

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

**PREAMBLE**

- 1. Permission to initiate this rulemaking was granted under A.R.S. § 41-1039(A) by the governor on:**

May 2, 2023

<b><u>2. Article, Part or Sections Affected (as applicable)</u></b>	<b><u>Rulemaking Action</u></b>
R9-7-101.01	Renumber
R9-7-101.01	Amend
R9-7-102	Amend
R9-7-302	Amend
R9-7-305	Amend
R9-7-311	Amend
R9-7-313	Amend
R9-7-318	Amend
R9-7-709	Amend
R9-7-709	Amend
R9-7-710	Amend
R9-7-711	Amend
R9-7-712.01	New Section
R9-7-718	Amend
R9-7-719	Amend
R9-7-720	Amend
R9-7-721	Amend
R9-7-723	Amend
R9-7-727	Amend
R9-7-728	Amend
R9-7-744	Amend
Exhibit A	Amend
R9-7-1909	Renumber

**3. Citations to the agency’s statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):**

Authorizing statutes: A.R.S. §§ 30-654(B)(5), 36-132(A)(1), 36-136(G)

Implementing statutes: A.R.S. §§ 30-654, 30-657, 30-671, 30-672, and 30-673

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

Notice of Rulemaking Docket Opening: 30 A.A.R. XXX, April 26, 2024

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

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

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or

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**6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:**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 approval for the rulemaking according to A.R.S. § 41-1039(A), 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 and changes specified in the five-year-review reports for the affected Sections. 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, while protecting the health and safety of patients, staff, and the general public.

**7. 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.

**8. 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

**9. A statement that the agency is exempt from the requirements under A.R.S. § 41-1055(G) to obtain and file a preliminary summary of the economic, small business, and consumer impact under A.R.S. § 41-1055(D)(2):**

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

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

Close of record: Tuesday, May 28, 2024, 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, 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 business competitiveness analysis was received by the Department.

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

Not applicable

**13. The full text of the rules follows:**

**TITLE 9. HEALTH SERVICES**  
**CHAPTER 7. DEPARTMENT OF HEALTH SERVICES**  
**RADIATION CONTROL**

**ARTICLE 1. GENERAL PROVISIONS**

Section

- ~~R9-7-100~~R9-7-101.01. Interpretations  
R9-7-102. Definitions

**ARTICLE 3. RADIOACTIVE MATERIAL LICENSING**

Section

- R9-7-302. Source Material; Exemptions  
R9-7-305. General Licenses – Source Material  
R9-7-311. Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices that Contain Radioactive Material  
R9-7-313. Specific Terms and Conditions  
R9-7-318. Transfer of Radioactive Material

**ARTICLE 7. MEDICAL USES OF RADIOACTIVE MATERIAL**

Section

- R9-7-709. Sealed Sources or Devices for Medical Use  
R9-7-710. Radiation Safety Officer and Associate Radiation Safety Officer Training  
R9-7-711. Authorized Medical Physicist Training  
R9-7-712.01. Training for Experienced Radiation Safety Officers, Teletherapy or Medical Physicists, Authorized Medical Physicists, Authorized Users, Nuclear Pharmacists, and Authorized Nuclear Pharmacists  
R9-7-718. Mobile Medical Service  
R9-7-719. Training for Uptake, Dilution, and Excretion Studies  
R9-7-720. Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations  
R9-7-721. Training for Imaging and Localization Studies Not Requiring a Written Directive  
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  
R9-7-728. Training for Use of Sealed Sources for Diagnosis

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

Exhibit A. Medical Use Groups

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

Section

R9-7-1909. ~~Interpretations~~ Renumbered

R9-7-1943. General Security Program Requirements

## ARTICLE 1. GENERAL PROVISIONS

### ~~R9-7-1909~~R9-7-101.01. Interpretations

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the rules in this ~~Article~~ Chapter by any officer or employee of the Department other than a written interpretation by the Arizona Assistant Attorney General counsel assigned to the Department will be recognized as binding upon the Department.

### 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 present 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 microstructure 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 or an Agreement State;  
or

A medical use permit issued by a Commission 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, and containing~~ 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, revised January 20, 2023, 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~~ April 10, 1974, ~~both~~ incorporated by reference, ~~and~~ available under R9-7-101. ~~This incorporated material contains, and containing~~ 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 ( $HE,50 = \sum w_T HT,50$ ).

“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  $0.4 \text{ Bq/cm}^2$  ( $1 \times 10^{-5} \text{ } \mu\text{Ci/cm}^2$ ) for beta and gamma emitters and low toxicity alpha emitters, or  $0.04 \text{ Bq/cm}^2$  ( $1 \times 10^{-6} \text{ } \mu\text{Ci/cm}^2$ ) 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  $3.7 \times 10^{10}$  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/cm<sup>2</sup>).

“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 ( $HE = \sum S wTHT$ ).

“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, and containing not future editions or amendments, 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 (“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/cm<sup>2</sup>).

“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, transformers, 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 unknown. 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  $2 \times 10^{-3}$  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 (10<sup>6</sup> 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:

<i>Prefix</i>	<i>Multiplier Symbol</i>	<i>Value</i>
eka	E	10 <sup>18</sup>
peta	P	10 <sup>15</sup>
tera	T	10 <sup>12</sup>
giga	G	10 <sup>9</sup>
mega	M	10 <sup>6</sup>
kilo	k	10 <sup>3</sup>
milli	m	10 <sup>-3</sup>
micro	u	10 <sup>-6</sup>
nano	n	10 <sup>-9</sup>
pico	p	10 <sup>-12</sup>
femto	f	10 <sup>-15</sup>
atto	a	10 <sup>-18</sup>

“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 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.

“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.

“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 radioactive source located in the radiation source housing.

“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~~ R9-7-101, 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, radiographic 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~~ December 27, 2022; 49 CFR 171, revised ~~April 19, 2017~~ December 21, 2022; 49 CFR 172, revised ~~November 23, 2015~~ December 27, 2022; 49 CFR 173, revised

~~March 6, 2019~~ December 27, 2022; 49 CFR 174, revised ~~February 28, 2019~~ December 27, 2022; 49 CFR 175, revised ~~October 18, 2018~~ December 27, 2022; 49 CFR 176, ~~November 7, 2018~~ December 21, 2020; 49 CFR 177, revised ~~September 25, 2013~~ December 27, 2022; 49 CFR 178, revised ~~November 7, 2018~~ July 26, 2022; 49 CFR 179, revised ~~September 25, 2018~~ December 21, 2020; and 49 CFR 180, revised ~~March 30, 2017~~ July 26, 2022, 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/cm<sup>2</sup>).

“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 refining. 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 exposure 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 3. RADIOACTIVE MATERIAL LICENSING

#### R9-7-302. Source Material; Exemptions

- A. Any person is exempt from this Article to the extent the person receives, possesses, uses, delivers or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20th of 1 percent (0.0005) of the mixture, compound, solution, or alloy.
- B. Any person is exempt from this Article to the extent the person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material, provided that, the person does not refine or process the ore except as authorized in a specific license.
- C. Any person is exempt from the requirements for a license set forth in this Article if the person receives, possesses, uses, or transfers:
  - 1. Any quantities of thorium contained in:
    - a. Incandescent gas mantles;
    - b. Vacuum tubes;
    - c. Welding rods;
    - d. Electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium;
    - e. Germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting, provided that each lamp does not contain more than 2 grams of thorium;
    - f. Rare earth metals, compounds, mixtures, or products containing not more than 0.25 percent by weight thorium, uranium, or any combination of thorium and uranium; or
    - g. Individual neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;
  - 2. Source material contained in the following products:
    - a. Glazed ceramic tableware manufactured before August 27, 2013, provided that the glaze contains not more than 20 percent by weight source material ~~by weight~~;
    - b. Glassware containing not more than 2 percent by weight source material or, for glassware manufactured before August 27, 2013, 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass or ceramic used in construction; or
    - c. Piezoelectric ceramic containing not more than 2 percent by weight source material ~~by weight~~;

