NOTICES OF FINAL RULEMAKING

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

NOTICE OF FINAL RULEMAKING

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

[R05-475]

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R12-1-102	Amend
R12-1-301	Amend
R12-1-304	Amend
R12-1-305	Amend
R12-1-306	Amend
R12-1-308	Amend
R12-1-309	Amend
R12-1-311	Amend
R12-1-312	Amend
R12-1-313	Amend
R12-1-315	Amend
R12-1-319	Amend
R12-1-320	Amend
R12-1-321	Repeal
R12-1-323	Amend
R12-1-325	New Section
R12-1-405	Amend
R12-1-408	Amend
R12-1-412	Amend
R12-1-413	Amend
R12-1-415	Amend
R12-1-418	Amend
R12-1-419	Amend
R12-1-430	Amend
R12-1-433	Amend
R12-1-441	Amend
R12-1-453	New Section
R12-1-501	Amend
R12-1-100	Amend
R12-1-1302	Amend
R12-1-1306	Amend

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

General: A.R.S. § 30-654(B)

Specific: A.R.S. §§ 30-657, 30-671(B), 30-672, and 30-673

3. The effective date of the rules:

February 7, 2006

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

Notice of Rulemaking Docket Opening: 11 A. A. R. 106, January 3, 2005

Notice of Proposed Rulemaking: 11 A. A. R. 1610, May 6, 2005

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

Name: Daniel H. Kuhl

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

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6. An explanation of the rule, including the agency's reason for initiating the rule:

R12-1-102 contains general definitions that will assist the reader in understanding the requirements for use of ionizing radiation sources regulated in Chapter 1. New terms will assist the regulated community in understanding the new Nuclear Regulatory Commission (NRC) regulatory standards that are being added to Articles 3 and 4 of Chapter 1.

Article 3 contains radioactive material licensing standards. A number of changes are made to Article 3 as a result of a five-year review that was accepted by G.R.R.C. on October 7, 2003. Also, changes are made to keep Arizona's rules compatible with NRC regulations. The Agency is required to maintain compatible rules as part of the agreement Arizona has with the NRC. One noteworthy change is the registration of generally licensed gauging devices that the NRC believes are hazardous to the public if not accounted for on a regular basis. The Agency will assess a $100 fee for the registration. As part of this amendment, manufacturers of these gauging devices will be required to assist the Agency in holding gauging device users accountable for safe gauge operation and maintenance. Other changes to Article 3 include: language changes to the requirements regarding manufacture and distribution of radiopharmaceuticals and sealed sources used in the practice of medicine, which are regulated in Article 7; a new requirement that a radioactive material licensee notify the Agency if the licensee is going out of business; a new requirement that regulatory jurisdiction be determined at temporary job sites at federal facilities before a licensee initiates any work with radioactive material; and a new requirement that a licensee follow timely procedures when decommissioning a radioactive material use site.

Article 4 establishes radiation safety standards that must be met by users of ionizing radiation. Numerous clarifications are made in Article 4 to maintain standards that are compatible with NRC regulations. Included are: changes to R12-1-415 that will allow an additional 50 mRem exposure to a declared pregnant woman and the removal of a provision that refers to a pregnant woman withdrawing her declaration; a change in R12-1-430 that permits a teletherapy licensee to be exempted from the posting requirements in R12-1-429, if the newly listed conditional controls are met; and a new rule, R12-1-453, is added that requires a licensee or registrant to notify an individual who has been exposed to radiation to provide the same report that is sent to the Agency to the individual who was exposed to radiation.

The newly formatted Article 5 regulates only industrial radiography performed with radioactive material. One new definition is added to Article 5 that will aid in understanding the new regulatory standards. The rulemaking activities involving Article 5 are required by the NRC as part of the agreement between the Agency and the federal government.

Instruction for workers in Article 10 is amended to comply with the worker training standards of the NRC. There are no significant changes associated with this amendment.

Article 13 describes the various license and registration categories and associated fees. In R12-1-1306, License Category D4 is amended to list a registration category for generally licensed gauging devices that will be regulated by the Agency with the amendment to Article 3 in R12-1-306(B)(3)(o). The $100 registration fee is new, in that it will be applied to a new group of licensees, not regulated under D4. Licensees who would have been regulated under D4 will be folded into another category of DU users under Category D5. Currently, there are no DU users licensed under the D4 category. The different categories are defined in R12-1-1302. The descriptions for D4 and D5 are being amended to reflect the changes to the category system described above.

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

None

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

Not applicable

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

A single change in this rulemaking package will result in a small economic impact. The affected radioactive material users possess the generally licensed gauging devices proposed for category D4 in R12-1-1306 and described in R12-1-306. These devices have not been directly regulated by the Agency in the past. A review of the available manufacturing and shipping records has disclosed 24 gauging device users that will be affected by the new registration requirements and payment of a $100 annual registration fee. The Agency has contacted the device manufacturers to determine who has received the affected gauging devices. This ongoing communication has resulted in the larger number of affected gauge users than was listed in the Notice of Rulemaking Docket Opening. There is concern that some of these devices have been lost, misplaced, or improperly disposed of. All of which could result in safety hazards to the public and potential costs to the Agency and the citizens of Arizona. These costs could far exceed the registration cost proposed for one of these devices. Also, all future Arizona users will be required to pay the annual fee. The total number of affected gauging device users is unknown at this time; however, it is believed that the number of users in Arizona is less than 50.

The Agency believes the gauging device users will not have any other costs associated with the registration process proposed by the Agency. The user is already responsible for doing inventories and leak tests of the gauge's radiation source, as required in the existing conditions of the manufacturer's general license. The gauge user will also be responsible for proper disposal at the end-of-use. This can be somewhat costly if the manufacturer of the gauging device is no longer in business and able to take the device for disposal.

Accountability is the ultimate goal of this new rule. With the current general licensing process, the user is required to ensure that every gauging device is present at its place of use and is not leaking radioactive material to the environment, but there is no follow up by the manufacturer. The major area of concern is disposal if the gauging device is no longer useful. The user must dispose of the device by a means that is acceptable to the Agency. Future disposal methods will be no different than what is accepted under the current general license, but the Agency will be present to ensure that acceptable disposal procedures are followed. Because there is no difference between what the manufacturer and the Agency requires for disposal of the gauging devices, there should be no additional disposal costs if the devices are registered with the Agency.

The remainder of the rulemaking will result in no new economic impact to the affected radiation users and members of the public. The vast majority of the rules are simply updated. In those cases where there is a new rule, the rule is affecting a group of radiation users that is very familiar with the Agency's regulatory authority and the cost of doing business.

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

Nonsubstantive changes were made as result of the comments received during the public hearing. No members of the public or regulated community attended the meeting. In R12-1-306(B)(2) an incorrect reference was made to R12-1-306(B)(4)(i). The corrected reference is R12-1-306(B)(4)(k).

In R12-1-1306, an error in the table of fees was corrected. The fee for Category F7 is not changing. Only spelling, format, and grammatical changes were offered by members of the Radiation Regulatory Hearing Board and the Governor's Regulatory Review Council (G.R.R.C.) staff.

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

No written comments were received from the public. Likewise, during the public hearing no comments were received from the public participants. However, the Agency Board and G.R.R.C. staff have offered a number of suggestions concerning punctuation, format, and grammatical corrections.

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

None

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

Rule		Incorporation
R12-1-306(B)(1)		10 CFR 31.5(b) and (c)
R12-1-306(B)(3)(g)		10 CFR 110
R12-1-306(D)(1)	(2004)	10 CFR 32.57 and 70.39
R12-1-306(E)(3)		10 CFR 32
R12-1-311(C)		10 CFR 32.26
R12-1-311(C)(2)		10 CFR 32.29
R12-1-311(D)(1)(f)		10 CFR 31.5(c)(13)(i)
R12-1-311(E)(2)		10 CFR 32.53 through 32.56, and 32.101
R12-1-311 (F)(2)		10 CFR 32.57, 32.58, 32.59, 32.102, and 70.39

R12-1-311(I)(2)		10 CFR 32.61, 32.62, and 32.103
R12-1-311(J)		10 CFR 32.72
R12-1-311(L)	(2004)	10 CFR 32.74
R12-1-323(C)		10 CFR 30.35, 40.36, and 70.25
R12-1-323(E)(1)		10 CFR 30.36(g)(1)
R12-1-323(E)(5)		10 CFR 30.36(i)
R12-1-323(E)(6)		10 CFR 30.36(j)
R121-1-433(A)		10 CFR 71.4
R12-1-433(B)(1)	(2004)	49 CFR 172.403, and 172.436 through 172.440

14. Was this rule previously made as an emergency rules?

No.

15. The full text of the rules follows:

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

ARTICLE 1. GENERAL PROVISIONS

Section
R12-1-102. Definitions

ARTICLE 3. RADIOACTIVE MATERIAL LICENSING

Section
R12-1-301. Ownership, Control, or Transfer of Radioactive Material
R12-1-304. License Types
R12-1-305. General ~~License~~ Licenses - Source Material
R12-1-306. General License -- Radioactive Material Other Than Source Material
R12-1-308. Filing Application for Specific Licenses
R12-1-309. General Requirements for the Issuance of Specific Licenses
R12-1-311. Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices that Contain Radioactive Material
R12-1-312. Issuance of Specific Licenses
R12-1-313. Specific Terms and Conditions ~~of Licenses~~
R12-1-315. Renewal of License
R12-1-319. Modification, Revocation, or Termination of a License
R12-1-320. Reciprocal Recognition of Licenses
R12-1-321. ~~Preparation of Radioactive Material for Transport~~ Repealed
R12-1-323. Financial Assurance and Recordkeeping for Decommissioning
R12-1-325. ~~Repealed~~ Timeliness in Decommissioning Facilities

ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

Section
R12-1-405. Form of Records
R12-1-408. Occupational Dose Amounts for Adults
R12-1-412. Determination of Prior Occupational Dose
R12-1-413. Planned Special Exposures
R12-1-415. Dose ~~Limits for~~ Equivalent to an Embryo or Fetus
R12-1-418. Surveys and Monitoring
R12-1-419. Conditions Requiring Individual Monitoring of External and Internal Occupational Dose
R12-1-430. Exceptions to Posting Requirements
R12-1-433. Procedures for Receiving and Opening Packages
R12-1-441. Records of Waste Disposal

ARTICLE 1. GENERAL PROVISIONS

R12-1-102. Definitions

Terms defined in A.R.S. § 30-651 have the same meanings when used in this Chapter. The following terms have the definitions below. Additional subject specific definitions are used in other Articles.

"A_1"	No change
"A_2"	No change
"Absorbed dose"	No change
"Accelerator"	No change
"Accelerator produced material"	No change
"Act"	No change
"Activity"	No change
"Adult"	No change
"Agency" or "ARRA"	No change
"Agreement State"	No change
"Airborne radioactive material"	No change
"Airborne radioactivity area"	No change
"ALARA"	No change
"Analytical x-ray equipment"	No change
"Analytical x-ray system"	No change
"Annual"	No change
"Background radiation"	No change
"Becquerel"	No change
"Bioassay"	No change
"Brachytherapy"	No change
"Byproduct material"	No change
"Calendar quarter"	No change
"Calibration"	No change
"Certifiable cabinet x-ray system"	No change
"Certified cabinet x-ray system"	No change

"CFR"	No change
"Chelating agent"	No change
"Civil penalty"	No change
"Collective dose"	No change
"Committed dose equivalent"	No change
"Committed effective dose equivalent"	No change
"Curie"	No change
"Current license or registration"	No change
"Deep-dose equivalent"	No change
"Depleted uranium"	No change
"Dose"	No change

"Dose equivalent ~~(H_T)~~" (H_T) 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"	No change
"Dosimeter"	No change

"Effective dose equivalent ~~(H_E)~~" (H_E) means the sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = S\ w_T H_T$).

