

NOTICE OF PROPOSED EXPEDITED RULEMAKING
TITLE 9. HEALTH SERVICES
CHAPTER 7. DEPARTMENT OF HEALTH SERVICES
RADIATION CONTROL

PREAMBLE

<u>1.</u>	<u>Article, Part, of Section Affected (as applicable)</u>	<u>Rulemaking Action</u>
	R9-7-102	Amend
	R9-7-433	Amend
	R9-7-443	Amend
	R9-7-445	Amend
	R9-7-448	Amend
	R9-7-454	Amend
	R9-7-523	Amend
	R9-7-611.01	Amend
	R9-7-702	Amend
	R9-7-710	Amend
	R9-7-711	Amend
	R9-7-712	Amend
	R9-7-723	Amend
	R9-7-727	Amend
	R9-7-744	Amend
	R9-7-745	Amend
	R9-7-746	Amend
	R9-7-904	Amend
	R9-7-1512	Amend
	R9-7-1723	Amend
	R9-7-1957	Amend
<u>2.</u>	<u>Citations to the agency’s statutory authority for the rulemaking to include the authorizing statute (general) and the implementing statute (specific):</u>	
	Authorizing Statutes: A.R.S. §§ 30-654(B)(5) and 36-136(G)	
	Implementing Statutes: A.R.S. §§ 30-654, 30-656, 30-657, 30-671 through 30-672.01, 30-681 through 30-689, and 30-721	

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 expedited rulemaking:

Notice of Rulemaking Docket Opening: 28 A.A.R. XXXX, August 26, 2022 (to be entered by *Register* editor)

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

Name: Brian D. Goretzki, Chief, Bureau of Radiation Control

Address: Arizona Department of Health Services

Public Health Licensing Services

4814 South 40th Street

Phoenix, AZ 85040

Telephone: (602) 255-4840

Fax: (602) 437-0705

E-mail: Brian.Goretzki@azdhs.gov

or

Name: Stephanie Elzenga, Interim Office Chief

Address: Arizona Department of Health Services

Office of Administrative Counsel and Rules

150 N. 18th Ave., Suite 200

Phoenix, AZ 85007

Telephone: (602) 542-1020

Fax: (602) 364-1150

E-mail: Stephanie.Elzenga@azdhs.gov

5. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, under A.R.S. § 41-1027, to include an explanation about the rulemaking:

Arizona Revised Statutes (A.R.S.) § 30-654(B)(5) requires the Arizona Department of Health Services (Department) to make rules deemed necessary to administer A.R.S. Title 30, Chapter 4, Control of Ionizing Radiation. The Department has adopted these rules in A.A.C. Title 9, Chapter 7. Arizona is an Agreement State by the Document negotiated between the U.S. Atomic Energy Commission (now U.S. Nuclear Regulatory Commission) and the Governor of Arizona in March of 1967 under A.R.S. § 30-656. In order to remain in compliance with the Agreement, Arizona must adopt regulations related to the control of radioactive material in a manner that is consistent with federal regulations. The U.S. Nuclear Regulatory Commission periodically issues changes, denoted as Regulation Toolbox: Review Summary Sheets for Regulation Amendments (RATS IDs), that are required to be incorporated by Agreement States. Several RATS IDs have not yet

been incorporated into Arizona's rules related to radioactive material. After receiving an exception from the rulemaking moratorium established by Executive Order 2022-01, the Department is revising the rules in A.A.C. Title 9, Chapter 7, by expedited rulemaking to make changes to conform to the RATS IDs 2020-1, 2020-2, 2020-3, 2021-1, 2021-2, and 2022-1, and make corresponding changes elsewhere in the rules. The Department believes that these changes are consistent with the purpose for A.R.S. § 41-1027 in that this rulemaking does not increase the cost of regulatory compliance, does not increase a fee, or reduce a procedural right of regulated persons, and either adopts or incorporates by reference, without material change, federal statutes and regulations, or clarifies language of a rule without changing its effect.

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:

The Department did not review or rely on any study for this rulemaking.

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:

Under A.R.S. § 41-1055(D)(2), the Department is not required to provide an economic, small business, and consumer impact statement.

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

Not applicable

10. Where, when, and how persons may provide written comment to the agency on the proposed expedited rule under A.R.S. § 41-1027(C):

Close of record: Monday, September 19, 2022, 4:00 p.m.

A person may submit written comments on the proposed expedited rules no later than the close of record to either of the individuals listed in item 4.

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:

According to A.R.S. Title 30, Chapter 2, Article 2, as amended by Laws 2017, Ch. 313, the Department is authorized to issue licenses and registrations for sources of ionizing radiation and those persons using these sources. This licensing and registration must be compatible with requirements in the Agreement. The rules refer to permits both general and specific. The general permit applies to certain levels of radioactive material, and specific permits are issued by rule for quantities and uses that are specific to the user and their training or scope of practice.

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 rules are not more stringent than federal law. Applicable federal law includes: 10 CFR 20.1906; 10 CFR 20.2201; 10 CFR 20.2202; 10 CFR 20.2207; 10 CFR 30.50; 10 CFR 34.47; 10 CFR 34.83; 10 CFR 35.50; 10 CFR 35.55; 10 CFR 35.57; 10 CFR 35.390; 10 CFR 35.490; 10 CFR 35.690; 10 CFR 35.3045; 10 CFR 35.3047; 10 CFR 37.27; 10 CFR 39.65; Appendix A to 10 CFR part 37; 10 CFR 71.4; 10 CFR 71.97.

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 such analysis was submitted.

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

- In R9-7-102: 21 CFR 1020.40, revised April 1, 2019, in the definition of “Certifiable cabinet x-ray system”; 21 CFR 1010.2 and 21 CFR 1020.40, revised April 1, 2019, in the definition of “Certified cabinet x-ray system”; 40 CFR 190, revised December 1, 1979, and 40 CFR 191, revised December 20, 1993, in the definition of “Generally applicable environmental radiation standards”; 49 CFR 173.403, revised January 8, 2015, in the definition of “Nuclear waste”; 10 CFR 35.50(a) or (c)(1) and 10 CFR 35.59, revised March 27, 2006, in the definition of “Radiation Safety Officer”; and 49 CFR 107, revised April 19, 2017; 49 CFR 171, revised April 19, 2017; 49 CFR 172, revised November 23, 2015; 49 CFR 173, revised March 6, 2019; 49 CFR 174, revised February 28, 2019; 49 CFR 175, revised October 18, 2018; 49 CFR 176, November 7, 2018; 49 CFR 177, revised September 25, 2013; 49 CFR 178, revised November 7, 2018; 49 CFR 179, revised September 25, 2018; and 49 CFR 180,

revised March 30, 2017, in the definition of “Regulations of the U.S Department of Transportation.”

- In R9-7-433: 10 CFR 71.4, January 1, 2005, in subsection (A); 49 CFR 172.403 and 172.436 through 172.440, October 1, 2004, in subsection (B)(1).
- In R9-7-454: 10 CFR 20.2207(a) through (e), revised August 9, 2021, and 10 CFR 20.2207(f), revised January 1, 2008, in subsection (A); 10 CFR 20.2207(f), revised August 9, 2021, in subsection (B); 10 CFR 20.2207(g), revised August 9, 2021, in subsection (C).
- In R9-7-702: 21 CFR 310.3(c) and 21 CFR 600.3, revised April 1, 2006, in the definition of “Radioactive drug;” 21 CFR 361.1, revised April 1, 2006, in the definition of “Radioactive Drug Research Committee” (RDRC).
- In R9-7-723: 10 CFR 35.392, revised January 1, 2013, in subsection (B); 10 CFR 35.394, revised January 1, 2013, in subsection (C); 10 CFR 35.396, revised January 1, 2013, in subsection (D).
- In R9-7-904: Radiation Oncology in Integrated Cancer Management, Report of the Inter-Society Council for Radiation Oncology, December 1991, in subsection (G).
- In R9-7-1512: 10 CFR 71.97, revised January 1, 2015, in subsection (A)
- In R9-7-1927: 10 CFR 73, revised December 12, 2018, in subsection(A)(4); and 10 CFR 37.7, revised November 29, 2019, in subsection (C)(1).
- In R9-7-1957: 10 CFR part 73, revised December 12, 2018, in subsection (A)(4); 10 CFR 37.7, revised November 29, 2019, in subsection (C)(1).

13. The full text of the rule follows:

TITLE 9. HEALTH SERVICES

CHAPTER 7. DEPARTMENT OF HEALTH SERVICES - RADIATION CONTROL

ARTICLE 1. GENERAL PROVISIONS

Section

R9-7-102. Definitions

ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

Section

R9-7-433. Procedures for Receiving and Opening Packages

R9-7-443. Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation

R9-7-445. Notification of Incidents

R9-7-448. Additional Reporting

R9-7-454. Nationally Tracked Sources

ARTICLE 5. SEALED SOURCE INDUSTRIAL RADIOGRAPHY

Section

R9-7-523. Personnel Monitoring

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

Section

R9-7-611.01. Electronic Brachytherapy to Deliver Interstitial and Intracavitary Therapeutic Radiation Dosage

ARTICLE 7. MEDICAL USES OF RADIOACTIVE MATERIAL

Section

R9-7-702. Definitions

R9-7-710. Radiation Safety Officer and Associate Radiation Safety Officer Training

R9-7-711. Authorized Medical Physicist Training

R9-7-712. Authorized Nuclear Pharmacist Training

R9-7-723. Training for Use of Unsealed Radioactive Material Requiring a Written Directive, Including Treatment of Hyperthyroidism, and Treatment of Thyroid Carcinoma

R9-7-727. Training for Use of Manual Brachytherapy Sources and Training for the Use of Strontium-90 Sources for Treatment of Ophthalmic Disease

R9-7-744. Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

R9-7-745. Report and Notification of a Medical Event

R9-7-746. Report and Notification of a Dose to an Embryo, Fetus, or Nursing Child

ARTICLE 9. PARTICLE ACCELERATORS

Section

R9-7-904. Registration of Particle Accelerators Used in the Practice of Medicine

ARTICLE 15. TRANSPORTATION

Section

R9-7-1512. Advance Notification of Shipment of Irradiated Reactor Fuel and Nuclear Waste

ARTICLE 17. WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

Section

R9-7-1723. Personnel Monitoring

**ARTICLE 19. PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2
QUANTITIES OF RADIOACTIVE MATERIAL**

Section

R9-7-1957. Reporting of Events

ARTICLE 1. GENERAL PROVISIONS

R9-7-102. Definitions

Terms defined in A.R.S. § 30-651 have the same meanings when used in this Chapter, unless the context otherwise requires. Additional subject-specific definitions are used in other Articles.

“A1” means the maximum activity of special form radioactive material permitted in a type A package. These values are either listed in 10 CFR 71, Appendix A, Table A-1, or may be derived in accordance with the procedures prescribed in 10 CFR 71, Appendix A.

“A2” means the maximum activity of radioactive material, other than special form radioactive material, low specific activity (LSA) material, and surface contaminated object (SCO) material, permitted in a Type A package. These values are either listed in 10 CFR 71, Appendix A, Table A-1, or may be derived in accordance with the procedure prescribed in 10 CFR 71, Appendix A.

“Absorbed dose” means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

“Accelerator” means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV. For purposes of this definition, “particle accelerator” is an equivalent term.

“Accelerator produced material” means any material made radioactive by irradiating it in a particle accelerator.

“Act” means A.R.S. Title 30, Chapter 4.

“Activity” means the rate of disintegration, transformation, or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

“Adult” means an individual 18 or more years of age.

“Agreement State” means any state with which the United States Nuclear Regulatory Commission has entered into an effective agreement under Section 274(b) of the Atomic Energy Act of 1954, as amended (73 Stat. 689). “Nonagreement State” means any other state.

“Airborne radioactive material” means any radioactive material dispersed in the air in the form of aerosols, dusts, fumes, mists, vapors, or gases.

“Airborne radioactivity area” means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed radioactive material, exist in concentrations:

In excess of the derived air concentrations (DACs) specified in Appendix B, Table I of Article 4 of these rules; or

That an individual present in the area without respiratory protective equipment could

exceed, during the hours an individual is pre-sent in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

“ALARA” means as low as is reasonably achievable, making every reasonable effort to maintain exposures to radiation as far below the dose limits in these rules as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

“Analytical x-ray equipment” means equipment used for x-ray diffraction or x-ray-induced fluorescence analysis.

“Analytical x-ray system” means a group of components utilizing x-rays to determine the elemental composition or to examine the micro-structure of materials.

“Annual” means done or performed yearly. For purposes of Chapter 1, any required activity done or performed within plus or minus two weeks of the annual due date is considered done or performed in a timely manner.