3. Photographic film, negatives, and prints containing uranium or thorium;
4. Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that the exemption contained in this subsection does not authorize the chemical, physical, or metallurgical treatment or processing of the finished product or part;
5. Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of counterweights, provided that:
  - a. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: “DEPLETED URANIUM”;
  - b. Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: “UNAUTHORIZED ALTERATIONS PROHIBITED”;
  - c. The exemption contained in subsection (C)(5) does not authorize the chemical, physical, or metallurgical treatment or processing of any counterweight other than repair or restoration of any plating or other covering; and
  - d. The requirements specified in subsections (C)(5)(a) and (b) need not be met by counterweights manufactured prior to December 31, 1969; provided, that these counterweights were manufactured under a specific license issued by the Atomic Energy Commission and were impressed with the legend, ~~“CAUTION—RADIOACTIVE MATERIAL—URANIUM”~~ “UNAUTHORIZED ALTERATIONS PROHIBITED”;
6. Natural or depleted uranium metal used as shielding and constituting part of any shipping container; provided that:
  - a. The shipping container is conspicuously and legibly impressed with the legend “CAUTION – RADIOACTIVE SHIELDING – URANIUM,” and
  - b. The uranium metal is encased in mild steel or equally fire resistant metal with minimum wall thickness of 1/8 inch (3.2 mm);
7. Thorium or uranium contained in or on finished optical lenses or mirrors, provided that each lens or mirror does not contain more than 10 percent by weight thorium or uranium or, for lenses manufactured before August 27, 2013, 30 percent by weight of thorium; and that the exemption contained in this Section does not authorize either:
  - a. The shaping, grinding, or polishing of such lens or mirror or manufacturing

processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror; or

- b. The receipt, possession, use, or transfer of uranium or thorium contained in contact lenses, spectacles, or the eyepieces of binoculars or other optical instruments;
- 8. Uranium contained in detector heads of fire detection units, provided that each detector head contains not more than 5 nanocuries (185 Bq) of uranium; or
- 9. Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:
  - a. The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide), and
  - b. The thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.
- D.** No person may initially transfer for sale or distribution a product containing source material to persons exempt under subsection (C), or equivalent regulations of the NRC or another Agreement State, unless authorized by a license issued under R9-7-318 to initially transfer such products for sale or distribution.
- E.** Persons authorized to manufacture, process, or produce these materials or products containing source material by ~~an~~ another Agreement State, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued under R9-7-318 for distribution only and are exempt from the requirements of Articles 4 and 10 of this Chapter, and R9-7-309(1) and (2).
- F.** The exemptions in subsections (C), (D), and (E) do not authorize the manufacture of any of the products described.

**R9-7-305. General Licenses – Source Material**

- A.** A general license is hereby issued authorizing commercial and industrial firms; research, educational, and medical institutions; and Federal, State, and local government agencies to receive, possess, use, and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities.
  - 1. No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer

source material under this subsection may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year.

2. As applicable:

- a. No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under this subsection may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under this subsection unless it is accounted for under the limits of subsection (A)(1);
- b. No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under this subsection; or
- c. No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under this subsection may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

**B.** ~~A Any person who receives, possesses, uses, or transfers source material under in accordance with a general license granted under subsection (A) is exempt from the provisions of Article 4 and Article 10 of this Chapter, provided the receipt possession, use, or transfer is within the terms of the general license, except that such person shall comply with the provisions of R9-7-434 and R9-7-452. This exemption does not apply to any person who is also in possession of source material under a specific license issued under this Article.:~~

1. Is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings, except as may be authorized by the Department in a specific license;
2. Shall not abandon such source material, but source material may be disposed of as follows:
  - a. A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of this subsection is exempt from the



requirements to obtain a license under Article to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under this Chapter;  
or

b. In accordance with R9-7-434.

3. Is subject to the provisions in 10 CFR 40.56 and R9-7-101, R9-7-101.01, R9-7-102, R9-7-107, R9-7-308, R9-7-313(A) through (E), R9-7-313(I), R9-7-318, R9-7-405, R9-7-443, R9-7-444, R9-7-445, and R9-7-1213 through R9-7-1220; and

4. Shall not export such source material except in accordance with 10 CFR 110.

**C.** Any person who receives, possesses, uses, or transfers source material in accordance with subsection (A) shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Department about such contamination and may consult with the Department as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in R9-7-452.

**D.** Any person who receives, possesses, uses, or transfers source material in accordance with a general license granted under subsection (A) is exempt from the provisions of Article 4 and Article 10 of this Chapter, provided the receipt, possession, use, or transfer is within the terms of the general license, except that such person shall comply with the provisions of R9-7-434 and R9-7-452. This exemption does not apply to any person who is also in possession of source material under a specific license issued under this Article.

**E.** No person may initially transfer or distribute source material to persons generally licensed under subsection (A)(1) or (2), or equivalent regulations of the NRC or another Agreement State, unless authorized by a specific license issued in accordance with R9-7-318 or equivalent provisions of the NRC or another Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample.

**C.F.** This subsection grants a general license that authorizes a person to receive acquire, possess, use, or transfer, in accordance with subsections (G) through (J), depleted uranium contained in industrial products and devices provided:

1. ~~The~~ the depleted uranium is contained in the industrial product or device for the purpose of providing a concentrated mass in a small volume of the product or device;

**2.G.** The general license in subsection (F) applies only to industrial products or devices have been

manufactured or initially transferred in accordance with a specific license governed by R9-7-311(J), or in accordance with a specific license issued by the NRC or another Agreement State that authorizes manufacture of the products or devices for distribution to persons generally licensed by the NRC or an Agreement State; ~~and.~~

~~3.H.~~ ~~The person files~~ Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by subsection (F) shall file an ARRA 23 “Registration Certificate -- Use of Depleted Uranium Under General License” with the Department. The person shall provide the information requested on the certificate and listed in Exhibit E. The person shall submit the information within 30 days after first receipt or acquisition of the depleted uranium, returning the completed registration certificate to the Department. The person shall report in writing to the Department any change in information originally submitted to the Department on ARRA 23. The person shall submit the change report within 30 days after the effective date of the described change.

~~D.I.~~ A person who receives, acquires, possesses, or uses depleted uranium according to the general license provided under subsection ~~(E)~~ (F) shall:

1. Not introduce depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;
2. Not abandon the depleted uranium;
3. Transfer the depleted uranium as prescribed in R9-7-318. If the transferee receives the depleted uranium under a general license established by subsection ~~(E)~~ (F), the transferor shall furnish the transferee with a copy of this subsection and a copy of the registration certificate. If the transferee receives the depleted uranium under a general license governed by a regulation of the NRC or another Agreement State that is equivalent to subsection ~~(E)~~ (F), the transferor shall furnish the transferee a copy of the equivalent rule and a copy of the registration certificate, accompanied by a letter explaining that use of the product or device is regulated by the NRC or an Agreement State under requirements substantially similar to those in this Section; and
4. Within 30 days of any transfer, report in writing to the Department the name and address of the person receiving the depleted uranium; ~~and.~~
5. ~~Not export depleted source material except under a license issued by the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 110.~~

~~E.J.~~ A person who receives, acquires, possesses, uses, or transfers depleted uranium in accordance with a general license granted under subsection ~~(E)~~ (F) is exempt from the requirements in

Articles 4 and 10 of this Chapter with respect to the depleted uranium covered by that general license.

- ~~F. Any person who receives, possesses, uses, or transfers source material in accordance with subsection (A) shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Department about such contamination and may consult with the Department as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in R9-7-452.~~
- ~~G. No person may initially transfer or distribute source material to persons generally licensed under subsection (A)(1) or (2), or equivalent regulations of the NRC or another Agreement State, unless authorized by a specific license issued in accordance with R9-7-318 or equivalent provisions of another Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample.~~

**R9-7-311. Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices that Contain Radioactive Material**

- A. Licensing the manufacture and distribution of devices to persons generally licensed under R9-7-306(A).
  - 1. The Department shall grant a specific license to manufacture or distribute each device that contains radioactive material, excluding special nuclear material, to persons generally licensed under R9-7-306(A) or equivalent regulations of the U.S. NRC, an Agreement State, or the Licensing State if:
    - a. The applicant satisfies the requirements of R9-7-309;
    - b. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, pro-posed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:
      - i. The device can be safely operated by persons not having training in radiological protection;
      - ii. Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive a dose in excess of 10 percent of the limits specified in R9-7-

408; and

iii. Under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

(1) Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye: 150 mSv (15 rem);

(2) Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter; 2 Sv (200 rem);

(3) Other organs: 500 mSv (50 rem);

c. Each device bears a durable, legible, clearly visible label or labels that contain in a clearly identified and separate statement:

i. Instructions and precautions necessary to assure safe installation, operating, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

ii. The requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for the testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

iii. The information called for in one of the following statements in the same or substantially similar form:

The receipt, possession, use, and transfer of this device, Model \_\_\_\_\_, Serial No. \_\_\_\_\_, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

**CAUTION – RADIOACTIVE MATERIAL**

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(name of manufacturer or distributor)

The receipt, possession, use and transfer of this device, Model \_\_\_\_\_, Serial No. \_\_\_\_\_, are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION – RADIOACTIVE MATERIAL

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(name of manufacturer or distributor)

