the quality assurance and quality control program meets or exceeds the recommendations by the manufacturer; and~~:
   i. The quality assurance and quality control program for the acquisition system meets or exceeds the recommendations by the manufacturer; and
   ii. The quality assurance and quality control program for the printer meets or exceeds the recommendations by the image receptor manufacturer. In the absence of recommendations by the image receptor manufacturer for the specified printer, the quality control and assurance program meets or exceeds the recommendations of the printer manufacturer; and
   iii. The quality assurance and quality control program for the interpretation monitors meets or exceeds the recommendations by the image receptor manufacturer. In the absence of recommendations by the image receptor manufacturer for the specified monitors, the quality control and assurance program meets or exceeds the recommendations of the interpretation monitors manufacturer; and
k. No change

~~C.~~ ~~Personnel.~~
~~1. Each registrant shall require personnel who perform mammography, which includes the production, processing, and interpretation of mammograms and related quality assurance activities, to meet the following requirements:~~
~~a. An interpreting physician shall meet federal requirements (Contained in 21 CFR 900.12(a)(1), revised April 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material 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 Medical Board 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;~~
~~v. Have completed 15 hours of continuing medical education credits in mammography during the preceding three years; and~~
~~vi. Have received at least eight hours of training specific to each mammographic modality before engaging in independent interpretation.~~
~~b. A mammographic technologist shall meet federal requirements (Contained in 21 CFR 900.12(a)(2), revised April 1, 2008, incorporated by reference, and available under R12-1-101. This incorporated material 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 technologist certificate;~~
~~ii. Have performed at least 200 mammographic examinations in the preceding two years;~~
~~iii. Have completed 15 hours of continuing medical education credits in mammography during the preceding three years; and~~
~~iv. Have received at least eight hours of training specific to each mammographic modality to be used by the technologist in performing mammographic examinations.~~

~~c. A radiologic physicist shall meet federal requirements (Contained in 21 CFR 900.12(a)(3), revised April 1, 2008, incorporated by reference and available under R12-1-101. This incorporated material 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 mammographic facility survey and evaluating at least 10 mammographic units;~~
~~v. Have, after completing the experience requirements in subsection (C)(1)(c)(iv), continuing experience surveying two mammographic facilities and evaluating six mammographic units during the preceding two years;~~
~~vi. Have completed 15 hours of continuing medical education credits in mammography during the three preceding years;~~
~~vii. Have received at least eight hours of training specific to any modality surveyed; 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.~~**C.** Mammographic films and reports.
1. No change
2. No change

R12-1-615. ~~Repealed~~ Mammography Personnel

A. Personnel.
1. Each registrant shall require personnel who perform mammography, which includes the production, processing, and interpretation of mammograms and related quality assurance activities, to meet the following requirements:
   a. An interpreting physician shall meet federal requirements (Contained in 21 CFR 900.12(a)(1), revised April 1, 2013, incorporated by reference, and available under R12-1-101. This incorporated material 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 meet the requirements of the mammography quality standards act regulations for quality standards of interpreting physicians;
      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 in the preceding two years;
      v. Have completed 15 hours of continuing medical education credits in mammography during the preceding three years; and
      vi. Have received at least eight hours of training specific to each mammographic modality before engaging in independent interpretation.
   b. A mammographic technologist shall meet federal requirements (Contained in 21 CFR 900.12(a)(2), revised April 1, 2013, incorporated by reference, and available under R12-1-101. This incorporated material 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 technologist certificate;
      ii. Have performed at least 200 mammographic examinations in the preceding two years;
      iii. Have completed 15 hours of continuing medical education credits in mammography during the preceding three years; and
      iv. Have received at least eight hours of training specific to each mammographic modality to be used by the technologist in performing mammographic examinations.
   c. A radiologic physicist shall meet federal requirements (Contained in 21 CFR 900.12(a)(3), revised April 1, 2013, incorporated by reference and available under R12-1-101. This incorporated material 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 mammographic

facility survey and evaluating at least 10 mammographic units;

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

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

vii. Have received at least eight hours of training specific to any modality surveyed; and

2. Each registrant shall maintain records documenting the requirements in subsection (A)(1) for three years from the date the requirement is met and make the records available for Agency inspection.

B. Radiologic physicists shall apply for and renew their certification on agency approved forms. In addition to Agency supplied forms, applicants must also submit documentation showing education, mammography specific training, education, and board certification. Upon renewal, an applicant must submit documentation showing current continuing education requirements are met.