“Approved individual” means an individual whom the licensee has determined to be trustworthy and reliable for unescorted access in accordance with subpart B of this part and who has completed the training required by 10 CFR 37.43(c).

“Associate Radiation Safety Officer” means an individual who:

Meets the requirements in 10 CFR 35.50 and 10 CFR 35.59; and

Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on:

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

A medical use permit issued by a ~~Commission~~ NRC master material licensee.

“Authorized medical physicist” means an individual who meets the requirements in R9-7-711; or is identified as an authorized medical physicist or teletherapy physicist on:

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

A medical use permit issued by a NRC master material licensee;

A permit issued by the Department, the NRC, or another Agreement State broad scope medical use licensee; or

A permit issued by a NRC master material license broad scope medical use permittee.
“Authorized nuclear pharmacist” means a pharmacist who meets the requirements in R9-7-712;
or is:

Identified as an authorized nuclear pharmacist on a specific license issued by the Department, the NRC, or another Agreement State that authorizes medical use or the practice of nuclear pharmacy;

Identified as an authorized nuclear pharmacist on a permit issued by a NRC master material licensee that authorizes medical use or the practice of nuclear pharmacy;

Identified as an authorized nuclear pharmacist on a permit issued by the Department, the NRC, or another Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

Identified as an authorized nuclear pharmacist on a permit issued by a NRC master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

Identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

Designated as an authorized nuclear pharmacist in accordance with R9-7-311(G).

“Authorized user” means a physician, dentist, or podiatrist who meets the requirements in R9-7-719, R9-7-723, R9-7-727, R9-7-728, or R9-7-744; or is identified as an authorized user on:
The Department, NRC, or another Agreement State license that authorizes the medical use of radioactive material;

A permit issued by a NRC master material licensee that is authorized to permit the medical use of radioactive material;

A permit issued by the Department, the NRC, or another Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

A permit issued by a NRC master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

“Background investigation” means an assessment of an individual’s prior actions and experience conducted by a licensee or applicant, to support the determination of the individual’s trustworthiness and reliability in accordance with 10 CFR 37.25.

“Background radiation” means radiation from cosmic sources; not technologically enhanced naturally occurring radioactive material, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of

nuclear explosive devices or from past nuclear accidents, such as Chernobyl, that contribute to background radiation and are not under the control of a licensee. "Background radiation" does not include sources of radiation regulated by the Department.

"Becquerel" (Bq) means the International System (SI) unit for activity and is equal to 1 disintegration per second (dps or tps).

"Bioassay" means the determination of kinds, quantities, or concentrations, and in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these rules, "radiobioassay" is an equivalent term.

"Brachytherapy" means a method of radiation therapy in which an encapsulated source or group of sources is utilized to deliver beta or gamma radiation at a distance of up to a few centimeters, by surface, intracavitary or interstitial application.

"Byproduct material" means:

Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material;

The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

Any discrete source of radium-226 that is produced, extracted, or converted after extraction, for use for a commercial, medical, or research activity; or any material that, has been made radioactive by use of a particle accelerator; and is produced, extracted, or converted after extraction, for use for a commercial, medical, or research activity; and

Any discrete source of naturally occurring radioactive material, other than source material, that the NRC, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security and; before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

"Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar

quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. A licensee or registrant shall not change the method of determining calendar quarters for purposes of this Chapter except at the beginning of a calendar year.

“Calibration” means the determination of:

The response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or

The strength of a source of radiation relative to a standard.

“Carrier” means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

“Certifiable cabinet x-ray system” means an existing uncertified x-ray system that meets or has been modified to meet the certification requirements specified in 21 CFR 1020.40, revised April 1, 2019, incorporated by reference, and available under R9-7-101. This incorporated material contains no future editions or amendments.

“Certificate holder” means a person who has been issued a certificate of compliance or other package approval by the Department or NRC.

“Certificate of Compliance” (CoC) means the certificate issued by the NRC under 10 CFR 71, Subpart D, which authorizes the design of a package for the transportation of radioactive material.

“Certified cabinet x-ray system” means an x-ray system that has been certified in accordance with 21 CFR 1010.2, as being manufactured and assembled on or after April 10, 1975, in accordance with the provisions of 21 CFR 1020.40, both sections revised April 1, 2019, incorporated by reference, and available under R9-7-101. This incorporated material contains no future editions or amendments.

“CFR” means Code of Federal Regulations.

“Chelating agent” means amine polycarboxylic acids, hydroxycarboxylic acids, gluconic acid, and polycarboxylic acids.

“Civil penalty” means the monetary fine which may be imposed on licensees by the Department, pursuant to A.R.S. § 30-687, for violations of the Act, this Chapter, or license conditions.

“Collective dose” means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

“Committed dose equivalent” (HT,50) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

“Committed effective dose equivalent” (HE,50) is the sum of the products of the weighting

factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($HE,50 = S wT,HT,50$).

“Consortium” means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a federal facility or a medical facility.

“Contamination” means the presence of a radioactive substance on a surface in quantities in excess of 0.4 Bq/cm² (1×10^{-5} μ Ci/cm²) for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm² (1×10^{-6} μ Ci/cm²) for all other alpha emitters.

“Fixed contamination” means contamination that cannot be removed from a surface during normal conditions of transport.

“Non-fixed contamination” means contamination that can be removed from a surface during normal conditions of transport.

“Criticality Safety Index (CSI)” means the dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages, overpacks or freight containers containing fissile material during transportation. Determination of the criticality safety index is described in 10 CFR 71.22, 10 CFR 71.23, and 10 CFR 71.59. The criticality safety index for an overpack, freight container, consignment or conveyance containing fissile material packages is the arithmetic sum of the criticality safety indices of all the fissile material packages contained within the overpack, freight container, consignment or conveyance.

“Curie” means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of $3.7E + 10^{10}$ transformations per second (tps).

“Current license or registration” means a license or registration issued by the Department and for which the licensee has paid the license or registration fee for the current year according to R9-7-1304.

“Deep-dose equivalent” (Hd), which applies to external whole body exposure, is the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm²).

“Depleted uranium” means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

“Discrete source” means a radionuclide that has been processed so that its concentration within a

material has been purposely increased for use for commercial, medical, or research activities. “Dose” is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these rules, “radiation dose” is an equivalent term. “Dose equivalent” (HT) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

“Dose limits” means the permissible upper bound of radiation doses established in accordance with these rules. For purposes of these rules, “limits” is an equivalent term.

“Dosimeter” (See “Individual monitoring device”)

“Effective dose equivalent” (HE) means the sum of the products of the dose equivalent to each organ or tissue (HT) and the weighting factor (wT) applicable to each of the body organs or tissues that are irradiated ($HE = \sum S wT$).

“Effluent release” means any disposal or release of radioactive material into the ambient atmosphere, soil, or any surface or subsurface body of water.

“Embryo/fetus” means the developing human organism from conception until the time of birth.

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

“Enclosed radiography” means industrial radiography conducted by using cabinet radiography or shielded room radiography.

“Cabinet radiography” means industrial radiography conducted by using an x-ray machine in an enclosure not designed for human admittance and which is so shielded that every location on the exterior meets the conditions for an “unrestricted area.”

“Shielded room radiography” means industrial radiography conducted using an x-ray machine in an enclosure designed for human admittance and which is so shielded that every location of the exterior meets the conditions for an “unrestricted area.”

“Entrance or access point” means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

“Exhibit” for purposes of these rules, is equivalent in meaning to the word “Schedule” as found in previously issued rules, current license conditions, and regulation guide.

“Explosive material” means any chemical compound, mixture, or device which produces a

substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

“Exposure” means:

Being subjected to ionizing radiation or radioactive materials.

The quotient of dQ by dm where “ dQ ” is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass “ dm ” are completely stopped in air. The special unit of exposure is the roentgen (R).

“Exposure rate” means the exposure per unit of time.

“External dose” means that portion of the dose equivalent received from any source of radiation outside the body.

“Extremity” means the hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

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

“FDA” means the United States Food and Drug Administration.

“Field radiography” means industrial radiography, utilizing a portable or mobile x-ray system, which is not conducted in a shielded enclosure.

“Field station” means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary job sites.

“Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities” means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

“Generally applicable environmental radiation standards” means standards issued by the U.S. Environmental Protection Agency (EPA), 40 CFR 190, revised December 1, 1979, and 40 CFR 191, revised December 20, 1993, incorporated by reference, and available under R9-7-101, under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material. This incorporated material contains no future editions or amendments.

“Gray” (Gy) means the International System (SI) unit of absorbed dose and is equal to 1 joule per kilogram. One gray equals 100 rad.

“Hazardous waste” means those wastes designated as hazardous in A.R.S. § 49-921(5).

“Healing arts” means the practice of medicine, dentistry, osteopathy, podiatry, chiropractic, and veterinary medicine.

“Health care institution” means every place, institution, or building which provides facilities for medical services or other health-related services, not including private clinics or offices which do not provide overnight patient care.

“High radiation area” means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in one hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

“Human use” means the internal or external administration of radiation or radioactive materials to human beings.

“Impound” means to abate a radiological hazard. Actions which may be taken by the Department in impounding a source of radiation include seizing the source of radiation, controlling access to an area, and preventing a radiation machine from being utilized.

“Indian Tribe” means an Indian or Alaska native Tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a.

“Individual” means any human being.

“Individual monitoring” means the assessment of:

Dose equivalent

By the use of individual monitoring devices, or

By the use of survey data, or

Committed effective dose equivalent

By bioassay; or

By determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. (See the definition of DAC-hours in Article 4).

“Individual monitoring device” means a device designed to be worn by a single individual for the assessment of dose equivalent. For purposes of this Chapter, “dosimeter” and “personnel dosimeter,” are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, optical stimulation devices, and ~~personal~~ personnel (“lapel”) air sampling devices.

“Individual monitoring equipment” means one or more individual monitoring devices. For purposes of this Chapter, “personnel monitoring equipment” is an equivalent term.

“Industrial radiography” means the examination of the macroscopic structure of materials by non-destructive methods utilizing sources of ionizing radiation.

“Injection tool” means a device used for controlled subsurface injection of radioactive tracer material.

“Inspection” means an examination or observation by a representative of the Department, including but not limited to tests, surveys, and monitoring to determine compliance with rules, orders, requirements and conditions of the License or certificate of registration.

“Interlock” means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

“Internal dose” means that portion of the dose equivalent received from radioactive material taken into the body.

“Irradiate” means to expose to radiation.

“Laser” (light amplification by the stimulated emission of radiation) means any device which can produce or amplify electromagnetic radiation with wavelengths in the range of 180 nanometers to 1 millimeter primarily by the process of controlled stimulated emission.

“Lens dose equivalent” (LDE) means the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeters (300 mg/cm²).

“License” means the grant of authority, issued pursuant to Articles 3 and 14 of this Chapter and A.R.S. §§ 30-671, 30-672, and 30-721 et seq., to acquire, possess, transfer, and use sources of radiation. The types of licenses issued by the Department are described in R9-7-1302.

“Licensed material” means radioactive material received, possessed, used, transferred, or disposed of under a general or specific license issued by the Department.

“Licensed practitioner” means a person licensed or otherwise authorized by law to practice medicine, dentistry, osteopathy, chiropractic, podiatry, or naturopathy in this state.

“Licensee” means any person who is licensed by the Department under this Chapter to acquire, possess, transfer, or use sources of radiation.

“Licensing State” means any state having regulations equivalent to this Chapter relating to, and an effective program for the regulation of, naturally occurring and accelerator-produced radioactive material (NARM).

“Limits” (See “Dose limits”)

“Local components” means those parts of an analytical x-ray system that are struck by x-rays, including radiation source housings, port and shutter assemblies, collimator, sample holders, cameras, goniometer, detectors and shielding but not including power supplies, trans-formers, amplifiers, readout devices, and control panels.

“Logging supervisor” means the individual who provides personal supervision of the utilization of sources of radiation at the well site.

“Logging tool” means a device used subsurface to perform well logging.

“Lost or missing licensed or registered source of radiation” means licensed or registered source of radiation the location of which is un-known. Included are licensed radioactive material or a registered radiation source that has been shipped but has not reached its planned destination and whose location cannot be readily traced or ascertained in the transportation system.

“Low-level waste” means waste material which contains radioactive nuclides in concentrations or quantities which exceed applicable standards for unrestricted release but does not include:

High-level waste, such as irradiated reactor fuel, liquid waste from reprocessing

irradiated reactor fuel, or solids into which any such liquid waste has been converted;

Waste material containing transuranic elements with contamination levels greater than 10 nanocuries per gram (370 kilobecquerels per kilogram) of waste material; or

The tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content.

