NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by 1st submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Due to time restraints, the Secretary of State's Office will no longer edit the text of proposed rules. We will continue to make numbering and labeling changes as necessary.

Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for adoption, amendment, or repeal of any rule. A.R.S. §§ 41-1013 and 41-1022.

NOTICE OF PROPOSED RULEMAKING

TITLE 12. NATURAL RESOURCES

CHAPTER 1. RADIATION REGULATORY AGENCY

PREAMBLE

1.	Section Affected	Rule Making Action
	R12-1-102	Amend
	Article 2	Amend
	R12-1-202	Amend
	Appendix A	Amend
	Article 3	Amend
	R12-1-301	Repeal
	R12-1-301	Renumber
	R12-1-301	Amend
	R12-1-302	Renumber
	R12-1-302	Amend
	R12-1-303	Renumber
	R12-1-303	Amend
	R12-1-304	Renumber
	R12-1-304	Amend
	R12-1-305	Renumber
	R12-1-305	Amend
	R12-1-306	Renumber
	R12-1-306	Amend
	R12-1-307	Renumber
	R12-1-308	Renumber
	R12-1-308	Amend
	R12-1-309	Renumber
	R12-1-309	Amend
	R12-1-310	Renumber
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	R12-1-313	Amend
	R12-1-314	Renumber
	R12-1-314	Amend
	R12-1-315	Renumber
	R12-1-315	Amend
	R12-1-316	Renumber
	R12-1-316	Amend
	R12-1-317	Renumber
	R12-1-317	Amend

R12-1-318	Renumber
R12-1-318	Amend
R12-1-319	Renumber
R12-1-319	Amend
R12-1-320	Renumber
R12-1-320	Amend
R12-1-321	Renumber
R12-1-321	Amend
R12-1-322	Renumber
R12-1-322	Amend
R12-1-323	Renumber
R12-1-323	New Section
Schedule (Exhibit) A	Amend
Schedule (Exhibit) B	Amend
Schedule C	Repeal
Schedule (Exhibit) D	Amend
Schedule (Exhibit) E	Amend
Exhibit E	New Section
R12-1-407.	Amend
R12-1-408	Amend
R12-1-409	Amend
R12-1-411	Amend
R12-1-415	Amend
R12-1-418	Amend
R12-1-419	Amend
R12-1-442	Amend
R12-1-449	New Section
R12-1-450	New Section
R12-1-511	Amend
R12-1-541	Amend
R12-1-606	Amend
R12-1-612	Amend
Article 7	Amend
R12-1-701	Amend
R12-1-702	Amend
R12-1-703	Repeal
R12-1-703	New Section
R12-1-704	Repeal
R12-1-704	New Section
R12-1-705	New Section
R12-1-706	New Section
R12-1-707	New Section
R12-1-708	New Section
R12-1-709	New Section
R12-1-710	New Section
R12-1-711	New Section
R12-1-712	New Section
R12-1-713	New Section
R12-1-714	New Section
R12-1-715	New Section
R12-1-716	New Section
R12-1-717	New Section
R12-1-718	New Section
R12-1-719	New Section
Exhibit A	New Exhibit
R12-1-801	Amend
R12-1-802	Amend
R12-1-803	Amend
R12-1-804	Amend
R12-1-805	Amend
R12-1-806	Amend
R12-1-902	Repeal
R12-1-903	Amend
R12-1-904.	Amend
R12-1-911	Amend

R12-1-1001	Amend
R12-1-1002	Amend
R12-1-1003	Amend
R12-1-1004	Amend
R12-1-1005	Amend
R12-1-1006	Amend
R12-1-1007	Amend
R12-1-1008	Amend
R12-1-1209	Amend
R12-1-1210	Amend
R12-1-1211	Amend
R12-1-1212	Amend
R12-1-1213	Amend
R12-1-1214	Amend
R12-1-1215	Amend
R12-1-1216	Amend
R12-1-1217	Amend
R12-1-1218	Amend
R12-1-1219	Amend
R12-1-1220	Amend
R12-1-1222	Amend
R12-1-1223	New Section
Table A	New Table
R12-1-1301	Amend
R12-1-1302	Amend
R12-1-1303	Amend
R12-1-1304	Amend
R12-1-1305	Amend
R12-1-1306	Amend
R12-1-1307	Amend
R12-1-1308	Amend
R12-1-1309	New Section

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

   General: A.R.S. §§ 30-654(B), 41-1073 to 1078

   Specific: A.R.S. §§ 30-657, 30-671(B) 30-672, 30-681, 30-682, 30-683(C), 30-686, 30-687, 30-688, 30-693, and 30-696

3. **A list of all previous notices appearing in the Register addressing the proposed rule:**

   Notice of Rulemaking Docket Opening: 3 A.A.R. 1990, July 25, 1997.

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

   Name: Dan Kuhl

   Address: Arizona Radiation Regulatory Agency
   4814 South 40th Street
   Phoenix, Arizona 85040

   Telephone: (602) 255-4845 ext. 233

   Fax: (602) 437-0705

5. **An explanation of the rule, including the agency's reasons for initiating the rule:**

   R12-1-102

   The definition of "Background radiation" is modified to bring it in alignment with the law governing the Agencies rules.

   The definition for "Exhibit" is added to explain name changes of listings that occur at the end of some of the articles in Title 12, Chapter1.

   The definition of "Temporary jobsite' is amended to limit a temporary jobsite to 6 months. This limitation was added to the definition on June 30, 1996 and inadvertently deleted in 1997. Therefore this is a correction only.

   The definition of "TODE" is amended to correctly reference a subsection in R12-1-419.

   A definition for "Workload" is added so persons affected by R12-1-202 will know what information is required with the x-ray registration application.

   R12-1-202

Changes are made to the application, for registration of radiation producing machine requirements. Some are made for clarification purposes while others are made to improve safety. An applicant will be required to meet the particle accelerator safety standards in Article 9 prior to registering.

Article 2, Appendix A, Registration Forms

Corrections are made to spelling and format. Addition of the requirement to provide credentials for the radiation safety officer and the physician operating the particle accelerator in the practice of radiation therapy is added The authority to request this information is in R12-1-904(2).

R12-1-301

This rule is repealed to eliminate the numbering problem that exists in Article 3. Because the terms "Decommissioning" and "Emergency Plan" are used in a single rule, their definitions are relocated in the rule where each term is used, R12-1-322 and R12-1-323, rather than the definition list in Article 1.

Note: The following rule numbers are the corrected numbers. Each number was originally a digit higher. (R12-1-302 thorough R12-1-323 becomes R12-1-301 thorough R12-1-322)

R12-1-301

This rule describes general requirements for ownership, control, and transfer of radioactive material. References to requirements in Article 7 and Article 15 are added for clarification purposes.

R12-1-302

This rule lists exemptions for source material licensing. Only clarification changes are made.

R12-1-303

Exemptions for licensing radioactive material other than source material are listed in this rule. Only clarification changes are made.

R12-1-304

A list of license types is presented. Only clarification changes are made.

R12-1-305

Requirements for source material general licenses are listed. Only format and clarification changes are made.

R12-1-306

Listed are the requirements for general licenses other than source material. Only minor format, clarification, and rule reference changes are made.

R12-1-307

Only the rule number is changed.

R12-1-308

Requirements that must be met when filing an application for a specific license are listed. Subsection (C) now references a list of required information that must be provided with the application. The list is added as Schedule (E) to this Article.

R12-1-309

Requirements that must be met before the Agency will issue a specific license are listed. Listed are various references containing use requirements in this Article and other Articles in Chapter 1. Added are references to decommissioning requirements in R12-1-323 and specific use requirements contained in Articles 5, 7, and 17. These references are added to insure all safety issues are addressed.

R12-1-310

Subsections (A) through (F), dealing with specific licensing requirements for radioactive material use in radiography and medicine, are moved to Articles 5 and 7, where these specialized uses are regulated. Requirements that must be met by broad scope license applicants remain in this rule. Also, reference changes are made due to the moving of the requirements mentioned above to other Articles and to Article 17, reference to which had been inadvertently deleted during past rule making.

R12-1-311

Requirements affecting applicants desiring to manufacture, assemble, repair, or distribute commodities, products, or devices containing radioactive material are contained in this rule. The majority of changes are wording corrections and reference changes. Many changes involve incorporation-by-reference to update the rules. An exemption to manufacturing requirements is added in subsection (J), allowing nuclear pharmacies to provide radiopharmaceuticals to licensed recipients according to A.R.S.§ 32-1904.

R12-1-312

This rule requires that the Agency issue a license if the applicant meets the application requirements and allows the Agency to incorporate additional safety requirements as license conditions. A prelicense inspection may be performed by the Agency to verify that all application requirements are met. Only minor word changes are presented.

R12-1-313

Described are specific conditions and terms of licenses. Licensed activities governed by the Act, transfer requirements, and Agency notification of licensed program changes are dealt with in this rule. Only minor word changes are presented.

R12-1-314

The expiration date of a license is described. A word change is made to improve clarity.

R12-1-315

Requirements for renewing a license are listed. A minor word change is made.

R12-1-316

The method for amending a license is described. A minor word change is made.

R12-1-317

Under this rule the Agency is required to follow specific procedures in renewing or amending a license. A minor word change is made.

R12-1-318

The rule details the steps that must be followed in transferring radioactive material to properly authorized recipients. Minor word changes are made.

R12-1-319

Procedures for modification, revocation, and termination of licenses are listed. Minor word changes are made.

R12-1-320

This rule is modified to better delineate the requirements that must be met when the Agency recognizes the license of a radioactive material user that wishes to enter the state to conduct licensed activities, licensed by another Agreement state or the Nuclear Regulatory Commission (NRC). Many word and reference changes are made.

R12-1-321

The licensee is required to follow the rules in Article 15 when preparing radioactive material for transport. A minor word change is made.

R12-1-322

Certain radioactive material users are required to have an emergency plan, preventing radiation exposure to the public. With the exception of adding the definition of "emergency plan" to this rule from the previous R12-1-301, repealed with this rule making package, only minor word changes are made to the rule.

R12-1-323

A decommissioning plan and funding rule is added so that licensees possessing certain amounts of radioactive material sequester enough funds to insure that a contaminated facility or an inventory of radioactive material or waste can be cleaned up in a safe manner that is not costly to the State. This requirement is added by incorporating by reference the decommissioning requirement contained in the Code of Federal Regulations. This new rule is a NRC compatibility requirement for all Agreement States. Currently, the Agency is ensuring that certain programs have a decommissioning plan by requiring it as a license condition, as authorized in A.R.S.§ 30.654(B)(13).

Schedule C

Moved to Article 7 as Exhibit A with the other requirements moved from R12-1-310 to Article 7.

Schedule D

This schedule becomes Exhibit C.

Schedule E

This schedule becomes Exhibit D.

Exhibit E

A new Exhibit E is added. This schedule contains a listing of the information that must be provided by a radioactive material

license applicant. The information is requested in a license application form as required in R12-1-308. This Exhibit is added as required by a recently passed law requiring agencies to list in their rules the information requested in a license or registration application.

R12-1-407

Six licence categories are exempted from the record requirements in this rule due to the low hazard associated with their radiation use programs.

R12-1-408, R12-1-409, R12-1-411, and R12-1-415:

These rules are concerned with radiation exposure limits. In each rule a correction is made to a rule reference, R12-1-419, and a wording correction is made in R12-1-409.

R12-1-418

Because of its importance, a subsection dealing with calibration of survey instruments is repealed because a separate new survey meter calibration rule, R12-1-449, is added. The requirement is buried in a rule that specifically deals with monitoring, an entirely different safety issue.

R12-1-419

This rule is the cornerstone for the standards that must be followed when determining which radiation workers are required to use personnel monitoring. The rule in its original form is incorrectly formatted. Rewording and format changes are made to the rule.

R12-1-442

A reference is added to clarify this rule that regulates the shipment of radioactive waste to a licensed disposal facility.

R12-1-449

This new rule requires the radiation user performing radiation surveys as part of a radiation safety program to calibrate survey instruments according to the specified standard. This requirement is moved from a subsection in R12-1-418 because of its importance in a safety program (see R12-1-418).

R12-1-450

A new rule is added regulating the use and inventory of sealed sources for unspecified use. These requirements are not new. They are currently addressed in license conditions and in Articles 3, 5, 7, and 17, which regulate sources of specific use.

R12-1-511

A minimum training level for enclosed radiography x-ray machine users is added to the industrial radiography application requirements. Other minor word changes are made.

R12-1-541

Changes are made to clarify the record keeping requirements placed on cabinet and shielded room x-ray systems. Wording is changed to require shielded room x-ray machine operators to correctly use personnel monitoring (PM) devices. The current wording incorrectly requires radiography sealed sources to use PM devices.

R12-1-606

Minor changes are made to the fluoroscopic installation requirements. Unit conversions are added throughout the rule and wording changes are made to clarify the use of protective devices during fluoroscope operation. Personnel monitoring will no longer be required for operators of portable or mobile C-arm fluoroscopic x-ray machines.

R12-1-612

Radiation leakage record retention requirements for x-ray and electron therapy systems are modified. Machines having an energy range greater than 1 Mev must retain records for the life of the systems's operation. The information content of the therapy calibration report is explicitly defined. Qualifications are revised to more explicitly define minimal standards for individuals performing a calibration on a particle accelerators. The change aligns these qualifications with those of individuals calibrating teletherapy systems regulated in Article 7.

R12-1-701

With the major changes and additions to Article 7 the scope is now expanded to include the use of unsealed sources of radioactive material in the healing arts.

R12-1-702

This section is amended to include definitions that will aid in understanding the requirements in other sections added to Article 7. Of particular interest is the change in definition of a misadministration from the definition now contained in R12-1-311(E). This proposed definition is consistent with the definition contained in 10 CFR 35, and is less stringent in terms of current report-

ing requirements.

R12-1-703

This rule contains the licensing requirements that were moved from R12-1-311. Included is a change in the standard for the allowable level of molybdenum-99 breakthrough in technetium generator eluate. The level will now be consistent with federal standards in 10 CFR 35. The old requirements in this rule are moved to R12-1-714

R12-1-704

This section is added to describe the necessary supervision that is needed for use of radiation from radioactive material in the healing arts. Included is a definition for supervision, licensing requirements, and a requirement that a supervising physician be physically present during therapy procedures. This requirement is new and is added because of the potential safety hazards of use by an unqualified user. The old requirements in this rule are moved to R12-1-716.

R12-1-705

This section is added. The rule requires all medical licensees to have a Radiation Safety Officer. Qualifications are not listed in this article. This requirement is added to address potential safety hazards.

R12-1-706

Parts of this section contain new requirements. The Radiation Safety Committee required for all medical institutions in R12-1-703, must meet the requirements contained in this rule. With these additions the standards, formerly listed in R12-1-311, are now equivalent to those contained in 10 CFR 35. This requirement is added to address potential safety hazards.

R12-1-707

This rule requires each medical licensee to have in place a functioning Quality Management Program that will provide high confidence that radiation is administered as directed by the ordering physician. The rule is very broad, allowing each licensee to establish the standard and procedures employed to insure the high level of confidence. This requirement is added to address potential safety hazards.

R12-1-708

This requirement is not new; it is moved from R12-1-311(E). However, the standards requiring reporting are less stringent than those currently listed in Article 3. As previously noted in the R12-1-702 discussion the proposed reporting requirement is based on a new definition for misadministrations, that is equivalent to the definition for misadministration in 10 CFR 35. This rule is made less stringent because of the low hazard associated with diagnostic procedures using radioactive material.

R12-1-710

This requirement, allowing visiting qualified physicians to supervise the use of radioactve material during periods when the authorized user is absent, is a new rule. However, it has been a condition of all medical licenses for a number of years. This authorization is added as a rule at this time to streamline licensing procedures.

R12-1-711

This rule is not new; it is moved from Article 3. However, its format is expanded to better define which radioactive sealed sources are acceptable for use by medical licensees. Licensees will now be able to possess calibration and reference sealed sources containing up to 15 mCi without listing them on their specific license.

R12-1-712

This new rule contains requirements that must be met by licensees that possess radioactive sealed sources. Included are inventory and authorized procedures. These requirements were previously addressed by license condition and are added at this time to streamline licensing.

R12-1-713

This is a new rule. Each medical licensee that administers radiopharmaceuticals is required to possess a dose calibrator and use it to measure the amount of radioactivity prior to administering a dose to a patient. This requirement is added to address potential safety hazards.

R12-1-714

Formerly R12-1-703, this rule addresses concerns associated with the use of sealed sources in the practice of brachytherapy. Of interest is the deletion of the specific leak testing requirements which duplicate requirements contained in R12-1-417.

R12-1-716

Formerly R12-1-704. Contained in this rule are requirements that must be met when practicing teletherapy.

R12-1-717

This is a new rule. Added are requirements for the use of remote after-loading brachytherapy devices. These devices have been

prevalent in the medical therapy arena for about 10 years. The requirements listed in this rule have been addressed in license condition. The rule is added at this time to streamline licensing practices.

R12-1-718

This is a new rule. Requirements for performing stereotactic radiosurgery are added at this time to streamline licensing practices. These requirements have been addressed by license condition for about one year.

R12-1-719

This is a new rule. The release of patients containing radiopharmaceuticals is currently addressed by license condition. The standard in this proposed rule will be consistent with 10 CFR 35, which allows release of radioactive patients with exposure levels higher than the current level accepted in license condition, provided certain administrative controls have been put in place. It is being added at this time to streamline licensing practices.

Exhibit A

This exhibit is added to accommodate moving Groups I through V from Article 3 to Article 7. Minimal changes include the addition of carbon-11 to Group II, strontium-89 and samarium-153 to Group IV, and the addition of "product license application" (PLA) where appropriate in the Groups to accommodate licensing of new radiopharmaceuticals developed under this FDA approved category.

R12-1-801

Only minor changes are made to improve understandability of this statement that defines the scope of the rules contained in this Article.

R12-1-802

Only minor changes are made to the definitions needed for the understanding of the rules contained in this Article.

R12-1-803

This rule contains the requirements for the use of enclosed beam x-ray systems. Only minor changes are made to improve understandability.

R12-1-804

This rule contains the requirements for the use of open beam x-ray systems. Deleted are all references to radioactive material. Added is an exemption to the requirement that an interlock system to be used, provided the listed criteria are met; a requirement for an interlock system if the x-ray tube can be removed from the system; and the requirement for the registrant to perform a radiation survey to demonstrate that levels in the vicinity of the open beam system does not exceed acceptable levels. Other changes are made to improve understandability.

R12-1-805

This rule contains administrative responsibilities that must be met by analytical x-ray operations. The wording is modified to improve understandability.

R12-1-806

Operation requirements for analytical x-ray systems. Major wording changes are made to clarify and strengthen the requirements listed in the rule. The requirement to maintain personnel monitoring records is deleted because the requirement already exists in Article 4.

R12-1-902

This rule is being repealed because the requirement to register a particle accelerator is addressed in Article 2 which is referenced in a new subsection of R12-1-903.

R12-1-903

General requirements for issuance of a registration for a particle accelerator are listed. A new reference to the requirements in Article 2 is added and the requirement to have a radiation safety committee is deleted because this section deals with requirements affecting all accelerators. Also, a number of changes are made to improve understandability.

R12-1-904

This rule contains special requirements for users of particle accelerators in the practice of medicine. Added is a requirement for a radiation safety committee to oversee the use of particle accelerators for human research. This is not a new requirement; it is simply moved from R12-1-903. Also, qualifications are added for physicians and physicists wishing to qualify to use and calibrate particle accelerators for medical purposes. These standards are not new; Currently they are used to qualify users of teletherapy systems in Article 7. Other new requirements added to this rule include the need to have in place a quality management program as is described in R12-1-707, and the need to have a particle accelerator facility inspected by the Agency prior to initiation of patient treatment. Applicants have been providing descriptions of quality management programs with their applications

for approximately 2 years, without complaint. Other changes are made to improve understandability.

R12-1-911

Radiation survey requirements for particle accelerator facilities are listed. Included, are new survey record retention requirements. Additional wording changes are made to improve understandability and clarity.

R12-1-1001

The purpose and scope of Article 10 are listed. Only minor wording changes are made.

R12-1-1002

Notice to worker posting requirements are listed. Minor rule reference changes are made with minimal wording changes.

R12-1-1003

The rule describes instructions that must be given to workers in areas of radiation. Minor word changes are made.

R12-1-1004

This rule stipulates individual notification requirements for those individuals exposed to radiation, entering or working in areas where radiation is used. Again, wording changes are made to improve understanding and clarity.

R12-1-1005

This rule allows a worker to have another individual represent the worker during an Agency inspection. Minor word changes are made for clarity.

R12-1-1006

This rule allows Agency inspectors to meet privately with licensee or registrant workers during an Agency inspection. Changes are made to improve clarity.

R12-1-1007

Under this rule a licensee or registrant worker may request an Agency inspection. Minor word changes are made.

R12-1-1008

If the Agency refuses to perform an inspection, requested according to R12-1-1007, the worker making the request for an inspection may request a review of the Agency's decision. Minor word changes are made.

R12-1-1209

A Notice of Violation will be provided to a licensee or a registrant following an inspection if an inspector finds violations during the inspection. The word "Division" is added to better define the proposed sanction and proposed civil penalty, if applicable. The Divisions are listed in R12-1-1215.

R12-1-1210

The rule describes action that can be taken by the Agency Director based on the response of the licensee or registrant receiving the violation. Rule references are changed to correspond with changes made in the rules being referenced in Article 12. Some minor word changes are made to improve clarity; for example the addition of "initial" before the word "order."

R12-1-1212

A licensee or registrant may request a hearing upon receiving an initial order. To correctly reference the Board, the first letter is capitalized in subsection (B).

R12-1-1213

Listed are the 5 severity levels of violations. In subsections (A), (B), (C), and (E) the format of the listed criteria is changed to promote easier reference, and a statement is added to subsections (A)(2) and (3) to better differentiate the kind of information that must be available to affect the violation outcome. In subsection (C), the reference to the radiation protection program required in R12-1-407 is now correctly made. A licensee or registrant with a violation governed by subsection (C)(3) can be treated as a severity level IV violation if the radiation protection program previously discussed, is in place.

R12-1-1214

The mitigating factors that may affect the outcome of violations are listed. Subsection (A) is deleted because of the difficulty in discovering the listed criteria. The Director will be given more latitude in determining when a civil penalty should be reduced or waived. The remaining subsections contain wording changes to improve understandability.

R12-1-1215

Listed are the various license and registration divisions. The division lists are reformatted to improve ease of reference. New

categories have been added to the division lists. Added are particle accelerator, research and development, laboratory, NORM (for definition see: NARM" in Article 1) commercial disposal site, and low level waste disposal site. These license categories are defined in R12-1-1306. Added in subsection (D) are classifications of individuals who may use sources of radiation, but are not required to have a license or registration. These classifications are necessary because such individuals may act in an unsafe manner that requires the Agency to administer sanctions against them.

R12-1-1216

The schedule of civil penalties is listed in this rule. Minor word changes are made to improve clarity and to include registrants in subsection (C). The word "registrant" was inadvertently deleted during the original rule making.

R12-1-1217

This rule contains augmented consequences for violations that have the prescribed characteristics. Many changes are made to this rule to improve the practicality of the multitiered penalty system described in it.

R12-1-1218

The timing and method of payment of civil penalties is described in this rule. The word "final" is added to insure the reader knows which order is of concern in the rule.

R12-1-1219

Unsafe conditions may result in a license or registration being revoked. If the conditions listed in this rule exist, the affected individual will have to show cause why the license or registration should not be revoked. "Show cause" is added to the rule title to better describe the rule content and the word "suspended" is added to the penalty statements to provide the Agency with greater flexibility.

R12-1-1220

The Director may take escalated enforcement actions such as suspending or modifying a license or registration, or impounding a radiation source, if a violation meets the criteria in this rule. The wording is rearranged for ease of reference and to improve clarity.

R12-1-1222

Before the Agency initiates formal proceedings, a licensee or registrant may request an enforcement conference. The outcome of the conference, a consent agreement, is added to the rule wording so that a licensee or registrant understands the value of an enforcement conference in eliminating the need for formal proceedings that can be quite expensive.

R12-1-1223

The legislature has required that the Agency add time frames during which the Agency will process license and registration applications, and requests for amendments to existing licenses and registrations. According to the new law this requirement is to be in place by December 31, 1998.

Table A

Contained in this table are the time frames that must be met by the Agency in processing applications and amendments as described in R12-1-1223. The list is based on the categories that are described in R12-1-1302 and R12-1-1306.

R12-1-1301

A single definition is listed. The definition for "combined" is modified to clarify how fee payments are handled when a combination license is issued by the Agency.

R12-1-1302

Definitions for each of the license and registration categories are listed. With this amendment a Category A license can be combined with any other type of license, and references to Article 3 subsections are corrected to agree with amendments that have occurred in Article 3. Added are license categories for:

a. Research and development, and laboratory categories that were inadvertently left out of the rule making when the categories were listed in 1993. There are many licensees of this type at this time.

b. A "NORM" commercial disposal site category is added to accommodate any future sites of this type. There are no licensees of this type at this time.

Other minor changes are made for clarification purposes.

R12-1-1303

An applicant is required to pay the current fee upon submitting an application for license or registration. Minor word changes are made.

R12-1-1304

Each year licensees and registrants are required to pay an annual fee. Minor word changes are made.

R12-1-1305

The required method of payment is described. Minor word changes are made.

R12-1-1306

The fee table for all regulated categories is listed in the table. New fees for the new categories set forth in R12-1-1302 are listed. Other minor word changes are made to improve clarity.

R12-1-1307

Special license fees for reciprocity recognition, radioactive waste transfers, and a low-level radioactive waste site licensing are listed. The later of the three is added as a new category to address safety concerns if an application is received for a waste site. Other minor word changes are made.

R12-1-1308

A fee for requested inspections is listed. The only change of consequence is the mileage charge from .25 cents per mile to the most current rate established by the Department of Revenue.

R12-1-1309

The rule adds the requirement for an applicant to respond to a deficiency letter in the specified time-frame. If not responded to in a timely manner, the application will be treated as if it has been abandoned. A new application and fee will be required.

6. **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

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

Disposal site licensing fees:

R12-1-1302

A $200,000 licensing fee is proposed for naturally occurring radioactive material (NORM) commercial disposal site.

R12-1-1307

A $3,000,000 licensing fee is proposed for a Low-level Radioactive Waste Disposal Site License. The fee is being justified using existing site licensing that occurred in California.

Other Changes and Additions:

R12-1-311

Nuclear pharmacies will be allowed to function under Board of Pharmacy rules in dispensing certain radiopharmaceuticals per physician prescription, that are not approved by the FDA for commercial distribution and use. This should decrease cost while at the same time expediting patient care.

R12-1-323

The decommissioning rule could potentially add substantial cost to users of very large quantities of radioactive material, in that funds must be set aside at the time of application to insure that all radiation hazards are safely disposed of at termination of the program. Decommissioning must occur according to the prescribed schedule.

R12-1-1223

The establishment of time-frames for Agency processing of applications for licenses and registrations is established in an effort to decrease cost to the potential radiation user by expediting the initiation of the business enterprise being licensed.

R12-1-1302 and R12-1-1306

Other new categories are added to insure radiation use is occurring in a safe manner. The cost is determined by factoring in the cost of application review, inspection, administrative costs, and degree of hazard associated with the specific radiation use. The following categories and associated annual costs are noted:

C16	Research and Development (R&D)	$750
C17	Laboratory (LAB)	$600
D19	NORM waste site	$200.000 (See above)

Note: R&D and LAB licensees are paying these fees at this time classified under the D18 category.

R12-1-1309

This could potentially cause an economic burden on an applicant if information is not provided to the Agency in the specified time-frame. The applicant would be required to submit a new application with a second application fee. There would also be delay in initiating any business activity involving the use of radiation.

Other changes and additions are made to improve clarity, consistency and understanding of the rules. In Article 5 requirements are moved from Article 3 to better organize and portray the requirements. In Article 2 facility requirements are now stated in rule. In the past a description was requested on the registration application form. Also, a listing of needed specific and general license application information, currently requested on the application form, will be located in Exhibit E at the end of Article 3. The majority of changes are made as a result of five-year-review reports, which are an on-going process to keep the rules current. The economic impact to all affected parties for these changes should be minimal.

8. **The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:**

Name:	Dan Kuhl
Address:	Arizona Radiation Regulatory Agency 4814 South 40th Street Phoenix, Arizona 85040
Telephone:	(602) 255-4845, Ext. 233
Fax:	(602) 437-0705

9. **The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rules or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:**

An oral proceeding is scheduled for October 14, 1998 at 10:00 A.M. at the address listed below. A person may submit written comments concerning the proposed rules by submitting them no later than 5 P.M., October 14, 1998, to the following person:

Name:	Aubrey Godwin, Director
Location:	Arizona Radiation Regulatory Agency
Address:	4814 South 40th Street Phoenix, Arizona 85040
Telephone:	(602) 255-4845
Fax:	(602) 437-0705

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

Not applicable.