- d. The model, serial number, and name of manufacturer or distributor may be omitted from the label if the information location is specified in labeling affixed to the device;
  - e. Each device with a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label that provides the device model number and serial number, the isotope and quantity, the words, “Caution-Radioactive Material,” the radiation symbol described in R9-7-428, and the name of the manufacturer or initial distributor; ~~and~~
  - f. Each device meets the criteria in 10 CFR 31.5(c)(13)(i) (revised ~~January 1, 2013~~ December 19, 2014, incorporated by reference, ~~and~~ available under R9-7-101, and containing no future editions or amendments. ~~This incorporated material contains no future editions or amendments~~) and bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing, if separable, or the device if the source housing is not separable, that includes the words, “Caution-Radioactive Material,” and, if practicable, the radiation symbol described in R9-7-428; ~~and~~
  - g. The device has been registered in the Sealed Source and Device Registry.
2. In the event the applicant desires that the device undergo mandatory testing at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, the application shall contain sufficient information to demonstrate that the longer interval is justified by performance characteristics of the device or similar de-vices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Department shall consider information which includes, but is not limited to:
- a. Primary containment (source capsule),

- b. Protection of primary containment,
  - c. Method of sealing containment,
  - d. Containment construction materials,
  - e. Form of contained radioactive material,
  - f. Maximum temperature withstood during prototype tests,
  - g. Maximum pressure withstood during prototype tests,
  - h. Maximum quantity of contained radioactive material,
  - i. Radiotoxicity of contained radioactive material, and
  - j. Operating experience with identical devices or similarly designed and constructed devices.
3. In the event the applicant desires that the general licensee under R9-7-306(A), or under equivalent regulations of the NRC or an Agreement State or Licensing State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the application shall include written instructions to be followed by the general licensee, estimated calendar quarter doses associated with the activity or activities, and bases for the estimates. The submitted information shall demonstrate that performance of the activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of 10 percent of the limits specified in R9-7-408.
4. A licensee authorized under subsection (A) to distribute a device to a generally licensed person shall provide, if a device that contains radioactive material is to be transferred for use under the general license granted in R9-7-306(A), the name of each person that is licensed under ~~R9-7-311(A)~~ subsection (A) and the information specified in this subsection for each person to whom a device will be transferred. The licensee shall provide this information before the device may be transferred. In the case of transfer through another person, the licensee shall provide the listed information to the intended user before initial transfer to the other person.
- a. The licensee shall provide:
    - i. A copy of the general license, issued under R9-7-306(A);<sub>2</sub>
    - ii. A copy of R9-7-443 and R9-7-445;<sub>2</sub>
    - iii. A list of the services that can only be performed by a specific licensee;<sub>2</sub>
    - iv. Information on authorized disposal options, including estimated costs of

- disposal; and
  - v. A list of civil penalties for improper disposal.
- b. The licensee shall:
- i. Report on a quarterly basis to the responsible Agreement State or NRC all transfers of devices to persons for use under a general license in accordance with 10 CFR 32.52, revised ~~January 1, 2013~~ December 19, 2014, incorporated by reference, ~~and~~ available under R9-7-101. ~~This incorporated material contains, and containing~~ no future editions or amendments;
  - ii. Maintain all information concerning transfers and receipts of devices that supports the reports required by subsection (A)(4)(b)(i); and
  - iii. Maintain records required by subsection (A)(4)(b)(i) for a period of at least three years following the date of the recorded event.
5. If radioactive material is to be transferred in a device for use under an equivalent general license of the NRC or another Agreement State, each person that is licensed under R9-7-304(B) shall provide the information specified in this subsection to each person to whom a device will be transferred. The licensee shall provide this information before the device is transferred. In the case of transfer through another person, the licensee shall provide the listed information to the intended user before initial transfer to the other person. The licensee shall provide:
- a. A copy of the Agreement State's requirements that are equivalent to R9-7-306(A), R9-7-443, and R9-7-445, and to A.R.S. § 30-657. If a copy of NRC regulations is provided to a prospective general licensee in lieu of the Agreement State's requirements, the licensee shall explain in writing that use of the device is regulated by the Agreement State. If certain requirements do not apply to a particular device, the licensee may omit the requirement from the material provided;
  - b. A list of the services that can only be performed by a specific licensee;
  - c. Information on authorized disposal options, including estimated costs of disposal; and
  - d. The name, title, address, and telephone number of the individual at the Agreement State regulatory agency who can provide additional information.
6. A licensee may propose to the Department an alternate method of informing the customer.

7. If a licensee has notified the Department of bankruptcy under R9-7-313(E) or is terminating under R9-7-319, the licensee shall provide, upon request, to the Department, the NRC, or another Agreement State, records of the disposition as required under A.R.S. § 30-657.
8. A licensee authorized to transfer a device to a generally licensed person, shall comply with the following requirements:
  - a. The person licensed under subsection (A) shall report all transfers of devices to persons for use under a general license obtained under R9-7-306(A), and all receipts of devices from persons licensed under R9-7-306(A) to the Department, the NRC, or other affected Agreement State. The report shall be submitted on a quarterly basis, in a clear and legible form, and contain the following information:
    - i. The identity of each general licensee by name and mailing address for the location of use. If there is no mailing address for the location of use, the person licensed under subsection (A) shall submit an alternate address for the general licensee, along with information on the actual location of use;
    - ii. The name, title, and telephone number of a person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the applicable laws;
    - iii. The date of transfer;
    - iv. The type, model number, and serial number of the device transferred; and
    - v. The quantity and type of radioactive material contained in the device.
  - b. If one or more intermediaries will temporarily possess the device at the intended place of use before its possession by the in-tended user, the report shall include the information required of the general licensee in subsection (A)(4) for both the intended user and each intermediary, clearly identifying the intended user and each intermediary.
  - c. For devices received from a general licensee, licensed under R9-7-306(A), the report shall include:
    - i. The identity of the general licensee by name and address;
    - ii. The type, model number, and serial number of the device received;
    - iii. The date of receipt; and



- iv. In the case of a device not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.
  - d. If the person licensed under subsection (A) makes a change to a device possessed by a general licensee so that the label must be changed to update required information, the report shall identify the general licensee, the device, and the changes to information on the device label.
  - e. The report shall cover a calendar quarter, be filed within 30 days of the end of each calendar quarter, and clearly indicate the period covered by the report.
  - f. The report shall clearly identify the person licensed under subsection (A) submitting the report and include the license number of the license.
  - g. If no transfers are made to or from persons generally licensed under R9-7-306(A) during a reporting period, the person licensed under subsection (A) shall submit a report indicating the lack of activity.
9. The licensee shall maintain records of all transfers for Department inspection. Records shall be maintained for at least three years after termination of the license to manufacture the generally licensed devices regulated under R9-7-306(A).
- B.** The Department shall grant a specific license to manufacture, assemble, repair, or initially transfer luminous safety devices that contain tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under R9-7-306(B), if the applicant satisfies:
- 1. The general requirements specified in R9-7-309; and
  - 2. The requirements of 10 CFR 32.53 through 32.56, revised ~~January 1, 2015~~ July 25, 2012, incorporated by reference, ~~and~~ available under R9-7-101. ~~This incorporated material contains, and containing~~ no future editions or amendments.
- C.** The Department shall grant a specific license to manufacture or initially transfer calibration or reference sources that contain americium-241, radium-226, or plutonium for distribution to persons generally licensed under R9-7-306(C) if the applicant satisfies:
- 1. The general requirements of R9-7-309; and
  - 2. The requirements of 10 CFR 32.57, 32.58, 32.59, and 70.39, revised ~~January 1, 2015~~ July 25, 2012, incorporated by reference, ~~and~~ available under R9-7-101. ~~This incorporated material contains, and containing~~ no future editions or amendments.
- D.** The Department shall grant a specific license to distribute radioactive material for use by a physician under the general license in R9-7-306(D) if:
- 1. The general requirements of R9-7-309; and
  - 2. The requirements of 10 CFR 32.57, 32.58, 32.59, and 70.39, revised ~~January 1, 2015~~ July

25, 2012, incorporated by reference, and available under R9-7-101. ~~This incorporated material contains, and containing~~ no future editions or amendments.