“Low Specific Activity (LSA) material” means radioactive material with limited specific activity which is nonfissile or is excepted under 10 CFR 71.15, and which satisfies the descriptions and limits set forth in the following section. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents.

The LSA material must be in one of three groups:

LSA—I.

Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides that are intended to be processed for the use of these radionuclides;

Natural uranium, depleted uranium, natural thorium or their compounds or mixtures, provided they are unirradiated and in solid or liquid form;

Radioactive material other than fissile material, for which the A2 value is unlimited; or

Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with appendix A.

LSA—II.

Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or

Other radioactive material in which the activity is distributed throughout and the

estimated average specific activity does not exceed 10^{-4} A2/g for solids and gases, and 10^{-5} A2/g for liquids.

LSA—III. Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of 10 CFR 71.77, in which:

The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.);

The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that even under loss of packaging, the loss of radioactive material per package by leaching, when placed in water for 7 days will not exceed 0.1 A2; and

The estimated average specific activity of the solid, excluding any shielding material, does not exceed 2×10^{-3} A2/g.

“Major processor” means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material or exceeding four times Type B quantities as sealed sources but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in 10 CFR 71.4.

“Medical dose” means a radiation dose intentionally delivered to an individual for medical examination, diagnosis, or treatment.

“Member of the public” means any individual except when that individual is receiving an occupational dose.

“MeV” means Mega Electron Volt which equals 1 million volts (106 eV).

“Mineral logging” means any well logging performed in a borehole drilled for the purpose of exploration for minerals other than oil or gas.

“Minor” means an individual less than 18 years of age.

“Monitoring” means the measurement of radiation, radioactive material concentrations, surface area activities, or quantities of radioactive material, and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, “radiation monitoring” and “radiation protection monitoring” are equivalent terms.

“Multiplier” means a letter representing a number. The use of a multiplier is based on the code given below:

Prefix	Multiplier Symbol	Value
eka	E	10^{18}

peta	P	10^{15}
tera	T	10^{12}
giga	G	10^9
mega	M	10^6
kilo	k	10^3
milli	m	10^{-3}
micro	u	10^{-6}
nano	n	10^{-9}
pico	p	10^{-12}
femto	f	10^{-15}
atto	a	10^{-18}

“NARM” means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material. This term should not be confused with “NORM” which is defined as naturally occurring radioactive material.

“Natural radioactivity” means the radioactivity of naturally occurring radioactive substances.

“Normal operating procedures” means the entire set of instructions necessary to accomplish the intended use of the source of radiation. These procedures shall include, but are not limited to, sample insertion and manipulation, equipment alignment, routine maintenance by the licensee, and data recording procedures which are related to radiation safety.

“NRC” means Nuclear Regulatory Commission, the U.S. Nuclear Regulatory Commission, or its duly authorized representatives.

“NRC Document Control Desk” means the Nuclear Regulatory Document Control Desk. ATTN: Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

“Nuclear waste” means any highway route controlled quantity (defined in 49 CFR 173.403, revised January 8, 2015, incorporated by reference, available under R9-7-101, and containing no future editions or amendments) of source, byproduct, or special nuclear material required to be in NRC-approved packaging while transported to, through, or across state boundaries to a disposal site, or to a collection point for transport to a disposal site. Additional requirements associated with transportation of radioactive material can be found in Article 15.

“Occupational dose” means the dose received by an individual in the course of employment in which the individual’s assigned duties involve exposure to sources of radiation, whether in the possession of a licensee, registrant, or other person. Occupational dose does not include a dose received from background radiation, medical administration of radiation to the individual, exposure to an individual who has been administered radioactive material and released in

accordance with R9-7-717, voluntary participation in a medical research program, or as a member of the public.

“Open beam system” means an analytical x-ray system in which an individual could place some body part in the primary beam path during normal operation.

“Ophthalmic physicist” means an individual who:

Meets the requirements in 10 CFR 35.433(a)(2) and 10 CFR 35.59; and

Is identified as an ophthalmic physicist on a:

Specific medical use license issued by the Department, the NRC, or another Agreement State;

Permit issued by a Department, NRC, or another Agreement State broad scope medical use licensee;

Medical use permit issued by a NRC master material licensee; or

Permit issued by a NRC master material ~~licensee~~ licensee broad scope medical use permittee.

“Package” means the packaging together with its radioactive contents as presented for transport.

“Particle accelerator” (See “Accelerator”)

“Permanent radiographic installation” means a fixed, shielded installation or structure designed or intended for industrial radiography and in which industrial radiography is regularly performed.

“Personnel dosimeter” (See “Individual monitoring device”)

“Personnel monitoring equipment” (See “Individual monitoring device”)

“Personal supervision” means supervision in which the supervising individual is physically present at the site where sources of radiation and associated equipment are being used, watching the performance of the supervised individual and in such proximity that immediate assistance can be given if required.

“PET” (See Positron Emission Tomography (PET))

“Pharmacist” means an individual licensed by this state to compound and dispense drugs, prescriptions, and poisons.

“Physician” means an individual licensed pursuant to A.R.S. Title 32, Chapters 13 or 17.

“Positron Emission Tomography (PET)” means an imaging technique using radionuclides to produce high resolution images of the body’s biological functions.

“Positron Emission Tomography radionuclide production facility” means a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

“Preceptor” means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an

authorized nuclear pharmacist, a Radiation Safety Officer, or an Associate Radiation Safety Officer.

“Primary beam” means radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radio-active source located in the radiation source housing.

“Promptly” means with little or no delay.

“Public dose” means the dose received by a member of the public from radiation from radioactive material released by a licensee or registrant, or exposure to a source of radiation used in a licensed or registered operation. It does not include an occupational dose or a dose received from background radiation, medical administration of radiation to the individual, exposure to an individual who has been administered radioactive material and released in accordance with R9-7-717, or voluntary participation in a medical research program.

“Pyrophoric liquid” means any liquid that ignites spontaneously in dry or moist air at or below 130° F (54.4° C).

“Pyrophoric solid” means any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently that it creates a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

“Qualified expert” means an individual certified in the appropriate field by the American Board of Radiology or the American Board of Health Physics, or having equivalent qualifications that provide the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs; or an individual certified in Therapeutic Radiological Physics or X-ray and Radium Physics by the American Board of Radiology, or having equivalent qualifications that provide training and experience in the clinical applications of radiation physics to radiation therapy, to calibrate radiation therapy equipment. The detailed requirements for a particular qualified expert may be provided in the respective Articles of this Chapter. For clarification purposes, a qualified expert is not always an authorized medical physicist; however, an authorized medical physicist is included within the definition of “qualified expert.”

“Quality Factor” (Q) means the modifying factor, listed in Tables I and II of this Article, that is used to derive dose equivalent from absorbed dose.

“Quarter” (See “Calendar quarter”)

“Rad” means the special unit of absorbed dose. One rad equals 100 ergs per gram, or 0.01 gray.

“Radiation” means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed

electrons, high-speed protons, and other particles capable of producing ions. For purposes of these rules, this term is synonymous with ionizing radiation. Equivalent terminology for non-ionizing radiation is defined in Article 14.

“Radiation area” means any area accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

“Radiation dose” (See “Dose”)

“Radiation machine” means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.

“Radiation Safety Officer” (RSO) means the individual who:

For license conditions:

Meets the requirements in 10 CFR 35.50(a) or (c)(1), revised July 16, 2018, and 10 CFR 35.59, revised March 27, 2006, incorporated by reference, available under R9-7-10, and containing no future editions or amendments; or

Is identified as a Radiation Safety Officer on a specific medical use license issued by the Department, the NRC or another Agreement State; or a medical use permit issued by a NRC master material licensee; or

For registration conditions, is designated by the registrant as the individual who has the knowledge, authority, and responsibility to apply appropriate radiation protection principles to ensure radiation safety and compliance with the Act, this Chapter, and any registration conditions.

“Radiation Safety Officer” (RSO) means the individual who:

For license conditions:

Meets the requirements of R9-7-407, and for a medical license meets the training requirements of R9-7-710; or

Is identified as a Radiation Safety Officer on a specific medical use license issued by the Department, the NRC, or another Agreement State; or a medical use permit issued by a NRC master material licensee; or

Meets the requirements in R9-7-512 on a specific industrial license issued by the Department, the NRC, or another Agreement State; or an industrial use permit issued by a NRC master material licensee; or

For registration conditions, is designated by the registrant as the individual who has the knowledge, authority, and responsibility to apply appropriate radiation protection principles to ensure radiation safety and compliance with the Act, this Chapter and any

registration conditions.

“Radioactive marker” means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

“Radioactive material” means any solid, liquid, or gas which emits radiation spontaneously.

“Radioactivity” means emission of electromagnetic energy or particles or both during the transformation of unstable atomic nuclei.

“Radiographer” means any individual who performs or personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of this Chapter and all conditions of the license or certificate of registration.

“Radiographer’s assistant” means any individual who, under the personal supervision of a radiographer, uses sources of radiation, radio-graphic exposure devices, related handling tools, or survey instruments in industrial radiography.

“Registrant” means any person who is registered with the Department and is legally obligated to register with the Department pursuant to these rules and the Act.

“Registration” is the process by which a person becomes a registrant pursuant to Article 2 or 14 of this Chapter. With the exception of registration of persons who install or service radiation machines, the types of registrations issued by the Department are described in R9-7-1302.

“Regulations of the U.S. Department of Transportation” means the federal regulations in 49 CFR 107, revised April 19, 2017; 49 CFR 171, revised April 19, 2017; 49 CFR 172, revised November 23, 2015; 49 CFR 173, revised March 6, 2019; 49 CFR 174, revised February 28, 2019; 49 CFR 175, revised October 18, 2018; 49 CFR 176, November 7, 2018; 49 CFR 177, revised September 25, 2013; 49 CFR 178, revised November 7, 2018; 49 CFR 179, revised September 25, 2018; and 49 CFR 180, revised March 30, 2017, incorporated by reference, available under R9-7-101, and containing no future editions or amendments.

“Rem” means the special unit of dose equivalent (see “Dose equivalent”). The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem - 0.01 sievert).

“Research and Development” means exploration, experimentation, or the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and Development does not include the internal or external administration of radiation or radioactive material to human beings.

“Restricted area” means any area where the licensee or registrant controls access for purposes of

protecting individuals from exposure to radiation and radioactive material. A restricted area does not include any areas used for residential quarters, although a room or separate rooms in a residential building may be set apart as a restricted area.

“Roentgen” (R) means the special unit of exposure and is equal to the quantity of x or gamma radiation which causes ionization in air equal to 258 microcoulomb per kilogram (see “Exposure”).

“Safety system” means any device, program, or administrative control designed to ensure radiation safety.

“Sealed source” means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

“Sealed Source and Device Registry” means the national registry that contains all the registration certificates, generated by both the NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for each source or device.

“Shallow dose equivalent” (HS), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm²).

“Shielded position” means the location within a radiographic exposure device or storage container which, by manufacturer’s design, is the proper location for storage of the sealed source.

“Sievert” means the SI unit of dose equivalent (see “Dose equivalent”). The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

“Site boundary” means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

“Source changer” means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those also used for transporting and storage of sealed sources.

“Source holder” means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.

“Source material” means:

Uranium or thorium, or any combination of uranium or thorium, in any physical or chemical form; or

Ores that contain by weight 1/20 of 1 percent (0.05 percent) or more of uranium, thorium, or any combination of uranium and thorium.

Source material does not include special nuclear material.

“Source material milling” means any activity that results in the production of byproduct material as defined by the second subsection under the definition of “Byproduct material.”

“Source of radiation” or “source” means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

“Special form radioactive material” means radioactive material that satisfies all of the following conditions:

It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

The piece or capsule has at least one dimension not less than 5 millimeters (0.2 inch); and
It satisfies the test requirements specified in 10 CFR 71.75. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation designed in accordance with the requirements of 10 CFR 71.4 in effect on March 31, 1996 (see 10 CFR part 71, revised as of January 1, 1996), and constructed before April 1, 1998; and special form material that was successfully tested before September 10, 2015 in accordance with the requirements of 10 CFR 71.75(d) in effect before September 10, 2015 may continue to be used. Any other special form encapsulation must meet the specifications of this definition.

“Special nuclear material in quantities not sufficient to form a critical mass” means Uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; Uranium-233 in quantities not exceeding 200 grams; Plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: for each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed one. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{X \text{ gms } U235}{350} + \frac{Y \text{ gms } U233}{200} + \frac{Z \text{ gms } Pu}{200} \leq 1$$

“Storage area” means any location, facility, or vehicle which is used to store, transport, or secure a radiographic exposure device, storage container, sealed source, or other source of radiation when it is not in use.