11. **Incorporations by reference and their location in the rules:**

10 CFR Part 32	R12-1-306(E)(3)	Page 87
10 CFR Part 32.26	R12-1-311(C)	Page 123
10 CFR Part 32.29	R12-1-311(C)	Page 123
10 CFR Part 32.53-56, and 32.101	R12-1-311(E)	Page 131
10 CFR Part 32.57, 58, 32.102 and 70.39	R12-1-311(F)(2)	Page 137
10 CFR 32.61, 32.62 and 32.101	R12-1-311(I)(2)	Page 135
10 CFR Part 30.35 and 40.36	R12-1-323(C)	Page 163
10 CFR Part 30.36(g)(1)	R12-1-323(E)(1)	Page 164
10 CFR Part 30.36(i)	R12-1-323(H)(5)	Page 165
10 CFR Part 30.36(j)	R12-1-323(E)(6)	Page 165
10 CFR Part 32.72	R12-1-703(C)(2)(a)	Page 224
10CFR Part 35	R12-1-704(C)	Page 234
10 CFR Part 35(J)	Exhibit A	Page 256
10 CFR Part 35.25	Exhibit A	Page 256
10 CFR Part 61	R12-1-1302(D)(1)	Page 316

12. **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 2. RADIATION MACHINE REGISTRATION OR LICENSING, INSTALLATION AND SERVICE REGISTRATION, AND MAMMOGRAPHIC FACILITY CERTIFICATION ~~REGISTRATION AND~~

~~CERTIFICATION OF IONIZING RADIATION MACHINE FACILITIES, REGISTRATION OF SERVICES, AND LICENSING OF NONIONIZING RADIATION MACHINE FACILITIES~~

R12-1-202. Application Requirements for Registration or Certification of Ionizing and Nonionizing Radiation Machines ~~Machine Facilities~~: Notification

ARTICLE 3. ~~LICENSING OF~~ RADIOACTIVE MATERIAL LICENSING

~~R12-1-301. Definitions~~
~~R12-1-302.~~ R12-1-301. Ownership, Control, or Transfer of Radioactive Material
~~R12-1-303.~~ R12-1-302. Source Material; ~~;~~ Exemptions
~~R12-1-304.~~ R12-1-303. Radioactive Material Other than Source Material; ~~;~~ Exemptions
~~R12-1-305.~~ R12-1-304. ~~Types of~~ Licenses Types
~~R12-1-306.~~ R12-1-305. General License ~~Licenses~~ -- Source Material
~~R12-1-307.~~ R12-1-306. General License ~~Licenses~~ -- Radioactive Material Other than Source Material
~~R12-1-308.~~ R12-1-307. Repealed
~~R12-1-309.~~ R121-1-308. Filing Application for Specific Licenses
~~R12-1-310.~~ R12-1-309. General Requirements for the Issuance of Specific Licenses
~~R12-1-311.~~ R12-1-310. Special Requirements for Issuance of ~~Certain~~ Specific Broad Scope Licenses ~~for Radioactive Material~~
~~R12-1-312.~~ R12-1-311. Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices Which Contain Radioactive Material
~~R12-1-313.~~ R12-1-312. Issuance of Specific Licenses
~~R12-1-314.~~ R12-1-313. Specific Terms and Conditions of Licenses
~~R12-1-315.~~ R12-1-314. Expiration of License ~~Licenses~~
~~R12-1-316.~~ R12-1-315. Renewal of License
~~R12-1-317.~~ R12-1-316. Amendment of Licenses at Request of Licensee
~~R12-1-318.~~ R12-1-317. ARRA Action on Applications to Renew or Amend
~~R12-1-319.~~ R12-1-318. Transfer of Radioactive Material
~~R12-1-320.~~ R12-1-319. Modification, Revocation, and Termination of Licenses
~~R12-1-321.~~ R12-1-320. Reciprocal Recognition of Licenses ~~For Byproduct, Source and Special Nuclear Material (In Quantities Not Sufficient to Form a Critical Mass)~~
~~R12-1-322.~~ R12-1-321. Preparation of Radioactive Material For Transport
~~R12-1-323.~~ R12-1-322. The Need For an Emergency Plan For Response to a Release of Radioactive Material.
R12-1-323. Financial Assurance and Record Keeping for Decommissioning
Exhibit A ~~Schedule A~~ Exempt Concentrations
Exhibit B ~~Schedule B~~ Exempt Quantities
~~Schedule C Groups of Medical Uses of Radioactive Material~~
Exhibit C ~~Schedule D~~ Limits for Broad Licenses
Exhibit D ~~Schedule E~~ Radioactive Material Quantities Requiring Consideration for an Emergency Plan
Exhibit E Application Information

ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

R12-1-407. Radiation Protection Programs
R12-1-408. Occupational Dose Limits for Adults
R12-1-409. ~~Compliance with Requirements for~~ Summation of External and Internal Doses
R12-1-411. Determination of Internal Exposure
R12-1-415. Dose to an Embryo or / Fetus
R12-1-418. Surveys and Monitoring
R12-1-419. Conditions Requiring Individual Monitoring of External and Internal Occupational Dose
R12-1-442. Agency Inspection of Shipments of Waste
R12-1-449. Survey Instruments
R12-1-450. Sealed Source Requirements

ARTICLE 5. RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

R12-1-511. License and Registration Application Requirements For Industrial Radiography
R12-1-541. Enclosed Radiography Using X-ray Machines

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

R12-1-606. Fluoroscopic Systems ~~installations~~

R12-1-612. X-ray and Electron Therapy Systems with Energies of 1 MeV and Above

ARTICLE 7. USE OF RADIONUCLIDES IN THE HEALING ARTS ~~USE OF SEALED RADIOACTIVE SOURCES IN THE HEALING ARTS~~

R12-1-701. Scope
R12-1-702. Definitions
~~R12-1-703~~ ~~Interstial, Intracavitary, and superficial applications~~
R12-1-703 License for Medical Use of Radioactive Material
~~R12-1-704~~ ~~Teletherapy~~
R12-1-704. Supervision
R12-1-705. Radiation Safety Officer
R12-1-706. Radiation Safety Committee
R12-1-707. Quality Management Program
R12-1-708. Misadministration Reports and Records
R12-1-709. Reserved
R12-1-710. Visiting Authorized User
R12-1-711. Calibration and Reference Sources
R12-1-712. Sealed Sources
R12-1-713. Dose Calibrators
R12-1-714. Brachytherapy
R12-1-715. Reserved
R12-1-716. Teletherapy
R12-1-717. High Dose Remote After-loading Brachytherapy Devices
R12-1-718. Gamma Stereotactic Radiosurgery
R12-1-719. Release of Individuals Containing Radiopharmaceuticals or Radioactive Sealed Sources from Restricted Areas
Exhibit A Groups of Medical Uses of Radioactive Material

ARTICLE 8. RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY OPERATIONS

R12-1-801. Scope
R12-1-802. Definitions
R12-1-803. Enclosed Beam X-ray Systems ~~beam x-ray systems~~
R12-1-804. Open Beam X-ray Systems ~~beam x-ray systems~~
R12-1-805. Administrative Responsibilities ~~responsibilities~~
R12-1-806. Operating Requirements ~~procedures~~

ARTICLE 9. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

R12-1-902. Reserved ~~Registration Requirements~~
R12-1-903. General Requirements for the Issuance of a Registration for Particle Accelerators
R12-1-904. Special Registration Requirements for Medical ~~Human~~ Use of Particle Accelerators
R12-1-911. Radiation Survey Requirements ~~monitoring requirements~~

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

R12-1-1001. Purpose and Scope ~~scope~~
R12-1-1002. Posting ~~of~~ Notices for Workers ~~notices to workers~~
R12-1-1003. Instructions to Workers ~~workers~~
R12-1-1004. Notifications and Reports to Individuals
R12-1-1005. Licensee, Registrant, and Worker Representation During Agency Inspection ~~Presence of representatives of licensees or registrants and workers during inspection~~
R12-1-1006. Consultation with Workers During Inspections ~~workers during inspection~~
R12-1-1007. Inspection Requests by Workers ~~workers for inspection~~
R12-1-1008. Inspection ~~Inspections~~ Not Warranted; Review ~~warranted; review~~

ARTICLE 12. ADMINISTRATIVE PROVISIONS

R12-1-1209. Notice of Violation
R12-1-1210. Response to Notice of Violation
R12-1-1211. Initial Orders
R12-1-1212. Request for Hearing in Response to an Initial Order
R12-1-1213. Severity Levels of Violations
R12-1-1214. Mitigating Factors
R12-1-1215. License and Registration Divisions
R12-1-1216. ~~Base Schedule of~~ Civil Penalties
R12-1-1217. Augmentation of Civil Penalties
R12-1-1218. Payment of Civil Penalties
R12-1-1219. Additional Sanctions - Show Cause
R12-1-1220. Escalated Enforcement
R12-1-1222. Enforcement Conferences
R12-1-1223. Registration and Licensing Time-Frames
Table A Registration and Licensing Time-Frames

ARTICLE 13. LICENSE AND REGISTRATION FEES

R12-1-1301. Definition
R12-1-1302. Types of Licenses and Registrations
R12-1-1303. Fee for Initial License and Initial Registration
R12-1-1304. Annual Fees for Licenses and Registrations
R12-1-1305. Method of Payment
R12-1-1306. Table ~~Schedule~~ of Fees
R12-1-1307. Special License Fees
R12-1-1308. Fee for Requested Inspections
R12-1-1309. Abandonment of License or Registration Application

ARTICLE 1. GENERAL PROVISIONS

R12-1-102. Definitions

"A_1" 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 "AREA" 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.
"Background radiation" means radiation from cosmic sources; not technologically enriched naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material less than ten times the quantities listed in Article 4, Appendix B, Table II; and global fallout as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include sources of radiation from radioactive materials regulated by the Agency..
"Becquerel" No change.
"Bioassay" No change.
"Brachytherapy" No change.
"By-product material" No change.
"Calendar quarter" No change.
"Calibration" 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" No change.
"Deep-dose equivalent" No change.
"Depleted uranium" No change.
"Dose" No change.
"Dose equivalent (H_T)" No change.
"Dose limits" No change.
"Dosimeter" No change.
"Effective dose equivalent (H_E)" No change.
"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" For purposes of these rules, is equivalent in meaning to the word "Schedule" as found in previously issued rules, current license conditions and regulation guide.
"Explosive material" No change.
"Exposure" No change.
"Exposure rate" No change.
"External dose" No change.
"Extremity" No change.
"Eye dose equivalent" 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 devices" 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.
"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 safety officer" No change.
"Radioactive marker" No change.
"Radioactive material" No change.
"Radioactivity" No change.
"Radiographer" No change.
"Radiographer's assistant" No change.
"Radiographic exposure device" 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.
"Shallow dose equivalent" No change.
"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" 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.
"Teletherapy" No change.
"Temporary job site" means any location where sources of radiation are used other than the specified locations listed on a license document. Storage of sources of radiation at a temporary jobsite shall not exceed 6 months unless the Agency has granted an amendment authorizing storage at that jobsite.
"Test" No change.
"These rules" No change.
"Total Effective Dose Equivalent" (TEDE) ~~"TEDE"~~ means total effective dose equivalent, the sum of the deep-dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.
"Total Organ Dose Equivalent" (TODE) ~~"TODE"~~ means total organ dose equivalent, the sum of the deep-dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in R12-1-419(D(1)(d) ~~R12-1-419(C)(1)(d) of these rules~~.
"Unrefined and unprocessed ore" No change.
"Unrestricted area" No change.
"U.S. Department of Energy" No change.
"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" means the degree of use of an x-ray or gamma-ray source per unit time.
"Year" No change.

ARTICLE 2. RADIATION MACHINE REGISTRATION OR LICENSING, INSTALLATION AND SERVICE

REGISTRATION, AND MAMMOGRAPHIC FACILITY CERTIFICATION ~~REGISTRATION AND CERTIFICATION OF IONIZING RADIATION FACILITIES, REGISTRATION OF SERVICES, AND LICENSING OF NONIONIZING RADIATION MACHINE FACILITIES~~

R12-1-202 Application Requirements for Registration or Certification of Ionizing and Nonionizing Radiation Machines ~~Machine Facilities~~: Notification

A. A person shall not ~~No person shall~~ receive, possess, use, or transfer a radiation machine except as authorized in ~~pursuant to~~ this Article.

B. The owner or persons possessing ~~having possession of~~ any nonexempt radiation machine shall apply for registration of the machine with the Agency ~~such machine with the Agency within 90 days following the effective date of this Article. Subsequent applications for registration shall be submitted~~ within 30 days after its acquisition. ~~acquisition of such machine~~. The person applying for registration of a radiation producing machine shall use the appropriate form ~~application shall be on the forms as prescribed~~ in Appendix A of ~~to~~ this Article.

C. No change

D. In addition to the application forms, the applicant shall ~~remit the appropriate registration fee, pursuant to R12-1-1301, et seq.~~ remit the appropriate registration or licensing fee listed in R12-1-1306.

E. With the application forms for registration of radiation machines, except dental and mammography facilities, the applicant shall provide a scale drawing of the room in which a stationary x-ray system is located. The drawing shall denote the type of materials and the thickness (or lead equivalence) of each barrier of the room (walls, ceilings, floors, doors, windows). The drawing shall also denote the type and frequency of occupancy in adjacent areas including those above and below the x-ray room of concern (e.g., hallways, offices, parking lots, and lavatories ~~toilets~~). Estimates of workload shall also be provided with the drawing.

Appendix A. Registration and Licensing Forms

ARRA-4X
January 1996

ARIZONA RADIATION REGULATORY AGENCY

ATTACHMENT TO ARRA-4 FOR THE REGISTRATION OF MEDICAL/DENTAL OR VETERINARIAN DIAGNOSTIC X-RAY SOURCE OF RADIATION

FACILITY NAME REGISTRATION # (if available)

DATE

MACHINE INFORMATION
Diagnostic X-Ray

Fluoroscopic w/image Intensifier ____		Bone Densitometer ____
Fluoroscopic wo/image Intensifier ____	Tomographic ____	Cephalometric ____
Combination w/image Intensifier ____	Panographic ____	Intra Oral ____
Combination wo/image Intensifier ____	Radiographic ____	Other Dental ____
Computerized Axial Tomographic ____	Photoflurographic ____	Other Medical ____

This Machine is Mobile ____ Stationary ____ Portable ____ Transportable ___

EQUIPMENT

	MANUFACTURER/MODEL NO.	SERIAL NO.	MAX. KVP	MAX. MA.	PHYSICAL LOCATION
Control Panel					
Rad. Tube #1					
Tube #2					
Tube #3					
Tube #4					
Flouro. Tube #1					
Flouro. Tube #2					

ADDITIONAL ~~SHIELDING~~ INFORMATION
(Use additional pages, if necessary)

INSTRUCTIONS

1. Excluding dental and mammography units, please provide a scale drawing of the facility, including construction material, and your calculations of the shielding needed to assure compliance with A.A.C. R12-1-408 and R12-1-416. The calculations shall meet the standards specified in R12-1-603(C)(2). For your assistance Regulatory Guide 10.5 is available to guide you in supplying these items.
2. Please provide the specific instructions including any restrictions provided to the equipment operators. Regulatory Guide 10.5 will assist you in completing this portion of the application.
3. Please note that R12-1-604(B) requires each registrant to maintain for each x-ray machine:
   a. Maximum rating of technique factors;
   b. Aluminum equivalent filtration of the useful beam, including routine variations;
   c. Records of surveys, calibrations, maintenance, modifications, and the names of persons who performed the service;
   d. A copy of all correspondence with the Agency relating to the x-ray machine.
4. Please note that R12-1-206(C) requires transferor provide to each registrant, the supplies and x-ray machine necessary to comply with the requirements of the rules relating to the usage of the equipment transferred.

RETAIN A COPY FOR YOUR RECORDS

Appendix A. Registration and Licensing Forms *Continued*

ARRA-4XT
January 1996

ARIZONA RADIATION REGULATORY AGENCY

ATTACHMENT TO ARRA-4 FOR MEDICAL THERAPY X-RAY SOURCE OF RADIATION <1 Mev

FACILITY NAME REGISTRATION # (if available)

DATE

MACHINE INFORMATION
Medical Therapeutic X-Ray

< 150kVp ____ 151 - 999kVp ____

EQUIPMENT

	MANUFACTURER / MODEL NO.	SERIAL NO.	MAX. KVP	MAX. MA.	PHYSICAL LOCATION
Control Panel					
Therapy Tube #1					
Therapy Tube #2					
Therapy Tube #3					

ADDITIONAL ~~SHIELDING AND CALIBRATION~~ INFORMATION
(Use additional pages, if necessary)

INSTRUCTIONS

1. Please provide a scale drawing of the facility, including construction material, and your calculations of the shielding needed to assure compliance with A.A.C. R12-1-408 and R12-1-416. The calculations shall meet the standards specified in R12-1-603 (C)(2). For your assistance, Regulatory Guide 11.5 is available to guide you in supplying these items. You may wish to submit the consultant design report for the facility instead.

2. Please provide the specific instructions including any restrictions provided to the equipment operators. Regulatory Guide 11.5 will assist you in completing this portion of the application.

3. Please note that R12-1-611(C), (D), and (E) require each registrant to maintain for each x-ray machine:
   a. A record of the radiation protection survey of the facility;
   b. A record of the calibrations of the Unit;
   c. For Units > 150kVp, a record of the monthly spot check must be maintained;

4. Please provide a copy of 3(a) and 3(b) above when they are initially completed for this installation.

RETAIN A COPY FOR YOUR RECORDS

Appendix A. Registration and Licensing Forms *Continued*

ARRA-4PAT
January 1996

ARIZONA RADIATION REGULATORY AGENCY

ATTACHMENT TO ARRA-4 FOR MEDICAL THERAPY PARTICLE ACCELERATOR SOURCE OF RADIATION ≥ 1 Mev

FACILITY NAME REGISTRATION # (if available)

DATE

CLASSIFICATION OF PROFESSIONAL IN CHARGE OF MACHINE

General Practitioner ____ Health Physicist ____ Registered X-Ray Technologist ____

Radiologist ____ ~~Non-Registered X-Ray Tech~~ ____ Osteopath ____ Other ____

PARTICLE ACCELERATOR INFORMATION

Betatron____ Cyclotron ____ Van de Graaff ~~Graff~~ ____ Other Medical therapy ____

EQUIPMENT

	MANUFACTURER / MODEL NO.	SERIAL NO.	MAX. Mev	MAX. MA.	PHYSICAL LOCATION
Photons					
Electrons					
Neutrons					

ADDITIONAL ~~SHIELDING~~ INFORMATION
(Use additional pages, if necessary)
INSTRUCTIONS

1. Please provide a scale drawing of the facility, including construction material, and your calculations of the shielding needed to assure compliance with A.A.C. R12-1-408 and R12-1-416. The calculations shall meet the requirements specified in R12-1-603 (C)(2). For your assistance Regulatory Guide 11.5 is available to guide you in supplying these items. You may wish to submit the consultant design report for the facility instead.
2. Please provide the specific instructions including any restrictions provided to the equipment operators. Regulatory Guide 11.5 will assist you in completing this portion of the application.
3. Please note that R12-1-611 (B) and (C) requires each registrant to maintain for each particle accelerator:
   a. Prior to initiating treatment, a radiation protection survey of the facility is made and the record retained. A copy must be provided to the Agency;
   b. A record of the calibrations of the Unit;
   c. A record of the monthly spot checks must be maintained.
4. Please provide the names of the Radiation Safety Officer and the physician(s) with their qualifications to be listed on the registration as authorized users of the particle accelerator.

RETAIN A COPY FOR YOUR RECORDS

Appendix A. Registration and Licensing Forms *Continued*

ARRA-4IG
January 1996

ARIZONA RADIATION REGULATORY AGENCY

ATTACHMENT TO ARRA-4 FOR INDUSTRIAL GAUGE OR ANALYTICAL X-RAY SOURCE OF RADIATION
(does **NOT** include Industrial Radiography)

FACILITY NAME REGISTRATION # (if available)

DATE

MACHINE INFORMATION
X-Ray Unit

Analytical ____ Industrial Gauge ____ This Machine is Mobile ____ or Fixed ____ Other ____

EQUIPMENT

	MANUFACTURER / MODEL NO.	SERIAL NO.	MAX. KVP	MAX. MA.	PHYSICAL LOCATION
Control Panel					
Rad. Tube #1					
Rad. Tube #2					
Rad. Tube #3					

ADDITIONAL ~~SHIELDING~~ INFORMATION
(Use additional pages, if necessary)
INSTRUCTIONS

1. Please provide a scale drawing of the facility, including construction material, and your calculations of the shielding needed to assure compliance with A.C.C. R12-1-408 and R12-1-416. The calculations should include the information required to assess the compliance with these regulations.

2. Please provide the specific instructions or procedures including any restrictions, such as beam stop usage, provided to the equipment operators.

3. Please note that R12-1-206 (C) requires the transferor provide each registrant with the supplies and x-ray equipment as necessary to comply with the requirements of the rules relating to the use of the equipment transferred.

RETAIN A COPY FOR YOUR RECORDS

Appendix A. Registration and Licensing Forms *Continued*

ARRA-4IR
January 1996

ARIZONA RADIATION REGULATORY AGENCY

ATTACHMENT TO ARRA-4 FOR AN INDUSTRIAL RADIOGRAPHY X-RAY SOURCE OF RADIATION (<1,000 kVp)

FACILITY NAME REGISTRATION # (if available)

DATE

TYPE PROGRAM

Cabinet ____ Fixed ____ Mobile ____

MACHINE INFORMATION

Floroscopic w/image Intensifier ____ Radiographic ____ Other ____

EQUIPMENT

	MANUFACTURER / MODEL NO.	SERIAL NO.	MAX. KVP	MAX. MA.	PHYSICAL LOCATION
Control Panel					
Rad. Tube #1					
Rad. Tube #2					
Rad. Tube #3					

ADDITIONAL ~~SHIELDING~~ INFORMATION

(Use additional pages, if necessary)

INSTRUCTIONS

1. Please provide a scale drawing of the facility, including construction material, and your calculations of the shielding needed to assure compliance with A.A.C. R12-1-408 and R12-1-416. If for temporary locations, please provide a copy of your operating and emergency procedures which contain the information required by R12-1-522.
2. Please provide the specific instructions including any restrictions provided to the radiographers.
3. Please note that R12-1-534 requires each registrant to maintain for each industrial x-ray radiography site:
   a. A copy of the registration form;
   b. Operating and emergency procedures;
   c. Agency rules;
   d. Survey records as required by R12-1-533 along with dosimetry records; and
   e. The latest instrument calibration which indicates the applicability to the x-ray energies in use at the site.

RETAIN A COPY FOR YOUR RECORDS

Appendix A. Registration and Licensing Forms *Continued*

ARRA-4PAR
January 1996

ARIZONA RADIATION REGULATORY AGENCY

ATTACHMENT TO ARRA-4 FOR AN INDUSTRIAL RADIOGRAPHY X-RAY SOURCE OF RADIATION (≥1 Mev)

FACILITY NAME REGISTRATION # (if available)

DATE

CLASSIFICATION OF PERSONNEL IN CHARGE OF MACHINE

Health Physicist ____ Radiographer ____ Other ____

MACHINE INFORMATION

Betatron____ Cyclotron ____ Van de Graaff ~~Graff~~ ____ Linear ____ Other ____

This Machine is Mobile ____ or Fixed ____

EQUIPMENT

MANUFACTURER / MODEL NO.	SERIAL NO.	MAX. MVP	MAX. MA.	PHYSICAL LOCATION

ADDITIONAL REQUESTED ~~SHIELDING~~ INFORMATION

(Use additional pages, if necessary)
INSTRUCTIONS

1. Please provide a drawing of the facility, including construction material, and your calculations of the shielding needed to assure compliance with A.A.C. R12-1-408 and R12-1-416. If for temporary locations, please provide a copy of your operating and emergency procedures which contain the information required by R12-1-522.
2. Please provide the specific instructions including any restrictions provided to the radiographers.
3. Please note that R12-1-534 requires each registrant to maintain for each industrial x-ray radiography site:
   a. A copy of the registration form;
   b. Operating and emergency procedures;
   c. Agency rules;
   d. Survey records as required by R12-1-533 along with dosimetry records; and
   e. The latest instrument calibration which indicates the applicability to the x-ray energies in use at the site.
4. Please provide the Radiation Safety Officer's name and his/her qualifications.

RETAIN A COPY FOR YOUR RECORDS

Appendix A. Registration and Licensing Forms *Continued*

ARRA-4PA
January 1996

ARIZONA RADIATION REGULATORY AGENCY

ATTACHMENT TO ARRA-4 FOR A PARTICLE ACCELERATOR SOURCE OF RADIATION (>1 Mev)

FACILITY NAME REGISTRATION # (if available)

DATE

CLASSIFICATION OF PERSONNEL IN CHARGE OF MACHINE

Health Physicist ____ Operator ____ Other ____

MACHINE INFORMATION

Betatron____ Cyclotron ____ Van de Graaff ~~Graff~~ ____ Linear ____ Other ____

This Machine is Mobile ____ or Fixed ____

EQUIPMENT

MANUFACTURER / MODEL NO.	SERIAL NO.	MAX. MVP	MAX. MA.	PHYSICAL LOCATION

ADDITIONAL ~~SHIELDING~~ INFORMATION
(Use additional pages, if necessary)
INSTRUCTIONS

1. Please provide a drawing of the facility, including construction material, and your calculations of the shielding needed to assure compliance with A.A.C. R12-1-408 and R12-1-416. If for temporary locations, please provide a copy of your operating and emergency procedures which contain the information required by R12-1-522.
2. Please provide the specific instructions including any restrictions provided to operators.
3. Please note that R12-1-1002 requires each registrant to maintain for each Particle Accelerator site:
   a. A copy of the registration form;
   b. Operating and emergency procedures;
   c. Agency rules.

ARTICLE 3. ~~LICENSING OF~~ RADIOACTIVE MATERIAL LICENSING

~~**R12-1-301. Definitions**~~

~~A. "Decommissioning" means to remove a radioactive material use facility safely from service and to reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the radioactive material use license.~~

~~B. "Emergency Plan" means a procedure that will be followed when an accident occurs involving licensed radioactive material for which responses by offsite response organizations that might be needed such as police, fire, and medical organizations.~~

~~R12-1-302~~ 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 ~~of these Regulations~~. Licensees engaged in industrial radiographic operations are subject to the requirements of 12 A.A.C. 1, Article 5; ~~and~~ licensees using ~~sealed sources~~ radioactive material in the healing arts are subject to the requirements of ~~Article 6~~ 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; ~~of these Regulations~~.

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

C. ~~Authority to transfer possession or control by the~~ A manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or by-product material whose subsequent possession, use, transfer, or ~~and~~ disposal by all other persons is exempt ~~are exempted~~ from regulatory requirements may only obtain authority to transfer possession or control of the material ~~be obtained only~~ from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. ~~Federal regulations adopted by reference in this Article are on file at the Office of the Secretary of State.~~

~~R12-1-303~~ R12-1-302. Source Material; ~~,~~ Exemptions

A. Any person is exempt from this Article to the extent the ~~that such~~ person receives, possesses, uses, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20th of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.

B. Any person is exempt from this Article to the extent the ~~that such~~ person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material, provided that, ~~except as authorized in a specific license,~~ the ~~such~~ person does ~~shall~~ not refine or process the ~~such~~ ore except as authorized in a specific license.

C. Any person is exempt from this Article if the ~~to the extent that such~~ person receives, possesses, uses, or transfers:

1. Any quantities of thorium contained in:
   a. Incandescent ~~incandescent~~ gas mantles;
   b. Vacuum ~~vacuum~~ tubes;
   c. Welding ~~welding~~ rods;
   d. Electric ~~electric~~ lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium;
   e. Germicidal ~~germicidal~~ lamps, sunlamps, and lamps for outdoor or industrial lighting, provided that each lamp does not contain more than 2 grams of thorium; ~~, or~~
   f. Rare ~~rare~~ earth metals, ~~and~~ compounds, mixtures, or ~~and~~ products containing not more than 0.25 percent by weight thorium, uranium, or any combination of thorium and uranium or ~~these~~;
   g. Individual ~~individual~~ neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;
2. Source material contained in the following products:
   a. Glazed ~~glazed~~ ceramic tableware, provided that the glaze contains not more than 20 percent ~~by weight~~ source material by weight,
   b. Glassware ~~glassware~~, glass enamel and glass enamel frit containing not more than 10 percent ~~by weight~~ source material by weight, but not including commercially manufactured glass brick, pane glass, ceramic tile or other glass, glass enamel or ceramic used in construction; or
   c. Piezoelectric ~~piezoelectric~~ ceramic containing not more than 2 percent ~~by weight~~ source material by weight;
3. Photographic film, negatives, and prints containing uranium or thorium;
4. Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed 4 percent by weight and that the exemption contained in this subsection does not ~~item shall not be deemed to~~ authorize the chemical, physical, or metallurgical treatment or processing of the finished ~~any such~~ product or part;
5. Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of counterweights ~~such counterweights~~, provided that:
   a. The ~~the~~ counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee according to ~~pursuant to~~ 10 CFR ~~Part~~ 40;
   b. Each ~~each~~ counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM";
   c. Each ~~each~~ counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED"; ~~, and~~
   d. The ~~the~~ exemption contained in this item does not ~~shall not be deemed to~~ authorize the chemical, physical, or metallurgical treatment or processing of any ~~such~~ counterweights other than repair or restoration of any plating or other covering; and
   e. The requirements specified in ~~R12-1-302.C.5 b. And c.~~ subsections (C)(5)(b) and (c) do not apply to ~~need not be met by~~ counterweights manufactured prior to December 31, 1969; provided, that these counterweights ~~such counterweights~~ are impressed with the legend, "CAUTION -- RADIO-

ACTIVE MATERIAL -- URANIUM"; ~~as previously required by the Regulations~~.

6. Natural or depleted uranium metal used as shielding and constituting part of any shipping container; provided that:
   a. The ~~the~~ shipping container is conspicuously and legibly impressed with the legend "CAUTION -- RADIOACTIVE SHIELDING -- URANIUM", and
   b. The ~~the~~ uranium metal is encased in mild steel or equally fire resistant metal with ~~of~~ minimum wall thickness of 1/8 ~~one-eighth~~ inch (3.2 mm).
7. Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent ~~by weight~~ of thorium by weight, and that the exemption contained in this item does not ~~shall not be deemed to~~ authorize either
   a. The ~~the~~ shaping, grinding, or polishing of a thoriated ~~such~~ lens or manufacturing processes other than the assembly of a thoriated lens ~~such lens~~ into optical systems and devices without any alteration of the lens, or
   b. The ~~the~~ receipt, possession, use, or transfer of thorium contained in contact lenses, ~~or in~~ spectacles, or ~~in~~ the eyepieces of ~~in~~ binoculars or other optical instruments;
8. Uranium contained in detector heads of ~~for use in~~ fire detection units, provided that each detector head contains not more than 5 nanocuries (185 Bq) of uranium; or
9. Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:
   a. The ~~the~~ thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide), and
   b. The thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

D. The ~~the~~ exemptions in subsection (C) ~~R12-1-302.C.~~ do not authorize the manufacture of any of the products described.