- E. The Department shall grant for a specific license to manufacture or distribute radioactive material for use under the general license of R9-7-306(E) if:
1. The applicant satisfies the general requirements specified in R9-7-309.
  2. The radioactive material is to be prepared for distribution in prepackaged units of:
    - a. Iodine-125 in units not exceeding 370 kBq (10 microcuries) each;
    - b. Iodine-131 in units not exceeding 370 kBq (10 microcuries) each;
    - c. Carbon-14 in units not exceeding 370 kBq (10 microcuries) each;
    - d. Hydrogen-3 (tritium) in units not exceeding 1.85 MBq (50 microcuries) each;
    - e. Iron-59 in units not exceeding 740 kBq (20 microcuries) each;
    - f. Cobalt-57 or selenium-75 in units not exceeding 370 kilobecquerels (10 microcuries) each;
    - g. Mock iodine-125 in units not exceeding 1.85 kBq (50 nanocuries) of iodine-129 and 185 Bq (5 nanocuries) of americium-241 each.
  3. Each prepackaged unit bears a durable, clearly visible label:
    - a. Identifying the radioactive contents as to chemical form and radionuclide and indicating that the amount of radioactivity does not exceed 370 kilobecquerels (10 microcuries) of iodine-125, iodine-131, cobalt-57, selenium-75, or carbon-14; 1.85 mega-becquerels (50 microcuries) of hydrogen-3 (tritium); 740 kilobecquerels (20 microcuries) of iron-59; or mock iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and 185 becquerels (0.005 microcurie) of americium-241 each; and
    - b. Displaying the radiation caution symbol described in R9-7-428, the words, "CAUTION, RADIOACTIVE MATERIAL," and the phrase "Not for Internal or External Use in Humans or Animals."
  4. One of the following statements, or a substantially similar statement that contains the information called for in the following statements appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure that accompanies the package:
    - a. This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation from the radioactive material, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations

and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

\_\_\_\_\_  
Name of Manufacturer

- b. This radioactive drug may be received, acquired, possessed, and used only by physicians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation from the radioactive material, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a Licensing State.

\_\_\_\_\_  
Name of Manufacturer

5. The label affixed to the unit, or the leaflet or brochure that accompanies the package, contains adequate information about the precautions to be observed in handling and storing the specified radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in R9-7-434.

**F.** The Department shall grant for a specific license to manufacture and distribute ice detection devices to persons generally licensed under R9-7-306(F) if the applicant satisfies:

1. The general requirements of R9-7-309; and
2. The criteria of 10 CFR 32.61 and 32.62, revised ~~January 1, 2015~~ July 25, 2012, incorporated by reference, ~~and~~ available under R9-7-101. ~~This incorporated material contains, and containing~~ no future editions or amendments.

**G.** The Department shall grant a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs that contain radioactive material for use by a person authorized in accordance with Article 7 of this Chapter, if the applicant meets all of the requirements in 10 CFR 30.32(j), revised November 21, 2023, or 10 CFR 32.72, revised ~~January 1, 2013~~ August 24, 2023, both incorporated by reference, ~~and~~ available under R9-7-101. ~~This incorporated material contains, and containing~~ no future editions or amendments.

1. Authorization under this Section to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.

2. Each licensee authorized under this Section to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:
  - a. Satisfy the labeling requirements in R9-7-431 for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium; and
  - b. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in R9-7-449.
3. A licensee that is a pharmacy authorized under this Section to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual who prepares PET radioactive drugs be an:
  - a. Authorized nuclear pharmacist that meets the requirements in R9-7-712, or
  - b. Individual under the supervision of an authorized nuclear pharmacist as specified in R9-7-706.
4. A pharmacy, authorized under this Section to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of R9-7-712.

**H.** The Department shall grant a specific license to manufacture and distribute generators or reagent kits that contain radioactive material for preparation of radiopharmaceuticals by persons licensed according to 9 A.A.C. 7, Article 7 if:

1. The applicant satisfies the general requirements of R9-7-309;
2. The applicant submits evidence that:
  - a. The generator or reagent kit is to be manufactured, labeled and packaged according to the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, a new drug application (NDA) approved by the Food and Drug Administration (FDA), a biologic product license issued by FDA, or a “Notice of Claimed Investigational Exemption for a New Drug” (IND) that has been accepted by the FDA; or
  - b. The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act;
3. The applicant submits information on the radionuclide; chemical and physical form,

packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

4. The label affixed to the generator or reagent kit contains information on the radionuclide, including quantity, and date of assay; and
5. The label affixed to the generator or reagent kit, or the leaflet or brochure that accompanies the generator or reagent kit, contains:
  - a. Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit; and
  - b. A statement that this generator or reagent kit (as appropriate) is approved for use by persons licensed by the Department under 9 A.A.C. 7, Article 7 or equivalent licenses of the U.S. Nuclear Regulatory Commission or an Agreement State or Licensing State. The labels, leaflets or brochures required by this subsection supplement the labeling required by FDA and they may be separate from or, with the approval of FDA, combined with the labeling required by FDA.

**I.** The Department shall grant a specific license to manufacture and distribute sources and devices that contain radioactive material to a person licensed in accordance with Article 7 of this Chapter for use as a calibration, transmission, or reference source or for medical purposes, if the applicant meets all of the requirements in 10 CFR 32.74, revised ~~January 1, 2015~~ July 25, 2012, incorporated by reference, and available under R9-7-101. ~~This incorporated material contains, and containing~~ no future editions or amendments.

**J.** Requirements for license to manufacture and distribute industrial products containing depleted uranium for mass volume applications.

1. The Department shall grant a specific license to manufacture industrial products and devices that contain depleted uranium for use under ~~R9-7-305(C)~~ R9-7-305(F) or equivalent regulations of the ~~U.S. Nuclear Regulatory Commission~~ NRC or an another Agreement State if:
  - a. The applicant satisfies the general requirements in R9-7-309;
  - b. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive a radiation dose in excess of 10 percent of the limits specified in R9-7-408; and

- c. The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.
2. In the case of an industrial product or device whose unique benefits are questionable, the Department shall approve an application for a specific license under this subsection only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.
3. The Department may deny any application for a specific license under this subsection if the end use or uses of the industrial product or device cannot be reasonably foreseen.
4. Each person licensed under subsection (J)(1) shall:
  - a. Maintain the level of quality control required by the license in the manufacture of the industrial product or device and the installation of the depleted uranium into the product or device;
  - b. Label or mark each unit to:
    - i. Identify the manufacturer of the product or device, the number of the license under which the product or device was manufactured or initially transferred, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and
    - ii. State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent ~~and the~~ regulations of the U.S. Nuclear Regulatory Commission or an Agreement State;
  - c. Assure that the depleted uranium, before being installed in each product or device, has been impressed with the following legend, clearly legible through any plating or other covering: “Depleted Uranium”;
  - d. Furnish a copy of the general license contained in ~~R9-7-305(C)~~ R9-7-305(F) and a copy of ARRA-23 to each person to whom depleted uranium in a product or device is transferred for use under a general license contained in ~~R9-7-305(C)~~ R9-7-305(F); or
  - e. Furnish a copy of the general license contained in the ~~U.S. Nuclear Regulatory Commission’s~~ U.S. Nuclear Regulatory Commission’s NRC’s or Agreement State’s regulation equivalent to ~~R9-7-305(C)~~ R9-7-305(F) and a copy of the ~~U.S. Nuclear Regulatory Commission’s~~ U.S. Nuclear Regulatory Commission’s NRC’s or

Agreement State's certificate, or alternatively, furnish a copy of the general license contained in ~~R9-7-305(C)~~ R9-7-305(F) and a copy of ARRA-23 to each person to whom depleted uranium in a product or device is transferred for use under a general license of the ~~U.S. Nuclear Regulatory Commission~~ NRC or an Agreement State, with a document explaining that use of the product or device is regulated by the ~~U.S. Nuclear Regulatory Commission~~ NRC or an Agreement State under requirements substantially the same as those in ~~R9-7-305(C)~~ R9-7-305(F);

- f. Report to the Department all transfers of industrial products or devices to persons for use under the general license in ~~R9-7-305(C)~~ R9-7-305(F). The report shall identify each general licensee by name and address, an individual by name or position who serves as the point of contact person for the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under ~~R9-7-305(C)~~ R9-7-305(F) during the reporting period, the report shall so indicate;
  - i. Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the ~~U.S. Nuclear Regulatory Commission~~ NRC general license in 10 CFR 40.25; or
  - ii. Report to the responsible state agency all transfers of devices manufactured and distributed under subsection (J)(4)(f) for use under a general license in that state's regulations equivalent to ~~R9-7-305(C)~~ R9-7-305(F);
  - iii. The report required in subsection (J)(4)(f)(i) or (ii) shall identify each general licensee by name and address, an individual by name or position who serves as the contact person for the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which a product or device is transferred to the generally licensed person;
  - iv. If no transfers have been made to ~~U.S. Nuclear Regulatory Commission~~ NRC licensees during the reporting period, this information shall be

reported to the ~~U.S. Nuclear Regulatory Commission~~ NRC;

- v. If no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement state agency; and
- vi. ~~Keep records~~ Records showing the name, address, and contact person for each general licensee to whom depleted uranium in industrial products or devices is transferred for use under a general license provided in ~~R9-7-305(C)~~ R9-7-305(F) or equivalent regulations of the ~~U.S. Nuclear Regulatory Commission~~ NRC or of ~~an~~ another Agreement State. ~~The records~~ shall be maintained for a period of at least three years and show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the reporting requirements of this Section.