"Effluent release"	No change
"Embryo/fetus"	No change
"Enclosed beam x-ray system"	No change
"Enclosed radiography"	No change
"Cabinet radiography"	No change
"Shielded room radiography"	No change
"Entrance or access point"	No change
"Exhibit"	No change
"Explosive material"	No change
"Exposure"	No change
"Exposure rate"	No change
"External dose"	No change
"Extremity"	No change
"Fail-safe characteristics"	No change
"Field radiography"	No change
"Field station"	No change
"Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities"	No change
"Generally applicable environmental radiation standards"	No change
"Gray"	No change
"Hazardous waste"	No change
"Healing arts"	No change
"Health care institution"	No change
"High radiation area"	No change
"Human use"	No change
"Impound"	No change

"Individual"	No change
"Individual monitoring"	No change
"Individual monitoring device"	No change
"Individual monitoring equipment"	No change
"Industrial radiography"	No change
"Injection tool"	No change
"Inspection"	No change
"Interlock"	No change
"Internal dose"	No change
"Irradiate"	No change
"Laser"	No change
"Lens dose equivalent"	No change
"License"	No change
"Licensed material"	No change
"Licensed practitioner"	No change
"Licensee"	No change
"Licensing State"	No change
"Limits"	No change
"Local components"	No change
"Logging supervisor"	No change
"Logging tool"	No change
"Lost or missing licensed or registered source of radiation"	No change
"Low-level waste"	No change
"Major processor"	No change
"Medical dose"	No change
"Member of the public"	No change
"MeV"	No change
"Mineral logging"	No change
"Minor"	No change
"Monitoring"	No change
"Multiplier"	No change
"NARM"	No change
"Normal operating procedures"	No change
"Natural radioactivity"	No change
"NRC"	No change
"Nuclear waste"	No change
"Occupational dose"	No change
"Open beam system"	No change
"Package"	No change
"Particle accelerator"	No change
"Permanent radiographic installation"	No change
"Personnel dosimeter"	No change
"Personnel monitoring equipment"	No change

"Personal supervision"	No change
"Pharmacist"	No change
"Physician"	No change
"Primary beam"	No change
"Public dose"	No change
"Pyrophoric liquid"	No change
"Pyrophoric solid"	No change
"Qualified expert"	No change
"Quality Factor"	No change
"Quarter"	No change
"Rad"	No change
"Radiation"	No change
"Radiation area"	No change
"Radiation dose"	No change
"Radiation machine"	No change
"Radiation safety officer"	No change
"Radioactive marker"	No change
"Radioactive material"	No change
"Radioactivity"	No change
"Radiographer"	No change
"Radiographer's assistant"	No change
"Registrant"	No change
"Registration"	No change
"Regulations of the U.S. Department of Transportation"	No change
"Rem"	No change
"Research and Development"	No change
"Restricted area"	No change
"Roentgen"	No change
"Safety system"	No change
"Sealed source"	No change

"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 (H_s)" which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of 1 square centimeter~~. "Shallow dose equivalent" (H_s), 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^2).

"Shielded position"	No change
"Sievert"	No change
"Site boundary"	No change
"Source changer"	No change
"Source holder"	No change
"Source material"	No change
"Source material milling"	No change
"Source of radiation" or "source"	No change

"Special form radioactive material"	No change
"Special nuclear material in quantities not sufficient to form a critical mass"	No change
"Storage area"	No change
"Storage container"	No change
"Subsurface tracer study"	No change
"Survey"	No change
"TEDE"	No change
"Teletherapy"	No change
"Temporary job site"	No change
"Test"	No change
"These rules"	No change
"Total Effective Dose Equivalent"	No change
"Total Organ Dose Equivalent"	No change
"Unrefined and unprocessed ore"	No change
"Unrestricted area"	No change
"U.S. Department of Energy"	No change

"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"	No change
"Waste handling licensees"	No change
"Week"	No change
"Well-bore"	No change
"Well-logging"	No change
"Whole body"	No change
"Wireline"	No change
"Wireline service operation"	No change
"Worker"	No change
"WL"	No change
"WLM"	No change
"Workload"	No change
"Year"	No change

ARTICLE 3. RADIOACTIVE MATERIAL LICENSING

R12-1-301. Ownership, Control, or Transfer of Radioactive Material

A. In addition to the requirements of this Article, all licensees are subject to the requirements of 12 A.A.C. 1, Article 1, Article 4, and Article 10. Licensees engaged in industrial radiographic operations are subject to the requirements of 12 A.A.C. 1, Article 5; licensees using radioactive material in the ~~healing arts~~ practice of medicine are subject to the requirements of 12 A.A.C. 1, Article 7; licensees transporting radioactive material are subject to the requirements contained in 12 A.A.C. 1, Article 15; and licensees using radioactive material in well logging operations are subject to the requirements in 12 A.A.C. 1, Article 17.

B. Notwithstanding any other provisions of this Article, any person may own radioactive material, provided that the ownership does not include the actual possession, custody, use, or physical transfer of radioactive material or the manufacture or production of any article ~~containing~~ that contains radioactive material without the applicable certification, license, or registration.

C. A manufacturer, processor, or producer of any equipment, device, commodity, or other product ~~containing~~ that contains source material or ~~byproduct~~ radioactive material whose subsequent possession, use, transfer, or disposal by all other persons is exempt from regulatory requirements may only obtain authority to transfer possession or control of the material from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

R12-1-304. License Types

Licenses for radioactive materials are of two types: general and specific.

1. ~~For a general license, no application is required and no licensing document is issued. The Agency may require that a person file a certificate for a particular general license. The licensee is subject to all other applicable portions of this Chapter and any limitations of the general license.~~ A general license is provided by rule, grants authority to a person for certain activities involving radioactive material, and is effective without the filing of an application with the Agency or the issuance of a licensing document to a particular person. However, registration with the Agency may be required by the particular general license.
2. ~~For a specific license, a person submits an application to the Agency. The Agency issues a license if the person satisfies all of the requirements for a license. The licensee is subject to all applicable portions of this Chapter and any limitations contained in the licensing document.~~ The Agency issues a specific license to a named person who has filed an application for a license under the applicable provision of this Chapter. A specific licensee is subject to all of the applicable rules in this Chapter and any limitation contained in the license document.

R12-1-305. General ~~License~~ Licenses - Source Material

A. ~~This subsection establishes a general license authorizing use and transfer of not more than 6.8 kg (15 pounds) of source material at any one time, for research, development, educational, commercial, or operational purposes, by persons in the following categories: commercial and industrial firms, research, educational and medical institutions, and State and local government agencies; provided that the person proceeding under this general license, receives no more than 68.2 kg (150 pounds) of source material in any one calendar year~~ This subsection grants a general license that authorizes a person such as commercial and industrial firms; research, educational, and medical institutions; and state and local government agencies to use, and transfer not more than 6.8 kg (15 pounds) of source material at any one time for research, development, educational, commercial, or operational purposes. A person authorized under this subsection shall not receive more than 68.2 kg (150 pounds) of source material in one calendar year.

B. ~~Persons who receive, possess, use, or transfer source material under the general license issued in subsection (A) are~~ A person who receives, possesses, uses, or transfers source material under a general license granted under subsection (A) is exempt from the provisions of 12 A.A.C. 1, Article 4 and Article 10, provided the receipt, possession, use, or transfer is within the terms of the general ~~license; however, this~~ license. This exemption does not apply to any person who is also in possession of source material under a specific license issued under this Article.

C. ~~Depleted uranium in industrial products and devices~~. This subsection grants a general license that authorizes a person to receive acquire, possess, use, or transfer depleted uranium contained in industrial products and devices provided:

1. ~~This subsection establishes a general license to receive, acquire, possess, use or transfer~~ The depleted uranium is contained in the industrial ~~products~~ product or ~~devices~~ device for the purpose of providing a concentrated mass in a small volume of the product or device~~.~~;
2. ~~The general license in subsection (C)(1) applies only to~~ The industrial products or devices ~~which have been~~ have been manufactured ~~under~~ or initially transferred in accordance with a specific license governed by R12-1-311(M), or a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State ~~authorizing~~ that authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State~~.~~;
3. ~~Depleted uranium~~ The person files an ARRA 23 "Registration Certificate -- Use of Depleted Uranium Under General License" with the Agency. 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 Agency. The person shall report in writing to the Agency any change in information originally submitted to the Agency on ARRA 23. The person shall submit the change report within 30 days after the effective date of the described change.
   a. ~~Persons who receive, acquire, possess, or use depleted uranium under the general license established by subsection (C)(1) shall file ARRA 23 "Registration Certificate -- Use of Depleted Uranium Under General License", with the Agency. The form, requesting the information in Exhibit E, shall be submitted within 30 days after the first receipt or acquisition of the depleted uranium. The general licensee shall furnish on ARRA 23 the following information.~~
      i. ~~Name, telephone number, and address of the general licensee;~~
      ii. ~~Location of use;~~
      iii. ~~A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in subsection (C)(1) and to prevent transfer of the depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and~~

~~iv. Name or title (or both), address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in subsection (C)(3)(a)(ii).~~

~~b. The general licensee possessing or using depleted uranium under the general license, established by subsection (C)(1) shall report in writing to the Agency any changes in information originally furnished on ARRA 23. The report shall be submitted within 30 days after the effective date of the described change.~~

~~4.~~ **D.** A person who receives, acquires, possesses, or uses depleted uranium ~~under~~ according to the general license ~~established by subsection (C)(1)~~ provided under subsection (C) shall:

~~a.~~1. ~~Shall not~~ 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;

~~b~~2. ~~Shall not~~ Not abandon the depleted uranium;

~~c.~~3. ~~Shall transfer~~ Transfer the depleted uranium as prescribed in R12-1-318. If the transferee receives the depleted uranium under ~~the~~ a general license established by subsection (C)~~(1)~~, the transferor shall furnish the transferee with a copy of this ~~rule~~ Section and a copy of the registration certificate. If the transferee receives the depleted uranium under a general license governed by a regulation of the U.S. Nuclear Regulatory Commission or an Agreement State that is equivalent to subsection (C)~~(1)~~, the transferor shall furnish the transferee a copy of ~~this~~ 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 U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially similar to those in this ~~rule~~ Section;

~~d.~~4. Within 30 days of any transfer, ~~shall~~ report in writing to the Agency the name and address of the person receiving the depleted uranium; and

~~e.~~5. ~~Shall not~~ Not export ~~the~~ depleted uranium except under a license issued by the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 110.

~~5.~~ **E.** ~~Any~~ A person ~~receiving, acquiring, possessing, using, or transferring~~ who receives, acquires, possesses, uses, or transfers depleted uranium in accordance with a ~~according to the~~ general license ~~established by~~ granted under subsection (C)~~(1)~~ is exempt from the requirements of 12 A.A.C. 1, Articles 4 and 10 with respect to the depleted uranium covered by that general license.

R12-1-306. General License -- Radioactive Material Other Than Source Material

A. ~~This subsection establishes~~ This subsection grants a general license that authorizes a person such as a commercial or industrial firm, ~~a general license~~ to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment ~~which have been~~ manufactured, tested, and labeled by the manufacturer ~~according to~~ in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission under 10 CFR 31.3. ~~This general license is subject to the provisions of 12 A.A.C. 1, Articles 1, 4, 10 and 12; Sections R12-1-303(A)(2), R12 1 313, R12 1 318, R12 1 319, and A.R.S. §§ 30 654(B)(13), 30 657(A) and (B), 30 681, and 30 685 through 30 689.~~ The devices regulated by this subsection include:

1. ~~Static elimination device.~~ Devices designed for use as static eliminators ~~which~~ that contain, as a sealed source or sources, radioactive material, consisting of a total of not more than 18.5 MBq (500 microcuries) of polonium-210 per device~~.~~; or
2. ~~Ion generating tube.~~ Devices designed for ionization of air ~~which~~ that contain, as a sealed source or sources, radioactive material, consisting of a total of not more than 18.5 MBq (500 microcuries) of polonium-210 per device or ~~a total of not more than~~ 1.85 GBq (50 millicuries) of hydrogen-3 (tritium) per device.

B. Certain measuring, gauging or controlling devices

1. ~~This subsection establishes~~ This subsection grants a general license that authorizes a person such as a ~~a general license for~~ commercial ~~and~~ or industrial ~~firms~~ firm; a research, educational ~~and~~ or medical ~~institutions~~ institution; ~~individuals for~~ an individual conducting business; ~~and State~~ or a state or local government ~~agencies~~ agency to receive, acquire, possess, use, or transfer radioactive material according to the provisions of ~~subsections (B)(2), (3), and (4), excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.~~ 10 CFR 31.5(b) and (c), January 1, 2005, which are incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. The material incorporated by reference contains no future editions or amendments.