~~R12-1-304~~ R12-1-303. Radioactive Material Other than Source Material; ~~,~~ Exemptions

A. Exempt concentrations
1. Except as provided in ~~R12-1-303.A.2~~ subsection (A)(2)., A ~~any~~ person is exempt from this Article if the ~~to the extent that such~~ person receives, possesses, uses, transfers or acquires products or materials containing radioactive material in concentrations not in excess of those listed in Exhibit ~~Schedule~~ A.
2. A ~~No~~ person ~~may~~ shall not introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under ~~R12-1-303.A.1.~~ subsection (A)(1) or equivalent Regulations of the U.S. Nuclear Regulatory Commission ~~NRC~~ or any Agreement State or Licensing State, except in accordance with a specific license issued under R12-1-311(A) ~~pursuant to R12-1-311.A.~~ or a ~~the~~ general license prescribed ~~provided~~ in R12-1-320.

B. Exempt items
1. ~~Certain items containing radioactive material.~~ Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, a ~~any~~ person is exempt from this Chapter to the extent that he or she receives, possesses, uses, transfers or acquires the following products:
   a. Timepieces, ~~or~~ hands, or dials containing not more than the following specified quantities of material and not exceeding the following specified levels of radiation:
      i. 925 MBq (25 millicuries) ~~(925 M Bq)~~ of tritium per timepiece,
      ii. 185 MBq (5 millicuries) ~~(185 M Bq)~~ of tritium per hand,
      iii. 555 MBq (15 millicuries) ~~(555 M Bq)~~ of tritium per dial (bezels ~~when used~~ are ~~shall be~~ considered ~~as~~ part of the dial),
      iv. 3.7 MBq (100 microcuries) ~~(3.7 M Bq)~~ of promethium-147 per watch or 7.4 MBq (200 microcuries) ~~(7.4 M Bq)~~ of promethium-147 per any other timepiece,
      v. 740 kBq (20 microcuries) ~~(740 k Bq)~~ of promethium-147 per watch hand or 1.48 MBq (40 microcuries) ~~(1.48 M Bq)~~ of promethium-147 per other timepiece hand,
      vi. 2.22.MBq (60 microcuries) ~~(2.22 M Bq)~~ of promethium-147 per watch dial or 4.44 MBq (120 microcuries) ~~(4.44 M Bq)~~ of promethium-147 per other timepiece dial (bezels ~~when used~~ are ~~shall be~~ considered ~~as~~ part of the dial),
      vii. The levels of radiation from hands and dials containing promethium-147 shall ~~will~~ not exceed, when measured through 50 milligrams per square centimeter of absorber:
         (1) For wrist watches, 1.0 µGy (0.1 millirad) per hour ~~(1.0 u Gy/hr)~~ at 10 centimeters from any surface of the watch,
         (2) For pocket watches, 1.0 µGy (0.1 millirad) per hour ~~(1.0 u Gy/hr)~~ at 1 centimeter from any surface,
         (3) For any other timepiece, 2.0 µGy (0.2 millirad) per hour ~~(2.0 u Gy/hr)~~ at 10 centimeters from any surface,
      viii. 37 kBq (1 ~~One~~ microcurie) ~~(37 k Bq)~~ of radium-226 in time pieces manufactured prior to October 1, 1978;
   b. Lock illuminators containing not more than 555 MBq (15 millicuries) ~~(555 M Bq)~~ of tritium or not more than 74 MBq (2 millicuries) ~~(74 M Bq)~~ of promethium-147 installed in automobile locks. The levels of radiation from each lock illuminator containing promethium-147 shall ~~will~~ not exceed 10 µGy (1 millirad) per hour ~~(10 u Gy/hr)~~ at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber;
   c. Balances of precision containing not more than 37 Mbq (1 millicurie) ~~(37 M Bq)~~ of tritium per balance or not more than 18.5 MBq (0.5 millicurie) ~~(18.5 M Bq)~~ of tritium per balance part;
   d. Automobile shift quadrants containing not more than 925 MBq (25 millicuries) ~~(925 MBq)~~ of tritium;
   e. Marine compasses containing not more than 27.75 GBq (750 millicuries) ~~(27.75 G Bq)~~ of tritium gas and other marine navigational instruments containing not more than 9.25 GBq (250 millicuries) ~~(9.25 G Bq)~~ of tritium gas;
   f. Thermostat dials and pointers containing not more than 925 MBq (25 millicuries) ~~(925 M Bq)~~ of tritium per thermostat;

g. Electron tubes: Provided that each tube does not contain more than one of the following specified quantities of radioactive material:
   i. 5.55 GBq (150 millicuries) ~~(5.55 G Bq)~~ of tritium per microwave receiver protector tube or 370 MBq (10 millicuries) ~~(370 M Bq)~~ of tritium per any other electron tube;
   ii. 37 kBq (1 microcurie) ~~(37 k Bq)~~ of cobalt 60;
   iii. 185 kBq (5 microcuries) ~~(185 k Bq)~~ of nickel 63;
   iv. 1.11 MBq (30 microcuries) ~~(1.11 M Bq)~~ of krypton 85;
   v. 185 kBq (5 microcuries) ~~(185 k Bq)~~ of cesium 137;
   vi. 1.11 MBq (30 microcuries) ~~(1.11 M Bq)~~ of promethium-147;

And provided further, that the level of radiation due to radioactive material contained in each electron tube does not exceed 10 µGy (1 millirad) per hour ~~(10 u Gy)~~ at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber. The term "electron tubes" includes spark gap tubes, power tubes, gas tubes, including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical current.

h. Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material provided that:
   i. Each source contains no more than 1 exempt quantity set forth in Exhibit ~~Schedule~~ B of this Article, and
   ii. Each instrument contains no more than ten exempt quantities. For the purposes of this Paragraph, an instrument's source(s) may contain either one type or different types of radionuclide and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Exhibit ~~Schedule~~ B of this Article, provided the sum of the fractions do ~~that sum of such fractions shall~~ not exceed unity.
   iii. For the purposes of this subsection (B)(1)(h) ~~Paragraph~~ only, 185 kBq (50 nanocurie) ~~(185 Bq)~~ of americium-241 is considered an exempt quantity under Exhibit ~~Schedule~~ B of this Article.
   iv. Spark gap irradiators containing not more than 37 kBq (1 microcurie) ~~(37 k Bq)~~ of cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons per hour (11.4 liters/hr or 0.0114 m^3/hr).

2. Resins containing scandium-46 and designed for sand consolidation in oil wells. A ~~Any~~ person is exempt from this Chapter if the ~~to the extent that such~~ person receives, possesses, uses, transfers or acquires synthetic plastic resins containing scandium 46 which are designed for sand consolidation in oil wells. The described ~~Such~~ resins shall have been manufactured or imported according to a ~~in accordance with a~~ specific license issued by the U.S. Nuclear Regulatory Commission, or shall ~~have been~~ manufactured according to ~~in accordance with~~ the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer of the described ~~such~~ resins according to ~~pursuant to~~ licensing requirements equivalent to those in 10 CFR 32.16 and 10 CFR 32.17 of the U.S. ~~Sections 32.16 and 32.17 or 10 CFR Part 32 of the Regulations of the~~ Nuclear Regulatory Commission. This exemption does not authorize the manufacture of any resins containing scandium-46.

3. Self-luminous products
   a. ~~Self-luminous products containing tritium, krypton-85, or promethium-147.~~ Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, a ~~any~~ person is exempt from this Chapter if the ~~to the extent that such~~ person receives, possesses, uses, transfers or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred under a ~~in accordance with a~~ specific license issued by the U.S. Nuclear Regulatory Commission and described in ~~pursuant to Section 32.22 of~~ 10 CFR ~~Part~~ 32.22, and the ~~which~~ license authorizes the transfer of the products to persons who are exempt from regulatory requirements. This exemption does not apply to tritium, krypton-85, or promethium-147 used in products for frivolous purposes or in toys or adornments.
   b. A ~~Radium-226. Any~~ person is exempt from this Chapter if the ~~to the extent that such~~ person receives, possesses, uses, or transfers articles containing less than 3.7 kBq (100 nanocuries) ~~(3.7 k Bq)~~ of radium-226, which were manufactured prior to October 1, 1978.

4. Gas and aerosol detectors containing radioactive material
   a. Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, a ~~any~~ person is exempt from this Chapter if the ~~to the extent that such~~ person receives, possesses, uses, transfers, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, provided that detectors containing radioactive material shall be ~~have been~~ manufactured, imported, or transferred according to a ~~in accordance with a~~ specific license issued by the U.S. Nuclear Regulatory Commission and described in ~~pursuant to Section 32.26 of~~ 10 CFR ~~Part~~ 32.26, or equivalent regulations of an Agreement or Licensing State, and the license ~~which~~ authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.
   b. Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State are ~~shall be considered~~ exempt under ~~R12-1-303.B.4.a.~~ subsection (B)(4)(a), provided that the device is labeled in accordance with the specific license authorizing distribution of the general licensed device, and ~~provided further~~ that the detectors ~~they~~ meet the requirements of R12-1-311 (C).

C. Exempt quantities

1. Except as provided in ~~R12-1-303.C.2. and 3.~~ subsections (C)(2) and (3), a ~~any~~ person is exempt from these rules if the ~~Regulations to the extent that such~~ person receives, possesses, uses, transfers or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Exhibit ~~Schedule~~ B of this Article.

   2. This subsection ~~Subsection R12-1-303.C.~~ does not authorize the production, packaging, or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

   3. Except as specified in subsection (C)(5)(b), a ~~No~~ person ~~may~~ shall not, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Exhibit ~~Schedule~~ B of this Article, knowing or having reason to believe the described ~~that such~~ quantities of radioactive material will be transferred to persons exempt under ~~R12-1-303.C.~~ subsection (C) or equivalent Regulations of the U.S. Nuclear Regulatory Commission or any Agreement State or Licensing State. A person may take actions in subsection (C)(3)(a) under a ~~, except in accordance with a~~ specific license issued by the U.S. Nuclear Regulatory Commission under ~~pursuant to Section 32.18 of~~ 10 CFR ~~Part~~ 32.18, or by the Agency according to ~~pursuant to~~ R12-1-311.~~(B.)~~ which license states that the radioactive material may be transferred by the licensee to persons exempt under ~~R12-1-303.C.~~ this subsection or the equivalent Regulations of the U.S. Nuclear Regulatory Commission or any Agreement State or Licensing State.

~~R12-1-305~~ R12-1-304. ~~Types of~~ Licenses Types

Licenses for radioactive materials are of 2 ~~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. ~~General licenses provided in this Article are effective without the filing of applications with the Agency or the issuance of licensing documents to the particular persons, although the filing of a certificate with the Agency may be required by the particular general license. The general license is subject to all other applicable portions of this Chapter and any limitations of the 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. ~~Specific licenses require the submission of an application to the Agency and the issuance of a licensing document by the Agency. The licensee is subject to all applicable portions of this Chapter, as well as any limitations specified in the licensing document. No change.~~

~~R12-1-306~~ R12-1-305. General License ~~Licenses~~ ~~Source~~ Material

A. This subsection establishes a ~~A~~ general license ~~is hereby issued~~ authorizing use and transfer of not more than 6.8 kg (15 pounds) ~~(6.8 kg)~~ of source material at any one time, for ~~use in~~ 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; ~~and~~ provided that the person proceeding under ~~, that no such person shall, pursuant to~~ this general license, receives ~~receive~~ no more than ~~a total of~~ 68.2 kg (150 pounds) ~~(68.2 kg)~~ of source material in any one calendar year.

B. Persons who receive, possess, use, or transfer source material under ~~pursuant to~~ the general license issued in ~~R12-1-305.A.~~ subsection (A) are exempt from the provisions of 12 A.A.C. 1, Article 4 and Article 10, ~~of this Chapter~~ provided the ~~to the extent that such~~ receipt, possession, use, or transfer is within the terms of the ~~such~~ general license; ~~provided,~~ however, this exemption does not apply to any person ~~that this exemption shall not be deemed to apply to any such person~~ who is also in possession of source material under a specific license issued under ~~pursuant to~~ this Article ~~part~~.

C. Depleted uranium in industrial products and devices.

1. This subsection establishes a ~~A~~ general license ~~is hereby issued~~ to receive, acquire, possess, use or transfer, ~~in accordance with the provisions of R12-1-305.C.2., 3., 4. and 5.~~ depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.
2. The general license in ~~R12-1-305.C.1.~~ subsection (C)(1) applies only to industrial products or devices which have been manufactured under a ~~either in accordance with a~~ specific license governed by ~~issued to the manufacturer of the products or devices pursuant to~~ R12-1-311.~~(M.)~~, or ~~in accordance with~~ a specific license issued ~~to the manufacturer~~ by the U.S. Nuclear Regulatory Commission or an Agreement State authorizing ~~which 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
   a. Persons who receive, acquire, possess, or use depleted uranium under ~~pursuant to~~ the general license established by ~~R12-1-305.C.1.~~ subsection (C)(1) shall file ARRA 23 ~~13~~ "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 ~~such~~ depleted uranium. The general licensee ~~registration~~ shall furnish on AREA 23 ~~ARRA 13~~ the following information.
      i. Name, telephone number, ~~name~~ and address of the general licensee ~~registrant~~;
      ii. Location of use;
      iii.~~ii.~~ A ~~a~~ statement that the general licensee ~~registrant~~ has developed and will maintain procedures designed to establish physical control over the depleted uranium described in ~~R12-1-305.C.1.~~ subsection (C)(1) and ~~designed~~ to prevent transfer of the ~~such~~ depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and
      iv.~~iii.~~Name ~~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 ~~R12-1-305.C.3.a.ii~~ subsection (C)(3)(a)(ii).
   b. The general licensee ~~registrant~~ possessing or using depleted uranium under the general license estab-

lished by ~~R12-1-305.C.1.~~ subsection (C)(1) shall report in writing to the Agency any changes in information originally furnished on ~~by him in~~ ARRA 23 ~~13 "Registration Certificate - Use of Depleted Uranium Under General License"~~. The report shall be submitted within 30 days after the effective date of the described ~~such~~ change.

4. A person who receives, acquires, possesses, or uses depleted uranium under ~~pursuant to~~ the general license established by ~~R12-1-305.C.1.~~ subsection (C)(1):
   a. Shall not introduce the ~~such~~ 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. Shall not abandon the ~~such~~ depleted uranium;
   c. Shall transfer the ~~or dispose of such~~ depleted uranium as prescribed in R12-1-318. ~~only by transfer in accordance with the provisions of R12-1-318. In the case where~~ If the transferee receives the depleted uranium under ~~pursuant to~~ the general license established by ~~R12-1-305.C.1.~~ subsection (C)(1), the transferor shall furnish the transferee with a copy of this rule ~~regulation~~ and a copy of the registration certificate. ~~ARRA 13. In the case where~~ If the transferee receives the depleted uranium under ~~pursuant to~~ a general license governed by a regulation of ~~contained in~~ the U.S. Nuclear Regulatory Commission's or Agreement State's ~~regulation~~ that is equivalent to ~~R12-1-305.C.1.~~ subsection (C)(1), the transferor shall furnish the transferee a copy of this rule ~~regulation~~ and a copy of the registration certificate ~~ARRA 13~~, accompanied by a letter ~~note~~ explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially similar to ~~the same as~~ those in this rule ~~regulation~~;
   d. Within 30 days of any transfer, shall report in writing to the Agency the name and address of the person receiving the depleted uranium ~~pursuant to such transfer~~; and
   e. Shall not export the ~~such~~ depleted uranium except under ~~in accordance with~~ a license issued by the U.S. Nuclear Regulatory Commission in ~~pursuant to~~ 10 CFR ~~Part~~ 110.
5. Any person receiving, acquiring, possessing, using, or transferring depleted uranium according to ~~pursuant to~~ the general license established by ~~R12-1-305.C.1.~~ subsection (C)(1) is exempt from the requirements of 12 A.A.C. 1, Articles 4 and 10 ~~of these Regulations~~ with respect to the depleted uranium covered by that general license.

~~R12-1-307~~ R12-1-306. General License ~~Licenses~~ – Radioactive Material Other Than Source Material

A. This subsection establishes a ~~Certain devices and equipment. A~~ general license is issued to transfer, receive, acquire, 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 ~~pursuant to Section 31.3 of 10 CFR Part 31~~. This general license is subject to the provisions of 12 A.A.C. 1, Articles 1, 4, 10 and 12 ~~of this Chapter and sections~~ Sections R12-1-303~~.A.2.~~(A)(2), R12-1-313, R12-1-318, R12-1-319, and R12-1-321, ~~of this Article~~ and A.R.S. §§ 30-654(B)(13) ~~30-654.B.13~~, 30-657(A) and (B) ~~30-657.A and B~~, 30-681, and 30-685 through 30-689 ~~of the Act~~.

1. Static elimination device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 microcuries) ~~(18.5 M Bq)~~ of polonium-210 per device.
2. Ion generating tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 18.5 MBq (500 microcuries) ~~(18.5 M Bq)~~ of polonium-210 per device or a total of not more than 1.85 GBq (50 millicuries) ~~(1.86 G Bq)~~ of hydrogen-3 (tritium) per device.

B. Certain measuring, gauging or controlling devices

1. This subsection establishes for ~~A general license is hereby issued to~~ commercial and industrial firms; ~~and to~~ research, educational and medical institutions;, individuals for conducting ~~in the conduct of their~~ business;, and State or local government agencies to receive, acquire, possess, use or transfer radioactive material according to ~~in accordance with~~ the provisions of ~~R12-1-306.B.2., 3, and 4.~~ subsections (B)(2), (3), and (4) , ~~radioactive material,~~ 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.
2. The general license in ~~R12-1-306.B.1.~~ subsection (B)(1) applies only to radioactive material contained in devices which have been manufactured and labeled according to ~~in accordance with the~~ specifications contained in a specific license issued by the Agency under ~~pursuant to~~ R12-1-311~~.D.~~(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. ~~thereon which is found in Section 179.21 of the Code of Federal Regulations, Title 21~~.
3. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device according to ~~pursuant to~~ the general license in ~~R12-1-306.B.1.~~ subsection (B)(1) :
   a. Shall ~~shall~~ assure that all labels are affixed to the device at the time of receipt, each ~~and~~ bearing a statement that removal of the label is prohibited, maintain the labels ~~are maintained~~ on the device ~~thereon~~ and ~~shall~~ comply with all instructions and precautions provided ~~by~~ on the ~~such~~ labels;
   b. Shall ~~shall~~ assure that the device is tested for leakage of radioactive material and proper operation of the actuation ~~on-off~~ mechanism and indicator, if any, at no longer than six-month intervals or the intervals ~~at such other intervals as are~~ specified on ~~in~~ the label; however;
      i. Devices ~~devices~~ containing only krypton need not be tested for leakage of radioactive material, ~~and~~

ii. Devices ~~devices~~ containing only tritium or not more than 3.7 MBq (100 microcuries) ~~(3.7 M Bq)~~ of other beta or ~~and/or~~ gamma emitting material or 370 kBq (10 microcuries) ~~(370 k Bq)~~ of alpha emitting material; and ~~and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;~~

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

c. Shall ~~shall~~ assure that the tests required by ~~R12-1-306.B.3.b.~~ subsection (B)(3)(b) and other testing, installation, servicing, and removal from installation involving shielding, containment or ~~the~~ radioactive material, ~~materials, its shielding or containment,~~ are performed:

i. According to ~~in accordance with~~ the instructions on any label ~~provided by the labels~~, or

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

d. Shall ~~shall~~ maintain records showing compliance with the requirements of ~~R12-1-306.B.3.b.~~ subsections (B)(3)(b) and (c). ~~and R12-1-306.B.3.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 from shielding, containment, or radioactive material. ~~installation concerning the radioactive material, its shielding or containment.~~ Records of tests for leakage of radioactive material required by ~~R12-1-306.B.3.b.~~ subsection(B)(3)(b) shall be maintained for 1 year after the next required leak test is performed or until the sealed source is disposed of or transferred ~~or disposed of~~. Records of tests of the actuator ~~on/off~~ mechanism and indicator required by ~~R12-1-306.B.3.b.~~ subsection (B)(3)(b) shall be maintained for 1 year after the next required test of the actuator ~~on/off~~ mechanism and indicator is performed or until the sealed source is disposed of or transferred ~~or disposed of~~. Records which are required by ~~R12-1-306.B.3.c.~~ subsection (B)(3)(c) shall be maintained for ~~a period of~~ 2 years from the date of the recorded event or until the device is disposed of or transferred ~~or disposed of~~;

e. Upon ~~upon the occurrence of a~~ failure ~~of or~~ damage ~~to~~, or any indication of ~~a~~ possible failure ~~of~~ or damage of ~~to, the~~ shielding ~~of the radioactive material~~ or the actuation ~~on-off~~ mechanism or indicator, or upon the detection of 185 Bq (5 nanocurie) ~~(185 Bq)~~ 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 ~~such devices~~, 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 ~~shall~~ not abandon the device containing radioactive material;

g. Except ~~except~~ as provided in ~~R12-1-306.B.3.h.~~ 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 ~~of a device to a specific licensee shall~~ furnish ~~to the Agency~~ a report to the Agency identifying ~~containing identification~~ of 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 ~~shall~~ transfer the device to another general licensee only:

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

ii. Where ~~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 ~~I~~. Shall ~~shall~~ comply with the provisions of ~~R12-1-423~~ R12-1-443 and R12-1-444 for reporting radiation incidents, theft, or loss of licensed material, but is ~~shall be~~ exempt from the other requirements of 12 A.A.C. 1, Articles 4 and 10.

4. The general license in ~~R12-1-306.B.1.~~ subsection (B)(1) does not authorize the manufacture of devices containing radioactive material.

5. The general license provided in ~~R12-1-306.B.1.~~ subsection (B)(1) is subject to the provisions of 12 A.A.C. 1, Articles 1, 3, 12, and 15 ~~of this Chapter,~~ and A.R.S.§§ 30-654(B)(13) ~~30-654.B.13~~, 30-657 (A) and (B) ~~30-657. A and B~~, 30-681, and 30-685 through 30-689 ~~of the Act~~.

C. Luminous safety devices for aircraft

1. This subsection establishes a ~~A~~ general license shall be issued for the receipt, acquisition, possession, and use of ~~is hereby issued to receive, acquire, possess, and use~~ tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided:

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

b. Each ~~each~~ device has been manufactured, assembled or imported according to a ~~in accordance with a~~ specific license issued by the U.S. Nuclear Regulatory Commission, or each device has been manufactured or assembled according to ~~in accordance with~~ the specifications contained in a specific license issued by the Agency or any Agreement State or Licensing State to the manufacturer or

assembler of the ~~such~~ device according to ~~pursuant to~~ licensing requirements equivalent to those in 10CFR 32.53 ~~Section 32.53 of 10 CFR 32 of the Regulations of the U.S. Nuclear Regulatory Commission~~.

2. Persons who receive, acquire, possess, or use luminous safety devices according to ~~pursuant to~~ the general license in ~~R12-1-306.C.1.~~ subsection (C)(1) are exempt from the requirements of 12 A.A.C. 1, Article 4 and Article 10 except that they shall comply with the provisions of ~~423~~ 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 ~~of this Chapter~~, and A.R.S.§§ 30-654(B)(13), 30-657(A), 30-657(B) ~~30-654.B.13, 30-657.A, 30-657.B~~, 30-681, and 30-685 through 30-689 of the Act.

D. Calibration and reference sources

1. This subsection establishes a ~~A~~ general license for ~~is hereby issued to~~ those persons listed below to receive, acquire, possess, use, and transfer, according to ~~in accordance with~~ the provisions of ~~R12-1-306.D.4. and 5.~~ 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 ~~A~~ general license for ownership, receipt, possession, use and transfer of ~~is hereby issued to own, receive, possess, use, and transfer~~ plutonium in the form of calibration or reference sources, ~~in accordance with the provisions of R12-1-306.D.4. and 5.~~ to any person who holds a specific license issued by the Agency authorizing receipt, possession ~~which authorizes him to receive, possess~~, use, and transfer of radioactive material.
3. This subsection establishes a ~~A~~ general license ~~is hereby issued~~ to receive, possess, use and transfer radium-226 in the form of calibration or reference sources, ~~in accordance with the provisions of R12-1-306.D.4. and 5.~~ to any person who holds a specific license issued by the Agency authorizing ~~which authorizes the~~ receipt, possession, use and transfer of radioactive material.
4. The general licenses in ~~R12-1-306.D.1., 2. and 3.~~ subsections (D)(1),(2), and (3) apply ~~only~~ to calibration or reference sources which have been manufactured according to ~~in accordance with~~ the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission in ~~pursuant to Section 32.57 of~~ 10 CFR ~~Part~~ 32.57 or ~~Section 70.39 of~~ 10 CFR ~~Part~~ 70.39. The general license also apply to calibration or reference sources ~~or~~ which have been manufactured according to ~~in accordance with~~ the specifications contained in a specific license issued to the manufacturer by the Agency or any Agreement State or Licensing State according to ~~pursuant to~~ licensing requirements equivalent to those contained in ~~Section 32.57 of~~ 10 CFR ~~Part~~ 32.57 or ~~Section 70.39 of~~ 10 CFR ~~Part~~ 70.39. ~~of the Regulations of the U.S. Nuclear Regulatory Commission.~~
5. The general licenses provided in ~~R12-1-306.D.1., 2. and 3.~~ 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 ~~of this Chapter~~ and A.R.S. §§30-654(B)(13), 30-657(A), 30-657(B) ~~30-654.B.13, 30-657.A, 30-657.B~~, 30-681, and 30-685 through 30-689 ~~of the Act~~. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources according to ~~pursuant~~ to these general licenses:
   a. Shall ~~shall~~ not possess at any one time, at any location of storage or use, more than 185 kBq (5 microcuries) ~~(185 k Bq)~~ of americium-241, ~~5 microcuries of~~ plutonium or ~~and 5 microcuries (185 k Bq) of~~ radium-226 in calibration or reference ~~calibration and such~~ sources;
   b. Shall ~~shall~~ not receive, possess, use, or transfer a calibration or reference ~~such~~ source unless the source, or the storage container, bears a label which includes one of the following statements ~~statement~~ or a substantially similar statement which contains the information called for in one of the following statements~~, as appropriate~~:
      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 ~~shall~~ not transfer, abandon, or dispose of a calibration or reference ~~such~~ 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 ~~shall~~ store a calibration or reference ~~such~~ 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 ~~shall~~ not use a calibration or reference ~~such~~ 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.

E. Medical diagnostic uses

Receipt, possession, use, transfer, ownership or acquisition of carbon-14 urea capsules containing 1 microcurie of carbon-14 urea for "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" diagnostic use contains no more than 1 microcurie.
2. Any 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 physician who desires to manufacture, prepare, process, produce, package, repackage, or transfer 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, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of Secretary of State. This incorporation by reference contains no future editions or amendments.
4. Nothing in this subsection relieves physicians from complying with applicable FDA and other federal and state requirements governing receipt, administration, and use of drugs.