- K.** A licensee who manufactures nationally tracked sources, as defined in Article 4, shall:
  - 1. Serialize the sources in accordance with 10 CFR 32.201, revised ~~January 1, 2013~~ November 8, 2006, incorporated by reference, ~~and~~ available under R9-7-101. ~~This incorporated material contains, and containing~~ no future editions or amendments; and
  - 2. Report manufacturing activities in accordance with R9-7-454.

**R9-7-313. Specific Terms and Conditions**

- A.** Each license issued under this Article is subject to all provisions of A.R.S. Title 30, Chapter 4 and to all rules, regulations, and orders of the Department.
- B.** A licensee shall not transfer, assign, or in any manner dispose of a license issued or granted under this Article or a right to possess or utilize radioactive material granted by any license issued under this Article unless the Department finds that the transfer is consistent with the Department's statutes and rules, and gives its consent in writing. An application for transfer of license must include:
  - 1. The identity, technical and financial qualifications of the proposed transferee; and
  - 2. Financial assurance for decommissioning information required by R9-7-323.
- C.** Each person licensed by the Department under this Article shall confine the use and possession of the material licensed to the locations and purposes authorized in the license.
- D.** Each license issued pursuant to the rules in Articles 3, 5, 7, and 15 of this Chapter shall be deemed to contain the provisions set forth in the Act, whether or not these provisions are expressly set forth in the license.
- E.** The Department may incorporate, in any license issued pursuant to the rules in this Chapter, at the



time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of byproduct material as it deems appropriate or necessary in order to:

1. Promote the common defense and security;
2. Protect health or to minimize danger to life or property;
3. Protect restricted data; or
4. Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and rules thereunder.

**F.** Licensees required to submit emergency plans in accordance with R9-7-322 shall follow the emergency plan approved by the Department. The licensee may change the approved plan without Department approval only if the changes do not reduce the commitment of the plan. The licensee shall furnish the change to the Department and to affected offsite response organizations within six months after the change is made. Proposed changes that reduce, or potentially reduce, the commitment of the approved emergency plan may not be implemented without prior application to and prior approval by the Department.

**G.** Each person licensed under this Section and each general licensee that is required to register under R9-7-306(A)(4)(o) shall notify the Department in writing if the licensee decides to permanently discontinue any or all activities involving materials authorized under the license. A specific licensee or general licensee shall notify the Department, in writing:

1. Immediately following the filing of a petition for bankruptcy under any Chapter of Title 11 of the United States Code if the petition for bankruptcy is by or against:
  - a. The licensee;
  - b. An entity (as defined in the bankruptcy code) controlling the licensee or listing the license or licensee as property of the estate; or
  - c. An affiliate (as defined in the bankruptcy code) of the licensee; and
2. Providing the following information:
  - a. The bankruptcy court in which the petition for bankruptcy was filed, and
  - b. The bankruptcy case title and number, and
  - c. The date the petition was filed.

**H.** Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with R9-7-720. The licensee shall record the results of each test and

retain each record for at least three years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in R9-7-720 at the time of generator elution, in accordance with ~~10 CFR 35.3204~~ R9-7-720(E) and (F).

**I. Inalienability of Licenses**

1. No license issued or granted pursuant to the regulations in this part shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Department, after securing full information, finds that the transfer is in accordance with the provisions of this ~~act~~ Act and gives its consent in writing.
2. An application for transfer of license must include:
  - a. The identity, technical and financial qualifications of the proposed transferee; and
  - b. Financial assurance for decommissioning information required by R9-7-323, 10 CFR 40.3 and 10 CFR 70.25.

**R9-7-318. Transfer of Radioactive Material**

- A.** A licensee shall not transfer radioactive material except as authorized under this Section.
- B.** Except as otherwise provided in the license and subject to the provisions of subsections (C) and (D), any licensee may transfer radioactive material:
  1. To the Department, after receiving prior approval from the Department;
  2. To the Department of Energy;
  3. To any person exempt from the rules in this Article to the extent permitted under the exemption;
  4. To any person authorized to receive radioactive material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Department, the ~~U.S. Nuclear Regulatory Commission~~ NRC, or any Agreement State or Licensing State, or to any person otherwise authorized to receive radioactive material by the Federal Government or any agency of the Federal Government, the Department, any Agreement State or Licensing State; or
  5. As otherwise authorized by the Department in writing.
- C.** Before transferring radioactive material to a specific licensee of the Department, the ~~U.S. Nuclear Regulatory Commission~~ NRC, or ~~an~~ another Agreement State or Licensing State, or to a general licensee who is required to register with the Department, the ~~U.S. Nuclear Regulatory Commission~~ NRC, or ~~an~~ another Agreement State or Licensing State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license

authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

**D.** The transferor shall use one or more of the following methods for the verification required by subsection (C):

1. The transferor shall possess, and read, a current copy of the transferee's specific license or registration certificate;
2. The transferor shall possess a written certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;
3. For emergency shipments the transferor shall accept oral certification by the transferee that the transferee is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided the oral certification is confirmed in writing within 10 days;
4. The transferor shall obtain information equivalent to that in subsection (D)(1) to (3) compiled by a reporting service from official records of the Department, the ~~U.S. Nuclear Regulatory Commission~~ NRC, or the licensing agency of ~~an~~ another Agreement State or Licensing State regarding the identity of any licensee and the scope and expiration date of any license, registration, or certificate; or
5. When none of the methods of verification described in subsections (D)(1) to (4) are readily available or when a transferor desires to verify that information received by one of the above methods is correct or up-to-date, the transferor shall obtain and record confirmation from the Department, the ~~U.S. Nuclear Regulatory Commission~~ NRC, or the licensing agency of ~~an~~ another Agreement State or Licensing State that the transferee is licensed to receive the radioactive material.

**E.** A transferor shall prepare and transport radioactive material as prescribed in the provisions of 9 A.A.C. 7, Article 15.

**F.** The Department shall approve an application for a specific license to initially transfer source material for use under R9-7- 305, or equivalent regulations of the NRC or another Agreement State, if:

1. The applicant satisfies the general requirements specified in R9-7-309; and
2. The applicant submits adequate information on, and the Department approves, the methods to be used for quality control, labeling, and providing safety instructions to recipients.

- G.** Each person licensed under ~~this Section~~ subsection (F) shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, "RADIOACTIVE MATERIAL."
- H.** Each person licensed under ~~this Section~~ subsection (F) shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.
- I.** Each person licensed under ~~this Section~~ subsection (F) shall provide the information specified in subsections (I)(1) and (2) to each person to whom source material is transferred for use under R9-7-305 or equivalent provisions in the NRC or Agreement State regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:
1. A copy of R9-7-305 and ~~R9-7-318~~ this Section, or relevant equivalent regulations of the NRC or another Agreement State; and
  2. Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the source material.
- J.** Each person licensed under ~~10 CFR 40.54~~ subsection (F) shall ~~file a report with the Department that includes the following information~~ report transfers as follows:
1. File a report with the Department, as specified in R9-7-1907(1) through (3), that includes the following information:
    - ~~1-a.~~ The name, address, and license number of the person who transferred the source material;
    - ~~2-b.~~ For each general licensee under R9-7-305 or equivalent NRC or Agreement State regulations to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and
    - ~~3-c.~~ The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.
  2. File a report with the Department and each responsible NRC and/or Agreement State agency that identifies all persons, operating under provisions equivalent to R9-7-305, to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to the NRC or another Agreement State being reported to:

- a. The name, address, and license number of the person who transferred the source material;
  - b. For each general licensee under R9-7-305 or equivalent NRC or Agreement State regulations to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and
  - c. The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients with the NRC or another Agreement State.
3. Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under R9-7-305 or equivalent NRC or another Agreement State provisions during the current period, a report shall be submitted to the Department indicating so. If no transfers have been made to general licensees in NRC jurisdiction or a particular Agreement State during the reporting period, this information shall be reported to the NRC or responsible Agreement State upon request of the Agency.
- K.** Each person licensed under ~~this Section~~ subsection (F) shall maintain all information that supports the reports required by this Section concerning each transfer to a general licensee for a period of one year after the event is included in a report to the Department, the NRC, or another Agreement State.

## ARTICLE 7. MEDICAL USES OF RADIOACTIVE MATERIAL

### R9-7-709. Sealed Sources or Devices for Medical Use

A For medical use, a licensee may only use:

1. Sealed sources, ~~including teletherapy sources,~~ or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under Article 3 of this Chapter, ~~equivalent regulations of the NRC~~ or equivalent requirements of ~~an~~ the NRC or another Agreement State; ~~or~~
2. Sealed sources or devices noncommercially transferred from another ~~medical licensee~~ under this Article or a licensee under equivalent requirements of the NRC or another Agreement State; or
3. Teletherapy sources manufactured and distributed in accordance with a license issued by the Department, under Article 3 of this Chapter or the equivalent requirements of the NRC, or another Agreement State.