“Storage container” means a device in which sealed sources are transported or stored.

“Subsurface tracer study” means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.

“Survey” means an evaluation of the production, use, release, disposal, or presence of sources of radiation or any combination thereof under a specific set of conditions to determine actual or potential radiation hazards. Such evaluations include, but are not limited to, tests, physical examination and measurements of levels of radiation or concentration of radioactive material present.

“TEDE” (See “Total Effective Dose Equivalent”)

“Teletherapy” means therapeutic irradiation in which the source of radiation is at a distance from the body.

“Temporary job site” means any location where sources of radiation are used other than the specified locations listed on a license document. Storage of sources of radiation at a temporary jobsite shall not exceed six months unless the Department has granted an amendment authorizing storage at that jobsite.

“Test” means the process of verifying compliance with an applicable rule, order, or license condition.

“These rules” means all Articles of 9 A.A.C. 7.

“Total Effective Dose Equivalent” (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

“Total Organ Dose Equivalent” (TODE) means the sum of the deep-dose equivalent and the committed dose equivalent to the organ receiving the highest dose. Determination of TODE is described in R9-7-411.

“Tribal official” means the highest ranking individual that represents Tribal leadership, such as the Chief, President, or Tribal Council leadership.

“Unrefined and unprocessed ore” means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or re-finishing. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

“Unrestricted area” means any area access to which is not controlled by the licensee for purposes of protection of individuals from expo-sure to radiation and radioactive material. Any area used for residential quarters is an unrestricted area.

“Uranium - natural, depleted, enriched.”

Natural uranium means uranium (which may be chemically separated) with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-

235, and the remainder by weight essentially uranium-238).

Depleted uranium means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

Enriched uranium means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

“U.S. Department of Energy” means the Department of Energy established by P.L. 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department of Energy exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers, and components; and transferred to the U.S. Energy Research and Development Administration and to the administrator of that agency under sections 104(b), (c), and (d) of the Energy Reorganization Act of 1974 (P.L. 93-438, October 11, 1974, 88 Stat. 1233 at 1237, 42 U.S.C. 5814, effective January 19, 1975) and retransferred to the Secretary of Energy under Section 301(a) of the Department of Energy Organization Act (P.L. 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977).

“Very high radiation area” means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose that exceeds 5 grays (500 rads) in one hour at one meter from a radiation source or one meter from any surface that the radiation penetrates.

“Waste” (See “Low-level waste”)

“Waste handling licensees” means persons licensed to receive and store radioactive wastes prior to disposal and persons licensed to dispose of radioactive waste.

“Week” means seven consecutive days starting on Sunday.

“Well-bore” means a drilled hole in which wireline service operations and subsurface tracer studies are performed.

“Well-logging” means the lowering and raising of measuring devices or tools which may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well and adjacent formations.

“Whole body” means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

“Wireline” means an armored cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.

“Wireline service operation” means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.

“Worker” means any individual engaged in work under a license or registration issued by the

Department and controlled by employment or contract with a licensee or registrant.

“WL” means working level, any combination of short-lived radon daughters in 1 liter of air that will result in the ultimate emission of $1.3E + 5$ MeV of potential alpha particle energy. The short-lived radon daughters are – for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

“WLM” means working level month, an exposure to one working level for 170 hours (2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month).

“Workload” means the degree of use of an x-ray or gamma-ray source per unit time.

“Year” means the period of time beginning in January used to determine compliance with the provisions of these rules. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

R9-7-433. Procedures for Receiving and Opening Packages

- A.** Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in 10 CFR 71.4, January 1, 2005, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Department. The material incorporated by reference contains no future editions or amendments. The licensee shall make arrangements to receive:
1. The package when the carrier offers it for delivery; or
 2. The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.
- B.** Each licensee shall:
1. Monitor the external surfaces of a package, labeled with a Radioactive White I, Yellow II, or Yellow III as specified in 49 CFR 172.403 and 172.436 through 172.440, October 1, 2004, which are incorporated by reference, published by the Office of Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Department. The material incorporated by reference contains no future editions or amendments. The licensee shall test the package for radioactive contamination, unless the package contains only radioactive material in the form of gas or in special form, as defined in R9-7-102; and
 2. Monitor the external surfaces of a package, labeled with a Radioactive White I, Yellow II, or Yellow III as specified in subsection (B)(1), for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, defined in 10 CFR 71, and referenced in subsection (A); and
 3. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.
- C.** The licensee shall perform the monitoring required by subsection (B) as soon as practical after receipt of the package, but not later than three hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.
- D.** The licensee shall immediately notify by telephone the final delivery carrier and the Department by telephone at 480-202-4982:

1. ~~when~~ When:
 - ~~1-a.~~ Removable radioactive surface contamination exceeds 22 dpm/cm² for beta-gamma emitting radionuclides or 2.2 dpm/cm² for alpha-emitting radionuclides, wiping a minimum surface area of 300 square centimeters (46 square inches), or the entire surface if less than 300 square centimeters (46 square inches); or
 - ~~2-b.~~ External radiation levels exceed the limits of 2 millisieverts (200 millirem) per hour; and
2. Include in the notification the following information:
 - a. The caller's name, official title, and call back telephone number;
 - b. The date and time of monitoring;
 - c. A description of how the limits in subsection (D)(1) were exceeded, including the amount of radiation detected;
 - d. The isotopes, quantities, and chemical and physical form of the licensed material in the package; and
 - e. Any personnel radiation exposure data available.

E. Each licensee shall:

1. Establish, maintain, and retain written procedures for safely opening packages that contain radioactive material, and
2. Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

F. Licensees transferring special form sources in vehicles owned or operated by the licensee to and from a work site are exempt from the contamination monitoring requirements of subsection (B) but are not exempt from the monitoring requirement in subsection (B) for measuring radiation levels that ensures that the source of radiation is still properly lodged in its shield.

R9-7-443. Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation

A. Each licensee or registrant shall report to the Department by telephone, as specified in R9-7-448(C), as follows:

1. Immediately after it becomes known to the licensee that licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C is stolen, lost, or missing under circumstances that indicate to the licensee that an exposure could result to individuals in unrestricted areas;
2. Within 30 days after it becomes known to the licensee that licensed radioactive material in an aggregate quantity greater than 10 times the quantity specified in Appendix C is

- stolen, lost, or missing, and is still missing; and
3. Immediately after it becomes known to the registrant that a radiation machine is stolen, lost, or missing.
- B.** Each licensee or registrant required to make a report according to subsection (A) shall, within 30 days after making the telephone report, make a written report to the Department that contains the following information:
1. A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model, serial number, type, and maximum energy of radiation emitted;
 2. A description of the circumstances under which the loss or theft occurred;
 3. A statement of disposition, or probable disposition, of the licensed or registered source of radiation;
 4. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;
 5. Actions that have been taken, or will be taken, to recover the source of radiation; and
 6. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.
- C.** After filing the written report required in subsection (B), the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of the information.
- D.** The licensee or registrant shall provide the Department with the names of individuals who may have received an exposure to radiation as a result of an incident reported to the Department under subsection (B).

R9-7-445. Notification of Incidents

- A.** Immediate notification: Each licensee or registrant shall immediately report to the Department, as specified in R9-7-448(C), any event involving a radiation source that may have caused or threatens to cause any of the following conditions:
1. An individual to receive:
 - a. A total effective dose equivalent of 0.25 Sv (25 rem) or more;
 - b. A lens dose equivalent of 0.75 Sv (75 rem) or more; or
 - c. A shallow-dose equivalent to the skin or extremities of 2.5 Gy (250 rads) or more; or

2. The release of radioactive material, inside or outside of a restricted area but not including a location where personnel are not normally stationed during routine operations, such as a hot-cell or process enclosure, so if an individual had been present for 24 hours, the individual could have received five times the annual limit on intake (~~this subsection do not apply to a location where personnel are not normally stationed during routine operations, such as a hot cell or process enclosure~~).
- B.** Twenty-four hour notification: Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Department, as specified in R9-7-448(C), any event involving loss of control of a radiation source possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:
1. An individual to receive, in a period of 24 hours
 - a. A total effective dose equivalent exceeding 0.05 Sv (5 rem);
 - b. A lens dose equivalent exceeding 0.15 Sv (15 rem); or
 - c. A shallow-dose equivalent to the skin or extremities exceeding 0.5 Gy (50 rads);
or
 2. The release of radioactive material, inside or outside of a restricted area but not including a location where personnel are not normally stationed during routine operations, such as a hot-cell or process enclosure, so, if an individual had been present for 24 hours, the individual could have received an intake in excess of one occupational annual limit of intake (~~this subsection does not apply to a location where personnel are not normally stationed during routine operations, such as a hot cell or process enclosure~~).
- C.** A licensee or registrant shall prepare any report filed with the Department according to this Section so that names of individuals who have received exposure to radiation or radioactive material are stated in a separate and detachable part of the report.
- ~~**D.** A licensee or registrant shall report to the Department by telephone in response to the requirements of this Section.~~
- E.D.** If the Department does not respond to the initial telephone call made according to subsection (A) or (B) and R9-7-448(C), the licensee or registrant shall report to the Department of Public Safety and continue with reasonable efforts to contact the Department Duty Officer until contact is made.
- F.E.** The provisions of this Section do not apply to a dose that results from a planned special exposure, if the dose is within the limits for planned special exposures and reported according to R9-7-413(C).

R9-7-448. Additional Reporting

- A.** Each licensee shall notify the Department, according to subsection (C), as soon as possible, but not later than four hours after the discovery of an event, and take immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed the limits specified in this Chapter or releases of licensed material that could exceed the limits specified in this Chapter. For purposes of this Section, event means a radiation accident involving a fire, explosion, gas release, or similar occurrence.
- B.** Each licensee shall notify the Department, according to subsection (C), within 24 hours after discovering any of the following events involving licensed material:
1. A contamination event that:
 - a. Requires that anyone having access to the contaminated area be restricted for more than 24 hours by the imposition of additional radiological controls to prohibit entry into the area;
 - b. Involves a quantity of radioactive material greater than five times the lowest annual limit on intake specified in Appendix B of this Article; and
 - c. Results in access to the contaminated area being restricted for a reason other than to allow radionuclides with a half-life of less than 24 hours to decay prior to decontamination.
 2. An event in which equipment is disabled or fails to function as designed when:
 - a. The equipment is part of a system designed to prevent releases exceeding the limits specified in this Chapter, to prevent exposures to radiation and radioactive materials exceeding limits specified in this Chapter, or to mitigate the consequences of an accident;
 - b. The equipment performs a safety function; and
 - c. No redundant equipment is available and operable to perform the required safety function.
 3. An event that requires urgent medical treatment of an individual with radioactive contamination on the individual's clothing or body.
 4. A fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:
 - a. The quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of this Article, and
 - b. The damage affects the integrity of the licensed material or its container.
- C.** Each licensee shall make reports ~~required by subsections (A) and (B) above~~ by telephone to the

Department at 480-202-4982 and, ~~To~~ to the extent that the information is available at the time of notification, include the following information provided in these reports shall include:

1. The ~~callers's~~ caller's name, official title, and call back telephone number;
2. A description of the event, including date and time;
3. The exact location of the event;
4. The isotopes, quantities, and chemical and physical form of the licensed material involved; and
5. Any personnel radiation exposure data available.

D. Each licensee who makes a report required by subsection (A) or (B) shall submit to the Department a written follow-up report within 30 days of the initial report. Written reports prepared as required by other rules may be submitted to fulfill this requirement if the reports contain all of the required information in this subsection. The report shall include the following:

1. A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;
2. The exact location of the event;
3. The isotopes, quantities, and chemical and physical form of the licensed material involved;
4. Date and time of the event;
5. Corrective actions taken or planned and the results of any evaluations or assessments; and
6. The extent of personnel exposure to radiation or to radioactive materials without identification of each exposed individual by name.

E. Each licensee that makes a report required by subsection (A) or (B) shall submit a written follow-up report to the Department within 30 days after the initial report.

R9-7-454. Nationally Tracked Sources

A. A licensee who manufactures, receives, transfers, disassembles, or disposes of a nationally tracked source shall complete and submit to the Nuclear Regulatory Commission's National Source Tracking System and the Department, a National Source Tracking Transaction Report that contains the information required in 10 CFR 20.2207(a) through (e), revised ~~January 1, 2008~~ August 9, 2021, incorporated by reference, and available under R9-7-101. This incorporated material contains no future editions or amendments. The report shall be submitted by the close of the next business day after the transaction using a reporting method specified in 10 CFR 20.2207(f), revised January 1, 2008, incorporated by reference, and available under R9-7-101. This incorporated material contains no future editions or amendments.