~~2. The general license in subsection (B)(1) applies only to radioactive material contained in devices which have been manufactured and labeled according to specifications contained in a specific license issued by the Agency under R12-1-311(D) or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes distribution of devices to persons generally licensed by the NRC or an Agreement State. Regulations promulgated under the Federal Food, Drug, and Cosmetic Act, authorizing the use of radioactive control devices in food production, require certain additional labeling prescribed in 21 CFR 179.21.~~

~~3. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device according to~~

~~the general license in subsection (B)(1):~~

~~a. Shall assure that all labels are affixed to the device at the time of receipt, each bearing a statement that removal of the label is prohibited, maintain the labels on the device and comply with all instructions and precautions provided on the labels;~~

~~b. Shall assure that the device is tested for leakage of radioactive material and proper operation of the actuation mechanism and indicator, if any, at no longer than six month intervals or the intervals specified on the label; however;~~

~~i. Devices containing only krypton need not be tested for leakage of radioactive material;~~

~~ii. Devices containing only tritium or not more than 3.7 MBq (100 microcuries) of other beta or gamma emitting material or 370 kBq (10 microcuries) of alpha emitting material; and~~

~~iii. Devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose,~~

~~c. Shall assure that the tests required by subsection (B)(3)(b) and other testing, installation, servicing, and removal from installation involving shielding, containment, or radioactive material, are performed:~~

~~i. According to the instructions on any label, or~~

~~ii. By a person holding a specific license from the Agency, the NRC, or an Agreement State or Licensing State to perform the specified activities;~~

~~d. Shall maintain records showing compliance with the requirements of subsections (B)(3)(b) and (c). The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal or other work concerning shielding, containment, or radioactive material. Records of tests for leakage of radioactive material required by subsection(B)(3)(b) shall be maintained for one year after the next required leak test is performed or until the sealed source is disposed of or transferred. Records of tests of the actuator mechanism and indicator required by subsection (B)(3)(b) shall be maintained for one year after the next required test of the actuator mechanism and indicator is performed or until the sealed source is disposed of or transferred. Records which are required by subsection (B)(3)(c) shall be maintained for two years from the date of the recorded event or until the device is disposed of or transferred;~~

~~e. Upon failure or damage, or any indication of possible failure or damage of shielding or the actuation mechanism or indicator, or upon the detection of 185 Bq (5 nanocurie) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding a specific license from the Agency, the NRC or an Agreement State or Licensing State to repair the device, or disposed of by transfer to a person authorized by a specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the Agency a report containing a brief description of the event and the remedial action taken;~~

~~f. Shall not abandon the device containing radioactive material;~~

~~g. Except as provided in subsection (B)(3)(h), shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the Agency, the NRC, or an Agreement State or Licensing State whose specific license authorizes the receipt of the device and, within 30 days after transfer, furnish a report to the Agency identifying the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;~~

~~h. Shall transfer the device to another general licensee only:~~

~~i. If the device remains in use at a particular location. The transferor shall give the transferee a copy of this rule and any safety documents identified on the label of the device and within 30 days after the transfer, report to the Agency the manufacturer's name, the model number of the device transferred, the name and address of the transferee, and the name or position or both of a contact person for the Agency; or~~

~~ii. Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee;~~

~~i. Shall comply with the provisions of R12-1-443 and R12-1-444 for reporting radiation incidents, theft, or loss of licensed material, but is exempt from the other requirements of 12 A.A.C. 1, Articles 4 and 10.~~

2. A general licensee shall receive a device from one of the specific licensees described in this Section or through a transfer made under subsection (4)(k).
3. A general license in subsection (B)(1) applies only to radioactive material contained in devices that have been manufactured or initially transferred and labeled in accordance with the requirements contained in:
   a. A specific license issued under R12-1-311(D); or
   b. An equivalent specific license issued by the NRC or another Agreement State.
4. A person who acquires, receives, possesses, uses, or transfers radioactive material in a device licensed under subsection (B)(1), shall:
   a. Ensure that all labels and safety statements affixed to a device at the time of receipt are maintained and not removed, and comply with all instructions and precautions on the labels.

b. Ensure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at other intervals as specified on the label.
   i. A general licensee need not test a device that contains krypton for leakage of radioactive material, and
   ii. A general licensee need not test a device for leakage of radioactive material if the device contains only tritium, not more than 3.7 Mbq (100 microcuries) of other beta or gamma emitting material, or 370 kBq (10 microcuries) of alpha emitting material, or the device is held in storage, in the original shipping container, before initial installation.

c. Ensure that the tests required by subsection (B)(4)(b) and other testing, installation, servicing, and removal from installation involving the radioactive material or its shielding or containment, are performed:
   i. In accordance with the device label instructions; or
   ii. By a person holding a specific license under R12-1-311(D) or in accordance with the provisions of a specific license issued by the NRC or an Agreement State which authorizes distribution of devices to persons generally licensed by the NRC or an Agreement State.

d. Maintain records of compliance with the requirements in subsections (B)(4) (b) and (c) that show the results of tests; the dates that required activities were performed, and the names of persons performing required activities involving radioactive material from the installation and its shielding or containment. The records shall be maintained for three years from the date of the recorded event or until transfer or disposal of the device.

e. Immediately suspend operation of a device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 185 Becquerel (0.005 microcurie) or more of removable radioactive material.
   i. A general licensee shall not operate the device until it has been repaired by the manufacturer or another person holding a specific license to repair this type of device that was issued by the Agency under R12-1-311(D), the NRC, or an Agreement State which authorizes distribution of devices to persons generally licensed by the NRC or an Agreement State.
   ii. If necessary the general licensee shall dispose of the device and any radioactive material from the device by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the Agency.
   iii. Within 30 days of an event governed by subsection (B)(4)(e) the general licensee shall furnish a report that contains a brief description of the event and the remedial action taken and, in the case of detection of 185 Becquerel (0.005 microcurie) or more of removable radioactive material or failure of or damage to a source likely to result in contamination of the general licensee's facility or the surrounding area, if applicable, a plan for ensuring that the general licensee's facility and surrounding area, if applicable, are acceptable for unrestricted use. The radiological criteria for unrestricted use in R12-1-452 may be used to prepare the plan, as determined by the Agency, on a case-by-case basis.

f. Not abandon a device that contains radioactive material.

g. Not export a device that contains radioactive material except in accordance with 10 CFR 110, January 1, 2005, which is incorporated by reference, published by the Office of the Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. The material incorporated by reference contains no future editions or amendments.

h. Transfer or dispose of a device that contains radioactive material only by export as authorized in subsection (B)(4)(g), transfer to another general licensee as authorized in subsection (B)(4)(k) or a person who is authorized to receive the device by a specific license issued by the Agency, the NRC, or an Agreement State, or collection as waste if authorized by equivalent regulations of an Agreement State, or the NRC, or as otherwise approved under subsection (B)(4)(j).

i. Within 30 days after the transfer or export of a device to a specific licensee, furnish a report to the Agency. The report shall:
   i. Identify the device by manufacturer's (or initial transferor's) name, model number, and serial number;
   ii. Provide the name, address, and license number of the person receiving the device (license number not applicable if exported); and
   iii. Provide the date of transfer or export.

j. Obtain written Agency approval before transferring a device to any other specific licensee that is not authorized in accordance with subsection (B)(4)(h).

k. Transfer a device to another general licensee only:
   i If the device remains in use at a particular location. The transferor shall provide the transferee with a copy of this Section, a copy of R12-1-443, R12-1-445, and R12-1-448 and any safety documents identified on the device label. Within 30 days of the transfer, the transferor shall report to the Agency the manufacturer's (or initial transferor's) name; the model number and the serial number of the device transferred; the transferee's name and mailing address for the location of use; and the name, title, and telephone number of the responsible individual appointed by the transferee in accordance with subsection (B)(4)(n); or

ii. If the device is held in storage in the original shipping container at its intended location of use before initial use by a general licensee, and by a person that is not a party to the transaction.

l. Comply with the provisions of R12-1-443, R12-1-444, R12-1-445, R12-1-447, and R12-1-448 for reporting and notification of radiation incidents, theft or loss of licensed material, and is exempt from the other requirements of 12 A.A.C. 1, Articles 4 and 10.

m. Respond to written requests from the Agency to provide information relating to the general license within 30 days from the date on the request, or a longer time period specified in the request. If the general licensee cannot provide the requested information within the specified time period, the general licensee shall request a longer period to supply the information before expiration of the time period, providing the Agency with a written justification for the request.

n. Appoint an individual responsible for knowledge of applicable laws and possessing the authority to take actions required to comply with applicable radiation safety laws. The general licensee, through this individual, shall ensure the day-to-day compliance with applicable radiation safety laws. This provision does not relieve the general licensee of responsibility.

o. Register, in accordance with subsections (B)(4)(p) and (q), any device that contains at least 370 millibecquerel (10 millicuries) of cesium-137, 3.7 millibecquerel (0.1 millicuries) of strontium-90, 37 millibecquerel (1 millicurie) of cobalt-60, or 37 millibecquerel (1 millicurie) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under subsection (B)(4)(q)(iv), represents a separate general licensee and requires a separate registration and fee.

p. Register each device annually with the Agency and pay the fee required by R12-1-1306, Category D4, if in possession of a device that meets the criteria in subsection (B)(4)(o). The general licensee shall register by verifying, correcting, and adding to the information provided in a request for registration received from the Agency. The registration information shall be submitted to the Agency within 30 days from the date on the request for registration.

q. In registering a device, furnish the following information and any other registration information specifically requested by the Agency:

i Name and mailing address of the general licensee;

ii. Information about each device, including the manufacturer (or initial transferor), model number, serial number, radioisotope, and activity (as indicated on the label);

iii. Name, title, and telephone number of the responsible individual appointed by the general licensee under subsection (B)(4)(n);

iv. Address or location at which each device is used and stored. For a portable device, the address of the primary place of storage;

v. Certification by the responsible individual that the information concerning each device has been verified through a physical inventory and review of label information; and

vi. Certification by the responsible individual that the individual is aware of the requirements of the general license.

r. Report a change in mailing address for the location of use or a change in the name of the general licensee to the Agency within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage.

s. Not use a device if the device has not been used for a period of two years. If a device with shutters is not being used, the general licensee shall ensure that the shutters are locked in the closed position. The testing required by subsection (B)(4)(b) need not be performed during a period of storage. However, if a device is put back into service or transferred to another person, and has not been tested during the required test interval, the general licensee shall ensure that the device is tested for leakage before use or transfer and that the shutter is tested before use. A device kept in standby for future use is excluded from the two-year time limit in this subsection if the general licensee performs a quarterly physical inventory regarding the standby devices.

5. A person that is generally licensed by an Agreement State with respect to a device that meets the criteria in subsection (B)(4)(o) is exempt from registration requirements if the device is used in an area subject to Agency jurisdiction for a period less than 180 days in any calendar year. The Agency does not request registration information from a general licensee if the device is exempted from licensing requirements in subsection (B)(4)(o).

~~4. The general license in subsection (B)(1) does not authorize the manufacture of devices containing radioactive material.~~

~~5~~6. The general license ~~provided in~~ granted under subsection (B)(1) is subject to the provisions of 12 A.A.C. 1, Articles 1, 3, 12, and 15, and A.R.S. §§ 30-654(B)(13), 30-657 (A) and (B), 30-681, and 30-685 through 30-689.

C. Luminous safety devices for aircraft

1. ~~This subsection establishes~~ This subsection grants a general license that authorizes a person ~~a general license for the receipt, acquisition, possession, and~~ to receive, acquire, possess, and use ~~of~~ tritium or promethium-147 contained in

luminous safety devices for use in aircraft, provided: that

a. Each each device contains not more than 370 GBq (10 curies) of tritium or 11.1 GBq (300 millicuries) of promethium-147; and

b. Each each device has been manufactured, assembled, or imported according to a specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled according to the specifications contained in a specific license issued to the manufacturer or assembler of the device by the Agency or any Agreement State or Licensing State to the manufacturer or assembler of the device according to in accordance with licensing requirements equivalent to those in 10 CFR 32.53.

2. Persons A person who receive, acquire, possess, or use receives, acquires, possesses, or uses a luminous safety devices device according to the general license granted in subsection (C)(1) are is; exempt from the requirements of 12 A.A.C. 1, Article 4 and Article 10 except that they shall comply with the provisions of R12-1-443 and R12-1-444.

3. This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium-147.

4. This general license does not authorize the ownership, receipt, acquisition, possession, or use of radioactive materials contained in instrument dials.