~~1. A general license is hereby issued to any physician to receive, possess, transfer, or use the radioactive material set forth below for the stated diagnostic uses, provided, however, that a the use is in accordance with the provision of R12-1-306.E.2., 3. and 4, the radioactive material is in the form of capsules, disposable syringes, or other prepackaged individual doses; and the radioactive material has been manufactured in accordance with a specific license issued under pursuant to R12-1-311.G. by the Agency, the U.S. Nuclear Regulatory Commission, or any Agreement State or Licensing State authorizing distribution under the general license granted in this Paragraph or its equivalent:~~

~~a. Iodine-131 as sodium iodide (NaI^{131}) for measurement of thyroid uptake;~~

~~b. Iodine-131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;~~

~~c. Iodine-125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;~~

~~d. Cobalt-57 for the measurement of intestinal absorption of cyanocobalamin;~~

~~e. Cobalt-58 for the measurement of intestinal absorption of cyanocobalamin;~~

~~f. Cobalt-60 for the measurement of intestinal absorption of cyanocobalamin; and~~

~~g. Chromium-51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time.~~

~~2. No physician shall receive, possess, use, or transfer radioactive material pursuant to the general license established by R12-1-306.E.1. until the physician has filed ARRA-5, "Certificate - Medical Use of Radioactive Material Under General License" with the Agency and received from the Agency a validated copy of the AREA-5 with certification number assigned. The generally licensed physician shall furnish on ARRA-5 and such other information as may be required by that form:~~

~~a. Name and address of the generally licensed physician;~~

~~b. A statement that the generally licensed physician is a duly licensed physician authorized to dispense drugs in the practice of medicine in this State; and~~

~~c. A statement that the generally licensed physician has appropriate radiation measuring instruments to carry out the diagnostic procedures which use radioactive material under the general license of R12-1-306.E. and that the physician is competent in the use of such instruments.~~

~~3. A physician who receives, possesses, or uses a pharmaceutical containing radioactive material pursuant to the general license established by R12-1-306.F.1. shall comply with the following:~~

~~a. The physician shall not possess at any one time, pursuant to the general license in R12-1-306.E.1. more than~~

~~i. 200 microcuries (3.7 M Bq) of iodine-131,~~

~~ii. 200 microcuries (3.7 M Bq) of iodine-125,~~

~~iii. 5 microcuries (185 k Bq) of cobalt-57,~~

~~iv. 5 microcuries (185 k Bq) of cobalt-58,~~

~~v. 5 microcuries (185 k Bq) of cobalt-60, and~~

~~vi. 200 microcuries (3.7 M Bq) of chromium-51;~~

~~b. The physician shall store the pharmaceutical until administered in the original shipping container, or a container providing equivalent radiation protection;~~

~~c. The physician shall use the pharmaceutical only for the uses authorized by R12-1-306.E.1.~~

~~d. The physician shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age; and~~

~~e. The physician shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Agency, the U.S. Nuclear Regulatory Commission or any Agreement State or Licensing State, or in any manner other than in the unopened, labeled shipping container, as received from the supplier, except by administering it to a patient.~~

~~4. The generally licensed physician possessing or using radioactive material under the general license of R12-1-306.E.1. shall report in duplicate to the Agency any changes in the information furnished in the "Certificate - Medical Use of Radioactive Material Under General License", ARRA-5. The report shall be submitted within 30 days after the effective date of the such change.~~

~~5. Any person using radioactive material pursuant to the general license of R12-1-306.E.1. is exempt from the requirements of Article 4 and Article 10 of these Regulations with respect to the radioactive material covered by the general license.~~

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

1. This subsection establishes a ~~A~~ general license for ~~is hereby issued to~~ any physician, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, ~~in accordance with the provisions of R12-1-306.F.2., 3., 4., 5., and 6.,~~ the following radioactive materials in prepackaged units:
   a. Iodine-125, in units not exceeding 370 kBq (10 microcuries) ~~(370 k Bq)~~ each for use in in vitro ~~in-vitro~~ clinical or laboratory tests not involving internal or external administration of radioactive material, or ~~the~~ radiation from such materials ~~therefrom~~, to human beings or animals.
   b. Iodine-131, in units not exceeding 370 kBq (10 microcuries) ~~(370 k Bq)~~ each for use in in vitro ~~in-vitro~~ clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation from such material ~~therefrom~~, to human beings or animals.
   c. Carbon-14, in units not exceeding 370 kBq (10 microcuries) ~~(370 k Bq)~~ each for use in in vitro ~~in-vitro~~ clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation from such materials ~~therefrom~~, to human beings or animals.
   d. Hydrogen-3 (tritium), in units not exceeding 1.85 MBq (50 microcuries) ~~(1.85 M Bq)~~ each for use in in vitro ~~in-vitro~~ clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation from such materials ~~therefrom~~, to human beings or animals.
   e. Iron-59, in units not exceeding 740 kBq (20 microcuries) ~~(740 k Bq)~~ each for use in in vitro ~~in-vitro~~ clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation from such material ~~therefrom~~, to human beings or animals.
   f. Cobalt-57, in units not exceeding 370 kBq (10 microcuries) ~~(370 k Bq)~~ each for use in in vitro ~~in-vitro~~ clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation from such material ~~therefrom~~, to human beings or animals.
   g. Mock iodine-125 reference or calibration sources, in units not exceeding 1.85 kBq (50 nanocurie) ~~(1.85 k Bq)~~ of iodine-129 and 185 Bq (5 nanocurie) ~~(185 Bq)~~ of americium-241 each, for use in in vitro ~~in-vitro~~ clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation from such material ~~therefrom~~, to human beings or animals.
2. A ~~No~~ person shall not acquire, receive, possess, use or transfer radioactive material according to ~~pursuant to~~ the general license established by ~~R12-1-306.F.1.~~ subsection (F)(1) until the person has filed ARRA-9, "Certificate -- In Vitro Testing with Radioactive Material Under General License", requesting the information listed in Exhibit E, with the Agency and received ~~from the Agency~~ a validated copy of ARRA-9 which shows the assigned ~~with~~ certification number ~~assigned~~. The physician, clinical laboratory, or hospital shall furnish on ARRA-9, the following information: ~~the following information and such other information as may be required by that form:~~
   a. Name, telephone number, and address of the physician, clinical laboratory, or hospital; and
   ~~b. The location of use; and~~
   b. ~~c.~~ 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 ~~as authorized under the general license in R12-1-306.F.1. and that such~~ tests will be performed only by personnel competent in the use of the appropriate instruments and to handle ~~in the handling of the~~ radioactive material.
3. A person who receives, acquires, possesses or uses radioactive material according ~~pursuant~~ to the general license established by ~~R12-1-306.F.1.~~ subsection (F)(1) shall comply with the following:
   a. The general licensee shall not possess at any one time, ~~pursuant to the general license in R12-1-306.F.1.~~ in storage or use, a total amount of iodine-125, iodine-131, iron-59, or ~~and/or~~ cobalt-57 in excess of 7.4 MBq (200 microcuries), or ~~nor~~ acquire or use in any one calendar month any more than ~~in excess of a total of~~ 18.5 MBq (500 microcuries) of these materials.
   b. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
   c. The general licensee shall use the radioactive material only for the uses authorized by ~~R12-1-306.F.1.~~ subsection (F)(1).
   d. The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it according to ~~pursuant to~~ a license issued by the Agency, the U.S. Nuclear Regulatory Commission, or any Agreement State or Licensing State, or ~~nor~~ transfer the radioactive material in any manner other than in the unopened, labeled shipping container ~~as~~ received from the supplier.
   e. The general licensee shall not dispose of the mock iodine-125 reference or calibration sources described above except as authorized by R12-1-434 ~~R12-1-416~~.
4. The general licensee shall not receive, acquire, possess, or use radioactive material according ~~pursuant~~ to ~~R12-1-306.F.1.~~ subsection (F)(1):
   a. Except as prepackaged units which are labeled according to ~~in accordance with~~ the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, or any Agreement State which 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 ~~R12-1-306.F.~~ subsection (F) or its equivalent federal law, and
   b. Unless ~~unless~~ one of the following statements, or a substantially similar statement which contains the same information ~~called for in one of the following statements~~, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:
      i. This radioactive material may be acquired, received, possessed, and used only by physicians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration

of the material, or the radiation from such material ~~therefrom~~, to human beings or animals. The acquisition, receipt, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of manufacturer

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

_____
Name of manufacturer

5. The physician, clinical laboratory or hospital possessing or using radioactive material under the general license in ~~of R12-1-306.F.1.~~ subsection (F)(1) shall report in writing to the Agency, any changes in the information furnished on ~~in~~ the ~~"Certificate — In Vitro Testing with Radioactive Material Under General License"~~, ARRA-9. The report shall be furnished within 30 days after the effective date of the ~~such~~ change.
6. Any person using radioactive material according to ~~pursuant to~~ the general license of ~~R12-1-306.F.1.~~ subsection (F)(1) is exempt from the requirements of 12 A.A.C. 1, Article 4 and Article 10 ~~of these Regulations~~ with respect to radioactive material covered by that general license, except that persons using mock iodine-125 sources described in ~~R12-1-306.F.1.g.~~ subsection (F)(1)(g) shall comply with the provisions of R12-1-434 ~~R12-1-416~~, and ~~R12-1-423~~ R12-1-443 and R12-1-444 of these rules ~~Regulations~~.
7. For the purposes of subsection (F)~~.~~, a licensed veterinary care facility is considered ~~shall be deemed to be~~ a "clinical laboratory".

G. Ice detection devices

1. This subsection establishes a ~~A~~ general license is ~~hereby~~ issued 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 µCi) ~~50 microcuries (1.85 M Bq)~~ 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 ~~in accordance with~~ the specifications contained in a specific license issued by the Agency or any Agreement State to the manufacturer of the ~~such~~ device under ~~pursuant to~~ licensing requirements equivalent to those in ~~Section 32.61 or~~ 10 CFR ~~Part~~ 32.61 ~~of the Regulations of the NRC~~.
2. Persons who receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices according ~~pursuant~~ to the general license in ~~R12-1-306.G.1.~~ subsection (G)(1):
   a. Shall ~~shall~~, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating ~~to the device~~, discontinue use of the device until it has been inspected, tested for leakage, and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State to manufacture or service ice detection ~~such~~ devices; or shall dispose of the device according ~~pursuant~~ to the provisions of ~~R12-1-416~~ R12-1-434~~:~~
   b. Shall ~~shall~~ assure that all labels affixed to the device at the time of receipt, and which bear a statement prohibiting ~~which prohibits~~ removal of the labels, are maintained on the devices ~~thereon~~; and
   c. Are ~~are~~ exempt from the requirements of 12 A.A.C. 1, Article 4 and Article 10, except the users of ice detection devices ~~that such persons~~ shall comply with the provisions of ~~416 and 423~~ R12-1-434, R12-1-443 and R12-1-444.
3. No change.
4. This general license is subject to the provisions of 12 A.A.C. 1, Articles 1, 3, 12, and 15 ~~of this Chapter~~, and A.R.S. §§ 30-654.B.13, 30-657.A, 30-657.B, 30-681, and 30-685 through 30-689 ~~of the Act~~.

~~R12-1-308~~ R12-1-307.Repealed.

~~R12-1-309~~ R12-1-308. Filing Application for Specific Licenses

A. An application ~~Applications~~ for a specific license ~~licenses~~ shall file ~~be filed on~~ an Agency application form. ~~a form prescribed by the Agency~~. The applicant ~~Applications~~ shall prepare the application ~~be prepared~~ in duplicate, one copy for ~~triplicate; two copies shall be filed with~~ the Agency and the other for ~~shall be maintained by~~ the applicant.

B. No change.

C. Each application shall contain the information specified in Exhibit (E) of this Article and be signed by the applicant, ~~or~~ licensee, or ~~a~~ person duly authorized to act for and ~~on behalf of~~ the applicant or licensee.

D. An application for a license may include a request for a license authorizing more than one activity authorized by R12-1-1302 ~~one or more activities~~.

E. In the ~~his~~ application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Agency, provided the ~~such~~ references are clear and specific.

F. The Agency shall make applications ~~Applications~~ and documents submitted to the Agency ~~may be made~~ available for public inspection, but ~~except that the Agency~~ may withhold any document or part of a document ~~thereof~~ from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

~~R12-1-310~~ R12-1-309. General Requirements for the Issuance of Specific Licenses

A license application shall ~~will~~ be approved if the Agency determines that:

1. The ~~the~~ applicant is qualified by reason of training and experience to use the material in question for the purpose requested according to ~~in accordance with~~ these rules in ~~Regulations in such~~ a manner that will ~~as to~~ minimize danger to public health and safety or property;
2. The ~~the~~ applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;
3. The ~~the~~ issuance of the license will not be inimical to the health and safety of the public;

4. The ~~the~~ applicant satisfies all ~~any~~ applicable special requirements in R12-1-310, R12-1-311, ~~and R12-1-323;~~ R12-1-322, R12-1-323, 12 A.A.C. 1, Article 5, 7, and 17; and
5. The ~~the~~ applicant demonstrates that a letter has been sent, return receipt requested, to the Mayor's office of the city, town, or, if not within an incorporated community, to the County Board of Supervisors of the county in which the applicant proposes to operate, which describes:
   a. The ~~the~~ nature of the proposed activity involving radioactive material;
   b. The ~~the~~ facility, including use and storage areas.

~~R12-1-311~~ R12-1-310. Special Requirements for Issuance of ~~Certain~~ Specific Broad Scope Licenses ~~for Radioactive Material~~

~~A. Human use of radioactive material in institutions. In addition to the requirements set forth in R12-1-309, a specific license for human use of radioactive material in institutions will be issued only if:~~
   ~~1. The applicant has appointed a radiation safety committee to oversee the use of licensed material throughout the institution and to review the institution's radiation safety program. Membership of the committee shall include at least the following: an authorized user for each type of use permitted by the licensee, a representative of the nursing staff, a representative of the institution's management, and the Radiation Safety Officer.~~
   ~~2. The applicant possesses adequate facilities for the clinical care of patients;~~
   ~~3. Any physician designated on the application as an individual user has substantial experience in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients; and~~
   ~~4. If the application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant's staff has substantial experience in the use of a variety of radioactive materials for a variety of human uses.~~

~~B. Specific licenses to individual physicians for human use of radioactive material~~
   ~~1. An application by an individual physician or group of physicians for a specific license for the human use of radioactive material may be approved if:~~
      ~~a. the applicant satisfies the general requirements specified in R12-1-309;~~
      ~~b. the application is for use in the applicant's practice in an office outside a medical institution;~~
      ~~c. the applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and~~
      ~~d. the applicant has substantial experience in the handling and administration of radio nuclides, and where applicable, the clinical management of radioactive patients.~~
   ~~2. The Agency will not approve an application by an individual physician or group of physicians for a specific license to receive, possess, or use radioactive material on the premises of a medical institution unless:~~
      ~~a. The use of radioactive material is limited to:~~
         ~~i. the administration of radiopharmaceutical for diagnostic or therapeutic purposes;~~
         ~~ii. the performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered;~~
         ~~iii. the performance of in vitro diagnostic studies, or~~
         ~~iv. the calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation and diagnostic instrumentation.~~
      ~~b. the physician brings the radioactive material with him/her and removes the radioactive material when he/she departs. (The institution cannot receive, possess, or store radioactive material other than the amount of material remaining in the patient); and~~
      ~~c. the medical institution does not hold a radioactive materials license under R12-1-310.A.~~

~~C. Specific licenses for certain groups of medical uses of radioactive material~~
   ~~1. Subject to the provisions of R12-1-310.C.2., 3. and 4., an application for a specific license pursuant to R12-1-310.A. or B. for any medical use or uses of radioactive material specified in one or more of Groups I to V, inclusive, of Schedule C of this Article will be approved for all of the materials within the group or groups in the application if:~~
      ~~a. The applicant satisfies the requirements of R12-1-310.A., B. and D.;~~
      ~~b. The applicant, or any physician designated in the application as an individual user, has adequate clinical experience in the types of uses included in the group or groups;~~
      ~~c. The applicant or the physicians and all other personnel who will be involved in the preparation and use of the radioactive material have adequate training and experience in the handling of radioactive material appropriate to their participation in the uses included in the group or groups;~~
      ~~d. The applicant's radiation detection and measuring instrumentation is adequate for conducting the procedures involved in the uses included in the group or groups;~~
      ~~e. The applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the uses included in the group or groups.~~
   ~~2. Any licensee or registrant who is authorized to use radioactive material pursuant to one or more groups in R12-1-310.C.1. and Schedule C of this Article is subject to the following conditions:~~
      ~~a. For Groups I, II, IV and V, no licensee or registrant shall receive, possess, or use radioactive material as a radiopharmaceutical unless manufactured in the form to be administered to the patient, labeled, packaged, and distributed in accordance with a specific license issued by the Agency pursuant to R12-1-311.J., a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.72 of 10 CFR Part 32, a specific license issued by an Agreement State or a Licensing State pursuant to equivalent regulations.~~
      ~~b. For Group III, no licensee or registrant shall receive, possess, or use generators or reagent kits containing radioactive material or shall use reagent kits that do not contain radioactive material to pre-~~

~~pare radiopharmaceuticals containing radioactive material, except:~~

~~I. Reagent kits not containing radioactive material that are approved by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State or Licensing State for use by persons licensed pursuant to R12-1-310.C. and Schedule C of this Article or equivalent regulations; or~~

~~ii. Generators or reagent kits containing radioactive material that are manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the Agency pursuant to R12-1-311.K., or a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Sec. 32.73 of 10 CFR Part 32, or a specific license issued by an Agreement State or a Licensing State pursuant to equivalent regulations.~~

~~iii. For Group III, any licensee or registrant who uses generators or reagent kits shall:~~

~~(1) Elute the generator or process radioactive material with the reagent kit, in accordance with instructions which are approved by the U.S. Nuclear Regulatory Commission, an Agreement State and are furnished by the manufacturer on the label attached to or in the leaflet or brochure which accompanies the generator or reagent kit;~~

~~(2) Before administration to patients, cause each elution or extraction of technetium-99m from a molybdenum-99/technetium-99m generator to be tested to determine either the total molybdenum-99 activity or the concentration of molybdenum-99. This testing shall be conducted according to written procedures and by personnel who have been specifically trained to perform the test;~~

~~(3) Prohibit the administration to patients of technetium-99m containing more than 1 microcurie (37k Bq) of molybdenum-99 per millicurie (37k Bq) of technetium-99m, or more than 5 microcuries (185 K Bqw) of molybdenum-99 per administered dose, at the time of administration; and~~

~~(4) Maintain for 2 years for Agency inspection, records of the molybdenum-99 test conducted on each elution from the generator and records of training given to personnel performing such tests.~~

~~iv. For Groups I, II and III any licensee using radioactive material for clinical procedures other than those specified in the product labeling (package insert) shall comply with the product labeling regarding:~~

~~(1) Chemical and physical form;~~

~~(2) Route of administration; and~~

~~(3) Dosage range.~~

~~Provided, however, that specific alternative routes of administration may be approved pursuant to R12-1-103 upon application to the Agency describing the radiation safety merits of the proposed alternative.~~

~~3. Any licensee who is licensed pursuant to R12-1-310.C.1. for one or more of the medical use groups in Schedule C also is authorized to use radioactive material under the general license in R12-1-306.F. for the specified in vitro uses without filing Form AARA-9 as required by R12-1-306.F.2.; provided, that the licensee is subject to the other provisions of R12-1-306.F.~~

~~4. Any licensee who is licensed pursuant to R12-1-310.C.1. for one or more of the medical use groups in Schedule C also is authorized, subject to the provisions of R12-1-310.C.4. and 5., to receive, possess, and use for calibration and reference standards:~~

~~a. Any radioactive material listed in Group I, Group II, or Group III of Schedule C of this Article with a half-life not longer than 100 days, in amounts not to exceed 15 millicuries (555 M Bq) total;~~

~~b. Any radioactive material listed in Group I, Group II, or Group III of Schedule C of this Article with half-life greater than 100 days in amounts not to exceed 200 microcuries (7.4 M Bq) total;~~

~~c. Technetium-99m in amounts not to exceed 30 millicuries (2.22 G Bq);~~

~~d. Any radioactive material, in amounts not to exceed 3 millicuries (222 M Bq) per source, contained in calibration or reference sources that have been manufactured, labeled, packaged, and distributed in accordance with:~~

~~I. A specific license issued by the Agency pursuant to R12-1-311.J.; or~~

~~ii. A specific license issued by the Nuclear Regulatory Commission pursuant to Section 32.72 of 10 CFR Part 32; or~~

~~iii. A specific license issued by an Agreement State or Licensing State pursuant to equivalent regulations.~~

~~5. Sealed source testing~~

~~a. Any licensee or registrant who possesses sealed sources as calibration or reference sources pursuant to R12-1-310.C.4. shall cause each sealed source containing radioactive material, other than hydrogen-3, with a half-life greater than thirty days in any form other than gas to be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, the sealed source should not be used until tested, provided, however, that no leak tests are required when:~~

~~I. The source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material, or~~

~~ii. The sealed source is stored and is not being used; such sources shall, however, be tested for leakage prior to any use or transfer unless they have been leak tested within six months prior to the date or use of transfer.~~

~~b. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which contamination might be expected to accu-~~

~~mulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Agency.~~

~~c. If the leak test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee or registrant shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Articles 3 and 4 of these Regulations. A report shall be filed within 5 days of the test with the Agency describing the equipment involved, the test results, and the corrective action taken;~~

~~6. Any licensee or registrant who possesses and uses calibration and reference sources pursuant to R12-1-310.C.4.d. shall:~~

~~a. Follow the radiation safety and handling instructions approved by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State and furnished by the manufacturer on the label attached to the source, or permanent container thereof, or in the leaflet or brochure that accompanies the source, and maintain such instruction in a legible and conveniently available form;~~

~~b. Conduct a quarterly physical inventory to account for all sources received and possessed. Records of the inventories shall be maintained for inspection by the Agency and shall include the quantities and kinds of radioactive material, location of sources, and the date of the inventory.~~

~~D. Human use of sealed sources. In addition to the requirements set forth in R12-1-309, a specific license for human use of sealed sources will be issued only if the applicant or, if the application is made by an institution, the individual user:~~

~~1. has specialized training in the diagnostic or therapeutic use of the sealed source considered, or has experience equivalent to such training, and~~

~~2. is a physician.~~

~~3. Licenses issued pursuant to R12-1-310.D. are subject to the additional provisions of Article 7 of this Chapter.~~

~~E. Misadministrations.~~

~~1. Definition of a misadministration. For this part, misadministration means the administration of:~~

~~a. A radiopharmaceutical or radiation from a sealed source other than the one intended;~~

~~b. A radiopharmaceutical or radiation to the wrong patient;~~

~~c. A radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician;~~

~~d. A diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent;~~

~~e. A therapeutic dose of a radiopharmaceutical differing from the prescribed dose by more than 10 percent; or~~

~~f. A therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent.~~

~~2. Reports of therapy misadministrations~~

~~a. Immediate telephone report. When a administration involves any therapy procedure, the licensee shall notify the Agency by telephone. The licensee shall also notify the referring physician of the affected patient and the patient or a responsible relative (or guardian), unless the referring physician personally informs the licensee either that he will inform the patient, or that in his medical judgment, telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other respectively. These notifications shall be made within 24 hours after the licensee discovers the misadministration. (If the referring physician or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee shall not delay medical care for the patient because of this.)~~

~~b. Written report. Within 15 days after the initial therapy misadministration report to the Agency, the licensee shall report, in writing, to the Agency and to the referring physician and furnish a copy of the report to the patient or the patient's responsible relative (or guardian) if either was previously notified by the licensee under Subparagraph a. of this Paragraph. The written report shall include the licensee's name, the referring physician's name, a brief description of the event, the effect on the patient, the action taken to prevent recurrence, whether the licensee informed the patient or the patient's responsible relative (or guardian), and if not, why not. The report shall not include the patient's name or other information which could lead to identification by the patient.~~

~~3. Reports of diagnostic misadministrations. When a misadministration involves a diagnostic procedure, the licensee shall notify, in writing, the referring physician and the Agency. Licensee reports of diagnostic misadministrations are due within 10 days after the end of the calendar quarters (defined by March, June, September and December) in which they occur. These written reports shall include the licensee's name, the referring physician's name, a description of the event, the effect on the patient, and the action taken to prevent recurrence. The report should not include the patient's name or other information which could lead to identification of the patient.~~

~~4. Records of all misadministrations. Each licensee shall maintain, for Agency inspection, records of all misadministrations of radiopharmaceuticals or radiation from teletherapy or brachytherapy sources. These records shall contain the names of all individuals involved in the event (including the physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number, a brief description of the event, the effect on the patient, and the action taken to prevent recurrence. These records shall be preserved until the Agency authorizes their disposition.~~

~~F. Use of sealed sources in industrial radiography. In addition to the requirements set forth in R12-1-309, a specific license for use of sealed sources in industrial radiography will be issued only if:~~

~~1. The applicant provides an adequate program for training radiographers and radiographer's assistants and submits to the Agency a schedule or description of such program which specifies the:~~

~~a. initial training,~~

~~b. periodic training;~~
~~c. on-the-job training;~~
~~d. means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with the Agency regulations and licensing requirements, and the operating and emergency procedures of the applicant, and~~
~~e. means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant;~~

~~2. The applicant has established and submits to the Agency satisfactory written operating and emergency procedures as needed to fulfill the requirements of Article 5 of these Regulations;~~

~~3. The applicant will have an internal inspection system adequate to assure that Agency regulations, Agency license provisions, and the applicant's operating and emergency procedures are followed by radiographers and radiographer's assistants. The inspection system shall include the performance of internal inspections at intervals not to exceed three months and the retention of records of such inspections for two years;~~

~~4. The applicant submits to the Agency a description of the overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and the responsibility for operation of the program;~~

~~5. The applicant who desires to conduct his own leak tests has established adequate procedures to be followed in leak testing sealed sources for possible leakage and contamination and submits to the Agency a description of such procedures including:~~
~~a. Instrumentation to be used,~~
~~b. Method of performing tests, e.g., points on equipment to be smeared and method of taking smear, and~~
~~c. Pertinent experience of the person who will perform the test; and~~

~~6. The applicant complies with appropriate provisions of Article 5.~~

~~C.~~A. The Agency shall issue 3 ~~three~~ classes of academic and industrial broad scope licenses, and only a single class A medical broad scope license.

1. A license is a broad scope class A license if it:
   a. Contains the exact wording "Any radioactive material with an Atomic Number 3 through 83" or "Any radioactive material with an Atomic Number ~~Numbers~~ 84 through 92" in License Item 6, and
   b. Contains the word "any" to authorize the chemical or physical form of the ~~those~~ materials in License Item 7.

   The license may authorize the radioactive materials in multi-curie quantities, and may authorize other radioactive materials and forms in addition to those listed in subsection (A)(1)(a) ~~the above~~.
2. A broad scope class B license is any specific license which authorizes the possession and use of the radioactive materials specified in Exhibit C ~~Schedule D~~ of 12 A.A.C. 1, Article 3 in any chemical or physical form and in quantities determined as follows:
   a. The possession limit, if only one radionuclide is possessed, is the quantity specified for that radionuclide in Exhibit C ~~Schedule D~~, Column I, or
   b. If 2 ~~two~~ or more radionuclides are possessed, the ratio of the quantity possessed the Agency shall determine to the applicable quantity specified in Exhibit C ~~Schedule D~~, Column I, for each ~~that~~ radionuclide ~~shall be determined~~. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.
3. A broad scope class C license is any specific license authorizing the possession and use of the radioactive materials specified in Exhibit C ~~Schedule D~~ of 12 A.A.C. 1, Article 3 in any chemical or physical form and in quantities determined as follows:
   a. The possession limit, if only one radionuclide is possessed, is the quantity specified for that radionuclide in Exhibit C ~~Schedule D~~, Column II, or
   b. If 2 ~~two~~ or more radionuclides are possessed, the ratio of the quantity possessed to the Agency shall determine the applicable quantity specified in Exhibit C ~~Schedule D~~, Column II, for each ~~that~~ radionuclide ~~shall be determined~~. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

B. The Agency shall approve:

41. An application for a class A broad scope license ~~will be approved~~ if:
   a. The ~~the~~ applicant satisfies the general requirements specified in R12-1-309; ~~;~~
   b. The ~~the~~ applicant has engaged in a reasonable number of activities involving the use of radioactive material. ~~(~~For purposes of this subsection, the requirement of "reasonable number of activities" can be satisfied by showing that the applicant has 5 years of ~~five years'~~ experience in the use of radioactive material. The Agency may accept less ~~Less~~ than 5 years of ~~five years'~~ experience ~~may be acceptable~~ if the applicant's qualifications are ~~described in the application appear to be~~ adequate for the scope of the proposed license; ~~),~~ and
   c. The ~~the~~ applicant has established administrative controls and provisions relating to organization, ~~and~~ management, procedures, record keeping, material control, ~~and~~ accounting, and management review that are necessary to assure safe operations, including:
      i. Establishment ~~the establishment~~ of a radiation safety committee composed of ~~such persons as~~ a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material; ~~;~~
      ii. Appointment ~~the appointment~~ of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; ~~;~~ and
      iii. Establishment ~~the establishment~~ of appropriate administrative procedures to assure:
         ~~(1).~~ Control ~~control~~ of procurement and use of radioactive material; ~~;~~
         ~~(2).~~ Completion ~~completion~~ of safety evaluations of proposed uses of radioactive material which take into consideration matters such ~~such matters~~ as the adequacy of facilities and equipment, training and experience of the user, ~~and the~~

operating or handling procedures; ; and

~~(3).~~ Review ~~review~~, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with ~~R12-1-310(G)(4)(c)(iii)(2)~~ this subsection prior to use of the radioactive material.

~~5~~2. An application for a class B broad scope license ~~will be approved~~ if:

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

b. The ~~the~~ applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control, and accounting, and management review that are necessary to assure safe operations, including:

i. Appointment ~~the appointment~~ of a radiation safety officer who is qualified by training and experience in radiation protection, and ~~who is~~ available for advice and assistance on radiation safety matters; ; and

ii. Establishment ~~the establishment~~ of appropriate administrative procedures to assure:

~~(1)~~ Control ~~control~~ of procurement and use of radioactive material; ;

~~(2)~~ Completion ~~completion~~ of safety evaluations of proposed uses of radioactive material which take into consideration matters such ~~such matters~~ as the adequacy of facilities and equipment, training and experience of the user, and the operating or ~~of~~ handling procedures; ; and

~~(3)~~ Review ~~review~~, approval, and recording by the radiation safety officer of safety evaluations of proposed uses prepared according ~~in accordance~~ with ~~R12-1-310(G)(5)(b)(ii)(2)~~ subsection (B)(2)(b)(ii) ~~above~~ prior to use of the radioactive material.

~~6~~3. An application for a class C broad scope license ~~will be approved~~ if:

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

b. The ~~the~~ applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

i. A ~~a~~ college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering; ; and

ii. At ~~at~~ least 40 hours of training and experience in the safe handling of radioactive material, and ~~in~~ the characteristics of ionizing radiation, units of ~~radiation~~ dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; ; and

c. The ~~the~~ applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

~~7~~C. Unless specifically authorized, broad-scope licensees shall not: ~~Broad scope licenses are subject to the following conditions:~~

~~a. Unless specifically authorized, persons licensed pursuant to R12-1-310(G)~~

~~i~~1. Conduct ~~conduct~~ tracer studies in the environment involving direct release of radioactive material; ;

~~ii~~2. Acquire ~~acquire~~, receive, possess, use, or transfer devices containing 3.7 petabecquerel(100,000 curies) ~~(3.7 petabecquerel)~~ or more of radioactive material in sealed sources used for irradiation of materials; ;

~~iii~~3. Conduct ~~conduct~~ activities for which a specific license is issued ~~by the Agency is required~~ under ~~any other Paragraph of R12-1-310 or~~ R12-1-311, and 12 A.A.C. 1, Articles 5, 7, or 17; ~~is required,~~ or

~~iv~~4. Add ~~add~~ or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

~~b~~D. ~~Each class A broad scope license issued under this section shall be subject to the condition that radioactive~~ Radioactive material possessed under the class A broad scope license shall ~~may~~ only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

~~c~~E. ~~Each class B broad scope license issued under this section shall be subject to the condition that radioactive~~ Radioactive material possessed under the class B broad scope license shall ~~may~~ only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety officer.