- B.** The initial National Source Tracking Transaction Report shall contain the information required in subsection (A), be submitted using a method specified in 10 CFR 20.2207(f) ~~and include the additional information required by 10 CFR 20.2207(h)(1) through (6), revised January 1, 2008~~ August 9, 2021, incorporated by reference, and available under R9-7-101. This incorporated material contains no future editions or amendments.
- C.** A licensee shall correct any error in previously filed National Source Tracking Transaction Reports or file a new report for any missed transaction within five business days of the discovery of the error or missed transaction in accordance with 10 CFR 20.2207(g), revised ~~January 1, 2008~~ August 9, 2021, incorporated by reference, and available under R9-7-101. This incorporated material contains no future editions or amendments.
- D.** A licensee who receives a nationally tracked sealed source shall not disassemble the source unless specifically authorized to do so by the Department.

ARTICLE 5. SEALED SOURCE INDUSTRIAL RADIOGRAPHY

R9-7-523. Personnel Monitoring

- A. A licensee shall not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a direct reading dosimeter, an operating alarm rate meter, and a personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor.~~ At permanent radiography installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarm rate meter is not required. A licensee shall:
1. Use a pocket dosimeter with a range from zero to 2 millisieverts (200 millirems). ~~The licensee shall~~ and ensure that each dosimeter is recharged at the start of each shift. Electronic ~~personal~~ personnel dosimeters are permitted in place of ion-chamber pocket dosimeters.;
 2. Assign a personnel dosimeter to each individual, who shall wear the assigned equipment.;
 3. Replace film badges at least monthly and ensure that all other personnel dosimeters that require replacement are ~~processed and evaluated by an accredited NVLAP processor and~~ replaced at ~~periods that do not exceed three months~~ at least quarterly.; and
 4. Ensure that all personnel dosimeters are evaluated at least quarterly or promptly after replacement, whichever is more frequent.
 4. ~~After replacement, ensure that each personnel dosimeter is processed as soon as possible.~~
- B. A licensee shall record exposures noted from direct reading dosimeters, such as pocket dosimeters or electronic ~~personal~~ personnel dosimeters, at the beginning and end of each shift. The licensee shall maintain the records for at least three years after the Department terminates the license.
- C. A licensee shall check pocket dosimeters and electronic ~~personal~~ personnel dosimeters for correct response to radiation at periods that do not exceed 12 months. The licensee shall record the results of each check and maintain the records for three years after the dosimeter check is performed. The licensee shall discontinue use of a dosimeter if it is not accurate within plus or minus 20 percent of the true radiation exposure.
- D. If an individual's pocket dosimeter ~~has an~~ is found to be off-scale reading, or the individual's electronic ~~personal~~ personnel dosimeter reads greater than 2 millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, a licensee shall ~~process~~ ensure that:

1. If the individual's personnel dosimeter requires processing, the personnel dosimeter is sent for processing and evaluation within 24 hours of after the suspect exposure;
 2. If the individual's personnel dosimeter does not require processing, the evaluation of the personnel dosimeter is started within 24 hours after the suspect exposure;
 3. ~~The licensee shall not allow the~~ The individual is not allowed to resume work associated with ~~sources of radiation~~ licensed material until the individual's radiation exposure has been determined. ~~Using information from the dosimeter, by the licensee's RSO or the RSO's designee; and~~
 4. ~~shall calculate the affected individual's cumulative radiation exposure as prescribed in Article 4 of this Chapter and include the~~ The results of this the determination in subsection (D)(2) is included in the personnel monitoring records maintained in accordance with subsection (B).
- E.** If the personnel dosimeter that is required by subsection (A) is lost or damaged, the licensee shall ensure that the worker ceases work immediately until the licensee provides a replacement personnel dosimeter that meets the requirements in subsection (A) and the RSO or the RSO's designee calculates the exposure for the time period from issuance to discovery of the lost or damaged personnel dosimeter. The licensee shall maintain a record of the calculated exposure and the time period for which the personnel dosimeter was lost or damaged in accordance with subsection (B).
- F.** The licensee shall maintain dosimetry reports ~~received from the accredited NVLAP personnel dosimeter processor~~ in accordance with subsection (B).
- G.** For each alarm rate meter a licensee shall ensure that:
1. At the start of each shift, the alarm functions (sounds) properly before an individual uses the device;
 2. Each device is set to give an alarm signal at a preset dose rate of 5 mSv/hr (500 mrem/hr); with an accuracy of plus or minus 20 percent of the true radiation dose rate;
 3. A special means is necessary to change the preset alarm function on the device; and
 4. Each device is calibrated at periods that do not exceed 12 months for correct response to radiation. The licensee shall maintain records of alarm rate meter calibrations in accordance with subsection (B).

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

R9-7-611.01. Electronic Brachytherapy to Deliver Interstitial and Intracavitary Therapeutic Radiation Dosage

- A.** Electronic brachytherapy devices used to deliver interstitial and intracavitary therapeutic radiation dosage shall be subject to the requirements of this Section, and unless otherwise specified in this Section shall be exempt from the requirements of R9-7-611.
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 μ Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instrument shall be capable of measuring as low as 10 μ Sv (1 mrem) per hour in the energy range of the electronic brachytherapy unit for which the survey instrument is to be used. Published correction factors utilized in conjunction with the instrument's readings may be used to achieve sensitivity. 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 R9-7-603(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 may be available, either as a portable shield

or as localized shielded material around the treatment site or both, in lieu of the requirements for room shielding. The shielding shall meet the requirements of R9-7-603(C).

5. For electronic brachytherapy devices capable of operating at or greater than 150 kVp, the facility must meet the requirements of R9-7-611(B)(4).

D. 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.

E. 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 reinitiated, 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.

F. 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 (J);
 - 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 (G) 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.

G. 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), (H), and (I) 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.

H. Safety Precautions for Electronic Brachytherapy Devices.

1. Any person in the treatment room, 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 new patient treatments involving the electronic brachytherapy device;
3. After the first treatment one of the following individuals shall be physically present during continuation of all patient treatments involving the electronic brachytherapy device:
 - a. A Qualified Medical Physicist, or
 - b. An authorized user, or
 - c. A certified therapy technologist (CTT) certified by the Arizona Medical Radiologic Technology Board of Examiners, under the direct supervision of an authorized user, who has been trained in the operation and emergency response for the electronic brachytherapy device;
4. When shielding is required by subsection (C)(4), surveys shall be conducted to ensure that the requirements of R9-7-408, R9-7-414, and R9-7-416 are met. Alternatively, a Qualified Medical Physicist shall designate shield locations sufficient to meet the requirements of R9-7-603(C) and R9-7-607(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.

I. 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 its electronic instrument or instruments brachytherapy source; the model numbers and serial numbers of the instrument or instruments used to calibrate the electronic brachytherapy device; and the name and signature of the Qualified Medical Physicist responsible for performing the calibration.

J. 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 (or the manufacturer's or Qualified Medical Physicist's documented recommendation not to exceed five percent), observed at the source calibration required by subsection (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 subsection (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~~ are 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 checklist shall be reviewed and signed by either the authorized user or Qualified Medical Physicist prior to the next patient use of the unit. 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 subsection (J)(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 subsection (J)(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 this Section 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 subsection (J)(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.
- K.** 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.
- L. 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:
 - a. Certified in:
 - i. 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
 - ii. Radiation oncology by the American Osteopathic Board of Radiology; or
 - iii. Radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology”; or
 - iv. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
 - b. 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.
 - 2. To satisfy the requirement in subsection (L)(1)(b) for:
 - a. 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. 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 or patient treatment settings or both;
 - iii. Using administrative controls to prevent medical events as described in R9-7-444;
 - 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; and
- c. 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~~ Council 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 or contraindications or both;
 - 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 or treatment plans as warranted by patients' reaction to radiation or both; and
 - iv. Post-administration follow-up and review of case histories.

3. A physician shall not act as an authorized user until such time as the physician's training has been reviewed and approved by the Department.
4. Notwithstanding the requirements of subsections (L)(1) through (L)(3), the registrant for any therapeutic radiation machine subject to this Section may also submit the training of the prospective authorized user physician for Department review on a case-by-case basis if the training includes substantially equivalent training as that listed in subsections (L)(1)(b) and (L)(2) and the training includes dosimetry calculation training and experience.

M. 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 Department, 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 Physicists in Medicine; 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 subsection under the supervision of a Qualified Medical Physicist during the year of work experience.

N. Qualifications of Operators.

Individuals who will be operating a therapeutic radiation machine for medical use shall be certified by the Department as a CTT by the Arizona Medical Radiologic Technology Board of Examiners.

O. 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 subsection (G). If the interval between patients exceeds one year, retraining of the individuals shall be provided.
 2. In addition to the requirements of subsection (L) for therapeutic radiation machine authorized users and subsection (M) 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 manufacturer's instruction for three years. The record shall include a list of the topics covered, the date of the instruction, the name or names of the attendee or attendees, and the name or names of the individual or individuals who provided the instruction.
- P.** 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.
- Q.** Medical events shall be reported to the Department. For purposes of this Section "medical event" means a therapeutic radiation dose from a machine:
1. Delivered to the wrong patient;
 2. Delivered using the wrong mode of treatment;
 3. Delivered to the wrong treatment site; or

4. Delivered in one week to the correct patient, using the correct mode, to the correct therapy site, but greater than 130 percent of the prescribed weekly dose; or
- R.** A therapeutic radiation dose from a machine with errors in the calibration, time of exposure, or treatment geometry that result in a calculated total treatment dose differing from the final, prescribed total treatment dose by more than 20 percent, except for treatments given in 1 to 3 fractions, in which case a difference of more than 10 percent constitutes a medical event.
- S.** Reports of therapy medical events:
1. Within 24 hours after discovery of a medical event, a registrant shall notify the Department by telephone by speaking to a Department staff member. The registrant shall also notify the referring physician of the affected patient and the patient or a responsible relative or guardian, unless the referring physician personally informs the registrant either that he or she will inform the patient, or that in his or her medical judgment, telling the patient or the patient's responsible relative or guardian would be harmful to one or the other, respectively. If the Department staff member, referring physician, or the patient's responsible relative or guardian cannot be reached within 24 hours, the registrant shall notify them as soon as practicable. The registrant shall not delay medical care for the patient because of notification problems.
 2. Within 15 days following the verbal notification to the Department, the registrant shall report, in writing, to the Department and individuals notified under subsection (S)(1). The written report shall include the registrant's name, the referring physician's name, a brief description of the event, the effect on the patient, the action taken to prevent recurrence, whether the registrant informed the patient or the patient's responsible relative or guardian, and if not, why not. The report shall not include the patient's name or other information that could lead to identification of the patient.
 3. Each registrant shall maintain records of all medical events for Department inspection. The records shall:
 - a. Contain the names of all individuals involved in the event, including:
 - i. The physician,
 - ii. The allied health personnel,
 - iii. The patient,
 - iv. The patient's referring physician,
 - v. The patient's identification number if one has been assigned,
 - vi. A brief description of the event,
 - vii. The effect on the patient, and

- viii. The action taken to prevent recurrence.
- b. Be maintained for three years beyond the termination date of the affected registration.

ARTICLE 7. MEDICAL USES OF RADIOACTIVE MATERIAL

R9-7-702. Definitions

“Authorized medical physicist” means an individual who meets the requirements in R9-7-711. For purposes of ensuring that personnel are adequately trained, an authorized medical physicist is a “qualified expert” as defined in Article 1.

“Authorized nuclear pharmacist” means a pharmacist who meets the requirements in R9-7-712.

“Authorized user” means a physician, dentist, or podiatrist who meets the requirements in R9-7-719, R9-7-721, R9-7-723, R9-7-727, R9-7-728, or R9-7-744.

“Brachytherapy” means a method of radiation therapy in which a sealed source or group of sealed sources is utilized to deliver beta or gamma radiation at a distance of up to a few centimeters, by surface, intracavitary, intraluminal, or interstitial application.

“CT” means computerized tomography.

“High dose rate afterloading brachytherapy” means the treating of human disease using the radiation from a radioactive sealed source containing more than 1 curie of radioactive material. The radioactive material is introduced into a patient’s body using a device that allows the therapist to indirectly handle the radiation source during the treatment. For purposes of the requirements in this Article “pulse dose rate afterloading brachytherapy” is included in this definition.

“Human research subject” means an individual who is or becomes a participant in research overseen by an IRB, either as a recipient of the test article or as a control. A subject may be either a healthy human, in research overseen by the RDRC, or a patient.

“Institutional review board” (IRB) is defined in R9-7-704(B).