5. This general license is subject to the provisions of 12 A.A.C. 1, Articles 1, 3, 12, and 15 and A.R.S. §§ 30-654(B)(13), 30-657(A), 30-657(B), 30-681, and 30-685 through 30-689.

a. Exempt from the requirements of 12 A.A.C. 1, Article 4 and Article 10 except that the person shall comply with the reporting and notification provisions of R12-1-443, R12-1-444; R12-1-445, R12-1-447, and R12-1-448;

b. Not authorized to manufacture, assemble, or repair a luminous safety device that contains tritium or promethium-147;

c. Not authorized to own, receive, acquire, possess, or use radioactive material contained in instrument dials; and

d. Subject to the provisions of 12 A.A.C. 1, Articles 1, 3, 12, and 15 and A.R.S. §§ 30-654(B)(13), 30-657(A) and (B), 30-681, and 30-685 through 30-689.

D. Calibration and reference sources

1. This subsection establishes a general license for those persons listed below to receive, acquire, possess, use, and transfer, according to the provisions of subsections (D)(4) and (5), americium-241 in the form of calibration or reference sources:

a. Any person who holds a specific license issued by the Agency which authorizes the receipt, possession, use, and transfer of radioactive material; and

b. Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes the receipt, possession, use, and transfer of special nuclear material.

2. This subsection establishes a general license for ownership, receipt, possession, use, and transfer of plutonium in the form of calibration or reference sources to any person who holds a specific license issued by the Agency authorizing receipt, possession, use, and transfer of radioactive material.

3. This subsection establishes a general license to receive, possess, use and transfer radium-226 in the form of calibration or reference sources to any person who holds a specific license issued by the Agency authorizing receipt, possession, use, and transfer of radioactive material.

4. The general licenses in subsections (D)(1), (2), and (3) apply to calibration or reference sources which have been manufactured according to the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission in 10 CFR 32.57 or 10 CFR 70.39. The general licenses also apply to calibration or reference sources which have been manufactured according to the specifications contained in a specific license issued to the manufacturer by the Agency or any Agreement State or Licensing State according to licensing requirements equivalent to those contained in 10 CFR 32.57 or 10 CFR 70.39

5. The general licenses provided in subsections (D)(1), (2), and (3) are subject to the provisions of 12 A.A.C. 1, Articles 1, 3, 4, 10, 12, and 15 and A.R.S. §§ 30-654(B)(13), 30-657(A), 30-657(B), 30-681, and 30-685 through 30-689. In addition, persons who own, receive, acquire, possess, use, or transfer 1 or more calibration or reference sources according to these general licenses:

a. Shall not possess at any 1 time, at any location of storage or use, more than 185 kBq (5 microcuries) of americium-241, plutonium, or radium-226 in calibration or reference sources;

b. Shall not receive, possess, use, or transfer a calibration or reference source unless the source, or the storage container, bears a label which includes 1 of the following statements or a substantially similar statement which contains the information called for in 1 of the following statements:

i. The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations 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. Do not remove this label.

CAUTION -- RADIOACTIVE MATERIAL -- THIS SOURCE CONTAINS (name of the appropriate material) -- DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

~~Name of manufacturer or importer~~

~~ii. The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of any Licensing State. Do not remove this label.~~

~~CAUTION -- RADIOACTIVE MATERIAL -- THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.~~

~~_____~~

~~Name of manufacturer or importer~~

~~c. Shall not transfer, abandon, or dispose of a calibration or reference source except by transfer to a person authorized by a license from the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State to receive the source;~~

~~d. Shall store a calibration or reference source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and~~

~~e. Shall not use a calibration or reference source for any purpose other than the calibration of radiation detectors or the standardization of other sources.~~

~~6. These general licenses do not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.~~

This subsection grants a general license that authorizes a person who holds a specific license to receive, possess, use, and transfer radioactive material if the Agency issues the license; or special nuclear material if the NRC issues the license. For americium-241, radium-226, and plutonium contained in calibration or reference sources, this subsection grants a general license in accordance with the provisions of subsections (D)(1), (2), and (3). For plutonium, ownership is included in the licensed activities.

1. This subsection grants a general license for calibration or reference sources that have been manufactured according to the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission under 10 CFR 32.57 or 10 CFR 70.39. This general license also governs calibration or reference sources that have been manufactured according to specifications contained in a specific license issued to the manufacturer by the Agency, an Agreement State, or a Licensing State, according to licensing requirements equivalent to those contained in 10 CFR 32.57 or 10 CFR 70.39, as applicable, January 1, 2004, which are incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington D.C. 20408, and on file with the Agency. The material incorporated by reference contains no future editions or amendments.
2. A general license granted under subsection (D) or (D)(1) is subject to the provisions of 12 A.A.C. 1, Articles 1, 3, 4, 10, 12, and 15 and A.R.S. §§ 30-654(B)(13), 30-657(A) and (B), 30-681, and 30-685 through 30-689. In addition, a person who owns, receives, acquires, possesses, uses, or transfers one or more calibration or reference sources under a general license granted under subsection (D) or (D)(1) shall:
   a. Not possess at any one time, at any location of storage or use, more than 185 kBq (5 microcuries) of americium-241, plutonium, or radium-226 in calibration or reference sources;
   b. Not receive, possess, use, or transfer a calibration or reference source unless the source, or the storage container, bears a label that includes one of the following statements, as applicable, or a substantially similar statement that contains the same information:
      i. The receipt, possession, use, and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.
      CAUTION -- RADIOACTIVE MATERIAL -- THIS SOURCE CONTAINS (name of the appropriate material) -- DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

      _____

      Name of manufacturer or importer

      ii. The receipt, possession, use, and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of any Licensing State. Do not remove this label.
      CAUTION -- RADIOACTIVE MATERIAL -- THIS SOURCE CONTAINS RADIUM-226. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

      _____

      Name of manufacturer or importer
   c. Not transfer, abandon, or dispose of a calibration or reference source except by transfer to a person authorized to receive the source by a license from the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State;
   d. Store a calibration or reference source, except when the source is being used, in a closed container designed, constructed, and approved for containment of americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

e. Not use a calibration or reference source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

3. The general license granted under subsections (D) or (D)(1) does not authorize the manufacture of calibration or reference sources that contain americium-241, plutonium, or radium-226.

E. ~~Medical diagnostic uses~~

~~Receipt~~ This subsection grants a general license that authorizes a person to receive, ~~possession~~ possess, use, transfer, ~~ownership or acquisition of~~ own, or acquire carbon-14 urea capsules, ~~containing 1~~ which contain one microcurie of carbon-14 urea for ~~"in vivo"~~ in vivo human diagnostic use~~:~~.

1. Except as provided in subsections (E)(2) and (3), a physician is exempt from the requirements for a specific license, provided that each carbon-14 urea capsule for ~~"in vivo"~~ in vivo diagnostic use contains no more than 1 microcurie.
2. ~~Any~~ A physician who desires to use the capsules for research involving human subjects shall obtain a specific license issued according to the specific licensing requirements in this Article.
3. ~~Any~~ A physician who desires to manufacture, prepare, process, produce, package, repackage, or transfer carbon-14 urea capsules for commercial distribution ~~carbon-14 urea capsules~~ shall obtain a specific license from the Agency, issued according to the requirements in 10 CFR 32, ~~1998 Edition~~ January 1, 2005, ~~published January 1, 1998~~, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, ~~incorporated by reference~~ and on file with the Agency ~~and the Office of Secretary of State~~. ~~This incorporation~~ The material incorporated by reference contains no future editions or amendments.
4. No change

F. ~~General license for use of radioactive material for certain in vitro clinical or laboratory testing~~

~~1. This subsection establishes a general license for any physician, clinical laboratory, or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, the following radioactive materials in prepackaged units:~~

This subsection grants a general license that authorizes any physician, clinical laboratory, or hospital to use radioactive material for certain in vitro clinical or laboratory testing.

1. The general licensee is authorized to receive, acquire, possess, transfer, or use, for any of the following stated tests, the following radioactive materials in prepackaged units:
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
   f. No change
   g. No change
2. A person shall not acquire, receive, possess, use, or transfer radioactive material according to the general license established by ~~subsection (F)(1)~~ this subsection until the person has filed with the Agency ARRA-9, "Certificate -- In Vitro Testing with Radioactive Material Under General License", ~~requesting~~ provided the information listed in Exhibit E, ~~with the Agency~~ and received a validated copy of ARRA-9, which ~~shows~~ indicates the assigned certification number. The physician, clinical laboratory, or hospital shall furnish on ARRA-9 the following information:
   a. No change
   b. A statement that the physician, clinical laboratory, or hospital has ~~appropriate~~ radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material and that tests will be performed only by personnel competent to use the ~~appropriate~~ instruments and handle the radioactive material.
3. A person who receives, acquires, possesses, or uses radioactive material according to the general license ~~established by subsection (F)(1)~~ granted under this subsection shall ~~comply with the following~~:
   a. ~~The general licensee shall not possess~~ Not possess at any one time, in storage or use, a combined total of not more than 7.4 MBq (200 microcuries) ~~total amount~~ of iodine-125, iodine-131, iron-59, or cobalt-57 in excess of 7.4 MBq (200 microcuries), or acquire or use in any ~~1~~ one calendar month ~~any~~ more than 18.5 MBq (500 microcuries) of ~~these materials~~ these radionuclides.
   b. ~~The general licensee shall store~~ Store the radioactive material, until used, in the original shipping container or in a container ~~providing~~ that provides equivalent radiation protection.
   c. ~~The general licensee shall use~~ Use the radioactive material only for the uses authorized by subsection (F)~~(1)~~.
   d. ~~The general licensee shall not transfer the~~ Not transfer radioactive material to a person who is not authorized to receive it according to a license issued by the Agency, the U.S. Nuclear Regulatory Commission, or any Agreement State or Licensing State, or ~~transfer the radioactive material~~ in any manner other than in ~~the~~ an unopened, labeled shipping container received from the supplier.
   e. ~~The general licensee shall not dispose of the~~ Not dispose of a mock iodine-125 reference or calibration ~~sources~~ source described ~~above~~ subsection (F)(1) except as authorized by R12-1-434.

4. The general licensee shall not receive, acquire, possess, transfer, or use radioactive material according to subsection (F)(1):
   a. Except as prepackaged units ~~which~~ that are labeled according to the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, or any Agreement State ~~which~~ that authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), iron-59, cobalt-57, or mock iodine-125 for distribution to persons generally licensed under subsection (F) or its equivalent federal law, and
   b. Unless one of the following statements, or a substantially similar statement ~~which~~ that contains the same information, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure ~~which~~ that accompanies the package:
      i. No change
      ii. No change

~~5. A physician, clinical laboratory or hospital possessing or using radioactive material under the general license in subsection (F)(1) shall report in writing to the Agency, any changes in the information furnished on the ARRA-9. The report shall be furnished within 30 days after the effective date of the change.~~

~~6. Any person using radioactive material according to the general license of subsection (F)(1) is exempt from the requirements of 12 A.A.C. 1, Article 4 and Article 10 with respect to radioactive material covered by that general license, except that persons using mock iodine-125 sources described in subsection (F)(1)(g) shall comply with the provisions of R12-1-434, R12-1-443, and R12-1-444 of these rules.~~

~~7. For the purposes of subsection (F), a licensed veterinary care facility is considered a "clinical laboratory".~~

5. A physician, clinical laboratory or hospital that possesses or uses radioactive material under a general license granted by subsection (F):
   a. Shall report to the Agency in writing, any change in the information furnished on the ARRA-9. The report shall be furnished within 30 days after the effective date of the change; and
   b. Is exempt from the requirements of 12 A.A.C. 1, Article 4 and Article 10 with respect to radioactive material covered by the general license, except that a person using mock iodine-125 sources, described in subsection (F)(1)(g), shall comply with the provisions of R12-1-434, R12-1-443, and R12-1-444 of this Chapter.
6. For the purposes of subsection (F), a licensed veterinary care facility is considered a "clinical laboratory".

G. ~~Ice detection devices~~

~~1. This subsection establishes~~ This subsection grants a general license that authorizes a person ~~a general license~~ to receive, acquire, possess, use, and transfer strontium-90, contained in ice detection devices, provided each device contains not more than 1.85 Mbq (50 microcuries) of strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured according to the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer of the device under licensing requirements equivalent to those in 10 CFR 32.61.