~~d~~F. ~~Each class C broad scope license issued under this section shall be subject to the condition that radioactive~~ Radioactive material possessed under the class C broad scope license shall ~~may~~ only be used by, or under the direct supervision of, individuals who satisfy the requirements of R12-1-310(B)(3((b) ~~R12-1-310(G)(6)(b)~~.

~~H. Measuring, gauging and controlling devices under specific licensure (Reserved)~~

~~I. Consultants (Reserved)~~

~~J. Uranium milling operations (Reserved)~~

~~R12-1-312~~ R12-1-311. Special Requirements for a Specific License to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices Which Contain Radioactive Material

A. Licensing the introduction of radioactive material into products in exempt concentrations.

1. In addition to the requirements set forth in R12-1-309, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another, to be transferred to persons exempt under R12-1-303(A)(1), shall be issued if: ~~R12-1-303.A.1. may be issued only if:~~

a. No change.

b. The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Exhibit A; ~~Schedule A, that~~ reconcentration of the radioactive material in concentrations exceeding those in Exhibit ~~Schedule~~ A is not likely; ~~, that~~ use of lower concentrations is not feasible; ; and ~~that the~~ product or material is not likely to be incorporated in any food, beverage, cosmetic, drug, or

other commodity or product designed for ingestion or inhalation by, or application to, a human being.

2. Each person licensed under ~~R12-1-311.A.~~ this subsection shall file an annual report with the Agency which identifies ~~shall identify~~ 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 ~~such~~ 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 ~~pursuant to R12-1-311.A.~~ during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and ~~shall~~ be filed within 30 days after June 30 ~~thereafter~~.

B. Licensing the distribution of naturally occurring and accelerator-produced radioactive material (NARM) in exempt quantities

1. An application for a specific license to distribute NARM to persons exempted from these rules according ~~Regulations pursuant~~ to R12-1-303.~~C.~~(C) will be approved if the applicant satisfies the requirements ~~requirement~~ of R12-1-309, and:
   a. No change.
   b. No change.
   c. The applicant submits copies of prototype labels and brochures and the Agency approves the ~~such~~ labels and brochures.
2. The license issued under ~~R12-1-311.B.1.~~ subsection (B)(1) is subject to the following conditions:
   a. No change.
   b. Each exempt quantity shall be separately and individually packaged. No more than 10 ~~such~~ packaged exempt quantities shall be contained in any outer package for transfer to persons exempt according to ~~pursuant to~~ R12-1-303.~~C.~~(C). The outer package shall be such that the dose rate at the external surface of the package does not exceed 5 µSv (0.5 millirem) per hour ~~(5 u Sv/hr)~~.
   c. No change.
      i. No change.
      ii. No change.
   d. In addition to the labeling information required by ~~R12-1-311 B.2.c.~~ subsection (B)(2)(c), the label affixed to the immediate container, or an accompanying brochure, shall
      i. No change.
      ii. No change.
      iii. No change.
3. Each person licensed under ~~R12-1-311.B.~~ 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.~~(C) or the equivalent regulations of a Licensing State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred 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 ~~thirty (30) days thereafter~~. If no transfers of radioactive material have been made according to ~~pursuant to R12-1-311.~~B. this subsection during the reporting period, the report shall so indicate.

C. The Agency shall approve an ~~Licensing the incorporation of NARM into gas and aerosol detectors. An~~ application for a specific license authorizing the incorporation of radioactive material other than source or by-product material, into gas and aerosol detectors to be distributed to persons exempt under R12-1-303(B) ~~R12-1-303.B will be approved~~ if the application satisfies requirements equivalent to those contained in ~~Section 32.26 of~~ 10 CFR ~~Part~~ 32.26 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of the Secretary of State which shall not contain any future editions or references, and provided:

1. The applicant satisfies the requirements of R12-1-309.
2. The licensee files annual reports ~~Annual reports as~~ required by ~~Section 32.29 of~~ 10 CFR ~~Part~~ 32.29, 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of the Secretary of State, ~~shall be filed~~ with the Agency. This incorporation by reference contains no future editions or references.

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

1. The Agency shall approve an ~~An~~ application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under R12-1-306.~~B.~~(B) or equivalent Regulations of the U.S. NRC, ~~or~~ an Agreement State, ~~will~~ or the Licensing State ~~will be approved~~ if:
   a. The ~~the~~ applicant satisfies the general requirements of R12-1-309,
   b. The ~~the~~ applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:
      i. The ~~the~~ device can be safely operated by persons not having training in radiological protection;
      ii. Under ~~under~~ ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive ~~in any period of one calendar quarter~~ a dose in excess of 10% of the limits specified ~~in the table of R12-1-402.A.~~ in R12-1-408; and
      iii. Under ~~under~~ accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

-Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye .....150 mSv(15 rem) ~~(150 m Sv)~~

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

-Other organs ..... 500 mSv (50

rem) ~~(500 m Sv)~~

c. No change.
   i. No change.
   ii. The requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for the ~~such~~ testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and
   iii. The information called for in one of the following statements in the same or substantially similar form:
      ~~(1)~~ 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)
      ~~(2)~~ 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. No change.

2. In the event the applicant desires that the device undergo mandatory testing ~~be required to be tested~~ at intervals longer than 6 months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, the application shall contain sufficient information to demonstrate that the ~~such~~ longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Agency shall ~~will~~ consider information which includes, but is not limited to:
   a. No change.
   b. No change.
   c. No change.
   d. No change.
   e. No change.
   f. Maximum temperature withstood during prototype tests ~~test~~;
   g. No change.
   h. No change.
   I. No change.
   j. No change.
3. In the event the applicant desires that the general licensee under R12-1-306.Be), or under equivalent Regulations of the NRC or an Agreement State or Licensing State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the application shall include written instructions to be followed by the general licensee, estimated calendar quarter doses associated with the ~~such~~ activity or activities, and bases for the ~~such~~ estimates. The submitted information shall demonstrate that performance of the ~~such~~ activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a ~~calendar quarter~~ dose in excess of 10% of the limits specified in ~~the table in R12-1-402.A.~~R12-1-408.
4. Each person licensed under ~~R12-1-311.D.~~ subsection D to distribute devices to general licensed persons shall:
   a. Furnish a copy of the general license contained in R12-1-306.~~B.~~(B) to each person to whom the individual directly or through an intermediate person transfers radioactive material in a device for use according to ~~pursuant to~~ the general license contained in R12-1-306.~~B.~~(B).
   b. Furnish a copy of the general license contained in the NRC or Agreement State's or Licensing State's regulation ~~Regulation~~ equivalent to R12-1-306.~~B.~~(B), or alternatively, furnish a copy of the general license contained in R12-1-306.~~B.~~(B) to each person to whom the individual, ~~he~~ directly or through an intermediate person transfers radioactive material in a device for use according to ~~pursuant to~~ the general license of the NRC, ~~or the~~ Agreement State, or Licensing State. If a copy of the general license in R12-1-306.~~B.~~(B) is furnished to ~~such~~ a person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. NRC, ~~or~~ Agreement State, or Licensing State under requirements substantially the same as those in R12-1-306.~~B.~~(B)
   c. Report to the Agency all transfers of ~~such~~ devices to persons for use under the general license in R12-1-306.~~B.~~(B). The ~~Such~~ report shall identify each general licensee by name and address, an individual by name or ~~andXor~~ position who serves as the contact person for ~~may constitute a point of contact between the Agency and~~ the general licensee, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall identify ~~include identification of~~ each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under R12-1-306.~~B.~~(B) during the report-

ing period, the report shall so indicate. The report shall cover each calendar quarter and ~~shall~~ be filed within 30 days after the end of the quarter ~~thereafter~~.

d. Report to the NRC all transfers of ~~such~~ devices to persons for use under the NRC general license in ~~Section 31.5 of~~ 10 CFR ~~Part~~ 31.5.

e. Report to the responsible Agreement State or Licensing State agency all transfers of ~~such~~ devices to persons for use under a general license in an Agreement State's regulation ~~Regulations~~ equivalent to R12-1-306.~~B.~~(B).

i. The ~~Such~~ reports shall identify each general licensee by name and address, an individual by name or ~~andXor~~ position who serves as the contact person for ~~may constitute a point of contact between the agency and~~ the general licensee, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall identify ~~include identification of~~ each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which ~~such~~ a device is transferred to the generally licensed person.

ii. No change.

iii. No change.

f. Keep records showing the name, address, and the ~~point of~~ contact person for each general licensee to whom the distributor ~~he~~ directly or through an intermediate person transfers radioactive material in devices for use according to ~~pursuant to~~ the general license provided in R12-1-306.~~B.~~(B), or equivalent Regulations of the NRC, ~~or~~ an Agreement State, or Licensing State. The records should show the date of each transfer, the isotope and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of this Section.

E. The Agency shall approve an ~~Special requirements for the manufacture, assembly, or repair of luminous safety devices for use in aircraft. An~~ application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under R12-1-306(C), if the applicant satisfies: ~~R12-1-306.C. will be approved subject to the following conditions:~~

1. The ~~applicant satisfies the~~ general requirements specified in R12-1-309; ~~;~~ and
2. The ~~applicant satisfies the~~ requirements of ~~Sections 32.53 through 32.56, and 32.101 of~~ 10 CFR ~~Part 32~~ 32.53 through 32.56 and 32.101, 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of Secretary of State, or their equivalent. These incorporations by reference contain no future editions or amendments.

F. The Agency shall approve an ~~Special requirements for license to manufacture calibration sources containing americium-241 or plutonium for distribution to persons generally licensed under R12-1-306(D). An~~ application for a specific license to manufacture calibration sources containing americium-241 or plutonium for distribution to persons generally licensed under R12-1-306.~~D.~~ (D) if the applicant satisfies: ~~will be approved subject to the following conditions:~~

1. The ~~applicant satisfies the~~ general requirements ~~requirement~~ of R12-1-309; ~~;~~ and
2. The ~~applicant satisfies the~~ requirements of 10 CFR 32.57, 32.58, 32.102, and 70.39, 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of Secretary of State, ~~Sections 32.57, 32.58, and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70~~ or their equivalent. These incorporations by reference contain no future editions or amendments.

G. ~~Manufacture and distribution of radioactive material for medical use under general license.~~ In addition to requirements set forth in R12-1-309, the agency shall issue a specific license authorizing the distribution of radioactive material for use by physicians under the general license in R12-1-306.~~E.~~(E) ~~will be issued~~ if:

1. The applicant submits evidence that the radioactive material is to be manufactured, labeled, and packaged under ~~in accordance with~~ a new drug application which the Commissioner of Food and Drugs, U.S. Food and Drug Administration has approved, or according to ~~in accordance with~~ a license for a biologic product issued by the FDA; and
2. No change.
   a. No change.
   b. No change.

H. The Agency shall approve an ~~Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license. An~~ application for a specific license to manufacture or distribute radioactive material for use under the general license of R12-1-306.~~F.~~(F) ~~will be approved~~ if:

1. The applicant satisfies the general requirements specified in R12-1-309.
2. The radioactive material is to be prepared for distribution in prepackaged units of:
   a. Iodine-125 in units not exceeding 370 kBq (10 microcuries) ~~(370 k Bq)~~ each;
   b. Iodine-131 in units not exceeding 370 kBq (10 microcuries) ~~(370 k Bq)~~ each;
   c. Carbon-14 in units not exceeding 370 kBq (10 microcuries) ~~(370 k Bq)~~ each;
   d. Hydrogen-3 (tritium) in units not exceeding 1.85 MBq (50 microcuries) ~~(1.85 M Bq)~~ each;
   e. Iron-59 in units not exceeding 740 kBq (20 microcuries) ~~(740 k Bq)~~ each;
   f. Cobalt-57 in units not exceeding 370 kBq (10 microcuries) ~~(370 k Bq)~~ each;
   g. Mock iodine-125 in units not exceeding 1.85 kBq (50 nanocuries) ~~(1.85 k Bq)~~ of iodine-129 and 185 Bq (5 nanocuries) ~~(185 Bq)~~ of americium-241 each.
3. Each prepackaged unit bears a durable, clearly visible label:
   a. Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 370 kBq (10 microcuries) ~~(370 k Bq)~~ of iodine-125, iodine-131, cobalt-57 or carbon-14; 1.85 MBq (50 microcuries) ~~(1.85 M Bq)~~ of hydrogen-3 (tritium), 740 kBq (20 microcuries) ~~(740 k Bq)~~ of iron-59; or

mock iodine-125 in units not exceeding 1.85 kBq (50 nanocurie) ~~(1.85 k Bq)~~ of iodine-129 and 185 Bq (5 nanocuries) ~~0.005 microcurie~~ of americium-241 each; and

b. Displaying the radiation caution symbol described in R12-1-428, ~~R12-1-411.A.1. and~~ the words, "CAUTION, RADIOACTIVE MATERIAL", and the phrase "Not for Internal or External Use in Humans or Animals".

4. No change.

a. This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories, or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation from the radioactive material ~~therefrom~~, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of manufacturer

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

_____
Name of manufacturer

5. The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information about ~~as to~~ the precautions to be observed in handling and storing the specified ~~such~~ radioactive material. In the case of the mock iodine-125 reference or calibration source, the information accompanying the source shall also contain directions to the licensee regarding the waste disposal requirements set out in R12-1-434. ~~R12-1-416 of these Regulations.~~

I. The Agency shall approve an ~~Licensing the manufacture and distribution of ice detection devices. An~~ application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under R12-1-306(G) if the applicant satisfies: ~~will be approved subject to the following conditions:~~

1. the ~~applicant satisfies the~~ general requirements of R12-1-309; ~~;~~ and
2. The ~~the~~ criteria of ~~Sections 32.61, 32.62, and 32.101 of 10 CFR Part 32~~ 10CFR 32.61, 32.62, ans 32.101, 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of the Secretary of State. ~~are met~~. These incorporations by reference contain no future editions or amendments.

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

1. The Agency shall approve an ~~An~~ application for a specific license to manufacture and distribute radiopharmaceuticals ~~containing radioactive material~~ for use by persons licensed under ~~pursuant to R12-1-310.C. for the uses listed in Group I, II, IV or V of Schedule C of this Article~~ 12 A.A.C. 1, Article 7 ~~will be approved~~ if:

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

b. The applicant submits evidence that:

i. The radiopharmaceutical ~~containing radioactive material~~ will be manufactured, labeled, and packed according to ~~in accordance with~~ the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, ~~such~~ as 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. No change.

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 ~~pursuant to R12-1-310.C. and Schedule C, Group I, Group II, Group IV or Group V, as~~ the requirements in 12 A.A.C. 1, Article 7 or an equivalent license ~~or under equivalent licenses~~ of the U.S. Nuclear Regulatory Commission or an Agreement State or Licensing State. The labels, leaflets, or brochures required by this paragraph supplement ~~are in addition to~~ the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, ~~may be~~ combined with the labeling required by FDA.

2. A radiopharmaceutical dispensed from a nuclear pharmacy according to A.R.S. §32-1904 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.

K. The Agency shall approve an ~~Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing radioactive material. An~~ application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed according to ~~pursuant to R12-1-310.C. for the uses listed in Group III of Schedule C of this~~ 12 A.A.C. 1, Article 7 ~~will be approved~~ if:

1. The applicant satisfies the general requirements of ~~specified in~~ R12-1-309;
2. The applicant submits evidence that:

a. The generator or reagent kit is to be manufactured, labeled and packaged according to ~~in accordance with~~ the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug

Administration (FDA), a biologic 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

b. The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act.

3. The applicant submits information on the radionuclide; ~~,~~ chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;
4. The label affixed to the generator or reagent kit contains information on the radionuclide, including quantity, and date of assay; and.
5. No change.
   a. No change.
   b. A statement that this generator or reagent kit (as appropriate) is approved for use by persons licensed by the Agency under ~~pursuant to R12-1-310.C. and Schedule C Group III of Article 3~~ 12 A.A.C. 1, Article 7 or ~~under~~ equivalent licenses of the U.S. Nuclear Regulatory Commission or an Agreement State or Licensing State. The labels, leaflets, or brochures required by this subsection supplement ~~are in addition~~ to the labeling required by FDA and they may be separate from or, with the approval of FDA, ~~may be~~ combined with the labeling required by FDA.

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

1. The Agency shall approve an ~~An~~ application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed under ~~pursuant to R12-1-310.C.~~ 12 A.A.C. 1, Article 7 for use as a calibration or reference source or for certain medical uses as sealed sources ~~may be approved~~ if:
   a. The applicant satisfies the general requirements in R12-1-309 ~~of this Article~~;
   b. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of ~~the~~ radiation safety, including:
      i No change.
      ii. No change.
      iii. No change.
      iv. No change.
      v. No change.
      vi. No change.
      vii. No change.
      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 ~~such~~ 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 ~~pursuant to R12-1-310.C.~~ 12 A.A.C. 1, Article 7 or ~~under~~ equivalent licenses of the U.S. Nuclear Regulatory Commission or an Agreement State or a Licensing State, provided~~, that such~~ 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 ~~be required to be tested~~ 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 ~~will~~ consider information that includes, but is not limited to:
   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.

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

1. The Agency shall approve an ~~An~~ application for a specific license to manufacture industrial products and devices containing depleted uranium for use under ~~pursuant to~~ R12-1-305(C) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State ~~may be approved~~ if:
   a. The applicant satisfies the general requirements ~~specified~~ in R12-1-309;
   b. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive ~~in any period of one calendar quarter~~ a radiation dose in excess of 10 percent of the limits specified in R12-1-408 ~~R12-1-402.A~~.
   c. No change.
2. In the case of an industrial product or device whose unique benefits are questionable, the Agency shall ~~will~~ approve an application for a specific license under this paragraph only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.
3. The Agency may deny any application for a specific license under this subsection if the end use(s) of the

industrial product or device cannot be reasonably foreseen ~~fore seen~~.

4. Each person licensed ~~pursuant to R12-1-311.M.1.~~under subsection (M)(1) shall:
   a. Maintain the level of quality control required by the license in the manufacture of the industrial product or device and ~~, and in~~ the installation of the depleted uranium into the product or device;
   b. Label or mark each unit to:
      i. Identify ~~identify~~ the manufacturer of the product or device, ~~and~~ the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and
      ii. State ~~state~~ that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or ~~of~~ an Agreement State;
   c. Assure that the depleted uranium, before being installed in each product or device, has been impressed with the following legend, clearly legible through any plating or other covering: "Depleted Uranium";
   d. Furnish a copy of the general license contained in R12-1-305(C) and a copy of ARRA-23 ~~ARRA-13~~ to each person to whom ~~he transfers~~ depleted uranium in a product or device is transferred for use under a ~~pursuant to the~~ general license contained in R12-1-305(C); or ~~or;~~
   e. Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to R12-1-305(C) and a copy of the U.S. Nuclear Regulatory Commission's or Agreement State's certificate, or alternatively, furnish a copy of the general license contained in R12-1-305(C) and a copy of ARRA-23 ~~ARRA-13~~ to each person to whom ~~he transfers~~ depleted uranium in a product or device is transferred for use under a ~~pursuant to the~~ general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a document ~~note~~ explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in R12-1-305(C);
   f. Report to the Agency all transfers of industrial products or devices to persons for use under the general license in R12-1-305(C). The ~~Such~~ report shall identify each general licensee by name and address, an individual by name or position who serves as the ~~may~~ constitute a point of contact person for ~~between the Agency and~~ the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which ~~such~~ a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under R12-1-305.~~C.~~ (C) during the reporting period, the report shall so indicate;
   i. Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in ~~Section 40.25 of~~ 10 CFR ~~Part~~ 40.25; or
   ii. Report ~~report~~ to the responsible State agency all transfers of devices manufactured and distributed under subsection (M)(4)(f) ~~pursuant to this paragraph~~ for use under a general license in that state's regulations equivalent to R12-1-305(C); ~~;~~
   iii. the report required in subsection (M)(4)(f)(i) or (ii) ~~(f). or (ii).~~ ~~above~~ shall identify each general licensee by name and address, an individual by name or ~~andXor~~ position who serves as the ~~may constitute a point of~~ contact person for ~~between the agency and~~ the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which a ~~such~~ product or device is transferred to the generally licensed person; ~~;~~
   iv. No change.
   v. No change.
   vi. Keep records showing the name, address, and point of contact person for each general licensee to whom ~~he transfers~~ depleted uranium in industrial products or devices is transferred for use under a ~~pursuant to the~~ 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 years and ~~shall~~ show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the reporting ~~report~~ requirements of this Section.

~~R12-1-313~~ R12-1-312. Issuance of Specific Licenses

A. Upon a determination that an application meets the requirements of the Act and the rules ~~regulations~~ of the Agency, the Agency shall ~~will~~ issue a specific license authorizing the proposed activity containing conditions and limitations as it deems appropriate or necessary.

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

C. ~~Prelicensing inspection.~~ The Agency may verify information contained in an application ~~applications~~ and secure additional information ~~deemed~~ necessary to make a ~~reasonable~~ determination on issuance of ~~as to whether to issue~~ a license and whether any special conditions should be attached to the license. The Agency may inspect ~~thereto by visiting~~ the facility or location where radioactive materials would be pos-

sessed or used, and discuss ~~by discussing~~ details of the proposed possession or use of the radioactive materials with the applicant or representatives designated by the applicant.

~~R12-1-314~~ R12-1-313. Specific Terms and Conditions of Licenses

A. Each license issued under ~~pursuant to~~ this Article is ~~shall be~~ subject to all provisions of A.R.S. Title 30, Chapter 4 ~~the Act, now or hereafter in effect~~, and to all rules, ~~regulations,~~ and orders of the Agency.

B. A licensee shall not transfer, assign, or in any manner dispose of a ~~No~~ license issued or granted under this Article or a ~~and no~~ right to possess or utilize radioactive material granted by any license issued under ~~pursuant to~~ this Article ~~shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person~~ unless the Agency shall, after securing full information, finds ~~find~~ that the transfer is consistent with the Agency's statutes and rules, and gives ~~in accordance with the provisions of the Act, and shall give~~ its consent in writing.

C. Each person licensed by the Agency under ~~pursuant to~~ this Article shall confine the use and possession of the material licensed to the locations and purposes authorized in the license.

D. No change.

E. No change.

1. No change.
   a. No change.
   b. No change.
   c. No change.
2. No change.
   a. No change
   b. No change.
   c. The date ~~of the filing of~~ the petition was filed.

~~R12-1-315~~ R12-1-314. Expiration of License ~~Licenses~~

Except as provided in R12-1-315(B), each specific license expires ~~shall expire~~ at the end of the day, in the month and year stated on the license ~~therein~~.

~~R12-1-316~~ R12-1-315. Renewal of License

A. An applicant shall file an application ~~Applications~~ for renewal of a specific license ~~licenses shall be filed~~ according to ~~in accordance with~~ 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 ~~shall~~ not expire until a final determination ~~the application has been finally determined~~ by the Agency.

~~R12-1-317~~ R12-1-316. Amendment of Licenses at Request of Licensee

An applicant shall file an application ~~Applications~~ for amendment of a specific license ~~shall be filed~~ by complying with ~~in accordance with~~ R12-1-308 and specifying ~~shall specify the respects in which the licensee desires the license to be amended and~~ the grounds for the amendment.

~~R12-1-318~~ R12-1-317. ARRA Action on Applications to Renew or Amend

In considering an application by a licensee to renew or amend a specific ~~the~~ license, the Agency shall ~~will~~ apply the criteria set forth in R12-1-309, ~~and~~ R12-1-310, or R12-1-311 as applicable.

~~R12-1-319~~ R12-1-318. Transfer of Radioactive Material

A. A licensee shall not ~~No licensee shall~~ transfer radioactive material except as authorized under ~~pursuant to~~ this Section.

B. Except as otherwise provided in the license and subject to the provisions of ~~R12-1-318.C. and~~ D. subsections (C) and (D), any licensee may transfer radioactive material:

1. To the Agency; ~~only~~ after receiving prior approval from the Agency;
2. No change.
3. To any person exempt from the rules ~~regulations~~ in this Article to the extent permitted under the ~~such~~ exemption;
4. To any person authorized to receive radioactive ~~such~~ material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Agency, the U.S. Nuclear Regulatory Commission, or any Agreement State or Licensing State, or to any person otherwise authorized to receive radioactive ~~such~~ material by the Federal Government or any agency of the Federal Government ~~thereof~~, the Agency, any Agreement State or Licensing State, or
5. No change.

C. No change.

D. The transferor shall use one or more of the following methods for the verification required by ~~R12-1-318.C.~~ subsection (C) are acceptable:

1. The transferor shall possess ~~may have in possession~~, and read, a current copy of the transferee's specific license or registration certificate;
2. The transferor shall possess ~~may have in possession~~ a written certification by the transferee that the transferee ~~he~~ is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;
3. For emergency shipments the transferor shall ~~may~~ accept oral certification by the transferee that the transferee ~~he~~ is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided~~, that~~ the oral certification is confirmed in writing within ten days;
4. The transferor shall ~~may~~ obtain information equivalent that in subsection (D)(1) to (3) ~~other sources of information~~ compiled by a reporting service from official records of the Agency, the U.S. Nuclear Regulatory Commission, or the licensing agency of an Agreement State or Licensing State regarding ~~as to~~ the identity of any licensee, ~~of licensees~~ and the scope and expiration date of any license, registration, or certificate ~~dates of licenses and registration~~; or
5. When none of the methods of verification described in ~~R12-1-318.D.1. to 4.~~subsections (D) (1) to (4) are readily available or when a transferor desires to verify that information received by one of the above ~~such~~ methods is correct or up-to-date, the transferor shall ~~may~~ obtain and record confirmation from the Agency, the U.S. Nuclear Regulatory Commission, or the licensing agency of an Agreement State or Licensing State that the transferee is licensed to receive the radioactive material.

E. A transferor shall prepare and ~~Preparation for shipment and~~ transport ~~of~~ radioactive material ~~shall be~~ as prescribed in ~~in accordance with~~ the provisions of 12 A.A.C. 1, Article 15 ~~of this Chapter~~.

~~R12-1-320~~ R12-1-319. Modification, Revocation, and Termination of Licenses

A. The terms and conditions of all licenses are ~~shall be~~ subject to amendment, revision, or modification ~~or the~~ license may be suspended or revoked by reason of amendments to the Agency's statutes ~~Act, or by reason of~~ rules~~, regulations,~~ and orders issued by the Agency.

B. The Agency may revoke, suspend, or modify any ~~Any~~ license ~~may be revoked, suspended, or modified~~, in whole or in part, for any material false statement in the application; ~~or~~ any omission or misstatement ~~statement~~ of fact required by statute, rule, or order ~~under provisions of the Act~~, or because of conditions revealed by the ~~such~~ application or ~~statement of fact or~~ any report, record, or inspection or other means that ~~which~~ would cause ~~warrant~~ the Agency to refuse to grant a license; ~~or an original application,~~ or any ~~for~~ violation of~~, or failure to observe any of the~~ license terms and conditions, or the Agency's statutes, rules, or orders ~~of the Act, or of the license, or of any rule, regulation, or order of the Agency~~.

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 ~~no license shall be modified, suspended, or revoked~~ unless, prior to the institution of proceedings ~~therefor~~, facts or conduct which may warrant such action ~~shall~~ have been called to the attention of the licensee in writing and the licensee has ~~shall have~~ been accorded an opportunity to demonstrate or achieve compliance ~~with all lawful requirements~~.

D. The Agency may terminate a specific license upon written request ~~submitted~~ by the licensee ~~to the Agency in writing~~.

~~R12-1-321~~ R12-1-320. Reciprocal Recognition of Licenses ~~For Byproduct, Source and Special Nuclear Material (In Quantities Not Sufficient to Form a Critical Mass)~~

A. A general license is established by the Agency to perform specific licensed activities in Arizona for a period not to exceed 180 days in any calendar year to any ~~Subject to these Regulations, 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, ~~and issued by the agency~~ having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, ~~is hereby granted a general license to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any calendar year~~ provided that:

1. The license ~~licensing document~~ does not limit the activity ~~authorized by such document~~ to specified installations or locations;
2. The out-of-state licensee notifies the Agency in writing at least 3 ~~three (3)~~ days prior to engaging in the licensed ~~such~~ activity. The ~~Such~~ notification shall indicate the location, period, and type of proposed possession and use within the State, and ~~shall~~ be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3 ~~three (3)~~ 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 ~~the~~ receipt of the initial notification from a person engaging in activities under the general license provided in ~~R12-1-320~~ this Section;
3. The out-of-state licensee complies with all applicable statutes and rules ~~Regulations~~ of the Agency and with all the terms and conditions of the license, except those ~~any such~~ terms and conditions ~~which may be~~ inconsistent with applicable statutes and rules ~~Regulations~~ of the Agency;
4. The out-of-state licensee supplies any ~~such~~ other information ~~as~~ the Agency requests ~~may request~~; and
5. The out-of-state licensee does ~~shall~~ not transfer or dispose of radioactive material possessed or used under the general license provided in this Section except by transfer to a person:
   a. Specifically ~~specifically~~ licensed by the Agency, or by the U.S. Nuclear Regulatory Commission to receive the radioactive ~~such~~ material; ~~,~~ or
   b. Exempt ~~exempt from the requirements for a license for such material~~ under R12-1-303(A).