“Manual brachytherapy” means a type of brachytherapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

“Medical event” means an event that meets the criteria in R9-7-745.

“Medical institution” means an organization in which several medical disciplines are practiced.

“Medical use” means the intentional internal or external administration of radioactive material, or the radiation from it, to an individual under the supervision of an authorized user.

“Nuclear cardiology” means the diagnosis of cardiac disease using radiopharmaceuticals.

“PET” means positron emission tomography.

“Physically present” means that a supervising medical professional is in proximity to the patient during a radiation therapy procedure so that immediate emergency orders can be communicated

to ancillary staff, should the occasion arise.

“Prescribed dosage” means the specified activity or range of activity of unsealed radioactive material as documented:

In a written directive; or

In accordance with the directions of the authorized user for procedures performed in accordance with the uses described in Exhibit A.

“Prescribed dose” means:

For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

For teletherapy, the total dose and dose per fraction as documented in the written directive;

For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

“Radiation Safety Officer” (RSO) for purposes of this Article, and in addition to the definition in Article 1 means an individual who:

Meets the requirements in R9-7-710, or

Is identified as a radiation safety officer on:

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

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

“Radioactive drug” is defined in 21 CFR 310.3(c) and includes a “radioactive biological product” as defined in 21 CFR 600.3, April 1, 2006, both of which are incorporated by reference, published by the Office of Federal Register, National Archives and Records Administration, Washington, DC 20408, and on file with the Department. These incorporated materials contain no future editions or amendments.

“Radioactive Drug Research Committee” (RDRC) means the committee established by the licensee to review all basic research involving the administration of a radioactive drug to human research subjects, taken from 21 CFR 361.1, April 1, 2006, which is incorporated by reference, published by the Office of Federal Register, National Archives and Records Administration, Washington, DC 20408, and on file with the Department. This incorporation by reference contains no future editions or amendments. Research is considered basic re-search if it is done for the purpose of advancing scientific knowledge, which includes basic information regarding the metabolism (including kinetics, distributions, dosimetry, and localization) of a radioactive drug or

regarding human physiology, pathophysiology, or biochemistry. Basic research is not intended for immediate therapeutic or diagnostic purposes and is not intended to determine the safety and effectiveness of a radioactive drug in humans.

“Radiopharmaceutical” means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of any such sub-stance. For purposes of this Article radiopharmaceutical is equivalent to radioactive drug.

“Remote afterloading brachytherapy device” means a device used in radiation therapy that allows the authorized user to insert, from a remote location, a radiation source into an applicator that has been previously inserted in an individual requiring treatment.

“Sealed Source and Device Registry” means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

“Stereotactic radiosurgery” means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a dose.

“Teletherapy” means therapeutic irradiation in which the sealed source of radiation is at a distance from the body.

“Therapeutic dosage” means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

“Therapeutic dose” means a radiation dose delivered from a source containing radioactive material to a patient or human research subject for palliative or curative treatment.

“Treatment site” means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

“Unit dosage” means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

“Written directive” means an authorized user’s written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in R9-7-707.

R9-7-710. Radiation Safety Officer and Associate Radiation Safety Officer Training

- A.** A licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer, described in R9-7-705, to be an individual who:

1. Is certified by a specialty board whose certification process includes all of the requirements in subsection (A)(2)(a) and (B) and whose certification has been recognized by the Department, the NRC, or an Agreement State. To have its certification process recognized, a specialty board shall require all candidates for certification to:
 - a. Meet the following minimum requirements:
 - i. Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or bio-logical science with a minimum of 20 college credits in physical science;
 - ii. Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and
 - iii. Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or
 - b. Meet the following minimum requirements:
 - i. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
 - ii. Have two years of full-time practical training and/or supervised experience in medical physics;
 - (1) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Department, the NRC, or another Agreement State; or
 - (2) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users qualified under subsection (B), R9-7-721, or R9-7-723; and
 - iii. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety;
2. Has:

- a. Completed a structured educational program consisting of both:
 - i. 200 hours of didactic and laboratory training in the following areas:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity;
 - (4) Radiation biology; and
 - (5) Radiation dosimetry; and
 - ii. One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Department, a NRC, or an Agreement State license or permit issued by a NRC master material licensee that authorizes similar type(s) of use(s) of radioactive material involving the following:
 - (1) Shipping, receiving, and performing related radiation surveys;
 - (2) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
 - (3) Securing and controlling radioactive material;
 - (4) Using administrative controls to avoid mistakes in the administration of radioactive material;
 - (5) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
 - (6) Using emergency procedures to control radioactive material; and
 - (7) Disposing of radioactive material; and
 - b. Obtained written certification, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer, that the individual has satisfactorily completed the requirements in subsection (A)(2)(a) and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use licensee;
3. Is:
- a. A medical physicist who has been certified by a specialty board whose certification process has been recognized by the Department, the NRC, or another Agreement State under R9-7-711(A) or equivalent, has experience with

radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer, and meets the requirements in subsection (B); or

b. An authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has Radiation Safety Officer responsibilities; or

4. Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical license and meets the requirements in subsection (B).

B. A licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer to have training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, an Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

C. Exceptions.

1. An individual identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on a Department, a NRC, or another Agreement State license or a permit issued by the NRC or an Agreement State broad scope licensee or master material license ~~permit~~ permittee or by a master material broad scope license permittee ~~of broad scope~~ May 5, 2007 on or before January 14, 2019, need not comply with the training requirements in subsections (A)(1) through (4).

2. A physician, dentist, or podiatrist identified as an authorized user for the medical use of radioactive material on a license issued by the Department, the NRC, or an Agreement State, a permit issued by a NRC master material licensee, a permit issued by the Department, the NRC, or an Agreement State broad scope licensee, or a permit issued ~~by~~ in accordance with a NRC master material broad scope license ~~broad scope~~ permittee May 5, 2007 on or before October 24, 2005, need not comply with the training requirements in this Article.

D. The training and experience required in this Section shall be obtained within the seven years preceding the date of application or the individual shall have had related continuing education and

experience since the required training and experience was completed.

E. Individuals who, under subsection (C), need not comply with training requirements described in this Section may serve as preceptors for, and supervisors of, applicants seeking authorization on Department licenses for the same uses for which these individuals are authorized.

F. Records Retention.

1. The licensee shall retain both a copy of the authority, duties, and responsibilities of the Radiation Safety Officer, as required by this Section, and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program for the duration of the license. The records must include the signature of the Radiation Safety Officer and licensee management.
2. For each Associate Radiation Safety Officer appointed under this Section, the licensee shall retain, for five years after the Associate Radiation Safety Officer is removed from the license, a copy of the written document appointing the Associate Radiation Safety Officer, signed by the licensee's management.

R9-7-711. Authorized Medical Physicist Training

A. A licensee shall require an authorized medical physicist to be an individual who:

1. Is certified by a specialty board whose certification process includes all of the training and experience requirements in subsections (A)(2)(a) and (B) and whose certification has been recognized by the Department, the NRC, or an Agreement State. To have its certification process recognized, a specialty board shall require all candidates for certification to:
 - a. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
 - b. Have two years of full-time practical training and/or supervised experience in medical physics:
 - i. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the NRC or an Agreement State; or
 - ii. In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in R9-7-710,

R9-7-719, R9-7-721, R9-7-723, R9-7-727, R9-7-728, or R9-7-744; and

- c. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or
2. Meets the following alternative training requirements:
- a. Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:
 - i. Performing sealed source leak tests and inventories;
 - ii. Performing decay corrections;
 - iii. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
 - iv. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
 - b. Has obtained written attestation that the individual has satisfactorily completed the requirements in both subsections (A)(2)(a) and (B); and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in this Section, or equivalent Agreement State or NRC requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.
- B.** A licensee shall require an authorized medical physicist to be an individual who has training for

the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

- C. Exceptions. An individual identified as a teletherapy or medical physicist on a Department, a NRC, or another Agreement State license or a permit issued by the NRC or another Agreement State broad scope licensee or master material license ~~permit~~ permittee or by a master material broad scope license permittee ~~of broad scope~~ on or before May 5, 2007 January 14, 2019, need not comply with the training requirements in subsection (A).
- D. The training and experience required in this Section shall be obtained within the seven years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.
- E. Individuals who, under subsection (C), need not comply with training requirements described in this Section may serve as preceptors for, and supervisors of, applicants seeking authorization on Department licenses for the same uses for which these individuals are authorized.

R9-7-712. Authorized Nuclear Pharmacist Training

- A. A licensee shall require the authorized nuclear pharmacist to be a pharmacist who:
 - 1. Is certified as a nuclear pharmacist by a specialty board whose certification process has been recognized by the Department, the NRC, or an Agreement State. To have its certification process recognized, a specialty board shall require all candidates for certification to:
 - a. Have graduated from a pharmacy program accredited by the Accreditation Council for Pharmacy Education (ACPE) (previously named the American Council on Pharmaceutical Education), ~~(ACPE)~~ or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;
 - b. Hold a current, active license to practice pharmacy in Arizona;
 - c. Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and
 - d. Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety,

radiation safety, pro- vision of information and consultation, monitoring patient outcomes, research and development; or

2. Has completed 700 hours in a structured educational program consisting of both:
 - a. 200 hours of classroom and laboratory training in the following areas:
 - i. Radiation physics and instrumentation;
 - ii. Radiation protection;
 - iii. Mathematics pertaining to the use and measurement of radioactivity;
 - iv. Chemistry of radioactive material for medical use; and
 - v. Radiation biology; and
 - b. Supervised practical experience in a nuclear pharmacy involving:
 - i. Shipping, receiving, and performing related radiation surveys;
 - ii. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
 - iii. Calculating, assaying, and safely preparing dosages for patients or human research subjects;
 - iv. Using administrative controls to avoid medical events in the administration of radioactive material; and
 - v. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and
3. Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subsection (A)(2) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

- B.** Exceptions. An individual identified as a nuclear pharmacist on a Department, a NRC, or an Agreement State license or a permit issued by the NRC or an Agreement State broad scope licensee or master material license ~~permit~~ permittee or by a master material broad scope license ~~permittee of broad scope~~ on or before the effective date of these rules January 14, 2019, need not comply with the training requirements in subsections (A)(1) through (A)(3).
- C.** The training and experience required in this Section shall be obtained within the seven years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.
- D.** Individuals who, under subsection (B), need not comply with training requirements described in this Section may serve as preceptors for, and supervisors of, applicants seeking authorization on

Department licenses for the same uses for which these individuals are authorized.

R9-7-723. Training for Use of Unsealed Radioactive Material Requiring a Written Directive, Including Treatment of Hyperthyroidism, and Treatment of Thyroid Carcinoma

A. Except as provided in R9-7-710, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under Group 300 in Exhibit A, Medical Use Groups of this Article to be a physician who:

1. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State, as specified in the NRC's Medical Uses Licensee Toolkit available through <https://www.nrc.gov>, and who meets the requirements in subsection (A)(2). To have its certification process recognized, a specialty board shall require all candidates for certification to:
 - a. Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in (A)(2) subsection (A)(2)(a). Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the ~~Committee on Post-Graduate~~ Council on Postdoctoral Training of the American Osteopathic Association; and
 - b. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, and quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or
2. Has:
 - a. Completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:
 - i. Classroom and laboratory training in the following areas:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity;

- (4) Chemistry of radioactive material for medical use; and
 - (5) Radiation biology; and
- ii. Work experience, under the supervision of an authorized user who meets the requirements in this Article, NRC, or equivalent Agreement State requirements, involving:
- (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - (3) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
 - (5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
 - (6) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:
 - (a) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required (Experience with at least three cases in the Category specified in subsection (A)(2)(a)(ii)(6)(b) also satisfies this requirement;
 - (b) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;
 - (c) Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or
 - (d) Parenteral administration of any other radionuclide, for which a written directive is required; and

administration of unsealed radioactive material requiring a written directive to be a physician who has completed the training requirements in 10 CFR 35.396, January 1, 2013, incorporated by reference, and available under R9-7-101. This incorporated material contains no future editions or amendments.