~~2. Persons who receive, acquire, possess, use, or transfer~~ A person who receives, acquires, possesses, uses, or transfers strontium-90 contained in ice detection devices ~~according to the general license in subsection (G)(1)~~ under a general license in accordance with subsection (G):

~~a.~~1. Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating, discontinue use of the device until it has been inspected, tested for leakage, and repaired by a person ~~holding~~ who holds a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State to manufacture or service ice detection devices; or ~~shall~~ dispose of the device according to the provisions of R12-1-434;

~~b.~~2. Shall assure that ~~all labels~~ each label, affixed to the device at the time of receipt, ~~and~~ which ~~bear~~ bears a statement ~~prohibiting~~ that prohibits removal of the labels, ~~are~~ maintained on the ~~devices~~ device; and

~~c.~~3. ~~Are~~ Is exempt from the requirements of 12 A.A.C. 1, Article 4 and Article 10, except that the ~~users~~ user of an ice detection ~~devices~~ device shall comply with the provisions of R12-1-434, R12-1-443 and R12-1-444.

~~3.~~4. ~~This general license does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices~~ Shall not manufacture, assemble, disassemble, or repair an ice detection device that contains strontium-90.

~~4.~~5. ~~This general license is~~ Is subject to the provisions of 12 A.A.C. 1, Articles 1, 3, 12, and 15, and A.R.S. §§ 30-654(B), 30-657(A)~~, 30-657~~ and (B), 30-681, and 30-685 through 30-689.

R12-1-308. Filing Application for Specific Licenses

A. No change
B. No change
C. No change
D. Unless R12-1-1302 precludes combination with a license of another category, an ~~An~~ application for a specific license may include a request for a license ~~authorizing~~ that authorizes more than one activity. ~~authorized by R12-1-1302~~.
E. No change
F. No change

R12-1-309. General Requirements for ~~the~~ Issuance of Specific Licenses

1. No change
2. No change
3. No change
4. The applicant satisfies all applicable special requirements in R12-1-310, R12-1-311, R12-1-322, R12-1-323, 12 A.A.C. 1, ~~Article~~ Articles 5, 7, and 17; and
5. No change
   a. The nature of the proposed activity involving radioactive material; and
   b. No change

R12-1-311. Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices that Contain Radioactive Material

A. No change

1. ~~In addition to the requirements set forth in R12-1-309,~~ The Agency shall grant a specific license ~~authorizing the introduction of~~ to introduce radioactive material into a product or material, owned by or in the possession of the specific licensee or another ~~to~~ that will be transferred to persons exempt under R12-1-303(A)(1), ~~shall be issued if:~~ if the applicant satisfies the requirements of R12-1-309 and:
   a. No change
   b. No change
2. ~~Each person licensed under this subsection shall file an annual report with the Agency which identifies the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; the name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made according to this subsection during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and be filed within 30 days after June 30.~~
   Each person licensed under subsection (A)(1) to initially transfer devices to generally licensed persons shall comply with the requirements of this subsection.
   a. The specific licensee shall report to the Agency in writing any transfer of a device to a person for use under the general license in R12-1-306(B) and any receipt of a device from a person licensed under R12-1-306(B). The specific licensee shall submit the report on a quarterly basis and ensure that the report contains 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 specific licensee 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 the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with applicable radiation safety 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 any person other than the intended user will temporarily possess the device at the place of use before its possession by the user, the specific licensee shall provide the same type of information provided under subsection (A)(2)(a) for the user and each person who will temporarily possess the device, clearly identifying each person.
   c. For a device received from a R12-1-306(B) general licensee, the specific licensee shall provide the identity of the general licensee by name and address, type of device, model number, and serial number of the device received, the date of receipt, and, in the case of a device not initially transferred by the specific licensee, the name of the manufacturer or initial transferor.
   d. If the specific licensee makes changes to a device possessed by a R12-1-306(B) general licensee that necessitate a label change, the specific licensee shall ensure that the report identifies the general licensee, the device, and the changes to information on the device label.
   e. The specific licensee shall prepare a report that covers each calendar quarter. The report shall be filed within 30 days of the end of the calendar quarter, and clearly indicate the period covered by the report.
   f. The report shall clearly identify the specific licensee submitting the report and include the license number of the specific licensee.
   g. If no transfers have been made to or from a person generally licensed under R12-1-306(B) during the reporting period, the specific licensee shall include this information in the report.
   h. The specific licensee shall report any transfer of a device to a person for use under a general license in an Agreement State's regulations that is equivalent to R12-1-306(B) and any receipt of a device from any general licensee in the Agreement State's jurisdiction. The specific licensee shall submit a clear and legible report that contains all

of 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 specific licensee 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 the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with applicable radiation safety 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.

i. If any person other than the intended user will temporarily possess the device at the place of use before its possession by the user, the specific licensee shall record the same type of information provided for the user and for each person who will temporarily possess the device, clearly identifying each person.

j. For a device received from a general licensee, the specific licensee shall provide the identity of the general licensee by name and address, type of device, model number, and serial number of the device received, the date of receipt, and, in the case of a device not initially transferred by the specific licensee, the name of the manufacturer or initial transferor.

k. If the specific licensee makes changes to a device possessed by a general licensee that necessitate a label change to update required information, the specific licensee shall ensure that the report identifies the general licensee, the device, and the changes to information on the device label.

l. The specific licensee shall prepare a report that covers each calendar quarter, is filed within 30 days from the end of the calendar quarter, and clearly indicates the period covered by the report.

m. The report shall clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

n. If no transfers have been made to or from a general licensee in a particular Agreement State during the reporting period, the specific licensee shall report this information to the Agency, NRC, or responsible Agreement State agency at the request of the agency.

3. The specific licensee shall maintain all information concerning transfer and receipt of each device that supports the reports required by subsection (A). Records maintained in accordance with this subsection shall be maintained for a period of 3 years following the date of the recorded event.

B. No change

1. ~~An application for~~ The Agency shall grant a specific license to distribute ~~NARM~~ naturally occurring and accelerator-produced radioactive material (NARM) to ~~persons~~ a person exempted from these rules according to R12-1-303(C) ~~will be approved~~ if the applicant satisfies the requirements of R12-1-309~~,~~ and:
   a. No change
   b. No change
   c. No change
2. The ~~licensee~~ specific license issued under subsection (B)(1) is subject to the following conditions:
   a. ~~No more than~~ The licensee may sell or transfer 10 exempt quantities ~~shall be sold or transferred~~ in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt ~~quantity~~ quantities provided the sum of the fractions ~~shall~~ does not exceed unity.
   b. ~~Each~~ The licensee shall individually package each exempt quantity. ~~shall be separately and individually packaged.~~ No more than 10 packaged exempt quantities shall be contained in any outer package for transfer to ~~persons~~ a person exempt according to R12-1-303(C). The licensee shall ensure ~~outer package shall be such~~ that the dose rate at the external surface of the outer package does not exceed 5 ~~uSv~~ microsieverts (0.5 millirem) per hour.
   c. The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label ~~which~~ that:
      i. No change
      ii. No change
   d. In addition to the labeling information required by subsection (B)(2)(c), the label affixed to the immediate container, or an accompanying brochure, shall:
      i. No change
      ii. No change
      iii. ~~Set forth appropriate~~ Provide additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.
3. Each person licensed under subsection (B) shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under R12-1-303(C) or ~~the~~ an equivalent ~~regulations~~ rule of a Licensing State, and ~~stating~~ state the ~~kinds and quantities~~ type and quantity of radioactive material transferred. ~~An~~ The licensee shall file an annual ~~summary~~ report with the Agency stating the total quantity of each radionuclide trans-

ferred under the specific license. ~~shall be filed with the Agency. Each report shall cover the year ending June 30, and shall be filed within 30 days after June 30. If no transfers of radioactive material have been made according to this subsection during the reporting period, the report shall so indicate.~~ The annual report shall be provided to the Agency even if no transfers of radioactive material have been made according to this subsection during the reporting period. The report shall cover the year ending June 30 and be filed within 30 days after June 30.

C. The Agency shall ~~approve an application for~~ grant a specific license ~~authorizing the incorporation of~~ to incorporate radioactive material, other than source or by-product material, into gas ~~and~~ or aerosol detectors to be distributed to persons exempt under R12-1-303(B) if the ~~application~~ applicant satisfies requirements ~~equivalent to those~~ contained in 10 CFR 32.26, ~~1998 Edition~~ January 1, 2005, ~~published January 1, 1998,~~ which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, ~~incorporated by reference~~ and on file with the Agency ~~and the Office of the Secretary of State which shall not contain any~~, and contains no future editions or ~~references~~ amendments, and provided:

1. The applicant satisfies the requirements of R12-1-309.
2. The licensee files annual reports required by 10 CFR 32.29, ~~1998 Edition~~ January 1, 2005, ~~published January 1, 1998~~, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, ~~incorporated by reference~~ and on file with the Agency ~~and the Office of the Secretary of State, with the Agency~~. ~~This incorporation~~ The material incorporated by reference contains no future editions or ~~references~~ amendments.

D. Licensing the manufacture and distribution of devices to persons generally licensed under R12-1-306(B).

1. The Agency shall ~~approve an application for~~ grant a specific license to manufacture or distribute ~~devices containing~~ each device that contains radioactive material, excluding special nuclear material, to persons generally licensed under R12-1-306(B) or equivalent regulations of the U.S. NRC, an Agreement State, or the Licensing State if:
   a. The applicant satisfies the ~~general~~ requirements of R12-1-309;
   b. No change
      i. No change
      ii. No change
      iii. No change
   c. Each device bears a durable, legible, clearly visible label or labels ~~which~~ that contain in a clearly identified and separate statement:
      i. No change
      ii. No change
      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
      _____
      (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
      _____
      (name of manufacturer or distributor)
   d. The model, serial number, and name of manufacturer or distributor may be omitted from ~~this~~ the label ~~provided they are elsewhere specified~~ 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 R12-1-428, and the name of the manufacturer or initial distributor; and
   f. Each device meets the criteria in 10 CFR 31.5(c)(13)(i), January 1, 2005, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency, and 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 R12-1-428.
2. No change

a. No change
b. No change
c. No change
d. No change
e. No change
f. No change
g. No change
h. No change
i. No change
j. No change

3. No change
4. A ~~person licensed~~ licensee authorized under subsection (D) to distribute ~~devices~~ a device to a generally licensed person shall ~~furnish to a generally licensed person to whom radioactive material is transferred, either directly or through an intermediate person:~~ provide, if a device that contains radioactive material is to be transferred for use under the general license granted in R12-1-306(B), the name of each person that is licensed under R12-1-311(D) 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. The licensee shall provide:
   ~~a. A copy of the general license requirements contained in R12-1-306(B) and a note explaining that use of the device is regulated by the NRC, Agreement State, or Licensing State under requirements substantially the same as those in R12-1-306(B); or~~
   ~~b. A copy of the general license contained in the NRC, Agreement State's, or Licensing State's regulation equivalent to R12-1-306(B).~~
   a. A copy of the general license, issued under R12-1-306(B);
   b. A copy of R12-1-443 and R12-1-445;
   c. A list of the services that can only be performed by a specific licensee;
   d. Information on authorized disposal options, including estimated costs of disposal; and
   e. A list of civil penalties for improper disposal.
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 R12-1-304(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 R12-1-306(A) and (B), and A.R.S. §§ 30-657, R12-1-443, and R12-1-445. 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 Agency an alternate method of informing the customer.
7. If a licensee has notified the Agency of bankruptcy under R12-1-313(E) or is terminating under R12-1-319, the licensee shall provide, upon request, to the Agency, the NRC, or another Agreement State, records of the disposition as required under A.R.S. § 30-657.

~~5~~8. A ~~person licensed under subsection (D), to initially~~ licensee authorized to transfer ~~devices~~ a device to a generally licensed ~~persons~~ person, shall comply with the following requirements:
   a. No change
      i. No change
      ii. No change
      iii. No change
      iv. No change
      v. No change
   b. If one or more ~~intermediate persons~~ intermediaries will temporarily possess the device at the intended place of use before its possession by the intended user, the report shall include the information required of the general licensee in subsection ~~(D)(5)(a)~~ (D)(4) for both the intended user and each ~~intermediate person~~ intermediary, clearly identifying the intended user and each ~~intermediate person~~ intermediary.

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

~~6~~9. The ~~person licensed under subsection (D)~~ licensee shall maintain records of all transfers for Agency inspection. Records shall be maintained for three years after termination of the license to manufacture the generally licensed devices regulated under R12-1-306(B).