B. Notwithstanding the provisions of ~~R12-1-320.A~~ R12-1-320.A., a general license is established by the Agency 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, ~~is hereby granted a general license to install, transfer, demonstrate or service the such a device in this State~~ provided that:

1. The person files a report ~~Such person shall file a report~~ with the Agency within 30 ~~thirty (30)~~ days after the end of each calendar quarter in which any device is transferred to or installed in this State. Each ~~such~~ report shall identify the ~~each~~ general licensee to whom the ~~such~~ device is transferred by name and address, the type of device transferred and the quantity and type of radioactive material contained in the device;
2. The device has been manufactured, labeled, installed, and serviced according to ~~in accordance with~~ the applicable provisions of the specific license issued to the ~~such~~ person by the U.S. Nuclear Regulatory Commission or an Agreement State;
3. The person entering the state ensures ~~Such person~~ shall assure that any labels required to be affixed to the device under rules ~~Regulations~~ of the authority which licensed manufacture of the device bear the following statement: ~~a statement that~~ "Removal of this label is prohibited"; and
4. The holder of the specific license furnishes ~~shall furnish to each general licensee to whom the licensee transfers the device or on whose premises it is installed~~ a copy of the general license contained in R12-1-306(B), or equivalent rules of the Agency ~~regulations of the agency~~ having jurisdiction over the manufacture or distribution of the device, to each general licensee to whom the licensee transfers the device or on whose premises the device is installed.

C. The Agency may withdraw, limit, or qualify the acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed under ~~pursuant to~~ a license ~~such licensing document~~, upon deter-

mining that an ~~such~~ action is necessary ~~in order~~ to prevent undue hazard to public health and safety, or property.

~~D. Licenses for naturally occurring and accelerator-produced radioactive material.~~

~~1. Subject to this Chapter, any person who holds a specific license from any Licensing State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, shall be is hereby granted a general license to conduct the activities authorized in the license such licensing document within this state for a period not in excess of 180 days in any calendar year provided that:~~

~~a. The license licensing document does not limit the activity authorized by the such document to specified installations or locations;~~

~~b. the out-of-state licensee notifies the Agency in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3-day period would impose an undue hardship on the out-of-state licensee, he 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 the receipt of the initial notification from a person engaging in activities under the general license provided in R12-1-320;~~

~~c. The out-of-state licensee complies with all applicable regulations of the Agency and with all the terms and conditions of the his licensing document, except those any such terms and conditions which may be inconsistent with applicable regulations of the Agency;~~

~~d. the out-of-state licensee supplies any such other information as the Agency request may request; and~~

~~e. the out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in R12-1-320 except by transfer to a person:~~

~~i. Specifically licensed by the Agency or by another Licensing State to receive such material; , or~~

~~ii. exempt from the requirements for a license for radioactive such material under R12-1-303(A).~~

~~2. Notwithstanding the provisions of R12-1-320.D.1., any person who holds a specific license issued by a Licensing State authorizing the holder to manufacture, transfer, install, or service a device described in R12-1-306(B)(1) within areas subject to the jurisdiction of the licensing body, is hereby granted a general license to install, transfer, demonstrate or service such a device in this State provided that:~~

~~a. Such person shall file a report with the Agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;~~

~~b. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by a Licensing State;~~

~~c. Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and~~

~~d. The holder of the specific license to each general licensee to whom he transfers such device or on whose premises it is installed.~~

~~3. The Agency may withdraw, limit, or qualify the acceptance of any specific license or equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.~~

~~R12-1-322~~ R12-1-321. Preparation of Radioactive Material for Transport

A ~~No~~ 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~~ R12-1-322. The Need for an Emergency Plan for Response to a Release of Radioactive Material.

A. For purposes of this rule "Emergency Plan" means a procedure that will be followed when an accident occurs involving licensed radioactive materials for which responses by offsite response organizations, such as police, fire, and medical organizations, might be needed.

~~A.~~B. Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in Exhibit D, "Radioactive Material Quantities Requiring Consideration for an Emergency Plan" ~~Schedule E "Quantities of Radioactive Material Requiring Consideration of the Need for an Emergency Plan for Responding to a Release,"~~ shall contain either:

1. No change.
2. No change.

~~B.~~C. One or more of the following factors may be used to support an evaluation submitted under ~~Paragraph A.1.~~subsection (B)(1) ~~of this Section~~:

1. No change.
2. No change.
3. The release fraction in the respirable size range would be lower than the release fraction shown in Exhibit D ~~Schedule E.~~ due to the chemical or physical form of the material;
4. The solubility of the radioactive material would reduce the dose received;
5. Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Exhibit D ~~Schedule E.~~;
6. Operating restrictions or procedures would prevent a release fraction as large as that shown in Exhibit D ~~Schedule E.~~; or
7. No change.

~~C.~~D. An emergency plan for responding to a release of radioactive material submitted under ~~Paragraph A.2. of this Section~~ subsection (B)(2) shall include the following information:

1. ~~Facility description.~~ A brief description of the licensee's facility and areas near the site that could expose a member of the public to a dose equal to or greater than the levels expressed in ~~Paragraph A.1. of this Section~~ subsection (A)(1).
2. ~~Types of accidents.~~ An identification of each type of radioactive materials accident for which protective actions may be needed.
3. ~~Classification of accidents.~~ A classification system for classifying accidents as alerts or site area emergencies.
4. ~~Detection of accidents.~~ Identification of the means of detecting each type of accident in a timely manner.
5. ~~Mitigation of consequences.~~ A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers on-site, and a description of the program for maintaining the equipment.
6. ~~Assessment of releases.~~ A brief description of the methods and equipment used to assess releases of radioactive materials.
7. ~~Responsibilities.~~ A brief description of the responsibilities of licensee personnel responsible for promptly notifying offsite response organizations and the Agency; also responsibilities for developing, maintaining, and updating the plan.
8. ~~Notification and coordination.~~ A commitment to and a brief description of the means to promptly notify offsite response organizations and request off-site assistance, including medical assistance for the treatment of contaminated and injured injure on-site workers when appropriate. A control point shall be established. The notification and coordination shall be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the Agency immediately after notification of the appropriate off-site response organizations and not later than 1 ~~one~~ hour after the licensee declares an emergency.
9. ~~Information to be communicated.~~ A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to off-site response organizations and to the Agency.
10. ~~Training.~~ A brief description of the frequency, performance objectives, and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical, and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.
11. ~~Safe shutdown.~~ A brief description of the means of restoring the facility to a safe condition after an accident.
12. ~~Exercises.~~ Provisions for conducting quarterly communications checks with off-site response organizations and biennial on-site exercises to test response to simulated emergencies. Quarterly communications checks with off-site response organizations shall include the verifying and updating of all necessary telephone numbers. The licensee shall invite off-site response organizations to participate in the biennial exercises. Their participation is not required. Exercises shall use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise, using individuals without ~~not having~~ direct implementation responsibility for the plan. Critiques of exercises shall evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques shall be corrected.
13. ~~Hazardous chemicals.~~ A certification that the applicant has met its responsibilities in A.R.S. §§ 26-341 through 26-353 (emergency Planning and Community Right-to-Know Act of 1986), if applicable to the applicant's activities at the proposed place of use of the radioactive material.

~~D.~~**E.** No change.

R12-1-323. Financial Assurance and Record Keeping for Decommissioning

A. For purposes of this rule:
1. "Decommissioning" means to remove a radioactive material use facility safely from service and to reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the radioactive material use license.
2. "By-product material" as used in 10 CFR, 30, means "radioactive material" which is defined in A.R.S. §30-651.
3. "Facility" means the entire site of radioactive material use, or any separate building or outdoor area where it is used.
4. "Appendix B to Part 30" as used in 10, CFR, 30, means Appendix E in 12 A.A.C. 1, Article 4.
5. "Financial security" means having a net worth of not less than $10,000.

B. When applying, each nongovernment applicant for a specific license authorizing 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, shall submit to the Agency certification of financial security, as required in A.R.S. §30-672(H).
1. Each affected licensee shall submit certification of financial security no later than 3 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 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, shall submit to the Agency a decommissioning funding plan or certification of financial assurance meeting the requirements in 10 CFR Part30.35 or 40.36, 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of Secretary of State. This incorporation by reference contains no future editions or amendments. Each effected licensee shall submit the plan or certification no later than 3 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 shall maintain records of information important to the safe and effective decommissioning of the facility in an iden-

tified location until the license is terminated by the Agency. The licensee shall maintain the following records during the decommissioning process:

1. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, and site. The licensee shall keep records identifying the involved radionuclides and associated quantities, forms, and concentrations.
2. As-built drawings showing modifications of structures and equipment in restricted areas where radioactive materials are used and stored, and locations of possible inaccessible contamination. If drawings are not available, the licensee shall provide appropriate records describing each location of possible contamination.
3. Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

E. Decommissioning procedures:

1. Upon expiration or termination of licensed activities, a licensee shall begin decommissioning its facility within 60 days of notifying the Agency of the decision to discontinue licensed activities, or within 12 months of the decision, submit to the Agency a decommissioning plan, as prescribed in 10 CFR Part 30.36(g)(1), 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of Secretary of State, containing no future editions or amendments, and 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. In addition to the notification requirements in subsection (E)(1), the licensee shall maintain in effect all decommissioning financial assurances required by this Section. The financial assurances shall be increased or may be decreased as appropriate to cover the cost estimate established for decommissioning in subsection (E)(1).
   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. The Agency shall extend the time periods established in subsection (E)(1) if a new time period is in the best interest of public health and safety.
   a. The licensee shall submit the request for the change no later than 30 days before the notification time frame specified in subsection (E)(1).
   b. If appropriate, the schedule for decommissioning activities, specified in subsection (E)(1), shall not commence until the Agency has made a determination on the request described in subsection (E)(3)(a).
4. Except as provided in subsection (E)(5), the licensee shall complete decommissioning of a facility as soon as practicable but no later than 24 months following the initiation of decommissioning; and except as provided in subsection (E)(5), when decommissioning involves the entire facility, the licensee shall request license termination as soon as practicable but no later than 24 months following initiation of decommissioning.
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, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of Secretary of State, containing 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, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of Secretary of State, containing no future editions or amendments.

Exhibit A ~~Schedule A~~
Exempt Concentrations
No change.
Exhibit B ~~Schedule B~~
Exempt Quantities
No change.

~~Schedule C~~
~~Groups of Medical Uses of Radioactive Material~~

~~Group I. Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution and excretion. This group does not include uses involving imaging and tumor localizations.~~

~~1. Iodine-123~~
~~2. Iodine-125~~
~~3. Iodine-131~~
~~4. Cobalt-57~~
~~5. Cobalt-58~~
~~6. Cobalt-60~~
~~7. Chromium-51~~
~~8. Iron-59~~
~~9. Potassium-42~~
~~10. Sodium-24~~
~~11. Technetium-99m~~

~~The above radioactive materials shall be used in the form of radiopharmaceuticals for which a "new drug application" (N.A.) or a "notice of claimed investigational exemption for a new drug" (IND) has been issued or accepted by the Food and Drug Administration (FDA). The radioactive material may be used for any procedures specified in the product labeling (package insert). The above radioactive materials shall be procured in the form of prepackaged individual doses.~~

~~Group II. Use of prepared radiopharmaceuticals diagnostic studies imaging and tumor localizations.~~

~~1. Iodine-123~~
~~2. Iodine-125~~
~~3. Iodine-131~~
~~4. Selenium-75~~
~~5. Technetium-99m~~
~~6. Ytterbium-169~~
~~7. Indium-111~~
~~8. Indium-113m~~
~~9. Chromium-51~~
~~10. Fluorine-18~~
~~11. Gallium-67~~
~~12. Gold-198~~
~~13. Thallium-201~~

~~The above radioactive materials shall be acquired and used in the form of a prepared radiopharmaceutical for which a "new drug application" (N.A.) or a "notice of~~

~~claimed investigational exemption for a new drug" (IND) has been accepted by the Food and Drug Administration (FDA). The radioactive material may be used for any procedures specified in the product labeling (package insert).~~

~~Group III. Use of generators and reagent kits for the preparation and use of radiopharmaceuticals containing radioactive material for certain diagnostic uses.~~

~~1. Molybdenum-99/Technetium-99m generators~~
~~2. Tin-113/Indium-113m generators~~
~~3. Technetium-99m (in bulk)~~

~~The above radioactive materials shall be acquired and used in the form of a prepared radiopharmaceutical for which a "new drug application" (N.A.) or a "notice of claimed investigational exemption for a new drug" (IND) has been accepted by the Food and Drug Administration (FDA). The radioactive material may be used for any procedures specified in the product labeling (package insert).~~

~~Group IV. Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety.~~

~~1. Iodine-131, in quantities of less than 30 millicuries~~
~~2. Phosphorus-32~~

~~The above radioactive materials shall be used in a radiopharmaceutical for which an (N.A.) or an (IND) has been issued or accepted by the Food and Drug Administration (FDA).~~

~~Group V. Use of prepared radiopharmaceuticals for certain therapeutic procedures that normally require hospitalization for purposes of radiation safety according to protocols approved by FDA.~~

~~1. Iodine-131~~
~~2. Gold-198~~

~~The above radioactive materials shall be used in a radiopharmaceutical for which an (N.A.) or an (IND) has been issued or accepted by the Food and Drug Administration (FDA).~~

Exhibit C ~~Schedule D~~
Limits for Broad Licenses (R12-1-310.~~G.~~)

Radioactive Material	Col. I curies	Col. II curies	Radioactive Material	Col. I curie	Col. II curies
Antimony-122	1	0.01	Iodine-131	0.1	0.001
Antimony-124	1	0.01	Iodine-132	10	0.1
Antimony-125	1	0.01	Iodine-133	1	0.1
Arsenic-73	10	0.1	Iodine-134	10	0.1
Arsenic-74	1	0.01	Iodine-135	1	0.1
Arsenic-76	1	0.01	Iridium-192	1	0.1
Arsenic-77	10	0.1	Iridium-194	10	0.1
Barium-131	10	0.1	Iron-55	10	0.1
Barium-140	1	0.01	Iron-59	1	0.1
Beryllium-7	10	0.1	Krypton-85	100	1.
Bismuth-210	0.1	0.001	Krypton-87	10	0.1
Bromine-82	10	0.1	Lanthanum-140	1	0.1
Cadmium-109	1	0.01	Lutetium-177	10	0.1
Cadmium-115m	1	0.01	Manganese-52	1	0.1
Cadmium-115	10	0.1	Manganese-54	1	0.1
Calcium-45	1	0.01	Manganese-56	10	0.1
Calcium-47	10	0.1	Mercury-197m	10	0.1
Carbon-14	100	1.	Mercury-197	10	0.1
Cerium-141	10	0.1	Mercury-203	1	0.1
Cerium-143	10	0.1	Molybdenum-99	10	0.1
Cerium-144	0.1	0.001	Neodymium-147	10	0.1
Cesium-131	100	1.	Neodymium-149	10	0.1
Cesium-134m	100	1.	Nickel-59	10	0.1
Cesium-134	0.1	0.001	Nickel-63	1	0.1
Cesium-135	1	0.01	Nickel-65	10	0.1
Cesium-136	10	0.1	Niobium-93m	1	0.1
Cesium-137	0.1	0.001	Niobium-95	1	0.1
Chlorine-36	1	0.01	Niobium-97	100	1.
Chlorine-38	100	1.	Osmium-185	1	0.1
Chromium-51	100	1.	Osmium-191m	100	1.
Cobalt-57	10	0.1	Osmium-191	10	0.1
Cobalt-58m	100	1.	Osmium-193	10	0.1
Cobalt-58	1	0.01	Palladium-103	10	0.1
Cobalt-60	0.1	0.001	Palladium-109	10	0.1
Copper-64	10	0.1	Phosphorus-32	1	0.01
Dysprosium-165	100	1.	Platinum-191	10	0.1
Dysprosium-166	10	0.1	Platinum-193m	100	1.
Erbium-169	10	0.1	Platinum-193	10	0.1
Erbium-171	10	0.1	Platinum-197m	100	1.
Europium-152 (9.2 h)	10	0.1	Platinum-197	10	0.1
Europium-152 (13 yr)	0.1	0.001	Polonium-210	0.01	0.0001
Europium-154	0.1	0.001	Potassium-42	1	0.01
Europium-155	1	0.01	Praseodymium-142	10	0.1
Fluorine-18	100	1.	Praseodymium-143	10	0.1
Gadolinium-153	1	0.1	Promethium-147	1	00.1
Gadolinium-159	10	0.1	Promethium-149	10	0.1
Gallium-72	10	0.1	Radium-226	0.01	0.0001
Germanium-71	100	1.	Rhenium-186	10	0.1
Gold-198	10	0.1	Rhenium-188	10	0.1
Gold-199	10	0.1	Rhodium-103m	1,000	10
Hafnium-181	1	0.1	Rhodium-105	10	0.1
Holmium-166	10	0.1	Rubidium-86	1	0.01
Hydrogen-3	100	1.	Rubidium-87	1	0.01
Indium-113m	100	1.	Ruthenium-97	100	1.
Indium-114m	1	0.1	Ruthenium-103	1	0.01
Indium-115m	100	1.	Ruthenium-105	10	0.1
Indium-115	1	0.1	Ruthenium-106	0.1	0.001
Iodine-125	0.1	0.001	Samarium-151	1	0.01
Iodine-126	0.1	0.001	Samarium-153	10	0.1
Iodine-129	0.1	0.001	Scandium-46	1	0.01

Radioactive Material	Col. I curie	Col. II curies
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85	1,000	10
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulfur-35	100	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1.
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1.
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-197	10	0.1
Vanadium-43	1	0.01
Xenon-131m	1,000	10
Xenon-133	100	1.
Xenon-135	100	1.
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1.
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than source material special nuclear material, or alpha emitting radioactive material not listed above	0.1	0.001

Exhibit D ~~SCHEDULE~~ E
Radioactive Material Quantities Requiring Consideration for an Emergency Plan (~~R12-1-323~~ R12-1-322)

Radioactive Material	Release Fraction	Quantity (Ci)
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9 (20 mg)
Carbon-14	.01	50,000
	Non CO	
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Gadolinium-153	.01	5,000
Germanium-68	.01	2,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Indium-114m	.01	1,000
Iodine-125	.5	10
Iodine-131	.5	10
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment beta-gamma	.001	10,000
Irradiated material, any form other than solid non-combustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged ~~packaged~~ mixed waste, beta gamma	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha	.0001	20

Combinations of radioactive materials listed above:

For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios ~~rations~~ of the quantity of each radioactive material authorized to the quantity listed for that material in Exhibit D ~~Schedule E~~ exceeds 1 ~~one~~.

NOTE: Waste packaged in Type B containers does not require an emergency plan.

Exhibit E
Application Information

1. Radioactive Material (RAM) Specific License Application Information

An applicant shall provide the following information in a specific license application before a license is issued to the applicant. The Agency shall provide an application form to an applicant with a guide, when possible, to insure that correct information is provided in the application:

Name and mailing address of applicant	Use location
Contact person	Telephone number
Users of RAM	Training of users
Radiation Safety Officer identity (RSO)	Duties of RSO
Description of RAM and uses	Description of radiation detection/measurement instruments and their calibration
Personnel monitoring	Bioassay program
Facility description	Survey program
Leak test program	Records management program
Instruction to personnel	Waste disposal program
Emergency procedures	Procedures for ordering, receiving, and opening packages
Description of animal use	Licensing fee provided with application
Copy of letter-of-intent to local governing body	Description of ALARA and quality management programs
Description of transportation procedures	Certifying signature
Other licensing requirements listed in:	Legal structure of licensee's operation

R12-1-310, R12-1-311, R12-1-312, R12-1-511, R12-1-703, and R12-1-1721

2. Radioactive Material (RAM) General License Application Information

An applicant shall provide the following information on a registration certificate. The certificate will be validated and returned to the applicant if the information provided is complete.

Name and address	Telephone number
Where will the radioactive material be used	Address of use location
Description of radioactive material use	Date
Authorizing signature and printed name	Position of person signing the form

ARTICLE 4, STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

R12-1-407. Radiation Protection Programs

A. No change.
B. No change.
C. No change.
D. Records.
1. No change.
   a. No change.
   b. No change.
2. The licensee or registrant shall retain the records required by subsection ~~subparagraph~~ (D)(1)(a) above for 3 ~~three~~ years after the termination of the license or registration. The licensee or registrant shall retain the records required by subsection ~~subparagraph~~ (D)(1)(b) above for 3 ~~three~~ years after the record is made.
3. The following licensees and registrants are exempt from the record requirements contained in this subsection:

B6-General Medical	D15-Possession Only
C9-Gas Chromatograph	E2-X-ray Machine class B
C10-General Industrial	E3- X-ray Machine class C

R12-1-408. Occupational Dose Amounts for Adults

A. No change.
B. No change.
C. The assigned deep-dose equivalent and shallow-dose equivalent is, ~~shall be~~ for the portion of the body receiving the highest exposure, determined as follows:
1. No change.
2. When a protective apron is worn and monitoring is conducted as specified in R12-1-419(B) ~~R12-1-419(A)(4)~~, the effective dose equivalent for external radiation shall be determined as follows:
   a. When only one individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25% of the limit specified in R12-1-408(A), the reported deep-dose equivalent value multiplied by 0.3 is ~~shall be~~ the effective dose equivalent for external radiation; or
   b. When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation is ~~shall be~~ assigned the value of the sum of the deep-dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep-dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

D. No change.
E. No change.
F. The licensee or registrant shall reduce the dose that an individual may ~~be allowed to~~ receive in the current year by the amount of occupational dose received while employed occupationally as a radiation worker by all previous employers. See R12-1-412.

R12-1-409. ~~Compliance with Requirements for~~ Summation of External and Internal Doses

A. If the licensee or registrant is required to monitor according to ~~pursuant to~~ both R12-1-419(B) and (C) ~~R12-1-419(A) and (B)~~, the licensee or registrant shall add ~~demonstrate compliance with the dose limits by summing~~ external and internal doses, and use the sum to demonstrate compliance with dose limits. If the licensee or registrant is required to monitor only according ~~pursuant~~ to R12-1-419(B)~~(A)~~ or only ~~pursuant to~~ according to R12-1-419 (C) ~~R12-1-419 (B)~~, ~~then~~ summation is not required to demonstrate compliance with ~~the~~ dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of ~~e~~xternal and internal doses according ~~pursuant~~ to subsections (B), (C), and (D) ~~below~~. The dose equivalents for the lens of the eye, the skin,

and the extremities are not included in the summation but are subject to separate limits (See R12-1-408(A)(2)).

B. ~~Intake by inhalation.~~ If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep-dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity (one):
1. No change.
2. No change.
3. No change.

C. ~~Intake by oral ingestion.~~ If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10% of the applicable oral ALI, the licensee or registrant shall account for this intake and include it in demonstrating compliance with the limits.

D. ~~Intake through Wounds or Absorption through skin.~~ The licensee or registrant shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for Hydrogen-3 and does not need to be evaluated or accounted for pursuant to this subsection.

R12-1-411. Determination of Internal Exposure

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

B. No change.

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

D. If the licensee or registrant chooses to assess intakes of Class Y material using the measurements given in subsection ~~R12-1-411~~(A)(2) or (3), the licensee or registrant may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by R12-1-444 or R12-1-445. This delay permits the licensee or registrant to make additional measurements basic to the assessments.

E. If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours is ~~shall be~~ either:
1. No change.
2. No change.

F. If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture is ~~shall be~~ the most restrictive DAC of any radionuclide in the mixture.

G. When a mixture of radionuclides in air exists, a licensee or registrant may disregard certain radionuclides in the mixture if:
1. The licensee or registrant uses the total activity of the mixture to demonstrate ~~in demonstrating~~ compliance with the dose limits in R12-1-408 and to comply ~~in complying~~ with the monitoring requirements in R12-1-419 ~~R12-1-419(B)~~, and
2. No change.
3. No change.

H. No change.
1. No change.
2. For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.5 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B. The licensee or registrant may, as a sampling assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the licensee or registrant uses the stochastic ALI, the licensee or registrant shall also demonstrate that the limit in R12-1-408(A)(1)(b) ~~R12-1-406(A)(1)(b)~~ is met.

R12-1-415. Dose to an Embryo/Fetus

A. The licensee or registrant shall ensure that the dose to an embryo/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 ~~in accordance with~~ R12-1-419(D)(4) and (5) ~~R12-1-419(C)(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 ~~so as~~ to satisfy the limit in subsection (A) above.

C. The dose to an embryo/fetus shall be taken as the sum of:
1. No change.
2. The dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

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

R12-1-418. Surveys and Monitoring

A. Each licensee or registrant shall make, or cause to be made, surveys that are necessary:
1. For ~~Are necessary for~~ the licensee or registrant to comply with Article 4, and
2. Under ~~Are necessary under~~ the circumstances to evaluate:
   a. No change.
   b. No change.
   c. No change.

~~**B.** The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured.~~

B.~~C.~~ No change.
1. No change.
2. No change.

C.~~D.~~ No change.

D.~~E.~~ Records.
1. Each licensee or registrant shall maintain records showing the results of surveys ~~and calibrations~~ required by this Section and R12-1-433(B). The licensee or registrant shall retain these records for 3 ~~three~~ years after the record is made.
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. Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this Article. ~~As a minimum each licensee or registrant shall:~~

B. ~~1.~~ At a minimum each licensee or registrant ~~Monitor occupational exposure to radiation and~~ shall supply and require the use of individual monitoring devices by:

1. ~~a.~~ Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in R12-1-408(A);
2. ~~b.~~ Minors and declared pregnant women likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in R12-1-414 or R12-1-415;
3. ~~c.~~ Individuals entering a high or very high radiation area; and
4. ~~d.~~ Individuals working with open beam fluoroscopic systems capable of delivering a stray radiation dose in excess of 100μSv (10 mRem) in one hour at a distance of 20 cm (7.9 in.) from the scattering medium. The dosimeter shall be located on the person according to the following requirements: ~~Individuals working with medical fluoroscopic equipment.~~
   a. ~~i.~~ An individual monitoring device used for the dose to an embryo or / fetus of a declared pregnant woman, according to r12-1-415(A) ~~pursuant to R12-1-408 (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 ~~regulations~~, the value to be used for determining the dose to an embryo or / fetus according to ~~pursuant to~~ R12-1-415 (C)(1), for occupational exposure to radiation from medical fluoroscopic equipment is ~~shall be~~ 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 her work environment by a qualified expert.
   b. ~~ii.~~ An individual monitoring device used for eye dose equivalent shall be located at the neck, or an unshielded location closer to the eye, outside the protective apron.
   c. ~~iii.~~ When only one individual monitoring device is used to determine the effective dose equivalent for external radiation according to ~~pursuant to~~ R12-1-408 (C)(2), it shall be located at the neck outside the protective apron. When 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.).

C. ~~2.~~ At ~~As~~ a minimum, each licensee or registrant shall monitor, to determine compliance with R12-1-411, the occupational intake of radioactive material ~~by~~ and assess the committed effective dose equivalent to:

1. ~~a.~~ Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B; and
2. ~~b.~~ Minors and declared pregnant women likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.5 mSv (0.05 rem).

D. ~~3.~~ Records.

1. ~~a.~~ Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring is required according to ~~pursuant to~~ this Section, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before January 1, 1994, need not be changed. These records shall include, when applicable:
   a. ~~i.~~ The deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;
   b. ~~ii.~~ The estimated intake of radionuclides, see R12-1-409;
   c. ~~iii.~~ The committed effective dose equivalent assigned to the intake of radionuclides;
   d. ~~iv.~~ The specific information used to calculate the committed effective dose equivalent according to ~~pursuant to~~ R12-1-411 (C);
   e. ~~v.~~ The total effective dose equivalent when required by R12-1-409; and
   f. ~~vi.~~ The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.
2. ~~b.~~ The licensee or registrant shall make entries of the records specified in ~~Paragraph C. 1. subsection (D)(1) above~~, at intervals not to exceed 1 year.
3. ~~c.~~ The licensee or registrant shall maintain at the inspection site the records specified in ~~Paragraph C. 1.~~ subsection (D)(1) ~~above~~, on Agency Form Z (available from the Agency), in accordance with the instructions for Agency Form Z, or in clear and legible records containing all the information required by this subsection.
4. ~~d.~~ The licensee or registrant shall maintain the records of dose to an embryo or / fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.
5. ~~e.~~ The licensee or registrant shall retain each required form or record for 3 ~~three~~ years after the Agency terminates each pertinent license or registration requiring the record.

R12-1-442. Agency Inspection of Shipments of Waste

Each shipment of waste to a ~~licensed~~ disposal facility, licensed under R12-1-1302(D(11), is ~~shall be~~ subject to inspection by the Agency prior to shipment. The waste shipper shall notify the Agency not less than 5 ~~five~~ working days prior to the scheduled shipment of the intent to transport waste to the licensed land disposal facility.

R12-1-449. Survey Instruments

A. Each licensee or registrant shall ensure that survey instruments used to show compliance with this Article have been calibrated before first use, annually, and following repair, unless otherwise specified in this Chapter.

B. To satisfy the requirements of subsection (A), the licensee or registrant shall:

1. For each scale to be calibrated, calibrate 2 readings separated by at least 50 percent of scale rating; and
2. Conspicuously note on the instrument the apparent radiation level, in appropriate units for the type of survey instrument being used, from a dedicated check source, determined at the time of calibration, and the date of calibration.

C. Each licensee or registrant shall check each survey instrument for proper operation with the dedicated check source before each use.

D. The licensee or registrant shall retain a record of each calibration required in subsection (A) for 3 years. The record shall include:
   1. A description of the calibration procedure; and
   2. A description of the source used, the certified dose rates from the source, the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

F. To meet the requirements of subsections (A),(B), and (C), the licensee or registrant may obtain the services of persons licensed or registered by the Agency, the NRC, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Licensing records of the service person authorization shall be maintained for 3 years by the licensee or registrant obtaining the service.