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

R9-7-727. Training for Use of Manual Brachytherapy Sources and Training for the Use of Strontium-90 Sources for Treatment of Ophthalmic Disease

- A. Except as provided in R9-7-710, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under this Article to be a physician who:
1. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State and who meets the requirements in subsection (A)(2). The names of board certifications that have been recognized by the NRC or an Agreement State are specified in the NRC's Medical Uses Licensee Toolkit available through <https://www.nrc.gov>. To have its certification process recognized, a specialty board shall require all candidates for certification to:
 - a. Successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee on Post-Graduate~~ Council on Postdoctoral Training of the American Osteopathic Association; and
 - b. Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or
 2. Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachy-therapy sources that includes:
 - a. 200 hours of classroom and laboratory training in the following areas:
 - i. Radiation physics and instrumentation;
 - ii. Radiation protection;
 - iii. Mathematics pertaining to the use and measurement of radioactivity;
 - iv. Radiation biology;
 - b. 500 hours of work experience, under the supervision of an authorized user who

meets the requirements in this Section, or equivalent NRC or Agreement State requirements at a medical institution, involving:

- i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - ii. Checking survey meters for proper operation;
 - iii. Preparing, implanting, and removing brachytherapy sources;
 - iv. Maintaining running inventories of material on hand;
 - v. Using administrative controls to prevent a medical event involving the use of radioactive material;
 - vi. Using emergency procedures to control radioactive material;
- c. Completing three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in this Section, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee on Post-Graduate~~ Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subsection (A)(2)(b); and
- d. Obtaining written attestation that the individual has satisfactorily completed the requirements in subsections (A)(2)(a) through (c) and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under Exhibit A, Medical Use Groups of this Article. The attestation must be obtained from either:
- i. A preceptor authorized user who meets the requirements in this Section or equivalent Agreement State or NRC requirements; or
 - ii. A residency program director who affirms in writing that the attestation represents the consensus of the residency pro-gram faculty where at least one faculty member is an authorized user who meets the requirements in this Section or equivalent Agreement State or NRC requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or

the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subsection (A)(2)(a) and (b).

B. A licensee who uses strontium-90 for ophthalmic treatments must ensure that certain activities as specified in subsection (C) are performed by either:

1. An authorized medical physicist; or
2. An individual who:
 - a. Is identified as an ophthalmic physicist on a:
 - i. Specific medical use license issued by the Department, the NRC, or another Agreement State,
 - ii. Permit issued by an NRC or other Agreement State broad scope medical use licensee,
 - iii. Medical use permit issued by ~~an~~ a NRC master material licensee, or
 - iv. Permit issued by ~~an~~ a NRC master material ~~licensee~~ license broad scope medical use permittee;
 - b. Holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university;
 - c. Has successfully completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and
 - d. Has documented training in:
 - i. The creation, modification, and completion of written directives;
 - ii. Procedures for administrations requiring a written directive; and
 - iii. Performing the calibration measurements of brachytherapy sources as detailed in R9-7-726.

C. The individuals who are identified in subsection (B)(1) or (2) shall:

1. Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under R9-7-726; and
2. Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in paragraph (a) of this Section will observe treatments, review the

treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

- D. Licensees shall retain a record of the activity of each strontium-90 source in accordance with R9-7-313.
- E. The training and experience shall have been obtained within the seven years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

R9-7-744. Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

- A. Except as provided in R9-7-710, a licensee shall require an authorized user of a sealed source for a use authorized under Group 600 in Exhibit A, Medical Use Groups of this Article to be a physician who:
 - 1. Is certified by a medical specialty board whose certification process has been recognized by the Department, the NRC or another Agreement State and who meets the requirements in subsection (A)(2)(e). The names of board certifications that have been recognized by the Department, the NRC or another Agreement State are specified in the NRC's Medical Uses Licensee Toolkit available through <https://www.nrc.gov>. To have its certification process recognized, a specialty board shall require all candidates to:
 - a. Successfully complete a minimum of three years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee on Post-Graduate~~ Council on Postdoctoral Training of the American Osteopathic Association; and
 - b. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote after-loaders and external beam therapy; or
 - 2. Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:
 - a. 200 hours of classroom and laboratory training in the following areas:
 - i. Radiation physics and instrumentation;
 - ii. Radiation protection;
 - iii. Mathematics pertaining to the use and measurement of radioactivity;

- iv. Chemistry of radioactive material for medical use; and
 - v. Radiation biology;
- b. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this Section, or equivalent Agreement State or NRC requirements at a medical institution, involving:
- i. Reviewing full calibration measurements and periodic spot-checks;
 - ii. Preparing treatment plans and calculating treatment doses and times;
 - iii. Using administrative controls to prevent a medical event involving the use of radioactive material;
 - iv. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
 - v. Checking and using survey meters; and
 - vi. Selecting the proper dose and how it is to be administered;
- c. Completing three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in this Section, or equivalent Agreement State or NRC requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee~~ Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subsection (A)(2)(b); and
- d. Obtaining written attestation that the individual has satisfactorily completed the requirements in subsections (A)(2)(a) through (c) and (B), and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be obtained from either:
- i. A preceptor authorized user who meets the requirements in this Section, NRC requirements, or equivalent Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or
 - ii. A residency program director who affirms in writing that the attestation represents the consensus of the residency pro-gram faculty where at least one faculty member is an authorized user who meets the requirements in

this Section, NRC requirements, or equivalent Agreement State requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subsection (A)(2)(a) through (c).

- B.** A licensee shall require an authorized user of a sealed source for a use authorized under Group 600 in Exhibit A, Medical Use Groups of this Article to receive training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.
- C.** The training and experience shall have been obtained within the seven years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.

R9-7-745. Report and Notification of a Medical Event

- A.** A licensee shall report any “medical” event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material results in:
 - 1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and
 - a. The total dose delivered differs from the prescribed dose by 20 percent or more;
 - b. The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
 - c. The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.
 - 2. A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an

organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

- a. An administration of a wrong radiopharmaceutical containing radioactive material;
 - b. An administration of a radiopharmaceutical containing radioactive material by the wrong route of administration;
 - c. An administration of a dose or dosage to the wrong individual or human research subject;
 - d. An administration of a dose or dosage delivered by the wrong mode of treatment; or
 - e. A leaking sealed source.
3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).
- B.** A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radio-active material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.
- C.** The licensee shall notify by telephone the Department no later than the next calendar day after discovery of the medical event.
- D.** The licensee shall submit a written report to the Department within 15 days after discovery of the medical event.
1. The written report shall include:
 - a. The licensee's name;
 - b. The name of the prescribing physician;
 - c. A brief description of the event;
 - d. Why the event occurred;
 - e. The effect, if any, on each individual who received the administration;
 - f. What actions, if any, have been taken or are planned to prevent recurrence; and
 - g. Certification that the licensee notified each individual (or the individual's responsible relative or guardian), and if not, why not.
 2. The report may not contain an individual's name or any other information that could lead to identification of the individual.

- E.** The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached with-in 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this subsection, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.
- F.** Aside from the notification requirement, nothing in this Section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.
- G.** A licensee shall:
1. Annotate a copy of the report provided to the Department with the:
 - a. Name of the individual who is the subject of the event; and
 - b. Identification number or, if no other identification number is available, the Social Security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and
 2. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

R9-7-746. Report and Notification of a Dose to an Embryo, Fetus, or Nursing Child

- A.** A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.
- B.** A licensee shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:
1. Is greater than 50 mSv (5 rem) total effective dose equivalent; or

2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.
- C.** The licensee shall notify the Department by telephone no later than the next calendar day after discovery of a dose to the embryo, fetus, or nursing child that requires a report in subsections (A) or (B).
- D.** The licensee shall submit a written report to the Department within 15 days after discovery of a dose to the embryo, fetus, or nursing child that requires a report in subsections (A) or (B). The written report shall include:
1. The licensee's name;
 2. The name of the prescribing physician;
 3. A brief description of the event;
 4. Why the event occurred;
 5. The effect, if any, on the embryo/fetus or the nursing child;
 6. What actions, if any, have been taken or are planned to prevent recurrence; and
 7. Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.
- E.** The report, required in subsection (D), shall not contain the individual's or child's name or any other information that could lead to identification of the individual or child.
- F.** The licensee shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both here-after referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under subsections (A) or (B), unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee shall not delay any appropriate medical care for the embryo, fetus, or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this subsection, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide the written description upon request.
- G.** A licensee shall:

1. Make a copy of the report provided to the Department and include with it the:
 - a. Name of the pregnant individual or the nursing child who is the subject of the event; and
 - b. Identification number or, if no other identification number is available, the Social Security number ~~or other identification number, if one has been assigned,~~ of the pregnant individual or the nursing child who is the subject of the event; and
2. Provide the copy of the information required in subsection (G)(1) to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

ARTICLE 9. PARTICLE ACCELERATORS

R9-7-904. Registration of Particle Accelerators Used in the Practice of Medicine

- A.** The requirements in this Section supplement the registration requirements in R9-7-903.
- B.** An applicant that is a “medical institution,” as defined in 9 A.A.C. 7, Article 7, and performing human research shall appoint a radiation safety committee that meets the following requirements:
 - 1. The committee shall consist of at least four individuals and shall include:
 - a. An authorized user of each type of use permitted by the registration,
 - b. The Radiation Safety Officer,
 - c. A representative of the nursing service, and
 - d. A representative of management who is neither an authorized user nor a Radiation Safety Officer, and
 - e. Any other members the registrant selects;
 - 2. The committee shall meet at least once in each 12-month period, unless otherwise specified by registration condition;
 - 3. To conduct business at least 50 percent of the membership of the committee shall be present including the Radiation Safety Officer and the management representative;
 - 4. The minutes of each radiation safety committee meeting shall include a reference of any discussion or documents related to the review required in R9-7-407(C);
 - 5. Review the radiation safety program for all sources of radiation as required in R9-7-407(C);
 - 6. Establish a table that contains investigational levels for occupational and public dose that, when exceeded, will initiate an investigation and consideration of actions by the Radiation Safety Officer; and
 - 7. Establish the safety objectives of the quality management program required by subsection (E).
- C.** The applicant shall ensure that an individual designated as an authorized user is an Arizona licensed physician; approved by the radiation safety committee, if applicable; and is:
 - 1. Certified in:
 - a. Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; 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. Engaged in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic techniques applicable to the use of a particle accelerator, 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 all of the following sub-jects:
 - i. Radiation physics and instrumentation,
 - ii. Radiation protection,
 - iii. Mathematics pertaining to the use and measurement of radiotherapy, and
 - iv. Radiation biology.
 - b. To satisfy the requirement for supervised work experience, training shall occur under the supervision of an authorized user at a medical institution and shall include:
 - i. Reviewing full calibration measurements and periodic spot checks,
 - ii. Preparing treatment plans and calculating treatment times,
 - iii. Using administrative controls to prevent misadministration,
 - iv. Implementing emergency procedures to be followed in the event of the abnormal operation of a particle accelerator, and
 - v. Checking and using 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~~ Council 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 at a medical institution. The supervised clinical experience shall include:
 - i. Examining individuals and reviewing their case histories to determine their suitability for treatment, noting any limitations or contraindications;
 - ii. Selecting the proper dose and how it is to be administered;
 - iii. Calculating the therapy doses and collaborating with the authorized user in the review of patients' or human re-search subjects' progress and consideration of the need to modify originally prescribed doses, as

warranted by patients' or human research subjects' reaction to radiation;
and

iv. Post-administration follow up and review of case histories.

- D.** With the application the applicant shall provide the name of each authorized user to the Department so the names can be listed on the registration form, and so that the Department can determine whether the authorized user's training and experience satisfies the requirements in subsection (C).
- E.** Each registrant shall establish and maintain a written quality management program to provide high confidence that the radiation produced by the particle accelerator will be administered as directed by an authorized user. The quality management program shall include, at minimum, the tests and checks listed in Appendix A.
- F.** Each registrant shall ensure that a particle accelerator is calibrated by an authorized medical physicist who meets the training and experience qualifications in R9-7-711.
- 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 Department 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, Report of the Inter-Society Council for Radiation Oncology, December 1991, the applicant shall provide to the Department for approval the justification for the larger ratio and the safety considerations that have been addressed in establishing the program. This report is incorporated by reference and available under R9-7-101. The incorporated material contains no future editions or amendments. The report is available from the American Association of Physicists in Medicine: online at <http://www.aapm.org/pubs/reports>; print copies may be purchased from Medical Physics Publishing, 4513 Vernon Blvd., Madison, WI 53705; toll free at (800) 442-5778.