### 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~~ another Agreement State. To have its certification process recognized, a specialty board shall require all candidates for certification to:
  - a. Meet the following minimum requirements:
    - i. Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;
    - ii. Have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience), including at least three years in applied health physics; and
    - iii. Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

- b. Meet the following minimum requirements:
    - i. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
    - ii. Have at least 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~~ another 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 or by a master material license permittee of broad scope May 5, 2007 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 a NRC master material license broad scope permittee May 5, 2007 need not comply with the training requirements in this Article.~~

**D.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.

**E.D.** Individuals who, under ~~subsection (C)~~ R9-7-712.01, 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.E.** 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 at least 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~~ another 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 at least 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 or by a master material license permittee of broad scope before May 5, 2007 need not comply with the training requirements in subsection (A).~~

~~**D.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.~~

~~**E.D.** Individuals who, under ~~subsection (C)~~ R9-7-712.01, 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~~ another Agreement State. To have its certification process recognized, a specialty board shall require all candidates for certification to:
  - a. Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;
  - b. Hold a current, active license to practice pharmacy in Arizona;
  - c. Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and
  - d. Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or
2. Has completed 700 hours in a structured educational program consisting of both:
  - a. 200 hours of classroom and laboratory training in the following areas:
    - i. Radiation physics and instrumentation;
    - ii. Radiation protection;
    - iii. Mathematics pertaining to the use and measurement of radioactivity;
    - iv. Chemistry of radioactive material for medical use; and
    - v. Radiation biology; and
  - b. Supervised practical experience in a nuclear pharmacy involving:
    - i. Shipping, receiving, and performing related radiation surveys;
    - ii. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
    - iii. Calculating, assaying, and safely preparing dosages for patients or human research subjects;
    - iv. Using administrative controls to avoid medical events in the administration of radioactive material; and
    - v. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

3. Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in subsection (A)(2) and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

~~**B.** Exceptions. An individual identified as a nuclear pharmacist on 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 or by a master material license permittee of broad scope before the effective date of these rules need not comply with the training requirements in subsections (A)(1) through (A)(3).~~

~~**C.B.**~~ 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.C.**~~ Individuals who, under ~~subsection (B)~~ R9-7-712.01, 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.

**R9-7-712.01. Training for Experienced Radiation Safety Officers, Teletherapy or Medical Physicists, Authorized Medical Physicists, Authorized Users, Nuclear Pharmacists, and Authorized Nuclear Pharmacists**

**A.** Exemptions from required training:

1. An individual identified 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 or by a master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before January 14, 2019, need not comply with the training requirements of R9-7-710, R9-7-711, or R9-7-712, respectively, except the Radiation Safety Officers and authorized medical physicists identified in this subsection must meet the training requirements in R9-7-710(B) or R9-7-711(B), as appropriate, for any material or uses for which they were not authorized prior to January 14, 2019.
2. Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics;

Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of R9-7-710 to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on a Department, a NRC, or another Agreement State license or NRC master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

3. Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in R9-7-711, for those materials and uses that these individuals performed on or before October 24, 2005.
4. A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of R9-7-710, R9-7-711, or R9-7-712, respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and during the time period identified in this subsection, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of this Section.

**B.** Exemptions from required training for physicians, dentists, or podiatrists:

1. Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Department, the NRC, or another Agreement State, a permit issued by a NRC master material licensee, a permit issued by a NRC or an Agreement State broad scope licensee, or a permit issued by a NRC master material license broad scope permittee on or before January 14, 2019, who perform only those medical uses for which they were authorized on or before January 14, 2019, need not comply with the training requirements of Article 7, Exhibit A, Groups 100 through 600.

2. Physicians, dentists, or podiatrists not identified as authorized users for the medical use of byproduct material on a license issued by the Department, the NRC, or another Agreement State, a permit issued by a NRC master material licensee, a permit issued by a NRS or an Agreement State broad scope licensee, or a permit issued in accordance with a NRC master material broad scope license on or before October 24, 2005, need not comply with the training requirements of Article 7, Exhibit A, Groups 100 through 600 for those materials and uses that these individuals performed on or before October 24, 2005, as follows:
- a. For uses authorized under Article 7, Exhibit A, Group 100 or 200, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;
  - b. For uses authorized under Article 7, Exhibit A, Group 300, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;
  - c. For uses authorized under Article 7, Exhibit A, Group 400 or 600, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and
  - d. For uses authorized under Article 7, Exhibit A, Group 500, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of

Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

3. Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements Article 7, Exhibit A, Groups 100 through 600 when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this subsection, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of this Section.

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

**R9-7-718. Mobile Medical Service**

A. A licensee providing mobile medical service shall:

1. Obtain a letter signed by the management of each client for which services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;
2. Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this sub-section shall include a constancy check;
3. Check survey instruments for proper operation with a dedicated check source before use at each client's address; and
4. Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in Article 4 of this Chapter.

B. A mobile medical service may not have radioactive material delivered from the manufacturer or the distributor to the client unless the client has a license allowing its possession. If applicable, radioactive material delivered to the client shall be received and handled in conformance with the client's license.

C. A licensee providing mobile medical services shall retain ~~the letter required in subsection (A)(1)~~ and the record of each survey required in subsection (A)(4) for at least three years from after the



date of the survey.

**R9-7-719. Training for Uptake, Dilution, and Excretion Studies**

- A. Except as provided in ~~R9-7-710~~ R9-7-712.01, ~~the~~ a licensee shall require an authorized user of unsealed radioactive material for the uses authorized under Group 100 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 the names of which are specified in the NRC's Medical Uses Licensee Toolkit available through <https://www.nrc.gov>, and who meets the requirements in subsection (A)(3).~~ as the names of which are specified in the NRC's Medical Uses Licensee Toolkit available through <https://www.nrc.gov>, and who meets the requirements in subsection (A)(3). To have its certification process recognized, a specialty board shall require all candidates for certification to:
    - a. Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in ~~subsection (A)(3)~~ subsections (A)(3)(a)(i) and (ii); and
    - b. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control;
  2. Is an authorized user under R9-7-721, R9-7-723, the or equivalent requirements of the NRC, or equivalent another Agreement State requirements; or
  3. Has:
    - a. Completed 60 hours of training and experience, including a minimum of eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:
      - 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 this Section, R9-7-712.01, R9-7-721, or R9-7-723,~~ this Section, R9-7-712.01, R9-7-721, or R9-7-723, or equivalent requirements of the NRC or another

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; and
- (6) Administering dosages of radioactive drugs to patients or human research subjects; and

b. Obtained written attestation that the individual has satisfactorily completed the requirements in subsection (A)(1) or subsection (A)(3)(a) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under Group 100 in 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, R9-7-712.01, R9-7-721, or R9-7-723; or equivalent requirements of the NRC; or equivalent another Agreement State requirements; or
- ii. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this Section, R9-7-712.01, R9-7-721, or R9-7-723; or equivalent requirements of the NRC; or equivalent another Agreement State 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)(3)(a).

- B. The training and experience in subsections (A)(1)(a) or (3)(a) shall have been obtained within the seven years preceding the date of application or the individual shall have had related continuing education and experience since the required training and experience was completed.
- C. Individuals who, under R9-7-710(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.

**R9-7-720. Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations**

- A. A licensee may not administer to humans a radiopharmaceutical that contains more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m) or, more than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).
- B. A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration ~~of the first eluate after receipt of~~ in each eluate from a generator to demonstrate compliance with subsection (A).
- C. A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with subsection (A).
- D. A licensee shall maintain a record of each molybdenum-99 concentration measurement or strontium-82 and strontium-85 concentrations measurements for at least three years following completion of the measurement.
- E. A licensee shall notify by telephone the ~~NRC Operations Center~~ Department and the distributor of the generator within seven calendar days after discovery that an eluate exceeded the permissible concentration listed in subsection (A) at the time of generator elution. The telephone report to the ~~NRC~~ Department must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects; when the distributor was notified; and the action taken.
- F. A licensee shall submit a written report, according to R9-7-1907(1) through (3), to the Department within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if

the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures, or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report required by subsection (E).