R12-1-450. Sealed Source Requirements

A. Any licensee who possesses and uses sealed sources containing radioactive material shall follow the radiation safety and handling instructions approved by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State and furnished by the manufacturer on the label attached to the source, on the permanent container of the sources or in the leaflet or brochure that accompanies the source, and maintain the instructions in a legible and conveniently available form.

B. Any licensee who possesses and uses calibration and reference sources shall, unless otherwise specified, conduct a physical inventory, at intervals not to exceed 6 months, to account for all sealed sources of radioactive material received and possessed under a radioactive material license. The records of the inventory shall be maintained for 3 years from the date of the inventory, and shall be available for inspection by the Agency. The information recorded shall include the kind and quantity of radioactive material, the model and serial number of the source or the device in which it is mounted, the location of the sealed source, the date of the inventory, and the signature of the person performing the inventory.

C. Any licensee who possesses and uses sealed sources in the practice of medicine shall conduct a physical inventory according to the requirements in 12 A.A.C. 1, Article 7.

ARTICLE 5. RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

R12-1-511. License and Registration Application Requirements For Industrial Radiography

If the licensee has satisfied ~~In addition to~~ the licensing requirements set forth in R12-1-309, the Agency shall issue a specific license or registration for industrial radiography ~~will be issued only~~ if:

1. The applicant has ~~provides~~ a program to provide ~~providing~~ the instruction specified in R12-1-521 for radiographers and assistant radiographers, or if applicable, a program to provide instruction to enclosed radiography x-ray machine operators. The applicant shall submit ~~and submits~~ to the Agency a schedule or description of the training program which specifies the:
   a. No change.
   b. No change.
   c. No change.
   d. Means of testing to be used by the licensee or registrant to determine a radiographer's or assistant radiographer's knowledge and understanding of, and ability to comply with the Agency's rules and licensing requirements, and the operating and emergency procedures of the applicant
2. No change.
2. No change.
3. The applicant has ~~will have~~ an internal inspection program ~~system~~ adequate to assure that Agency rules, Agency license and registration provisions, and the applicant's operating and emergency procedures are followed by radiographers, ~~and~~ radiographer's assistants, and enclosed radiography x-ray machine operators. The inspection program ~~system~~ shall include the ~~performance of~~ internal inspections at intervals not to exceed 3 ~~three~~ months and inspection record retention ~~the retention of records of such inspections~~ for 2 ~~two~~ years;
4. The applicant submits to the Agency a description of the overall organizational structure of the instruction program ~~the industrial radiography program~~, including specified delegations of authority and ~~the~~ responsibility for operation of the program;
5. No change.
   a. No change.
   b. No change.
   c. No change.
6. No change.

R12-1-541 Enclosed Radiography Using X-ray Machines

A. No change.
   1. No change.
   2. Physical radiation surveys shall be performed with a survey instrument appropriate for the energy range and levels of radiation to be assessed and ~~which has been~~ calibrated within the preceding 12 months

B. Cabinet x-ray systems not exempted in subsection (A) ~~above~~ shall comply with the record keeping requirements ~~all other applicable provisions~~ of this Article and the following special requirements:
   1. No change
   2. No change.
   3. No change
   4. The registrant shall make, or cause to be made, evaluations of each x-ray system to determine conformance with this Article, prior to placing such systems into use and thereafter at intervals not to exceed 3 ~~three~~ months. Records of such evaluations shall be retained for 2 ~~two~~ years, and
   5. Physical radiation surveys to satisfy the requirements of subsection (4) ~~paragraph (4) above~~ shall be performed only with instrumentation meeting the requirements of R12-1-504.

C. The registrant shall ensure that shielded ~~Shielded~~ room x-ray systems shall comply with the record keeping ~~all other applicable~~ requirements of this Article and the following special requirements;
   1. No change.
   2. No change.
   3. Each access point shall be provided with 2 ~~two~~ interlocks, each on a separate circuit so that failure of 1 ~~2~~ interlock will not affect the performance of the other;
   4. No change.
   5. The registrant shall make, or cause to be made, evaluations of each shielded room x-ray system prior to placing the system into use and thereafter at intervals not to exceed 3 months to determine conformation with this Article. Records of such evaluations shall be retained for 2 ~~two~~ years.
   6. No change.

7. No change.
8. No change.
9. An individual shall not ~~No individual shall~~ occupy the interior of any shielded room ~~enclosed~~ x-ray system during production of radiation; and
10. The registrant shall provide personnel monitoring devices that meet the requirements of R12-1-523(C) to ~~to, and require the use of, by~~ each shielded room x-ray machine operator, and require that each operator use the devices. ~~radiographer and radiographer's assistant appropriate personnel monitoring devices meeting the requirements of R12-1-523.~~
11. The registrant shall maintain records of:
    a. Quarterly inventories for mobile systems, as described in R12-1-506
    b. Utilization of all systems, as described in R12-1-507; and
    c. Records shall be maintained for 3 years from the date of the inventory or utilization.

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

R12-1-606. Fluoroscopic Systems ~~installations~~

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

B. No change.
   1. No change.
   2. No change.
   3. No change.
   4. No change.
      a. No change.
      b. No change.
      c. Compliance with subsection ~~R12-1-606~~(B)(4)(a) and (b) shall be determined with the image receptor positioned 35.5 centimeters (14 inches) from the panel or table top, at normal operating technical factors and with the attenuation block in the useful beam for systems with image intensification.

C. No change.
   1. No change.
   2. No change.
      a. No change.
      b. No change.
   3. No change.
      a. No change.
      b. No change.
      c. No change.
      d. No change.
      e. No change.
      f. In a lateral-type fluoroscope, the exposure rate shall be measured at a point 15 centimeters (5.9 ~~11.8~~ inches) from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters (5.9 ~~11.8~~ inches) to the centerline of the x-ray table.

D. The source to skin distance shall not be less than: ~~Source-to-skin distance~~
   ~~1. The source to skin distance shall not be less than:~~
   1. ~~a.~~ 38 centimeters (15 inches) on stationary fluoroscopes installed after the effective date of this Section;
   2. ~~b.~~ 35.5 centimeters (14 inches) on stationary fluoroscopes which are in operation prior to the effective date of this Section; January 2, 1996,
   3. ~~c.~~ 30 centimeters (11.8 inches) on all mobile fluoroscopes; and
   4. ~~d.~~ 20 centimeters (8 inches) for image intensified fluoroscopes used for specific surgical application. The registrant shall follow any precautionary measures in the users operating manual ~~The users' operating manual must provide precautionary measures to be adhered to during the use of this device~~.

E. Each fluoroscopic installation shall be subject to all of the following requirements for the control of stray radiation: ~~Stray radiation protection~~
   ~~1. Each fluoroscopic installation shall be subject to all of the following requirements for the control of stray radiation:~~
   1. ~~a.~~ A shielding device of at least 0.25 millimeter lead equivalent shall be provided for covering the Bucky-slot during fluoroscopy;
   2. ~~b.~~ Except for fluoroscopy performed using portable or mobile C-arm systems ~~C-Arm PM devices~~ and during surgical procedures, protective drapes, or hinged or sliding panels~~,~~ of at least 0.25 millimeters lead equivalent, shall be provided between the patient and fluoroscopist to intercept scattered radiation which would otherwise reach the fluoroscopist and others near the machine, but drapes and panels shall not be substituted for ~~and devices shall not substitute for wearing of~~ a protective apron; and
   3. ~~c.~~ Protective aprons of at least 0.25 millimeter lead equivalent shall be worn in the fluoroscopy room by each person, except the patient, whose body is likely to be exposed to 50 µSv/hr (5 mR/hr). ~~5mR/hr~~ or more ~~(50 uSv/hr)~~.

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

G. Systems ~~Mobile fluoroscopes. In addition to the requirements of this Section, systems~~ utilized for mobile fluoroscopy shall be provided with image intensification.

R12-1-612. X-ray and Electron Therapy Systems with Energies of 1 MeV and Above ~~electron therapy systems with energies of one MeV and above~~

A. No change
   1. No change.
      a. No change.
      b. No change.
      c. ~~Leakage radiation measurements.~~ Leakage radiation measurements made at any point 1 meter from the path of the charged particle between its point of origin and the target, window or scattering foil shall meet the requirements of subsection(A)(1)(a) and (b) when computed as a percentage of the dose rate equivalent of the unattenuated useful beam measured at 1 meter from the virtual source. Leakage radiation measurements at each point shall be averaged over an area up to but not exceeding 100 square centimeters (15.5 square inches).

d. The registrant shall maintain, for inspection by the Agency, records which show leakage radiation measurements for the life of the operation ~~a period of 3 years from the date of the respective measurements~~.

2. No change.
3. No change.
   a. No change.
   b. No change.
   c. No change.
   d. No change.
   e. No change.
   f. No change.
4. No change.
   a. No change
   b. No change.
   c. No change.
   d. No change.
   e. No change.
      i. No change.
      ii. No change.
      iii. No change.
   f. No change.
   g. No change.
      i. No change.
      ii. No change.
      iii. No change.
      iv. ~~Interruption switches.~~ It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption the equipment shall go to termination condition.
      v. ~~Termination switches.~~ It shall be possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions at any time from the operator's position at the treatment control panel.
5. No change.
   a. No change.
   b. No change.
   c. No change.
6. No change.
   a. No change.
   b. No change.
   c. No change.
   d. No change.
7. No change.
   a. No change.
   b. No change.
   c. No change.
   d. No change.
8. No change
   a. No change.
   b. No change.
   c. No change.
   d. No change
   e. No change.
   f. No change.
9. No change.
   a. No change.
   b. No change.
   c. No change.
10. No change.

B. Facility and shielding requirements.

1. In addition to protective barriers sufficient to ensure compliance with Article 4 of this Chapter, all of the following design requirements shall apply:
   a. No change.
   b. No change.
   c. Windows, mirrors, operable closed-circuit television, or other equivalent viewing systems shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. ~~When the viewing system is by electronic means (e.g., television), an alternate viewing system shall be provided for use in the event of failure of the primary system;~~
   d. No change.
   e. No change.
   f. No change.
2. A qualified expert trained and experienced in the principles of radiation protection shall perform a radiation protection survey on all installations prior to human use and after any change in an installation that might produce a radiation hazard. The person shall provide the survey results in writing to the individual in charge of the installation and transmit a copy of the survey results to the Agency. ~~All installations shall have a protection survey made by, or under the direction of, a person trained and experienced in the principles of radiation protection prior to human use and after any change in the installation which might produce a radiation hazard. The person shall report his findings in writing to the individual in charge of the installation and a copy of this report shall be transmitted to the Agency.~~
3. No changes.
   a. No change.
   b. No change.
   c. Calibration of a particle accelerator shall be made by, or under the supervision of a person having met the qualification requirements specified in R12-1-904(F) ~~trained and experienced in performing calibrations~~, and a copy of the calibration report shall be maintained by the registrant for inspection by the Agency
   d. No change.
      i. No change.
      ii. No change.
      iii. No change.
      iv. No change.
      v. The calibration determinations above shall be provided in sufficient detail such that the absorbed dose to tissue in the useful beam may be calculated to within +/-5% ~~width +-5 percent~~.
   e. No change.
   f. A copy of the current calibration report shall be available at the therapy control panel for use by the operator, and the report shall contain the following information:
      i. The action taken by the person performing the calibration if it indicates a change has occurred since the last calibration;

ii. A listing of the persons informed of the change in calibration results; and
iii. A statement as to the effect the change in calibration has had on the therapy doses prior to the current calibration finding.

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

D. No change.
1. Only ~~No individual other than~~ the patient shall be in the treatment room during irradiation.
2. No change.
3. No change.

ARTICLE 7. USE OF RADIONUCLIDES IN THE HEALING ARTS ~~USE OF SEALED RADIOACTIVE SOURCES IN THE HEALING ARTS~~

R12-1-701. Scope

~~The provisions of this Article apply to all licensees who use sealed sources in the healing arts and are in addition to, and not in substitution for, other applicable provisions of these regulations.~~

This Article establishes requirements for the use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this radionuclides. These requirements provide for the protection of the public health and safety, and are in addition to, and not in substitution for, other requirements in this Chapter.

R12-1-702. Definitions

"Authorized user" means a physician licensed in Arizona to practice medicine and who is identified as:
1. An authorized user on an Agency, Nuclear Regulatory Commission (NRC), or Agreement State license that authorizes the specified medical use; or
2. A user in a medical use broad scope program, licensed by the Agency, NRC or Agreement State to select its own authorized users in accordance with the training standards contained in this Article.

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

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

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

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

"Misadministration" means:
1. The administration of a radiopharmaceutical or the radiation from a sealed source, administered for therapy purposes and involving:
   a. The wrong radiopharmaceutical or sealed source; or
   b. The wrong patient; or
   c. The wrong route of administration; or
2. The administration of a diagnostic dose of a radiopharmaceutical involving:
   a. The wrong patient, or
   b. The wrong radiopharmaceutical, or
   c. The wrong route of administration; and
   d. A dose to an individual that exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ; or
3. A therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose differing from the final, prescribed total treatment dose by more than 10 percent.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of any such substance.

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

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

~~B.~~ Teletherapy" means therapeutic irradiation in which the sealed source of radiation is at a distance from the body.

"Written directive" means an order in writing for a specific individual, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation.

~~R12-1-703. Interstitial, intracavitary, and superficial applications~~

~~A. Accountability, storage and transit~~
~~1. Except as otherwise specifically authorized by the Agency, each licensee shall provide accountability of sealed sources and shall keep a record of the issue and return of all sealed sources to their place of storage.~~
~~2. When not in use, sealed sources and applicators containing sealed sources shall be kept in a protective enclosure of such material and wall thickness as may be necessary to assure compliance with the provisions of Article 4 of this Chapter.~~
~~3. Each licensee shall conduct a quarterly physical inventory to account for all sources and devices received and possessed. Records of the inventories shall be maintained for inspection by the Agency and shall include the quantities and kinds of radioactive material, location of sources and devices, and the date of the inventory.~~
~~4. Each licensee shall follow the radiation safety and handling instructions furnished by the manufacturer on the label attached to the source, device or permanent container thereof, or in the leaflet or brochure which accompanies the source or device, and maintain such instructions in a legible and conveniently available form.~~
~~5. Physicians, when transporting sealed sources or applicators containing sealed sources for their own use in the practice of medicine, shall transport such sources or applicators in packages of sufficient growth to withstand the rigors of normal transport and sufficient shielding to comply with the requirements of Article 4 of this Chapter. Any other transport of sealed sources or applicators~~

~~containing sealed sources shall comply with the provisions of Article 15.~~

~~B. Testing sealed sources for leakage and contamination~~

~~1. All sealed sources containing more than 100 microcuries (3.7M Bq) of radioactive material with a half-life greater than thirty days shall be tested for leakage contamination prior to initial use and at intervals not to exceed six (6) months. If there is reason to suspect that a sealed source might have been damaged, or might be leaking, it shall be tested for leakage before further use.~~

~~2. Leak tests shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample or, in the case of radium, the escape of radon at the rate of 0.001 microcurie per 24 hours. Any test conducted pursuant to R12-1-703(B)(1) which reveals the presence of 0.005 microcurie or more of removable contamination or, in the case of radium, the escape of radon at the rate of 0.001 microcurie or more per 24 hours shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with applicable provisions of Article 4.~~

~~3. Sealed sources containing radium shall in addition be tested for the escape of radon gas. The test shall be capable of detecting the escape of radon at the rate of 1.0 nanocurie (37 Bq) per 24 hours.~~

~~4. Each licensee shall assure that sealed sources containing radium-226, cesium-137 or cobalt-60 (as wire) are not opened while in the licensee's possession unless specifically authorized by a license issued by the Agency.~~

~~C. Radiation surveys~~

~~1. The maximum radiation level at a distance of 1 meter (40 in.) from the patient in whom brachytherapy sources have been inserted shall be determined by measurement using a calibrated survey instrument. This radiation level shall be entered on the patient's chart and other signs posted as required under R12-1-703(D).~~

~~2. The radiation levels in the patient's room and the surrounding area shall be determined and recorded, and the record maintained for inspection by the Agency.~~

~~3. The licensee shall assure that patients treated with cobalt-60, cesium-137, iridium-192, or radium-226 implants remain hospitalized until a source count and a radiation survey of the patient, using a calibrated survey instrument, confirm that all radiation-emitting implants have been removed.~~

~~D. Signs and records~~

~~1. In addition to the requirements of R12-1-411, the bed, cubicle or room of the hospital brachytherapy patient shall be marked with a sign indicating the presence of brachytherapy sources. This sign shall incorporate the radiation symbol and specify the radionuclide, the activity, date, and the individual(s) to contact for radiation safety instructions. The sign is not required if any of the exceptions in R12-1-412 of these regulations apply.~~

~~2. The following information shall be included in the patient's chart:~~

~~a. The radionuclide administered, number of sources, activity in millicuries and time and date of administration;~~

~~b. The exposure or dose rate at 1 meter, the time the measurement was made, and by whom;~~

~~c. The radiation symbol; and~~

~~d. The precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted under R12-1-402.~~

R12-1-703. License for Medical Use of Radioactive Material

A. In addition to the requirements set forth in R12-1-309, the Agency shall issue a specific license for medical use of radioactive material in medical institutions will be issued if:

1. The applicant has appointed a radiation safety committee, meeting the requirements in R12-1-706, that will oversee the use of licensed material throughout the medical institution and to review the medical institution's radiation safety program.
2. The applicant possesses facilities for the clinical care of patients;
3. Any physician designated on the application as an authorized user has substantial experience in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients; and
4. If the application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant's staff has substantial experience in the use of a variety of radioactive materials for a variety of medical purposes.

B. Specific licenses to individual physicians for medical use of radioactive material:

1. The Agency shall approve an application by an individual physician or group of physicians for a specific license governing the medical use of radioactive material if:
   a. The applicant satisfies the general requirements in R12-1-309;
   b. The application is for use in the applicant's practice at an office outside of a medical institution;
   c. The applicant has access to a medical institution with adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and
   d. The applicant has substantial experience in the handling and administration of radionuclides, and where applicable, the clinical management of radioactive patients.
2. The Agency shall not approve an application by an individual physician or group of physicians for a specific license to receive, possess, or use radioactive material on the premises of a medical institution unless:
   a. The use of radioactive material is limited to:
1. The administration of radiopharmaceuticals for diagnostic or therapeutic purposes;
2. The performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered;
3. The performance of in vitro diagnostic studies, or
4. The calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation and diagnostic instrumentation;
   b. The physician brings the radioactive material with and removes the radioactive material upon departure; and
   c. The medical institution does not hold a radioactive materials license under subsection (A).

C. Specific licenses for certain groups of medical uses of radioactive material

1. Subject to the provisions of subsections (C) (2), (3), and (4), the Agency shall approve an application for a specific license under subsections (A) or (B), for any medi-

cal use or uses of radioactive material specified in one or more of Groups I to V, inclusive, in Exhibit A of this Article for all of the materials within the group or groups in the application if:

a. The applicant satisfies the requirements of subsections (A), (B), and (D);

b. The applicant, or any physician designated in the application as an individual user meets the qualifications in R12-1-704;

c. All other personnel who will be involved in the preparation and use of the radioactive material have adequate training and experience in the handling of radioactive material appropriate to their participation in the uses included in the group or groups;

d. The applicant's radiation detection and measuring instrumentation is adequate for conducting the procedures involved in the uses included in the group or groups;

e. The applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the uses included in the group or groups.

2. Any licensee or registrant who is authorized to use radioactive material according to one or more groups in subsection (C) (1), and Exhibit A of this Article is subject to the following conditions:

a. For Groups I, II, IV and V, a licensee or registrant shall not receive, possess, or use radioactive material as a radiopharmaceutical unless manufactured in the form to be administered to the patient, labeled, packaged, and distributed according to a specific license issued by the Agency under R12-1-311(J), a specific license issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.72 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of Secretary of State (This incorporation by reference contains no future editions or amendments), or a specific license issued by an Agreement State or a Licensing State under equivalent rules.

b. For Group III, a licensee or registrant shall not receive, possess, or use generators or reagent kits that contain radioactive material to prepare radiopharmaceuticals containing radioactive material, except:

i. Reagent kits that do not contain radioactive material approved by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State or Licensing State for use by persons licensed under subsection (C) and Exhibit A of this Article or equivalent regulations; or

ii. Generators or reagent kits that contain radioactive material which are manufactured, labeled, packaged, and distributed according to a specific license issued by the Agency under R12-1-311(K).

c. For Group III, any licensee who uses generators or reagent kits shall:

i. Elute the generator according to instructions furnished by the manufacturer located on the generator label, leaflet, or brochure which accompanies the generator or reagent kit;

ii Before administration to patients, or distribution to authorized recipients for administration to patients, cause each elution or extraction of technetium-99m from a molybdenum-99/technetium-99m generator to be tested to determine either the total molybdenum-99 activity or the concentration of molybdenum-99, according to written procedures and by personnel who have been specifically trained to perform the test;

iii Prohibit the administration or distribution for administration of technetium-99m that, at the expiration date and time shown on the container label, contains more than 5.6 kBq (0.15 microcuries) of molybdenum-99 per 37 MBq (1 millicurie) of technetium-99m. The licensee shall determine an action level for molybdenum-99/technetium-99m at elution so that the above concentration is not exceeded by radiopharmaceutical expiration. For example, the maximum concentration is 2.6 kBq (0.07 microcurie) per 37 MBq (1 millicurie) at elution for a dose that expires 6 hours later. The licensee shall ensure that the limits above are not exceeded for any single patient dose by checking the expiration time on the container label. The results of each test performed to detect and quantify molybdenum-99 contamination and records of training given to personnel performing these tests shall be maintained for 3 years for Agency inspection; and

d. For Groups I, II, and III, any licensee using radioactive material for clinical procedures other than those specified in the product labeling or package insert shall do so according to an authorized user's directive. Any deviation from the product labeling shall be recorded. Records shall be maintained for Agency review for 3 years from the date of the administration of the radiopharmaceutical.

3. Any licensee who is licensed according to subsection (C) (1), for one or more of the medical use groups in Exhibit A also is authorized to use radioactive material under the general license in R12-1-306(F) for the specified in vitro uses without filing Form ARRA-9 as required by R12-1-306(F)(2); provided, that the licensee is subject to the other provisions of R12-1-306(F)

4. Any licensee who is licensed according to this Section is authorized to receive, possess, and use calibration and reference radioactive sealed sources in accordance with R12-1-711:

D. In addition to the requirements set forth in R12-1-309, the Agency shall issue a specific license for medical use of sealed sources will be issued only if the applicant or, if the application is made by a medical institution, the individual user has the qualifications listed in R12-1-704:

~~**R12-1-704. Teletherapy**~~

~~A. Equipment~~

~~1. The teletherapy equipment housing shall be so constructed that, at one (1) meter (40 in.) from the source, the maximum exposure rate does not exceed ten (10) milliroentgens per hour (87u Sv/hr) when the beam control mechanism is in the "off" position. The average exposure rate measured at a representative number of points about the housing, each one (1) meter (40 in.)~~

from the source, shall not exceed two (2) milliroentgens per hour (17u Sv/hr).

2. For teletherapy equipment installed after May 15, 1967, the leakage radiation measured at one (1) meter from the source when the beam control mechanism is in the "on" position shall not exceed one (1) roentgen per hour (8.7m Sv/hr) or 0.1 percent of the useful beam exposure rate whichever is less.
3. Adjustable or removable beam-defining diaphragms shall allow transmission of not more than five (5) percent of the useful beam exposure rate.
4. The beam control mechanism shall be of a positive design capable of acting in any orientation of the housing for which it is designed to be used. In addition to an automatic closing device, the mechanism shall be designed so that it can be manually returned to the "off" position with a minimum risk of exposure.
5. The closing device shall be so designed as to return automatically to the "off" position in the event of any breakdown or interruption of the activating force and shall stay in the "off" position until activated from the control panel.
6. When any door to the treatment room is opened, the beam control mechanism shall automatically and rapidly restore the unit to the "off" position and cause it to remain there until the unit is reactivated from the control panel.
7. There shall be at the housing and at the control panel a warning device that plainly indicates whether the beam is on or off and there shall be an independent radiation monitoring device which shall
   a. Continuously monitor the condition of the teletherapy beam and
   b. Provide a continuously visible signal to the operator.
8. The equipment shall be provided with a locking device to prevent unauthorized use.
9. The control panel shall be provided with a timer that automatically terminates the exposure after a preset time.
10. Provision shall be made to permit continuous observation of patients during irradiation.

B. No individual shall be in the treatment room during irradiation unless that individual is the patient. Mechanical restraining or supporting devices shall be used for positioning the patient, if necessary.

C. Testing for leakage and contamination. Teletherapy sources shall be tested for leakage and contamination in accordance with the procedures described in R12-1-702(B). Tests of leakage shall be made by wiping accessible surfaces of the housing port or collimator while the source is in the "off" position and measuring these wipes for transferred contamination.

D. Calibration requirements

1. Full calibration measurements shall be performed on each teletherapy unit:
   a. Prior to the first use of the unit for treating humans.
   b. Prior to treating humans:
      i. Whenever spot-check measurements indicate that the output value differs by more than 5 percent from the value obtained at the last full calibration corrected mathematically for decay;
      ii. Following replacement of the radiation source or following reinstallation of the teletherapy unit in a new location;
      iii. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
   c. At intervals not exceeding one year.
2. Full calibration measurements shall include determination of:
   a. The exposure or dose rate, to an accuracy within +/- 3 percent for the range of field sizes and for the range of distances (or for the axis distance) used in radiation therapy;
   b. The congruence between the radiation field and the field indicated by the light beam localizing device;
   c. The uniformity of the radiation field and its dependence upon the orientation of the useful beam;
   d. Timer accuracy; and
   e. The accuracy of all distance measuring devices used for treating humans.
3. Reserved.
4. The exposure rate or dose rate values shall be corrected mathematically for intervals not exceeding one month.
5. Full calibration measurements and dose rate corrections shall be performed by an expert qualified by training and experience in accordance with R12-1-704(G)(1)

E. Spot check measurements

1. Spot check measurements shall be performed on each teletherapy unit at intervals not exceeding one month.
2. Spot check measurements shall include determination of:
   a. Timer accuracy;
   b. The congruence between the radiation field and the field indicated by the light beam localizing device;
   c. The accuracy of all distance measuring devices used for treating humans;
   d. The exposure rate dose or a quantity related in a known manner to these rates for one typical set of operating conditions; and
   e. The difference between the measurement made and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for decay).
3. Spot check measurements shall be performed in accordance with procedures established by an expert qualified by training and experience in accordance with R12-1-704(G)(1). (A qualified expert need not actually perform the spot check measurements.) If a qualified expert does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by a qualified expert within 15 days.

F. Dosimetry systems

1. Full calibration measurements shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system shall have been calibrated within the previous two years and after any servicing that may have affected system calibration.
2. Spot check measurements shall be performed using a dosimetry system that has been calibrated in accordance with R12-1-704(F)(1) Alternatively a dosimetry system

~~used solely for spot check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with R12-1-704(F)(1) This alternative calibration method shall have been performed within the previous one year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.~~

~~G. Expert qualifications. The licensee shall determine if a person is an expert qualified by training and experience to calibrate a teletherapy unit and establish procedures for (and review the results of) spot check measurements. The licensee shall determine that the qualified expert:~~

~~1. Is certified by the American Board of Radiology in: Therapeutic Radiological Physics, Radiological Physics, Roentgen Ray and Gamma Ray Physics, or X ray and Radium Physics; or~~

~~2. Has the following minimum training and experience:~~

~~a. A Master's or Doctor's degree in physics, biophysics, radiological physics or health physics; and~~

~~b. One year of full time training in therapeutic radiological physics; and~~

~~c. One year of full time experience in radiotherapy facility, including personal calibration and spot check of at least one teletherapy unit.~~

~~3. Licensees that have their teletherapy units calibrated by persons who do not meet these criteria for minimum training experience may request a license amendment excepting them from R12-1-704(G). The request should include the name of the proposed qualified expert, a description of his training and experience, including information similar to that specified in R12-1-704(G)(2), reports of at least one calibration and spot check program based on measurements personally made by the proposed expert within the last ten years, and written endorsement of the technical qualifications of the proposed expert from personal knowledge by a physicist certified by the American Board of Radiology in one of the specialties listed in R12-1-704(G)(1)~~

~~H. Records. The licensee shall maintain for inspection by the Agency: records of the measurements, tests, corrective actions, instrument calibrations made under R12-1-704(D) and (E) and records of the licensee's evaluation of the qualified expert's training and experience made under R12-1-704(G).~~

~~1. Records of~~

~~a. Full calibration measurements and~~

~~b. Calibration of the instruments used to make these measurements shall be preserved for five years and after completion of the full calibration.~~

~~2. Records of~~

~~a. Spot check measurements and corrective actions and~~

~~b. Calibration of instruments used to make spot check measurements shall be preserved for five years after completion of the spot check measurements and corrective actions.~~

~~3. Records of the licensee's evaluation of the qualified experts training and experience shall be preserved for five years after the qualified expert's last performance of a full calibration of the licensee's teletherapy unit.~~

R12-1-704. Supervision

A. For purposes of this rule "supervision" means the exercise of control over or direction of the use of radioactive material in the practice of medicine by an authorized user named on a radioactive material license. Supervision does not require a supervising physician's constant physical presence if the supervising physician can be easily contacted by radio, telephone, or telecommunication.

B. A physician may use radioactive material if he or she is licensed by the Arizona Board of Medical Examiners or Board of Osteopathic Examiners in Medicine and Surgery listed as an authorized user on a radioactive material license issued by the Agency,NRC, or Agreement State, authorizing the use of radioactive material for medical purposes.