ARTICLE 15. TRANSPORTATION

R9-7-1512. Advance Notification of Shipment of Irradiated Reactor Fuel and Nuclear Waste

- A.** A licensee shall provide advance notification to the Governor, or the Director of the Department, of the shipment of licensed material as specified in 10 CFR 71.97, revised January 1, 2015, incorporated by reference, and available under R9-7-101. This incorporated material contains no future editions or amendments.
- B.** After June 11, 2013, each licensee shall provide advance notification to the Tribal official of participating Tribes referenced in paragraph (c)(3)(iii) of 10 CFR 71.97, or the Tribal official's designee, of the shipment of licensed material, within or across the boundary of the Tribe's reservation, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.
- C.** Advance notification is also required under this Section for the shipment of licensed material, other than irradiated fuel, meeting the following three conditions:
1. The licensed material is required by this ~~part~~ Chapter to be in Type B packaging for transportation;
 2. The licensed material is being transported to or across a State boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and
 3. The quantity of licensed material in a single package exceeds the least of the following:
 - a. 3000 times the A1 value of the radionuclides as specified in appendix A, Table A-1 for special form radioactive material;
 - b. 3000 times the A2 value of the radionuclides as specified in appendix A, Table A-1 for normal form radioactive material; or
 - c. 1000 TBq (27,000 Ci).
- D.** Procedures for submitting advance notification. (~~4~~)
1. The advance notification ~~must~~ shall be made in writing to:
 - ~~1-a.~~ The office of each appropriate ~~governor~~ Governor or ~~governor's~~ Governor's designee;
 - b. For the portion of the route through Arizona, the Department;
 - ~~2-c.~~ The office of each appropriate Tribal official or Tribal official's designee; and
 - ~~3-d.~~ The Director, Division of Security Policy, Office of Nuclear Security and Incident Response.
 2. A notification delivered by:
 - a. Mail must be postmarked at least seven days before the beginning of the seven-

- day period during which departure of the shipment is estimated to occur; and
- b. Any means other than mail must reach the Office of the Governor or of the Governor's designee or the Tribal official or Tribal official's designee at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.
3. Contact information for each State and participating Tribes, including telephone and mailing addresses of Governors and Governors' designees and of Tribal officials and Tribal official's designees, including telephone and mailing addresses, is available:
- a. At <https://scp.nrc.gov/special/designee.pdf>; or
- b. Or on request from the Director, Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.
4. Notification to the Department:
- a. By mail addressed to: ATTN: Arizona Department of Health Services; Bureau of Radiation Control; Radioactive Materials Program; 4814 South 40th Street, Phoenix, Arizona 85040;
- b. By hand delivery to the Department's offices at 4814 South 40th Street, Phoenix, Arizona 85040;
- c. By electronic submission, ram@azdhs.gov; and
- d. By telephone at 480-202-4982.
5. Each advance notification shall contain the following information:
- a. The name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or nuclear waste shipment;
- b. The license numbers of the shipper and receiver;
- c. A description of the irradiated reactor fuel or nuclear waste contained in the shipment, including the radionuclides and quantity;
- d. The point of origin of the shipment and the estimated time and date that departure of the shipment will occur;
- e. The estimated time and date that the shipment is expected to enter each State or Tribal reservation boundary along the route;
- f. The destination of the shipment, and the estimated time and date of arrival of the shipment at the destination; and
- g. A point of contact, with a telephone number, for current shipment information.
- E.** Revision notice: A licensee shall contact by telephone each individual previously notified

according to subsection (D)(1) to provide any information not previously available at the time of the initial notification or any changes to the information previously provided as soon as the information becomes available.

F. Cancellation notice: Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice:

1. To each individual previously notified according to subsections (D)(1) through (4),
2. Before the shipment would have commenced or as soon thereafter as possible, and
3. Identifying the advance notification to which the notice of cancellation pertains and stating in the notice that the shipment is cancelled.

G. Records: A licensee shall retain a copy of the advance notification and any revision notices or cancellation notices as a record for at least three years.

ARTICLE 17. WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

R9-7-1723. Personnel Monitoring

- A. A licensee shall not permit an individual to act as a logging supervisor or logging assistant unless that person wears, ~~at all times during the handling of licensed radioactive materials,~~ a personnel dosimeter at all times during the handling of licensed radioactive materials ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor.~~
- B. A licensee shall assign a personnel dosimeter to each individual, who shall wear the assigned equipment.
- C. A licensee shall replace film badges at least monthly and replace all other personnel dosimeters that require replacement at least quarterly. After replacement, a licensee shall evaluate all personnel dosimeters at least quarterly or promptly ~~process each personnel dosimeter after replacement, whichever is more frequent.~~
- D. A licensee shall provide bioassay services to each individual who uses licensed materials in subsurface tracer studies if required by the license.
- E. A licensee shall record exposures noted from personnel dosimeters required by subsection (A) and bioassay results and maintain these records for three years after the Department terminates the radioactive material license.

**ARTICLE 19. PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2
QUANTITIES OF RADIOACTIVE MATERIAL**

**R9-7-1927. Requirements for Criminal History Records Checks of Individuals Granted
Unescorted Access to Category 1 or Category 2 Quantities of Radioactive Material**

- A. General performance objective and requirements:
1. Except for those individuals listed in R9-7-1929 and those individuals grandfathered under R9-7-1925(B), each licensee subject to the provisions of this Article shall fingerprint each individual who is to be permitted unescorted access to category 1 or category 2 quantities of radioactive material. Licensees shall transmit all collected fingerprints to the NRC for transmission to the FBI. The licensee shall use the information received from the FBI as part of the required background investigation to determine whether to grant or deny further unescorted access to category 1 or category 2 quantities of radioactive materials for that individual.
 2. The licensee shall notify each affected individual that his or her fingerprints will be used to secure a review of his or her criminal history record, and shall inform him or her of the procedures for revising the record or adding explanations to the record.
 3. Fingerprinting is not required if a licensee is reinstating an individual's unescorted access authorization to category 1 or category 2 quantities of radioactive materials if:
 - a. The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his or her unescorted access authorization; and
 - b. The previous access was terminated under favorable conditions.
 4. Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to category 1 or category 2 quantities of radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee, based upon a background investigation conducted under this Article, the Fingerprint Orders, or 10 CFR part 73, revised December 12, 2018, incorporated by reference, available under R9-7-101, and containing no future editions or amendments. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the provisions of R9-7-1931(C).
 5. Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access

authorization to category 1 or category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

B. Prohibitions:

1. Licensees may not base a final determination to deny an individual unescorted access authorization to category 1 or category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:
 - a. An arrest more than 1 year old for which there is no information of the disposition of the case; or
 - b. An arrest that resulted in dismissal of the charge or an acquittal.
2. Licensees may not use information received from a criminal history records check obtained under this Section in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

C. Procedures for processing of fingerprint checks:

1. For the purpose of complying with this Article, licensees shall use an appropriate method listed in 10 CFR 37.7, revised November 29, 2019, incorporated by reference, available under R9-7-101, and containing no future editions or amendments; to submit to the U.S. Nuclear Regulatory Commission, Division of Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop ~~T-8B20~~ T-07D04M, Rockville, MD 20852, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by emailing MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at <https://www.nrc.gov/security/chp.html>.
2. Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." (For guidance on making electronic payments, contact the Division of Physical and Cyber Security Policy by e-mailing Crimhist.Resource@NRC.gov.) Combined payment for multiple applications is acceptable. The Commission publishes the amount of the fingerprint check application fee on the NRC's public website. (To find the current fee amount, go to the Licensee

Criminal History Records Checks & Firearms Background Check information page at <https://www.nrc.gov/security/chp.html> and see the link for “How do I determine how much to pay for the request?”.)

3. The U.S. Nuclear Regulatory Commission will forward to the submitting licensee all data received from the FBI as a result of the licensee’s application or applications for criminal history records checks.

R9-7-1957. Reporting of Events

A. General performance objective and requirements:

1. Except for those individuals listed in R9-7-1929 and those individuals grandfathered under R9-7-1925(B), each licensee subject to the provisions of this Article shall fingerprint each individual who is to be permitted unescorted access to category 1 or category 2 quantities of radioactive material. Licensees shall transmit all collected fingerprints to the NRC for transmission to the FBI. The licensee shall use the information received from the FBI as part of the required background investigation to determine whether to grant or deny further unescorted access to category 1 or category 2 quantities of radioactive materials for that individual.
2. The licensee shall notify each affected individual that his or her fingerprints will be used to secure a review of his or her criminal history record, and shall inform him or her of the procedures for revising the record or adding explanations to the record.
3. Fingerprinting is not required if a licensee is reinstating an individual’s unescorted access authorization to category 1 or category 2 quantities of radioactive materials if:
 - a. The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his or her unescorted access authorization; and
 - b. The previous access was terminated under favorable conditions.
4. Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to category 1 or category 2 quantities of radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee, based upon a background investigation conducted under this Article, the Fingerprint Orders, or 10 CFR part 73, revised December 12, 2018, incorporated by reference, available under R9-7-101, and containing no future editions or amendments. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance

with the provisions of R9-7-1931(C).

5. Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to category 1 or category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

B. Prohibitions:

1. Licensees may not base a final determination to deny an individual unescorted access authorization to category 1 or category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:
 - a. An arrest more than 1 year old for which there is no information of the disposition of the case; or
 - b. An arrest that resulted in dismissal of the charge or an acquittal.
2. Licensees may not use information received from a criminal history records check obtained under this Section in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

C. Procedures for processing of fingerprint checks:

1. For the purpose of complying with this Article, licensees shall use an appropriate method listed in 10 CFR 37.7, revised November 29, 2019, incorporated by reference, available under R9-7-101, and containing no future editions or amendments; to submit to the U.S. Nuclear Regulatory Commission, Division of Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop T-8B20, Rockville, MD 20852, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by emailing MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at <https://www.nrc.gov/security/chp.html>.
2. Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." (For guidance on making electronic payments, contact the Division of Physical and Cyber Security Policy by e-mailing Crimhist.Resource@NRC.gov.)

Combined payment for multiple applications is acceptable. The Commission publishes the amount of the fingerprint check application fee on the NRC’s public website. (To find the current fee amount, go to the Licensee Criminal History Records Checks & Firearms Background Check information page at <https://www.nrc.gov/security/chp.html> and see the link for “How do I determine how much to pay for the request?”.)

3. The U.S. Nuclear Regulatory Commission will forward to the submitting licensee all data received from the FBI as a result of the licensee’s application or applications for criminal history records checks.

Appendix A. - Table 1 - Category 1 and Category 2 Threshold

The terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only.

Radioactive Material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Americium-241	60	1,620	0.6	16.2
Americium-241/Be	60	1,620	0.6	16.2
Californium-252	20	540	0.2	5.40
Cobalt-60	30	810	0.3	8.10
Curium-244	50	1,350	0.5	13.5
Cesium-137	100	2,700	1	27.0
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,160	0.8	21.6
Plutonium-238	60	1,620	0.6	16.2
Plutonium-239/Be	60	1,620	0.6	16.2
Promethium-147	40,000	1,080,000	400	10,800
Radium-226	40	1,080	0.4	10.8
Selenium-75	200	5,400	2	54.0
Strontium-90	1,000	27,000	10	270
Thulium-170	20,000	540,000	200	5,400

Ytterbium-169	300	8,100	3	81.0
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Note: Calculations Concerning Multiple Sources or Multiple Radionuclides

The “sum of fractions” methodology for evaluating combinations of multiple sources or multiple radionuclides is to be used in determining whether a location meets or exceeds the threshold and is thus subject to the requirements of this part.

1. If multiple sources of the same radionuclide and/or multiple radionuclides are aggregated at a location, the sum of the ratios of the total activity of each of the radionuclides shall be determined to verify whether the activity at the location is less than the category 1 or category 2 thresholds of Table 1, as appropriate. If the calculated sum of the ratios, using the equation below, is greater than or equal to 1.0, then the applicable requirements of this part apply.
2. First determine the total activity for each radionuclide from Table 1. This is done by robbing the activity of each individual source, material in any device, and any loose or bulk material that contains the radionuclide. Then use the equation below to calculate the sum of the ratios by inserting the total activity of the applicable radionuclides from Table 1 in the numerator of the equation and the corresponding threshold activity from Table 1 in the denominator of the equation.

Calculations shall be performed in metric values (i.e., TBq) and the numerator and denominator values shall be in the same units.

~~R₁~~ R₁ = total activity for radionuclide 1

~~R₂~~ R₂ = total activity for radionuclide 2

~~R_n~~ R_n = total activity for radionuclide n

~~AR₁~~ AR₁ = activity threshold for radionuclide 1

~~AR₂~~ AR₂ = activity threshold for radionuclide 2

~~AR_n~~ AR_n = activity threshold for radionuclide n

n

$$\sum \left\{ \frac{\underline{R}_1}{\underline{AR}_1} + \frac{\underline{R}_2}{\underline{AR}_2} + \frac{\underline{R}_n}{\underline{AR}_n} \right\} \geq 1.0$$

i

$$\underline{R}_1 \quad \underline{R}_2 \quad \underline{R}_n$$

$$\frac{\text{---}}{\underline{AR}_1} \pm \frac{\text{---}}{\underline{AR}_2} \pm \dots \pm \frac{\text{---}}{\underline{AR}_n} \geq \underline{1.0}$$