E. The Agency shall ~~approve an application for~~ grant a specific license to manufacture, assemble, or repair luminous safety devices ~~containing~~ that contain tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under R12-1-306(C), if the applicant satisfies:

1. No change
2. The requirements of 10 CFR 32.53 through 32.56 and 32.101, ~~1998 Edition~~ January 1, 2005, which are incorporated by reference, ~~published January 1, 1998~~ published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, ~~incorporated by reference~~ and on file with the Agency ~~and the Office of the Secretary of State, or their equivalent~~. ~~These incorporations~~ The material incorporated by reference ~~contain~~ contains no future editions or amendments.

F. The Agency shall ~~approve an application for~~ grant a specific license to manufacture calibration sources ~~containing~~ that contain americium-241 or plutonium for distribution to persons generally licensed under R12-1-306(D) if the applicant satisfies:

1. No change
2. The requirements of 10 CFR 32.57, 32.58, 32.59, 32.102, and 70.39, ~~1998~~ January 1, 2005, which are incorporated by reference, ~~Edition, published January 1, 1998~~, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, ~~incorporated by reference~~ and on file with the Agency ~~and the Office of the Secretary of State, or their equivalent~~. ~~These incorporations~~ The material incorporated by reference ~~contain~~ contains no future editions or amendments.

G. ~~In addition to requirements set forth in R12-1-309, the~~ The Agency shall ~~issue~~ grant a specific license ~~authorizing the distribution of~~ to distribute radioactive material for use by ~~physicians~~ a physician under the general license in R12-1-306(E) if:

1. The applicant submits evidence that the radioactive material is to be manufactured, labeled, and packaged under a new drug application ~~which~~ that the Commissioner of Food and Drugs, U.S. Food and Drug Administration has approved, or according to a license for a biologic product issued by the FDA; and
2. One of the following statements, or a substantially similar statement ~~which~~ that contains the information called for in the following statements, appears on the label affixed to the container or appears in the leaflet or brochure ~~which~~ that accompanies the package:
   a. No change
   b. No change

H. The Agency shall ~~approve an application for~~ grant a specific license to manufacture or distribute radioactive material for use under the general license of R12-1-306(F) if:

1. No change
2. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
   f. No change
   g. No change
3. No change
   a. No change
   b. No change
4. One of the following statements, or a substantially similar statement ~~which~~ 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 ~~which~~ that accompanies the package:
   a. No change

b. No change

5. The label affixed to the unit, or the leaflet or brochure ~~which~~ 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 R12-1-434.

I. The Agency shall ~~approve an application for~~ grant a specific license to manufacture and distribute ice detection devices to persons generally licensed under R12-1-306(G) if the applicant satisfies:

1. No change
2. The criteria of 10 CFR 32.61, 32.62, and ~~32.101~~ 32.103, ~~1998~~ January 1, 2005 ~~Edition, published January 1, 1998~~, which are incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, ~~incorporated by reference~~ and on file with the Agency ~~and the Office of the Secretary of State~~. ~~These incorporations~~ The material incorporated by reference ~~contain~~ contains no future editions or amendments.

J. ~~Manufacture and distribution of radiopharmaceuticals for medical use under a license issued according to 12 A.A.C. 1, Article 7.~~

~~1. The Agency shall approve an application for a specific license to manufacture and distribute radiopharmaceuticals for use by persons licensed under 12 A.A.C. 1, Article 7 if:~~

~~a. The applicant satisfies the general requirements specified in R12-1-309; and~~

~~b. The applicant submits evidence that:~~

~~i. The radiopharmaceutical will be manufactured, labeled, and packed 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 biological product license issued by the FDA or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA; or~~

~~ii. The manufacture and distribution of the radiopharmaceutical is not subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act.~~

~~c. 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 which is appropriate for safe handling and storage of radiopharmaceuticals by group licensees; and~~

~~d. The label affixed to each package of the radiopharmaceutical contains information on the radionuclide; quantity, and date of assay; and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the Agency for distribution to persons licensed according to the requirements in 12 A.A.C. 1, Article 7 or an equivalent license 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 the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, combined with the labeling required by FDA.~~

~~2. A radiopharmaceutical dispensed from a nuclear pharmacy according to A.R.S. § 32-1904 is exempt from the requirements contained in subsection (J)(1). Labeling of such radiopharmaceuticals is governed by Board of Pharmacy rules and the conditions of a radioactive material license.~~

The Agency 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 32.72, January 1, 2005, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. The material incorporated by reference contains no future editions or amendments.

K. The Agency shall ~~approve an application for~~ grant a specific license to manufacture and distribute generators or reagent kits ~~containing~~ that contain radioactive material for preparation of radiopharmaceuticals by persons licensed according to 12 A.A.C. 1, Article 7 if:

1. No change
2. No change
   a. No change
   b. No change
3. No change
4. No change
5. The label affixed to the generator or reagent kit, or the leaflet or brochure ~~which~~ that accompanies the generator or reagent kit, contains:
   a. No change
   b. No change

L. ~~Manufacture and distribution of sources or devices containing radioactive material for medical use~~

~~1. The Agency shall approve an application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed under 12 A.A.C. 1, Article 7 for use as a calibration or reference~~

~~source or for certain medical uses as sealed sources if:~~

~~a. The applicant satisfies the general requirements in R12-1-309;~~

~~b. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of radiation safety, including:~~

~~i. The radioactive material contained, its chemical and physical form, and amount;~~

~~ii. Details of design and construction of the source or device;~~

~~iii. Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;~~

~~iv. For devices containing radioactive material, the radiation profile of a prototype device;~~

~~v. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;~~

~~vi. Procedures and standards for calibrating sources and devices;~~

~~vii. Legend and methods for labeling sources and devices as to their radioactive content;~~

~~viii. Instruction for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided that instructions which are too lengthy for the label may be summarized on the label and printed in detail on a brochure which is referenced on the label;~~

~~c. The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide; quantity, the date of assay, and a statement that the (name of source or device) is licensed by the Agency for distribution to persons licensed under 12 A.A.C. 1, Article 7 or equivalent license of the U.S. Nuclear Regulatory Commission or an Agreement State or a Licensing State, provided that labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source.~~

~~2. In the event the applicant desires that the source or device undergo mandatory testing for leakage of radioactive material at intervals longer than six months, the application shall include sufficient information to demonstrate that the longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source. In determining the acceptable interval for test of leakage of radioactive material, the Agency shall consider information that 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 sources or devices or similarly designed and constructed sources or devices.~~

The Agency 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 or reference source or for medical purposes, if the applicant meets all of the requirements in 10 CFR 32.74, January 1, 2004, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. The material incorporated by reference contains no future editions or amendments.

M. No change

1. The Agency shall ~~approve an application for~~ grant a specific license to manufacture industrial products and devices ~~containing~~ that contain depleted uranium for use under R12-1-305(C) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State if:
   a. No change
   b. No change
   c. No change
2. No change
3. No change
4. No change
   a. No change
   b. No change
      i. No change
      ii. No change
   c. No change

d. No change
e. No change
f. No change
   i. No change
   ii. No change
   iii. No change
   iv. No change
   v. No change
   vi. Keep 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 R12-1-305(C) or equivalent regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State. The records shall be maintained for a period of ~~two~~ 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.

R12-1-312. Issuance of Specific Licenses

A. ~~Upon a determination that an application meets the requirements of the Act and the rules of the Agency, the Agency shall issue a specific license authorizing the proposed activity containing conditions and limitations as it deems appropriate or necessary.~~ Upon determination that a license application meets the requirements of the Act and Agency rules, the Agency shall grant a specific license that may contain conditions or limitations if the Agency has determined that additional requirements regarding the proposed activity will protect health and safety.

B. The Agency may incorporate in any license at the time of issuance, or thereafter by ~~appropriate~~ rule~~,~~ or order, additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material in order to:
1. No change
2. Require reports and ~~the~~ recordkeeping, and ~~to~~ provide for inspections of activities under the license as may be ~~appropriate or~~ necessary to protect health and safety; and
3. No change

C. No change

R12-1-313. Specific Terms and Conditions ~~of Licenses~~

A. No change
B. No change
C. No change
D. Each person licensed under this Section and each general licensee that is required to register under R12-1-306(B)(4)(o) shall notify the Agency in writing ~~when~~ 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 Agency, 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.
   2. Providing the following information:
      a. The bankruptcy court in which the petition for bankruptcy was filed;
      b. The bankruptcy case title and number; and
      c. The date the petition was filed.

~~**E.** Each licensee shall notify the Agency, 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.~~
   ~~2. Providing the following information:~~
      ~~a. The bankruptcy court in which the petition for bankruptcy was filed;~~
      ~~b. The bankruptcy case title and number; and~~
      ~~c. The date the petition was filed.~~

R12-1-315. Renewal of License

A. An applicant shall file an application for renewal of a specific license according to R12-1-308.

B. ~~In any case in which a licensee, not less than 30 days prior to expiration of the existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, the existing license does not expire until a final determination by the Agency~~ If a licensee files a renewal application not less than 30 days before the license expiration date and the existing license and associated renewal application is in proper form, the existing license does not expire until a final renewal determination is made by the Agency.

R12-1-319. Modification, Revocation, or Termination of a License

A. No change

B. No change

C. Except in cases of willfulness or those in which the public health, interest, or safety requires otherwise, the Agency shall not modify, suspend, or revoke a license unless, ~~prior to~~ before the institution of proceedings, facts or conduct ~~which~~ that may warrant ~~such~~ action have been called to the attention of the licensee in writing and the licensee has been accorded an opportunity to demonstrate or achieve compliance.

D. The Agency may terminate a specific license upon a written request by the licensee~~,~~ ~~based on whether the~~ that provides evidence the licensee has met the termination criteria in R12-1-451, R12-1-452, and the decommissioning requirements in R12-1-323.

E. No change

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

R12-1-320. Reciprocal Recognition of Licenses

A. ~~A general license is established by the Agency~~ This subsection grants a general license to perform specific licensed activities in Arizona for a period not to exceed 180 days in any ~~calender~~ calendar year to any person who holds a specific license for activity involving the use of radioactive material from the U.S. Nuclear Regulatory Commission, Licensing State, or any Agreement State, ~~issued by the agency with jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained,~~ provided that:

1. No change
2. The out-of-state licensee notifies the Agency in writing at least three days ~~prior to~~ before engaging in the licensed activity. The notification shall indicate the location, period, and type of proposed possession and use within the State, and be accompanied by a copy of the pertinent licensing document. If, for a specific case, the three-day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Agency, obtain permission to proceed sooner. The Agency may waive the requirement for filing additional written notifications during the remainder of the calendar year, following receipt of the initial notification from a person engaging in activities under the general license provided in this Section;
3. No change
4. No change
5. No change
   a. No change
   b. No change

B. Notwithstanding the provisions of subsection (A)(1), ~~a general license is established by the Agency~~ this subsection grants a general license to manufacture, install, transfer, demonstrate, or service a device described in R12-1-306(B)(1) to any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission, Licensing State, or an Agreement State authorizing the same activities within areas subject to the jurisdiction of the licensing body, provided that:

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

C. No change

D. Before radioactive material can be used at a temporary job site within the state at any federal facility, a specific licensee shall determine the jurisdictional status of the job site. If the jurisdictional status is unknown, the specific licensee shall contact the controlling federal agency to determine whether the job site is under exclusive federal jurisdiction.

E. Before using radioactive material at a job site under exclusive federal jurisdiction, a specific licensee shall:

1. Obtain authorization from the NRC; and
2. Use the radioactive material in accordance with applicable NRC regulations and orders, and be able to demonstrate to the Agency that the correct license fee was paid to the NRC.

F. Before radioactive material can be used at a temporary job site in another state, a specific licensee shall obtain authorization from the state, if it is an Agreement State, or from the NRC for any non-Agreement State, either by filing for reciprocity or applying for a specific license.