**R9-7-721. Training for Imaging and Localization Studies Not Requiring a Written Directive**

Except as provided in ~~R9-7-710~~ R9-7-712.01, ~~the~~ a licensee shall require an authorized user of unsealed radioactive material for the uses authorized under Group 200 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 the names of which are specified in the NRC's Medical Uses Licensee Toolkit available through <https://www.nrc.gov>, ~~and who meets the requirements in subsection (3).~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:
  - a. Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in subsection ~~(3)~~ (3)(a); and
  - b. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control;
2. Is an authorized user under R9-7-723 and meets the requirements in subsection (3)(a)(ii)(7), the or equivalent NRC, or equivalent Agreement State requirements; or
3. Has:
  - a. Completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include:
    - 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 Section; ~~R9-7-710, R9-7-712.01;~~ or both subsection (3)(a)(ii)(7) and R9-7-723 ~~and in subsection (3)(b)(vii);~~ or the equivalent requirements of the NRC; or ~~equivalent~~ another Agreement State ~~requirements~~. An authorized nuclear pharmacist who meets the requirements in R9-7-712 may provide the supervised work experience for subsection (3)(a)(ii)(7). Work experience must involve:

- (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; and
- (7) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the elate for radionuclide purity, and processing the elate with reagent kits to prepare labeled radioactive drugs; and

b. Obtained written attestation that the individual has satisfactorily completed the requirements in subsection (3)(a) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under ~~Group~~ Groups 100 and 200 in 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; ~~R9-7-710, R9-7-712.01;~~ or both subsection (3)(a)(ii)(7) and R9-7-723; or equivalent NRC ~~requirements;~~ or ~~equivalent~~ Agreement State requirements; or
- ii. A residency program director who affirms in writing that the attestation

represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this Section; ~~R9-7-710~~, R9-7-712.01; or both subsection (3)(a)(ii)(7) and R9-7-723; or equivalent NRC requirements; or equivalent Agreement State 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 (3)(a).

**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~~ R9-7-712.01, ~~the~~ a 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 the names of which are 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 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~~ Section, R9-7-712.01, or equivalent NRC; or equivalent Agreement State requirements, involving a supervising authorized user, who meets the requirements in subsection (A)(2), must also have experience in administering dosages in the same dosage category or categories, as specified in subsection (A)(2)(a)(ii)(6), as the individual requesting authorized user status. The work experience must involve:
    - (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 from the following three categories, with radioactive drugs containing radionuclides in categories not included being regulated under Group 1000 in Exhibit A.

Medical Use Groups of this Article. This work experience must involve 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; and
  - (c) Parenteral administration of any ~~beta emitter, or a photon emitting radionuclide with a~~ radioactive drug that contains a radionuclide that is primarily used for the radionuclide's electron emission, beta radiation characteristics, alpha radiation characteristics, or 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~~
- b. Obtained written attestation, that the individual has satisfactorily completed the requirements in subsection (A)(2)(a) and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under Group 300 in Exhibit A, Medical Use Groups of this Article for which the individual is requesting authorized user status. 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 and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or
  - ii. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in



this Section, R9-7-712.01, or equivalent Agreement State or NRC requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency pro-gram 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).

- B. Except as provided in ~~R9-7-710~~ R9-7-712.01, a licensee shall require an authorized user of iodine-131 for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) to be a physician who has completed the training requirements in 10 CFR 35.392, ~~January 1, 2013~~ July 16, 2018, which is incorporated by reference, ~~and~~ available under R9-7-101. ~~This incorporated material contains,~~ and containing no future editions or amendments.
- C. Except as provided in ~~R9-7-710~~ R9-7-712.01, a licensee shall require an authorized user of iodine-131 for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries) to be a physician who has completed the training requirements in 10 CFR 35.394, ~~January 1, 2013~~ July 16, 2018, which is incorporated by reference, ~~and~~ available under R9-7-101. ~~This incorporated material contains,~~ and containing no future editions or amendments.
- D. Except as provided in ~~R9-7-710~~ R9-7-712.01, a licensee shall require an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive to be a physician who has completed the training requirements in 10 CFR 35.396, ~~January 1, 2013~~ July 16, 2018, which is incorporated by reference, ~~and~~ available under R9-7-101. ~~This incorporated material contains,~~ and containing 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~~ R9-7-712.01, ~~the~~ a licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under Group 400 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, the names of which are specified in the NRC's Medical Uses Licensee Toolkit available through <https://www.nrc.gov>, 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 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, R9-7-712.01, or equivalent NRC or Agreement State requirements at a medical institution authorized to use byproduct materials under Group 400 in Exhibit A, Medical Use Groups of this Article, 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~~ At least three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in this Section, R9-7-712.01, or equivalent NRC or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subsection (A)(2)(b); and
- d. 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 Group 400 in 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, R9-7-712.01, 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, R9-7-712.01, 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)~~ subsections (A)(2)(a) through (c).

**B.** Except as provided in R9-7-712.01, a licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

- 1. Is an authorized user under subsection (A) or equivalent Agreement State or NRC

requirements; or

(2) Has:

- a. Completed at least 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, including:
  - i. Radiation physics and instrumentation,
  - ii. Radiation protection,
  - iii. Mathematics pertaining to the use and measurement of radioactivity, and
  - iv. Radiation biology;
- b. Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals, including:
  - i. Examination of each individual to be treated,
  - ii. Calculation of the dose to be administered,
  - iii. Administration of the dose, and
  - iv. Follow up and review of each individual's case history; and
- c. Obtained written attestation, signed by a preceptor authorized user who meets the requirements in subsection (A) or (B), R9-7-712.01, or equivalent Agreement State or NRC requirements, that the individual has satisfactorily completed the requirements in subsections (B)(2)(a) and (b) and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

**B.C.** A licensee who uses strontium-90 for ophthalmic treatments must ensure that certain activities as specified in subsection ~~(C)~~ (D) 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 the Department or an NRC or other Agreement State broad scope medical use licensee,
    - iii. Medical use permit issued by an NRC master material licensee, or
    - iv. Permit issued by an NRC master material licensee 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.D.** The individuals who are identified in subsection ~~(B)(1) or (2)~~ (C)(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~~ subsection (A) 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.E.** Licensees shall retain a record of the activity of each strontium-90 source in accordance with R9-7-313.

**E.F.** 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.

**R9-7-728. Training for Use of Sealed Sources for Diagnosis**

**A.** Except as provided in ~~R9-7-710~~ R9-7-712.01, ~~the~~ a licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under Group 500 in Exhibit A, Medical Use Groups of this Article to be a physician, dentist, or podiatrist who:

- 1. Is certified by a medical specialty board whose certification process has been recognized by the NRC or an Agreement State, the names of which are specified in the NRC's Medical Uses Licensee Toolkit available through <https://www.nrc.gov>, and who meets

the requirements in subsections (A)(3) and (B) ~~and whose certification has been recognized by the Department, the NRC, or another Agreement State as specified in the NRC's Medical Uses Licensee Toolkit available through <https://www.nrc.gov>;~~

2. Is an authorized user for uses listed in Group 200 of Exhibit A, Medical Use Groups of this Article or equivalent NRC or Agreement State requirements; or
3. Has completed at least eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. ~~The training must include, including:~~
  - a. Radiation physics and instrumentation;
  - b. Radiation protection;
  - c. Mathematics pertaining to the use and measurement of radioactivity;
  - d. Radiation biology.

**B.** A licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under Group 500 in Exhibit A, Medical Use Groups of this Article to have completed training in the use of the device for the uses requested.

**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.

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

**A.** Except as provided in ~~R9-7-710~~ R9-7-712.01, 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 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~~ subsection (A), R9-7-712.01, 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 at least three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in ~~this Section~~ subsection (A), R9-7-712.01, or equivalent Agreement State or NRC requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subsection (A)(2)(b); and
  - d. 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 subsection (A), R9-7-712.01~~, 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.

**Exhibit A. Medical Use Groups**

**Group 100**

Included is the use of any unsealed radioactive material for use in uptake, dilution, or excretion studies and not requiring a written directive: ~~The radioactive material in this group shall be~~ Except for quantities



that require a written directive under R9-7-707, a licensee may use unsealed byproduct material prepared for medical use for uptake, dilution, or excretion studies that is:

1. Obtained from:
  - a. ~~a~~ A manufacturer or preparer licensed under R9-7-703(C)(2)(a), or equivalent NRC or Agreement State requirements; or
  - ~~2-b.~~ ~~Obtained from a~~ A PET radioactive drug producer licensed under R9-7-703 or equivalent NRC or an Agreement State license;
2. ~~excluding~~ Excluding production of PET radionuclides, prepared by:
  - a. ~~an~~ An authorized nuclear pharmacist who meets the requirements in R9-7-712;
  - b. a A physician who is an authorized user and who meets the requirements specified in R9-7-721; or both R9-7-721(3)(a)(ii)(7) and R9-7-723 and R9-7-721(3)(b)(vii); or
  - c. ~~an~~ An individual under the supervision, ~~of either~~ as specified in R9-7-706, of the authorized nuclear pharmacist in subsection (2)(a) or the physician who is an authorized user in subsection (2)(b); or
3. If a research protocol:
  - a. ~~Obtained from and prepared by an Agreement State or NRC~~ a Department, NRC, or another Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or
  - b. Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