R12-1-321. ~~Preparation of Radioactive Material for Transport~~ Repealed

~~A licensee shall not deliver any radioactive material to a carrier for transport, unless the licensee complies with the provisions of 12 A.A.C. 1, Article 15.~~

R12-1-323. Financial Assurance and Recordkeeping for Decommissioning

A. For purposes of ~~this rule~~ terminating specific licensed activities:
1. No change
2. No change
3. No change
4. No change
5. No change

B. When applying, each nongovernment applicant for a specific license ~~authorizing~~ that authorizes the possession and use of radioactive material, and each nongovernment holder of a license to possess and use radioactive material issued before the effective date of this ~~rule~~ Section, shall submit to the Agency a certification of financial security, as required in A.R.S. § 30-672(H). A licensee required to meet the requirement in subsection (C) is exempt from the requirements in this subsection.
1. ~~Each affected licensee shall submit certification of financial security no later than three months following the effective date of this rule.~~
2. ~~Licensees required to meet the requirements in subsection (C) are exempt from the requirements in this subsection.~~

C. When applying, each applicant for a specific license ~~authorizing~~ that authorizes the possession and use of radioactive material, and each holder of a license to possess and use radioactive material issued before the effective date of this ~~rule~~ Section, shall submit to the Agency a decommissioning funding plan or certification of financial assurance ~~meeting~~ that meets the requirements in 10 CFR 30.35, ~~or~~ 40.36, ~~1998 Edition~~ and 70.25, ~~published~~ January 1, ~~1998~~ 2005, which are incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, ~~incorporated by reference~~ and on file with the Agency ~~and the Office of Secretary of State~~. ~~This incorporation~~ The material incorporated by reference contains no future editions or amendments. ~~Each affected licensee shall submit the plan or certification no later than six months following the effective date of this rule.~~

D. Each licensee required to provide financial assurance for decommissioning a radioactive material facility under this ~~rule~~ Section shall maintain records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the Agency. The licensee shall maintain the following records during the decommissioning process:
1. No change
2. No change
3. No change

E. No change
1. Upon expiration or termination of ~~licensed~~ principal activities a licensee shall notify the Agency in writing whether the licensee is discontinuing licensed activities. ~~,a~~ The licensee shall begin decommissioning its facility within 60 days ~~of notifying~~ after the Agency receives notice of the decision to ~~discontinue licensed~~ permanently terminate principal activities, or within 12 months ~~of the decision~~ after receipt of notice, submit to the Agency a decommissioning plan, as prescribed in 10 CFR 30.36(g)(1), ~~1998 Edition~~ January 1, 2005, ~~published January 1, 1998~~, which is incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, ~~incorporated by reference~~ and on file with the Agency ~~and the Office of Secretary of State, containing~~. The material incorporated by reference contains no future editions or amendments~~, and~~. The licensee shall begin decommissioning upon approval of the plan if the license has expired or no licensed activities have been conducted at the licensee's facility for a period of 24 months.
2. No change
   a. ~~Any licensee who has not provided financial assurance to cover decommissioning shall do so 1 year from the effective date of this rule.~~
   b. The licensee may reduce the amount of the financial assurance following approval of the decommissioning plan, provided the radiological hazard is decreasing and the licensee has the approval of the Agency.
3. No change
   a. The licensee shall submit ~~the~~ a request for ~~the change~~ an extension no later than 30 days ~~before the notification time-frame specified in subsection (E)(1)~~ after the Agency receives the notice required in subsection (E)(1).
   b. If ~~appropriate,~~ a licensee has requested an extension, the ~~schedule for~~ licensee is not required to commence decommissioning activities~~, specified~~ required in subsection (E)(1), ~~shall not commence~~ until the Agency has made a determination on the request ~~described in~~ submitted to the Agency under subsection (E)(3)(a).

4. No change
5. The Agency shall approve a request for an alternate schedule for completion of decommissioning and license termination if the Agency determines that the alternative is warranted by consideration of the conditions specified in 10 CFR~~,~~ 30.36(i), ~~1998 Edition~~ January 1, 2005, ~~published January 1, 1998~~ , which are incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, ~~incorporated by reference~~ and on file with the Agency ~~and the Office of Secretary of State, containing~~. The material incorporated by reference contains no future editions or amendments.
6. As a final step in decommissioning, the licensee shall meet the requirements specified in 10 CFR ~~Part~~ 30.36(j), ~~1998 Edition~~ January 1, 2005, ~~published January 1, 1998~~, which are incorporated by reference, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, ~~incorporated by reference~~ and on file with the Agency ~~and the Office of Secretary of State, containing~~. The material incorporated by reference contains no future editions or amendments.

R12-1-325. ~~Repealed~~ Timeliness in Decommissioning Facilities

A. "Principal activities," as used in this Section, means activities authorized by the license that are essential to achieving the purposes for which the license was issued or amended. Storage, during which licensed material is not accessed for use, or disposal and other activities incidental to decontamination or decommissioning are not principal activities.

B. Each specific license revoked by the Agency expires at midnight on the date of the Agency's final determination to revoke the license, the expiration date stated in the determination, or as otherwise provided by Agency order.

C. Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material, until the Agency notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

1. Limit actions involving radioactive material to those related to decommissioning;
2. Continue to control entry to restricted areas until they are suitable for release in accordance with NRC requirements; and
3. Pay the applicable annual fee for the license category listed in R12-1-1306.

D. Within 60 days of the occurrence of any of the following, each licensee shall notify the Agency in writing of the occurrence and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity, so that the building or outdoor area is suitable for release in accordance with Agency requirements, or submit within 12 months of notification a decommissioning plan, if required by R12-1-323, and begin decommissioning upon approval of that plan if:

1. The license expires in accordance with subsection (B) or R12-1-314, unless the licensee submits a renewal application in accordance with R12-1-315;
2. The licensee decides to permanently terminate principal activities at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements;
3. No principal activities under the license have been conducted for a period of 24 months; or
4. No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements.

ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

R12-1-405. Form of Records

A. A licensee or registrant shall ensure that each record required by this Article is legible throughout the specified retention period. The record shall be the original, a reproduced copy, or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. As an alternative the record may be stored in electronic media capable of producing legible records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. A licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

B. In the records required by this Article, a licensee or registrant may record quantities in SI units in parentheses following each of the required units, curie, rad, and rem, and include multiples and subdivisions.

C. Notwithstanding subsection (B), the licensee or registrant shall ensure that information is recorded in the International System of Units (SI) or in SI and the units specified in subsection (B) on each shipment manifest as required in R12-1-439(A).

D. A licensee or registrant shall make a clear distinction among the quantities entered on the records required by this Section (e.g., total effective dose equivalent, shallow-dose equivalent, lens dose equivalent, deep-dose equivalent, committed effective dose equivalent).

R12-1-408. Occupational Dose Amounts for Adults

A. No change
1. No change
   a. No change
   b. No change
2. No change
   a. No change
   b. A shallow dose equivalent of 0.5 Sv (50 rem) to the skin of the whole body or to the skin of any extremity.

B. No change

C. The assigned deep-dose equivalent and shallow-dose equivalent ~~is~~ are, for the portion of the body receiving the highest exposure, determined as follows:
1. No change
2. If a protective apron is worn and monitoring is conducted as specified in ~~R12-1-419(B)~~, R12-1-419(B)(6), the effective dose equivalent for external radiation shall be determined as follows:
   a. No change
   b. No change
3. The assigned deep-dose equivalent shall be determined for the part of the body that receives the highest exposure. The assigned shallow-dose equivalent is the dose averaged over the contiguous 10 square centimeters of skin that receives the highest exposure. The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

D. No change

E. No change

F. No change

R12-1-412. Determination of Prior Occupational Dose

A. ~~For each individual who may enter a licensee's or registrant's restricted area and is likely to receive, in a year, an occupational dose requiring monitoring according to R12-1-419, the licensee or registrant shall:~~
For each individual who is likely to receive in a year an occupational dose that requires monitoring according to R12-1-419 the licensee shall:
1. No change
2. No change

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

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

D. No change
1. No change
2. No change
3. No change
   a. No change
   b. No change
4. No change

R12-1-413. Planned Special Exposures

A. No change
1. The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid ~~the higher exposure are~~ the dose estimated from the planned special exposure are unavailable or impractical.
2. No change
3. No change
   a. No change
   b. No change
   c. No change
4. No change

5. No change
   a. No change
   b. No change
6. No change
7. No change

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

C. No change

R12-1-415. Dose ~~Limits for~~ Equivalent to an Embryo or Fetus

A. A licensee or registrant shall ensure that the dose equivalent to an embryo or fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem). Records shall be maintained according to R12-1-419(D)(4) and (5).

B. The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman to satisfy the limit in subsection (A).

C. ~~The dose equivalent to an embryo or fetus is the sum of:~~
~~1. The deep-dose equivalent to the declared pregnant woman, and~~
~~2. The dose equivalent to the embryo or fetus from radionuclides in the embryo or fetus and radionuclides in the declared pregnant woman.~~

For purposes of this Section, the dose equivalent to the embryo or fetus is the sum of:
1. The deep-dose equivalent to the declared pregnant woman; and
2. The dose equivalent to the embryo or fetus resulting from radionuclides in the embryo or fetus and radionuclides in the declared pregnant woman.

D. ~~If by the time the woman declares pregnancy to the licensee or registrant, the dose equivalent to the embryo or fetus has exceeded 4.5 mSv (0.45 rem), the licensee or registrant is deemed to be in compliance with subsection (A), if the additional dose equivalent to the embryo or fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.~~
If the dose equivalent to the embryo or fetus is found to have exceeded 5 mSv (0.5 rem) or is within 0.5 mSv (0.05 rem) of this dose by the time the woman declares the pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with subsection (A) if the additional dose equivalent to the embryo or fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

~~E.~~ ~~A declaration of pregnancy shall remain in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.~~

R12-1-418. Surveys and Monitoring

A. Each licensee or registrant shall make, or cause to be made, surveys ~~that are necessary~~ if surveys are:
1. ~~For~~ Necessary for the licensee or registrant to comply with Article 4, and
2. ~~Under~~ Reasonable under the circumstances to evaluate:
   a. No change
   b. No change
   c. The potential radiological hazards ~~that could be present~~.

B. No change
1. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology, according to NVLAP procedures published March 1994 as NIST Handbook 150, and NIST Handbook 150-4, published August 1994, ~~by the U.S. Department of Commerce, incorporated by reference and on file with the Agency and the Office of the Secretary of State~~ which is incorporated by reference, published by the U.S. Government Printing Office, Washington D.C. 20402-9325, and on file with the Agency ~~containing~~. The material incorporated by reference contains no future editions or amendments; and
2. No change

C. No change

D. A licensee shall ensure that survey instruments and personnel dosimeters that are used to make quantitative measurements are calibrated in accordance with R12-1-449.

~~D.~~**E.** Records.
1. No change
2. No change
   a. No change
   b. No change
   c. No change
   d. No change

R12-1-419. Conditions Requiring Individual Monitoring of External and Internal Occupational Dose

A. No change

B. At ~~a~~ minimum each licensee or registrant shall supply and require the use of individual monitoring devices by the following personnel:

~~1. Adults likely to receive, in one year from sources external to the body, a dose in excess of 10% of the limits in R12-1-408(A);~~

~~2. Minors likely to receive, in one year, from radiation sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem), a lens dose equivalent in excess of 1.5 mSv (0.15 rem), or a shallow dose equivalent to the skin or to the extremities in excess of 5 mSv (0.5 rem).~~

~~3. Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem).~~

~~4. The following personnel:~~

~~a. Individuals operating mobile x-ray equipment; except dental intraoral systems, as described in R12-1-608;~~

~~b. Individuals holding animals for diagnostic x-ray procedures, as described in R12-1-613;~~

~~c. Individuals servicing enclosed beam x-ray systems with bypassed interlocks, as described in R12-1-803;~~

~~d. Individuals operating open beam fluoroscopic systems and ancillary personnel working in the room when the fluoroscopic system is in use, except when relieved of this requirement by license or registration condition under A.R.S. § 30-654(B)(13);~~

~~e. Individuals on their extremities when operating analytical x-ray machines with no safety devices, or if service is performed in the primary beam of the analytical x-ray machine, as described in R12-1-806(D).~~

~~f. Individuals performing industrial radiography or operating an uncertified enclosed x-ray machine, as described in Article 5;~~

~~g. Individuals performing well logging, as described in Article 17; and~~

~~C. Each licensee or registrant shall require that all individual monitoring devices be located on individuals according to the following requirements:~~

~~1. An individual monitoring device used for the dose to an embryo or fetus of a declared pregnant woman, according to R12-1-415(A), shall be located under the protective apron at the waist. A qualified expert shall be consulted to determine the dose to the embryo or fetus for the rare occasion in which this individual monitoring device has a monthly reported dose equivalent value in excess of 0.5 mSv (50 mrem). For purposes of these rules, the value to be used for determining the dose to an embryo or fetus according to R12-1-415(C)(1), for occupational exposure to radiation from medical fluoroscopic equipment, is the value reported by the individual monitoring device worn at the waist underneath the protective apron which has been corrected for the particular individual and the work environment by a qualified expert;~~