### **Group 200**

Included is the use of any unsealed radioactive material for use in imaging and localization not requiring a written directive. ~~PET radiopharmaceuticals may be used if the licensee meets the requirements in R9-7-716. The radioactive material in this group shall be~~ Except for quantities that require a written directive under R9-7-707, a licensee may use unsealed byproduct material prepared for medical use for imaging and localization studies that is:

1. Obtained from:
  - a. a A manufacturer or preparer licensed under R9-7-703(C)(2)(a), or equivalent NRC or Agreement State requirements; or
  - ~~2-b.~~ ~~Obtained from a~~ A PET radioactive drug producer licensed under R9-7-703 or equivalent NRC or an Agreement State license;

2. ~~excluding~~ Excluding production of PET radionuclides, prepared by:
  - a. ~~an~~ An authorized nuclear pharmacist who meets the requirements in R9-7-712;
  - b. ~~a~~ A physician who is an authorized user and who meets the requirements specified in R9-7-721; or both R9-7-721(3)(a)(ii)(7) and R9-7-723 and R9-7-721(3)(b)(vii); or
  - c. ~~an~~ An individual under the supervision, ~~of either~~ as specified in R9-7-706, of the authorized nuclear pharmacist in subsection (2)(a) or the physician who is an authorized user in subsection (2)(b); or
3. If a research protocol:
  - a. Obtained from and prepared by ~~an Agreement State or NRC~~ a Department, NRC, or another Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or
  - b. Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

### Group 300

Included is the use of any unsealed byproduct radioactive material, identified in R9-7-723(A)(2)(a)(ii)(6), prepared for medical use (radiopharmaceutical) and for which a written directive is required. ~~The radioactive material in this group shall be that is:~~

1. Obtained from:
  - a. ~~a~~ A manufacturer or preparer licensed under R9-7-703(C)(2)(a), or equivalent NRC or Agreement State requirements; or
  - ~~2-b.~~ ~~Obtained from a~~ A PET radioactive drug producer licensed under R9-7-703 or equivalent NRC or an Agreement State license;
2. ~~excluding~~ Excluding production of PET radionuclides, prepared by:
  - a. ~~an~~ An authorized nuclear pharmacist who meets the requirements in R9-7-712;
  - b. ~~a~~ A physician who is an authorized user and who meets the requirements specified in R9-7-721 or R9-7-723;
  - c. ~~an~~ An individual under the supervision, ~~of either~~ as specified in R9-7-706, of the authorized nuclear pharmacist in subsection (2)(a) or the physician who is an authorized user in subsection (2)(b); or
3. If a research protocol:
  - a. Obtained from and prepared by ~~an Agreement State or NRC~~ a Department, NRC,

or another Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

- b. Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

#### **Group 400**

~~Included is the use of any brachytherapy source for therapeutic medical use that is manufactured in accordance with R9-7-703(C)(2)(b) and~~ sources for manual brachytherapy. A licensee must use only brachytherapy sources:

1. Approved for therapeutic use in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or
2. Part of a research protocol that is approved for therapeutic use under In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA, and meets provided that the requirements of R9-7-709 are met.

#### **Group 500**

~~Included is the use of any sealed source that is manufactured in accordance with R9-7-703(C)(2)(b), and is approved for diagnostic use in the Sealed Source and Device Registry.~~

Included is the use of sealed sources and medical devices for diagnosis.

1. A licensee may only use sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.
2. A licensee may only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions

and limitations described in the Sealed Source and Device Registry.

3. Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of R9-7-709(1) are met.

### **Group 600**

Included is the use of sealed sources in ~~photon-emitting~~ remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units, ~~that are manufactured in accordance with R9-7-703(C)(2)(b) and:~~

1. ~~Approved for therapeutic use in the Sealed Source and Device Registry; or~~
2. ~~Part of a research protocol that is approved for therapeutic use under an active Investigational Device Exemption (IDE) application accepted by the FDA and meets the requirements of R9-7-709.~~

#### **A.** A licensee must only use sealed sources:

1. Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses: or
2. In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of R9-7-709(1) are met.

#### **B.** A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

1. Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or
2. In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of R9-7-709(1) are met.

### **Group 1000**

A licensee may use ~~radioactive~~ byproduct material or a radiation source approved for medical use which is not specifically addressed in ~~R9-7-309(4)~~ this Article if:

1. The applicant or licensee has submitted the information required by this Article; and
2. The applicant or licensee has received written approval from the Department in a license

or license amendment and uses the material in accordance with the rules and specific conditions the Department considers necessary for the medical use of the material.

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

**R9-7-1909. Interpretations Renumbered**

**R9-7-1943. General Security Program Requirements**

**A. Security plan:**

1. Each licensee identified in R9-7-1941(A) shall develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by this Article. The security plan shall, at a minimum:
  - a. Describe the measures and strategies used to implement the requirements of this Article; and
  - b. Identify the security resources, equipment, and technology used to satisfy the requirements of this Article.
2. The security plan shall be reviewed and approved by the individual with overall responsibility for the security program.
3. A licensee shall revise its security plan as necessary to ensure the effective implementation of Department requirements. The licensee shall ensure that:
  - a. The revision has been reviewed and approved by the individual with overall responsibility for the security program; and
  - b. The affected individuals are instructed on the revised plan before the changes are implemented.
4. The licensee shall retain a copy of the current security plan as a record for ~~3~~ at least three years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for ~~3~~ at least three years after the record is superseded.

**B. Implementing procedures:**

1. The licensee shall develop and maintain written procedures that document how the requirements of this Article and the security plan will be met.
2. The implementing procedures and revisions to these procedures shall be approved in writing by the individual with overall responsibility for the security program.
3. The licensee shall retain a copy of the current procedure as a record for ~~3~~ at least three years after the procedure is no longer needed. Superseded portions of the procedure shall be retained for ~~3~~ at least three years after the record is superseded.

**C. Training:**

1. Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training shall include instruction in:
  - a. The licensee's security program and procedures to secure category 1 or category 2 quantities of radioactive material, and in the purposes and functions of the security measures employed;
  - b. The responsibility to report promptly to the licensee any condition that causes or may cause a violation of Department requirements;
  - c. The responsibility of the licensee to report promptly to the local law enforcement agency and licensee any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material; and
  - d. The appropriate response to security alarms.
2. In determining those individuals who shall be trained on the security program, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of category 1 or category 2 quantities of radioactive material. The extent of the training shall be commensurate with the individual's potential involvement in the security of category 1 or category 2 quantities of radioactive material.
3. Refresher training shall be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. This training shall include:
  - a. Review of the training requirements of subsection (c) and any changes made to the security program since the last training;
  - b. Reports on any relevant security issues, problems, and lessons learned;
  - c. Relevant results of Department inspections; and
  - d. Relevant results of the licensee's program review and testing and maintenance.
4. The licensee shall maintain records of the initial and refresher training for ~~3~~ at least three years ~~from~~ after the date of the training. The training records shall include dates of the training, topics covered, a list of licensee personnel in attendance, and related information.

**D. Protection of information:**

1. Licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan,

- implementing procedures, and the list of individuals that have been approved for unescorted access.
2. Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan, ~~and~~ implementing procedures, and the list of individuals that have been approved for unescorted access.
  3. Before granting an individual access to the security plan or implementing procedures, licensees shall:
    - a. Evaluate an individual's need to know the security plan, ~~or~~ implementing procedures, or the list of individuals that have been approved for unescorted access; and
    - b. If the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee shall complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in R9-7-1925(A)(2) through (A)(7).
  4. Licensees need not subject the following individuals to the background investigation elements for protection of information:
    - a. The categories of individuals listed in R9-7-1929(A); or
    - b. Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in R9-7-1925(A)(2) through (A)(7), has been provided by the security service provider.
  5. The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan, ~~or~~ implementing procedures, or the list of individuals that have been approved for unescorted access.
  6. Licensees shall maintain a list of persons currently approved for access to the security plan, ~~or~~ implementing procedures, or the list of individuals that have been approved for unescorted access. When a licensee determines that a person no longer needs access to the security plan, ~~or~~ implementing procedures, or the list of individuals that have been approved for unescorted access, or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list



as soon as possible, but no later than ~~7~~ seven working days, and take prompt measures to ensure that the individual is unable to obtain the security plan or implementing procedures.

7. When not in use, the licensee shall store its security plan, ~~and~~ implementing procedures, and the list of individuals that have been approved for unescorted access in a manner to prevent unauthorized access. Information stored in non-removable electronic form shall be password protected.
8. The licensee shall retain as a record for ~~3~~ at least three years after the document is no longer needed:
  - a. A copy of the information protection procedures; and
  - b. The list of individuals approved for access to the security plan, ~~or~~ implementing procedures, or the list of individuals that have been approved for unescorted access.
9. State officials, State employees, and other individuals, whether or not licensees of the Commission or an Agreement State, who receive schedule information of the kind specified in subsection (D)(1) shall protect that information against unauthorized disclosure as specified in subsection (D)(2).