~~2. An individual monitoring device used for lens dose equivalent shall be located at the neck, or an unshielded location closer to the eye, outside the protective apron;~~

~~3. If only one individual monitoring device is used to determine the effective dose equivalent for external radiation according to R12-1-408(C)(2), it shall be located at the neck outside the protective apron. If a second individual monitoring device is used for the same purpose, it shall be located under the protective apron at the waist. (Note: The second individual monitoring device is required for a declared pregnant woman.)~~

~~D. At a minimum, each licensee or registrant shall monitor, to determine compliance with R12-1-411, the occupational intake of radioactive material and assess the committed effective dose equivalent to:~~

1. Adults likely to receive, in one year, an intake in excess of 10% of the applicable ALI in Table I, Columns 1 and 2, of Appendix B; ~~and~~

~~2. Minors likely to receive, in one year, a committed effective dose equivalent in excess of 1 mSv (0.1 rem); and~~

~~3. Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 1 mSv (0.1 rem).~~

2. Minors and declared pregnant women likely to receive, in one year, a committed effective dose equivalent in excess of 0.5 mSv (0.05 rem);
3. Adults likely to receive, in one year from radiation sources external to the body, a dose in excess of 10 percent of the limits in R12-1-408(A);
4. Minors likely to receive, in one year, from radiation sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem), a lens dose equivalent in excess of 1.5 mSv (0.15 rem), or a shallow dose equivalent to the skin or to

the extremities in excess of 5mSv (0.5 rem);
5. Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 1 mSv (0.1 rem) (Note: All of the occupational doses in R12-1-408 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.); and
6. Individuals entering a high or very high radiation area;
7. Individuals operating mobile x-ray equipment; except dental intraoral systems, as described in R12-1-608;
8. Individuals holding animals for diagnostic x-ray procedures, as described in R12-1-613;
9 Individuals servicing enclosed beam x-ray systems with bypassed interlocks, as described in R12-1-803;
10. Individuals operating open beam fluoroscopic systems and ancillary personnel working in the room when the fluoroscopic system is in use, except when relieved of this requirement by registration condition; and
11. Individuals performing well logging, as described in Article 17.

C. Each licensee shall monitor the occupational intake of radioactive material by and assess the committed effective dose equivalent to:
1. Adults likely to receive, in one year, an intake in excess of 10% of the applicable ALI in Table 1, Columns 1 and 2, of Appendix B;
2. Minors likely to receive, in one year, a committed effective dose equivalent in excess of 1 mSv (0.1 rem); and
3. Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 1 mSv (0.1 rem).

~~E.~~**D.** Records.
1. No change
   a. ~~The deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;~~
   b. ~~The estimated intake of radionuclides, see R12-1-409:~~
   c. ~~The committed effective dose equivalent assigned to the intake of radionuclides;~~
   d. ~~The specific information used to calculate the committed effective dose equivalent according to R12-1-411(C):~~
   a. The deep-dose equivalent to the whole body, lens dose equivalent, shallow-dose equivalent to the skin, and shallow-dose equivalent to the extremities;
   b. The estimated intake of radionuclides;
   c. The committed effective dose equivalent assigned to the intake of radionuclides;
   d. The specific information used to assess the committed effective dose equivalent according to R12-1-411(A) and (C), and when required R12-1-419.
   e. No change
   f. No change
2. No change
3. No change
4. No change
5. No change

R12-1-430. Exceptions to Posting Requirements

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

B. No change

C. No change

D. A hospital or clinic licensee is exempt from the posting requirements in R12-1-429 for a teletherapy room if:
1. Access to the room is controlled according to R12-1-731; and
2. Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation that exceeds the limits established in this Chapter.

~~D.~~**E.** A ~~licensee or~~ registrant is not required to post a caution sign in a room or area because of the presence of radiation machines used solely for diagnosis in the healing arts.

R12-1-433. Procedures for Receiving and Opening Packages

A. Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in 10 CFR 71.4, ~~2000 Edition,~~ January 1, 2005, which is incorporated by reference, ~~published January 1, 2000~~, published by the Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and ~~, incorporated by reference and~~ on file with the Agency. ~~and the Office of the Secretary of State, containing~~ The material incorporated by reference contains no future editions or amendments~~,~~ . The licensee shall make arrangements to receive:
1. No change
2. No change

B. No change
1. Monitor the external surfaces of a package, labeled with a Radioactive White I, Yellow II, or Yellow III as specified in 49 CFR 172.403 and 172.436 through 172.440, ~~1999 Edition~~ October 1, 2004, ~~published October 1, 1999~~ which are incorporated by reference, published by the Office of Federal Register, National Archives and Records Administration, Washington, D.C. 20408, and ~~, incorporated by reference and~~ on file with the Agency, ~~and the Office of the Secretary of State, containing~~ The material incorporated by reference contains no future editions or amendments~~,~~ . The licensee shall test the package for radioactive contamination, unless the package contains only radioactive material in the form of gas or in special form, as defined in R12-1-102; and
2. No change
3. No change

C. No change

D. The licensee shall immediately notify the final delivery carrier and~~, by telephone and telegram, mailgram, or facsimile, the Agency when~~ the Agency by telephone when:
1. No change
2. No change

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

F. No change

R12-1-441. Records of Waste Disposal

A. Each licensee shall maintain records of the disposal of licensed materials made in accordance with R12-1-435, R12-1-436, R12-1-437, R12-1-438, and disposal by burial in soil, including burials authorized before February 25, 1985.

B. ~~The records required by subsection (A) shall be maintained for three years after the Agency terminates the applicable license or registration~~. The licensee shall retain the records required by subsection (A) until the Agency terminates each pertinent license requiring the record. The licensee shall provide for the disposition of these records prior to license termination.

R12-1-453. Reports to Individuals of Exceeding Dose Limits

Any licensee or registrant that reports a personnel exposure to the Agency in accordance with R12-1-413(A)(6), R12-1-444, or R12-1-452 shall:
1. Notify the exposed individual of the exposure addressed in the report; and
2. Transmit the report to the exposed individual at the same time the Agency is notified of the exposure.

ARTICLE 5. SEALED SOURCE INDUSTRIAL RADIOGRAPHY

R12-1-501. Definitions

"Access panel"	No change
"Annual refresher safety training"	No change
"Aperture"	No change
"Associated equipment"	No change
"Certifying entity"	No change
"Collimator"	No change
"Control (drive) cable"	No change
"Control (drive) mechanism"	No change
"Control tube"	No change
"Door"	No change
"Exposure head"	No change
"Ground fault"	No change

"Guide tube (projection sheath)" means ~~a flexible or rigid tube used to guide the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and the exposure head~~ a flexible or rigid tube (i.e., "J" tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

"Hands-on experience"	No change

"Independent certifying organization"	No change
"Lay-barge radiography"	No change
"Port"	No change
"Practical examination"	No change

"Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

"Radiographic exposure device"	No change
"Radiographic operations"	No change
"S-tube"	No change
"Source assembly"	No change
"Underwater radiography"	No change

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

R12-1-1003. ~~Instructions to~~ Instruction for Workers

~~**A.** The licensee or registrant shall inform all individuals working in or frequenting any portion of a restricted area of:~~
- ~~1. The storage, transfer, or use of radioactive material or of radiation in the restricted area and the health protection problems associated with exposure to radioactive material or radiation;~~
- ~~2. Precautions or procedures to minimize exposure, and the purposes and functions of protective devices employed;~~
- ~~3. The applicable provisions of Agency rules and licenses for the protection of personnel from exposures to radiation or radioactive material occurring in each restricted area;~~
- ~~4. Their responsibility to report promptly to the licensee or registrant any condition which may lead to or cause a violation of Agency rules and licenses, or unnecessary exposure to radiation or radioactive material;~~
- ~~5. The appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and~~
- ~~6. The radiation exposure reports which workers may request under R12-1-1004.~~

~~**B.** The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.~~

A. A licensee or registrant shall ensure that each individual who, in the course of employment, is likely to receive in a year an occupational dose in excess of 1 mSv (100 mrem), receives instruction in all of the following subjects:
1. Storage, transfer, or use of radiation and radioactive material;
2. Health protection problems associated with exposure to radiation or radioactive material, precautions or procedures to minimize exposure, and purposes and functions of protective devices;
3. Applicable provisions in Agency rules, licenses, and registrations that protect of personnel from exposure to radiation or radioactive material, with an emphasis on the duties of workers;
4. The duty to promptly report to the licensee or registrant any condition that may lead to or cause a violation of a provision in an Agency rule, license, or registration or unnecessary exposure to radiation or radioactive material;
5. Correct response to warnings in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and
6. Radiation exposure reports that a worker may request according to R12-1-1004.

B. In determining whether subsection (A) applies to an individual, a licensee or registrant shall take into consideration assigned activities during normal and abnormal situations that involve exposure to radiation or radioactive material and could reasonably be expected to occur during the life of a facility. The licensee or registrant shall provide instruction that is commensurate with potential radiological health protection problems present in the work place.

ARTICLE 13. LICENSE AND REGISTRATION FEES

R12-1-1302. License and Registration Categories

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

B. No change
1. No change

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

C. No change

1. No change
2. No change
3. No change
4. No change
5. No change
6. No change
7. No change
8. No change
9. No change
10. No change
11. No change
12. No change
13. No change
14. No change
15. No change
16. No change
17. No change

D. Category D licenses are the following specific radioactive material licenses. Except for type D4, general industrial; type D5, depleted uranium; type D8 and D9, health physics; and type D14, additional facilities licenses, the Agency shall not combine a category D license with any other license.

1. No change
   a. No change
   b. No change
2. No change
3. No change
4. ~~A depleted uranium license is one which authorizes the use of depleted uranium as a concentrated mass or as shielding for other radiation sources within a device or machine. The Agency may combine a depleted uranium license with a medical teletherapy license; a broad industrial A, B or C license; a portable gauge license; a fixed gauge class A or B license; an industrial radiography class A or B license; or a self-shielded irradiator license.~~ A general industrial license is a registration of a gauging device in accordance with R12-1-306(B). The Agency may combine a general industrial license with a Class A, B, or C broad industrial, limited industrial, portable gauge, or Class A or B fixed gauge license.
5. ~~A depleted uranium general license is a registration of the use of the general license authorized pursuant to R12-1-305(C).~~
   A depleted uranium general license is a registration of the use of the general license authorized pursuant to R12-1-305(C) or the use of depleted uranium as a concentrated mass or as shielding for another radiation source within a device or machine. The Agency may combine a depleted uranium general license with a medical teletherapy; Class A, B, or C broad industrial; portable gauge; Class A or B fixed gauge; Class A or B industrial radiography; or self-shielded irradiator license. For registration purposes an applicant shall follow the registration instructions in R12-1-305(C).
6. No change
7. No change
8. No change
9. No change
10. No change
11. No change
12. No change
13. No change
14. No change
15. No change
16. No change
17. No change
18. No change

19. No change

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

F. No change
1. No change
2. No change
3. No change
4. No change
5. No change
6. No change
7. No change
8. No change
9. No change
10. No change
11. No change
12. No change

R12-1-1306. Table of Fees

A. The application and annual fee for each category and type are shown in Table 13-1.

Table 13-1

Category	Type	Annual fee
A1.	No change	
A2.	No change	
A3.	No change	
A4.	No change	
B1.	No change	
B2.	No change	
B3.	No change	
B4.	No change	
B5.	No change	
B6.	No change	
C1.	No change	
C2.	No change	
C3.	No change	
C4.	No change	
C5.	No change	
C6.	No change	
C7.	No change	
C8.	No change	
C9.	No change	
C10.	No change	
C11.	No change	
C12.	No change	
C13.	No change	
C14.	No change	
C15.	No change	
C16.	No change	
C17.	No change	
D1.	No change	
D2.	No change	
D3.	No change	
D4.	~~Depleted uranium~~ General industrial (with fee)	$ 100
D5.	No change	

D6. No change
D7. No change
D8. No change
D9. No change
D10. No change
D11. No change
D12. No change
D13. No change
D14. No change
D15. No change
D16. No change
D17. No change
D18. No change
D19. No change
E1. No change
E2. No change
E3. No change
E4. No change
E5. No change
E6. No change
F1. No change
F2. No change
F3. No change
F4. No change
F5. No change
F6. No change
F7. No change
F8. No change
F9. No change
F10. No change
F11. No change
F12. No change

Notes: (1) No change
(2) No change
(3) No change

B. No change

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