C. A physician, having the training and experience listed in 10 CFR 35. 1998 Edition, published January 1, 1998, is incorporated by reference and on file with the Agency and the Office of Secretary of State, or a physician under the supervision of a physician having the qualifications listed above, may use radioactive material for medical purposes. This incorporation by reference contains no future editions or amendments.

D. An authorized user, approved to prescribe radiopharmaceuticals for therapy purposes on a radioactive materials license, shall be physically present when a radiopharmaceutical is administered to human being for therapeutic purposes.

R12-1-705. Radiation Safety Officer

A licensee shall appoint a Radiation Safety Officer who is responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in according to this Chapter and Agency approved procedures.

R12-1-706. Radiation Safety Committee

A medical institution Radiation Safety Committee shall meet the following requirements:

1. Administrative requirements:
   a. Committee membership shall consist of at least 3 individuals and shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.
   b. The Committee shall meet at least once each calendar quarter, unless otherwise specified by license condition.
   c. To establish a quorum and to conduct business, one-half of the Committee's membership shall be present, including the Radiation Safety Officer and the management representative.
   d. The minutes of each Radiation Safety Committee meeting shall include:
      i. The date of the meeting;
      ii. Members present;
      iii. Members absent;
      iv. A summary of deliberations and discussions;
      v. Recommended actions and the numerical results of all ballots; and
      vi. A reference to the review required in R12-1-407.
   e. The Committee shall provide each member with a copy of the meeting minutes, and retain 1 copy for 3 years.
2. Oversight: the Committee shall:
   a. Review the radiation protection program for all sources of radiation as required in R12-1-407;
   b. Establish a table of investigational levels for occupational dose that, when exceeded, will initiate

investigations and considerations of action by the Radiation Safety Officer; and

c. Establish the safety objectives of the quality management program required by R12-1-707.

R12-1-707. Quality Management Program

Each licensee shall establish and maintain a written quality management program that radioactive material or radiation from it will be administered as directed by an authorized user. The quality management program shall include written policies and procedures to meet the specific patient safety objectives established by the Radiation Safety Committee or Radiation Safety Officer for licensees not required to have a Radiation Safety Committee.

R12-1-708. Misadministration Reports and Records

A. Reports of therapy misadministrations

1. When a administration involves any therapy procedure, the licensee shall notify the Agency by telephone. The licensee shall also notify the referring physician of the affected patient and the patient or a responsible relative or guardian, unless the referring physician personally informs the licensee either that he or she will inform the patient, or that in his or her medical judgment, telling the patient or the patient's responsible relative or guardian would be harmful to one or the other, respectively. These notifications shall be made within 24 hours after the licensee discovers the misadministration. If the referring physician or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee shall not delay medical care for the patient because of notification problems.

2. Within 15 days after the initial therapy misadministration report to the Agency, the licensee shall report, in writing, to the Agency and to the referring physician and furnish a copy of the report to the patient or the patient's responsible relative or guardian, depending on who was previously notified by the licensee under Subsection (A)(1). The written report shall include the licensee's name, the referring physician's name, a brief description of the event, the effect on the patient, the action taken to prevent recurrence, whether the licensee informed the patient or the patient's responsible relative or guardian, and if not, why not. The report shall not include the patient's name or other information that could lead to identification of the patient.

B. When a misadministration involves a diagnostic procedure, the licensee shall notify, in writing, the referring physician and the Agency. A licensee's report of a diagnostic misadministration is due within 10 days after the end of the calendar quarter (defined by March, June, September and December) in which the misadministration occurs. The written report shall include the licensee's name, the referring physician's name, a description of the event, the effect on the patient, and the action taken to prevent recurrence. The report shall not include the patient's name or other information that could lead to identification of the patient.

C. Records of all misadministrations. Each licensee shall maintain, for Agency inspection, records of all misadministrations of radiopharmaceuticals or radiation from teletherapy or brachytherapy sources. These records shall contain the names of all individuals involved in the event, including the physician, allied health personnel, the patient, and the patient's referring physician; the patient's social security number or other identification number if one has been assigned; a brief description of the event; the effect on the patient; and the action taken to prevent recurrence. These records shall be preserved until the Agency authorizes disposal.

R12-1-709. Reserved

R12-1-710. Visiting Authorized User

A. A licensee may permit any visiting authorized user to use licensed material for a medical purpose under the terms of the licensee's license for 60 days each year if:

1. The visiting authorized user has the prior written permission of the licensee's management and Radiation Safety Committee, if applicable;

2. The licensee has a copy of an Agency, Agreement State, Licensing State, or NRC license that identifies the visiting authorized user by name as a person authorized to use licensed material for medical purposes; and

3. Only those procedures for which the visiting authorized user is specifically authorized by an Agency, Agreement State, Licensing State, or NRC license are performed by that individual, and

B. A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in subsection (A).

C. A licensee shall retain a copy of the license specified in subsection (A)(2) for 3 years from the date of the last visit.

R12-1-711. Calibration and Reference Sources

Any person authorized by R 12-1-703 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference purpose:

A. Sealed sources manufactured and distributed by persons specifically licensed under 12 A.A.C. 1, Article 3 or equivalent provisions of the NRC, Agreement State or Licensing State and that do not exceed 1.1 GBq (30 millicuries) each;

B. Any radioactive material listed in Group I, Group II, or Group III of Exhibit A of this Article with a half-life not longer than 100 days, in amounts not to exceed 555 MBq (15 millicuries) total;

C. Any radioactive material listed in Group I, Group II, or Group III of Exhibit A of this Article with half-life greater than 100 days in amounts not to exceed 7.4 MBq (200 microcuries) total; and

D. Technetium-99m in individual amounts not to exceed 1.85 GBq (50 millicuries).

R12-1-712. Sealed Sources

A. Each medical and nuclear pharmacy licensee shall conduct a quarterly physical inventory to account for all radioactive sealed sources received and possessed. Records of the inventories shall be maintained for inspection by the Agency and shall include the quantities, kinds of radioactive material, location of sources, the date of the inventory, and signature of the person performing the inventory.

B. A licensee shall use radioactive sealed sources for medical purposes as prescribed in R12-1-450(A).

R12-1-713. Dose Calibrators

A medical use licensee shall possess a dose calibrator and use it to measure the amount of radioactivity administered to a person and prescribed in a written directive from an authorized user.

R12-1-714. Brachytherapy

A. Accountability, storage and transit

1. Except as otherwise specifically authorized by the Agency, each licensee shall keep a record of the issue and return of all sealed sources.

2. When not in use, the licensee shall keep sealed sources and applicators containing sealed sources in a protective

enclosure of such material and wall thickness as is necessary to assure compliance with the provisions of 12 A.A.C. 1, Article 4.

3. Each licensee shall conduct a quarterly physical inventory to account for all brachytherapy sources and devices containing brachytherapy sources received and possessed. Records of the inventories shall be maintained for inspection by the Agency and shall include the quantities and kinds of radioactive material, location of sources and devices, and the date of the inventory.
4. Each licensee shall follow the radiation safety and handling instructions furnished by the manufacturer on the label attached to the brachytherapy source, the device containing a brachytherapy source, the permanent container containing the brachytherapy source, or in the leaflet or brochure which accompanies the brachytherapy source or device, and maintain these ~~such~~ instructions in a legible and easily accessible form.
5 A physician, transporting a brachytherapy source or applicator containing a brachytherapy source for his or her own use in the practice of medicine, shall transport the brachytherapy source or applicator according to the requirements in 12 A.A.C. 1, Article 15.

B. A licensee shall perform leak testing on brachytherapy sources for radioactive contamination as required in R12-1-417.

C. Radiation surveys

1. The physician or other authorized user shall determine the maximum radiation level at a distance of 1 meter (40 in.) from the patient in whom brachytherapy sources have been inserted by measurement, using a calibrated survey instrument. This radiation level shall be entered on the patient's chart and other signs posted as required in subsection (D).
2. The physician or other authorized user shall determine and record the radiation level in the patient's room and the surrounding area. The licensee shall maintain the record for Agency inspection.
3. The licensee shall assure that patients treated with cobalt-60, cesium-137, iridium-192, or radium-226 implants remain hospitalized until a source count and a radiation survey of the patient, using a calibrated survey instrument, confirm that all radiation emitting implants have been removed.

D. Signs and records

1. In addition to the requirements in R12-1-429, the licensee shall mark the bed, cubicle or room of the hospital brachytherapy patient with a sign indicating the presence of brachytherapy sources. This sign shall incorporate the radiation symbol and specify the radionuclide, activity, date, and individual to contact for radiation safety instructions. The sign is not required if any of the exceptions in R12-1-430 apply.
2. The physician or authorized user shall include the following information in the patient's chart:
   a. The radionuclide administered, the number of sources, the activity in millicuries and the time and date of administration;
   b. The exposure or dose rate at 1 meter, the time the measurement was made, and by whom;
   c. The radiation symbol; and
   d. The precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted in R12-1-408.

R12-1-715. Reserved

R12-1-716 Teletherapy

A. The licensee shall use equipment that meets all of the following:

1. The teletherapy equipment housing is constructed so that, at 1 meter (40 in.) from the teletherapy source, the maximum exposure rate does not exceed 100μSv (10 mrem) per hour when the beam control mechanism is in the "off" position. The average exposure rate measure at a representative number of points about the housing, each 1 meter (40 in.) from the teletherapy source, does not exceed .20 μSv (2 mrem) per hour 1 meter (40 in.) from the source.
2. For teletherapy equipment installed after May 15, 1967, the leakage radiation measured at 1 meter from the source when the beam control mechanism is in the "on" position does not exceed 260 μC/kg (1 R) per hour or 0.1 percent of the useful beam exposure rate whichever is less.
3. Adjustable or removable beam-defining diaphragms allow transmission of not more than 5 ~~five (5)~~ percent of the useful beam exposure rate.
4. The beam control mechanism is of a design capable of acting in any orientation of the housing. The mechanism is designed so that it can be manually returned to the "off" position with a minimum risk of exposure.
5. The closing device is designed to return automatically to the "off" position in the event of any breakdown or interruption of power and stays in the "off" position until activated from the control panel.
6. When any door to the treatment room is opened, the beam control mechanism automatically and rapidly restores the unit to the "off" position and causes it to remain there until the unit is reactivated from the control panel.
7. There is at the housing and at the control panel a warning device that plainly indicates whether the beam is on or off and an independent radiation monitoring device which:
   a. Continuously monitors the condition of the teletherapy beam and
   b. Provides a continuously visible signal to the operator.
8. The equipment has a locking device to prevent unauthorized use.
9 The control panel has a timer that automatically terminates the exposure after a preset time.
10. The equipment permits continuous observation of patients during irradiation.

B. The authorized user shall ensure that no individual is in the treatment room during irradiation unless that individual is the patient. Mechanical restraining or supporting devices shall be used for positioning the patient, if necessary.

C. The licensee shall test the teletherapy sources for leakage and contamination as required in R12-1-417. The licensee shall also wipe accessible surfaces of the housing port or collimator while the source is in the "off" position, measuring the wipe samples for transferred contamination.

D. Calibration requirements

1. The licensee's expert, qualified by training and experience under subsection (G) shall perform full calibration measurements on each teletherapy unit:
   a. Prior to the first use of the unit for treating humans.
   b. Prior to treating humans:

i. Whenever spot-check measurements indicate that the output value differs by more than 5 percent from the value obtained at the last full calibration corrected mathematically for decay;
ii. Following replacement of the radiation source or following reinstallation of the teletherapy unit in a new location; or
iii. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

c. At intervals not exceeding one year.

2. Full calibration measurements include determination of:
a. The exposure or dose rate, to an accuracy within +/-3 percent for the range of field sizes and for the range of distances or the axis distance used in radiation therapy;
b. The congruence between the radiation field and the field indicated by the light beam localizing device;
c. The uniformity of the radiation field and its dependence upon the orientation of the useful beam;
d. Timer accuracy; and
e. The accuracy of all distance measuring devices used for treating humans.

3. Reserved.

4. The expert shall correct the exposure rate or dose rate values mathematically for intervals not exceeding 1 month.

E. Spot check measurements
1. The licensee's expert or other authorized agent shall perform spot check measurements on each teletherapy unit at intervals not exceeding 1 month.
2. Spot check measurements shall include determination of:
a. Timer accuracy;
b. The congruence between the radiation field and the field indicated by the light beam localizing device;
c. The accuracy of all distance measuring devices used for treating humans;
d. The exposure rate dose or a quantity related to this rate for 1 typical set of operating conditions; and
e. The difference between the measurement made and the anticipated output, expressed as a percentage of the anticipated output; For example, the value obtained at last full calibration corrected mathematically for decay).
3. The expert shall establish spot check measurement procedures. If the expert does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by the expert within 15 days.

F. Dosimetry systems
1. The licensee's expert shall perform full calibration measurements shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system shall have been calibrated within the previous 2 years and after any servicing that may have affected system calibration.
2. Spot check measurements shall be performed using a dosimetry system that has been calibrated as required in subsection (F)(1). Alternatively a dosimetry system used solely for spot check measurements may be calibrated by direct intercomparison with a system that has been calibrated according to the standards in subsection (F)(1). This alternative calibration method shall have been performed within the previous one year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.

G. The licensee shall determine if a person is an expert, qualified by training and experience to calibrate a teletherapy unit, establish procedures for spot check measurements, and review the results of such measurements. The licensee shall determine that the qualified expert:
1. Is certified by the American Board of Radiology in: Therapeutic Radiological Physics, Radiological Physics, Roentgen-Ray and Gamma-Ray Physics, or X-ray and Radium Physics; or
2. Has the following minimum training and experience:
a. A Master's or Doctor's degree in physics, biophysics, radiological physics or health physics;
b. One year of full-time training in therapeutic radiological physics; and
c. One year of full-time experience in radiotherapy facility, including personal calibration and spot check of at least one teletherapy unit.
3. Licensees, that have their teletherapy units calibrated by persons who do not meet the criteria in subsection (1) and (2) for minimum training experience, may request a license amendment excepting them from these training requirements. The request should include the name of the proposed qualified expert, a description of the expert's training and experience, including information similar to that specified in subsection (2), reports of at least 1 calibration and 1 spot check, based on measurements personally made by the proposed expert within the last 10 years, and a written endorsement of the expert's qualifications by a physicist certified by the American Board of Radiology in one of the specialties listed in subsection (1), based on personal knowledge.

H. The licensee shall maintain for inspection by the Agency: records of measurements, tests, corrective actions, and instrument calibrations made under subsections (D) and (E), and records of the licensee's evaluation of the qualified expert's training and experience under subsection (G).
1. The licensee shall preserve records of the following for 3 years after completion of each full calibration:
a. Full calibration measurements; and
b. Calibration of the instruments used to make the full calibration measurements.
2. The licensee shall preserve records of the following for 3 years after completion of each spot check:
a. Spot check measurements and corrective actions; and
b. Calibration of instruments used to make spot check measurements.
3. The licensee shall preserve records of the licensee's evaluation of the qualified expert's training and experience for 3 years after the qualified expert's last performance of a full calibration on the licensee's teletherapy unit.

R12-1-717. High Dose Remote After-loading Brachytherapy Devices

A. A licensee shall provide an after-loading irradiation facility shall be provided with a system permitting continuous observation of the patient from outside the treatment room during patient irradiation.

B. The licensee shall post written emergency instructions at the after-loading irradiation device operator console. These instructions shall inform the device operator of the procedures to be followed if the source fails to return to the shielded position.

C. The licensee shall ensure that the after-loading irradiator facility has the following:
1. Access to the room housing the after-loading irradiation device is controlled by a door at the entrance. The doors are normally closed.
2. The entrance to the treatment room is equipped with an electrical interlock system that will cause the source to return to the shielded position immediately the entrance door is opened. The interlock system is connected in such a manner that the source cannot be exposed until the entrance door is closed and the source "on-off" control is reset at the control panel.

D. The licensee shall test the electrical interlocks on the entrance door to the treatment room shall for proper operation at least once a month. Records of test results shall be maintained for 3 years for inspection by the Agency.

E. In the event of malfunction of the door interlock, the licensee shall lock the after-loading irradiation device in the "off" position and not use the after-loading, except as may be necessary to repair or replace the interlock system, until the interlock system is shown to be functioning properly.

F. Before initiation of a treatment program, and after each source exchange for the after-loading device.
1. The licensee shall perform radiation surveys of the following locations:
a. The after-loading device source housing, with the source in the shielded position. The maximum radiation level at 20 centimeters from the surface of the source housing shall not exceed 3 milliroentgens per hour.
b. All areas adjacent to the treatment room with the source in the exposed position. The licensee shall perform the survey, except subsection (F)(1)(b)(iii), with a patient-phantom in the primary beam of radiation and to clearly establish:
i. That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in R12-1-408 and R12-1-414.
ii. That quantities of radiation in unrestricted areas do not exceed the limits specified in R12-1-416.
iii. The intensity of the primary beam of radiation at a specified distance from the source.
2. The licensee shall retain records of the radiation surveys for 3 years for inspection by the Agency.

G. A person shall not perform the following work without written authorization by the Agency:
1. Installation and replacement of sources contained in an after-loading irradiation device; or
2. Any maintenance or repair operation on the after-loading irradiation device involving work on the source driving unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.

H. Before making any changes to treatment room shielding, treatment room location, or use of the after-loading irradiation device which could result in an increase in radiation levels in unrestricted areas outside the treatment room, the licensee shall perform a radiation survey performed in accordance with subsection (F)(1). A report describing each change, and giving the results of each survey shall be sent to the Agency.

R12-1-718. Gamma Stereotactic Radiosurgery

A. The licensee shall provide the manufacturer's written radiological safety and operating instructions to each person responsible for operation of a stereotactic radiosurgery system.

B. A person licensed by the Agency shall install the stereotactic radiosurgery system and perform all service and maintenance involving exposure to persons in the treatment room beyond normal "Beam-off" conditions.

C. In lieu of a direct source inventory, the licensee shall perform an indirect source inventory through completion of absolute calibrations of the radiation dose-rate at the intersection of all beam axes of the radiosurgery radiation unit on a 6 month basis. The magnitude of this dose-rate shall be compared with the appropriately decayed value of the initial or acceptance date, calibrated dose-rate at the intersection of all beam axes. This measured dose-rate shall serves as verification that all sources inserted into the gamma knife are still present.

D. The licensee shall ensure that a stereotactic radiosurgery facility has the following safeguards:
1. Access to the radiosurgery room is controlled by a door at each entrance. The doors are normally closed.
2. Each entrance to the radiosurgery room are equipped with an electrical interlock system that will turn the unit's primary beam of radiation off immediately if any entrance door is opened. The interlock system is connected in such a manner that the machine's primary beam of radiation cannot be turned on until all treatment room entrance doors are closed and the beam "ON-OFF" control is reset at the control panel.
3. In the event of malfunction of any door interlock, the radiosurgery system control is locked in the "OFF" position and not used, except as may be necessary to the repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.
4. The radiosurgery room has a system permitting continuous observation of the patient from outside the radiosurgery room during patient irradiation.
5. Written instructions, including the manufacturer's radiological safety and operating procedures, available at the stereotactic radiosurgery controls. These instructions inform the operator of the procedure to be followed in the event of malfunction. These instructions caution individuals on how to avoid exposure to radiation when in the treatment room and include specific instructions for:
a. Removing the patient from the treatment room;
b. Securing the room against unauthorized entry; and
c. Notifying the responsible physician or radiation safety officer.

E. The licensee shall test electrical interlocks on entrance doors to the radiosurgery room for proper operation at least once every 3 months. Records of test results shall be maintained for inspection by the Agency.

F. The licensee shall cease treatment of patients with the therapy unit if a safety related system of the unit is found inoperative, including couch or helmet drive mechanisms, positioning mechanisms, treatment timing systems, safety interlocks, or radiation field alarms.

G. Before initiation of a treatment program, and after each installation of radiosurgery sources.

1. The licensee shall perform radiation surveys of the following locations:
   a. The radiosurgery system source housing. The maximum and average radiation levels at 1 meter from the nearest source with the device's shielding door closed, shall not exceed 10 milliroentgens per hour and 2 milliroentgens per hour, respectively, for any of the device's sources, when all sources are installed.
   b Unrestricted areas adjacent to the treatment room, with the device's shielding door open. The survey shall be performed with a phantom in the primary beam of radiation and shall clearly establish that radiation levels in restricted and unrestricted areas do not exceed the limits specified in 12 A.A.C. 1, Article 4.
2. The licensee shall test the following safety equipment:
   a Electrical interlocks on entrance doors to the therapy treatment room;
   b. The therapy source "ON-OFF" indicators, both at the source housing and on the system control panel; and
   c. The radiosurgery system treatment timing device.

H. After any changes made in treatment room shielding, treatment room location, or use of the stereotactic radiosurgery system which could result in an increase in radiation levels in unrestricted areas outside of the therapy treatment room, the licensee shall conduct a radiation survey in according to subsection (G). A report describing the changes and giving the survey results shall be sent to the Agency no later than 30 days following completion of the changes.

R12-1-719. Release of Individuals Containing Radiopharmaceuticals or Radioactive Sealed Sources from Restricted Areas

A. A licensee may authorize the release of any individual who has received radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).

B. The licensee shall provide the released individual with oral and written instructions, on recommended actions that will make doses to other individuals as low as is reasonably achievable, if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 millisievert (0.1 rem), assuming no interruption of breast-feeding, the instructions shall also include:
   1. Guidance on the interruption or discontinuation of breast-feeding, and
   2. Information on the consequences of failure to follow the guidance.

C. The licensee shall maintain a record of the basis for authorizing the release of an individual for 3 years after the date of release if the total effective dose equivalent is calculated by using:
   1. The retained activity rather than the activity administered,
   2. An occupancy factor of less than 0.25 at 1 meter,
   3. The biological or effective half-life, or
   4. The shielding by tissue.

D. For 3 years after the date of release, the licensee shall maintain a record of instruction provided to a breast-feeding woman, if the radiation dose to an infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem).

Exhibit A

Groups of Medical Uses of Radioactive Material

Group I.

A. Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution, and excretion. This group does not include uses involving diagnostic study imaging, and tumor localization.
   1. Iodine-123
   2. Iodine-125
   3. Iodine-131
   4. Cobalt-57
   5. Cobalt-58
   6. Cobalt-60
   7. Chromium-51
   8. Iron-59
   9. Potassium-42
   10. Sodium-24
   11. Technetium-99m

B. A licensee shall use the radioactive material listed in subsection (A) in the form of a radiopharmaceutical prepared for medical purposes that is:
   1. Obtained from a manufacturer or preparer licensed according to 10 CFR 32.72, 1998 Edition, published January 1, 1998, or equivalent Agreement State requirements. This incorporation by reference is on file with the Agency and the Office of Secretary of State, and contains no future editions or amendments; or
   2. Prepared by an authorized nuclear pharmacist or a physician who is an authorized user on a radioactive material license, and meets the training and experience requirements in 10 CFR 35(J), or an individual under the supervision of either as specified in 10 CFR 35.25, 1998 Edition, published January 1, 1998, both references are incorporated by reference, and on file with the Agency and the Office of Secretary of State. These incorporations contain no future editions or amendments.

Group II.

C. A use of prepared radiopharmaceuticals for diagnostic study, imaging, and tumor localization.
   1. Iodine-123
   2. Iodine-125
   3. Iodine-131
   4. Selenium-75
   5. Technetium-99m
   6. Ytterbium-169
   7. Indium-111
   8. Indium-113m
   9. Chromium-51
   10. Fluorine-18
   11. Gallium-67
   12. Gold-198
   13. Thallium-201
   14. Rubidium-82
   15. Carbon-11

D. A licensee shall use the radioactive materials listed in subsection (C) in the form of radiopharmaceuticals prepared for medical purposes that is:
   1. Obtained from a manufacturer or preparer according to subsection (B)(1); or
   2. Prepared by an nuclear pharmacist or a physician who is an authorized according to subsection (B)(2)

Group III.

E. Use of generators and reagent kits for the preparation and use of radiopharmaceuticals containing radioactive material for certain diagnostic uses.
   1. Molybdenum-99/Technetium-99m generators
   2. Tin-113/Indium-113m generators
   3. Technetium-99m (in bulk)
   4. Rubidium-81/Krypton-81m

F. A licensee shall acquire and use the radioactive material listed in subsection (E) in the form of a radiopharmaceutical prepared for medical purposes that is:
   1. Obtained from a manufacturer or preparer according to subsection (B)(1); or
   2. Prepared by an nuclear pharmacist or a physician who is an authorized according to subsection (B)(2)

Group IV.

G. Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety.
   1. Iodine-131, in quantities of less than 30 millicuries
   2. Phosphorus-32
   3. Strontium-89
   3. Samarium-153

H. A licensee shall use the radioactive material listed in subsection (G) in the form of a radiopharmaceutical prepared for medical purposes that is:
   1. Obtained from a manufacturer or preparer according to subsection (B)(1); or
   2. Prepared by an nuclear pharmacist or a physician who is an authorized according to subsection (B)(2)

Group V.

I. Use of prepared radiopharmaceuticals for certain therapeutic procedures that normally require hospitalization for purposes of radiation safety.
   1. Iodine-131
   2. Gold-198

J. A licensee shall use the radioactive material listed in subsection (I) in the form of a radiopharmaceutical prepared for medical purposes that is:
   1. Obtained from a manufacturer or preparer according to subsection (B)(1); or
   2. Prepared by an nuclear pharmacist or a physician who is an authorized according to subsection (B)(2)

ARTICLE 8. RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY OPERATIONS

R12-1-801. Scope

The rules ~~regulations~~ in this Article establish requirements for the use of analytical x-ray equipment ~~machines, as defined in R12-1-802(A) by persons registering such machines under the provisions of R12-1-204 of these regulations.~~ The provisions of this article supplement ~~Article 8 are in addition to~~, and not in substitution for, other applicable provisions of this Chapter ~~these regulations~~.

R12-1-802. Definitions

~~A.~~ Analytical x-ray equipment" means devices or machines ~~equipment~~ used for x-ray diffraction or x-ray induced fluorescence analysis.

~~B.~~ "Analytical x-ray system" means a group of components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials.

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

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

~~E.~~ "Local component ~~components~~" means ~~mean~~ part of an analytical x-ray system and includes each area ~~areas~~ that is ~~are~~ struck by x-rays, such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, but does ~~do~~ not include power supplies, transformers, amplifiers, readout devices, and control panels.

~~F.~~ "Normal operating procedures" means instructions or procedures including ~~necessary to accomplish the analysis. These procedures shall include~~, but ~~are~~ not limited to, sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data recording procedures which are related to radiation safety.

~~G.~~ "Open beam x-ray system" means an analytical x-ray system ~~in~~ which permits an individual to place some body part in the primary beam path during normal operation.

~~H.~~ "Primary beam" means radiation which passes through an aperture of the source housing on ~~by~~ a direct path from the x-ray tube ~~or a radioactive source located in the radiation source housing~~.

R12-1-803. Enclosed Beam X-ray Systems ~~beam x-ray systems~~

A. Enclosed beam x-ray systems are exempt from other equipment requirements contained in this Article provided the enclosed ~~of Article 8 of this Chapter, however:~~
   ~~1.~~ ~~Enclosed~~ beam x-ray systems are ~~shall be so~~ designed and constructed so that radiation levels measured at 5 cm from any accessible surface of the enclosure housing the x-ray source do ~~shall~~ not exceed 5 μSv (0.5 mrem) in 1 ~~one~~ hour ~~(4.4 uSv/hr)~~.

B. ~~2.~~A registrant using enclosed ~~Enclosed~~ beam x-ray systems shall comply with applicable provisions of R12-1-804(A), R12-1-805(B), and 12 A.A.C. 1, Article 4 ~~of this Chapter~~.

~~C~~B. A registrant shall provide individuals ~~Individuals~~ performing maintenance, servicing, or alignment procedures, where bypassing of interlocks or other safety devices to gain access to the interior of the enclosure is required, ~~shall be provided with, and shall wear,~~ with appropriate personnel monitoring devices (i.e., wrist or finger badges). These individuals shall wear the devices while performing the work.

~~D~~C. Intentional bypassing of safety devices shall be authorized in advance by the individual responsible for radiation protection. Bypassing ~~Such bypassing~~ shall be terminated as soon as the activity described in subsection (C) is completed, or the equipment shall be labeled as out-of-service with a conspicuous sign until repairs are completed. ~~possible.~~

R12-1-804. Open Beam X-ray Systems ~~beam x-ray systems~~

A. A registrant shall label open beam x-ray system ~~Open beam x-ray systems shall be labeled~~ with a readily discernable sign or signs bearing the radiation symbol and the words
   1. "CAUTION -- HIGH INTENSITY X-RAY BEAM",or words having a similar warning ~~intent~~, on the x-ray source housing, and
   2. "CAUTION RADIATION -- THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" or ~~words having~~ a similar warning ~~intent~~, near any switch

that energizes ~~energies~~ an x-ray tube if the radiation source is an x-ray tube. ~~; or~~

~~3. "CAUTION — RADIOACTIVE MATERIAL", or words having a similar intent, on the source housing if the radiation source is a radionuclide.~~

B. A registrant shall incorporate ~~Open x-ray systems shall incorporate~~ all of the following warning devices:.

1. No change.
2. Shutter status (Open-Closed) indicators near each port on the radiation housing for systems which control the primary beam; ~~in this way; and~~
3. A clearly visible warning light labeled with the words "X-RAY ON", or ~~words having~~ a similar warning ~~intent, shall be~~ located near:
   ~~a.~~ ~~Near~~ any switch that energizes an x-ray tube and ~~shall be~~ illuminated only when the tube is energized; and; ~~or~~
   ~~b. In the case of a radioactive source, near any switch that opens a housing shutter, and shall be illuminated only when the shutter is open.~~
4. The warning devices in subsections (1) through (3) shall be labeled so that their purpose is easily identified.

C. A registrant shall ensure that any ~~Any~~ apparatus utilized in beam alignment procedures is ~~shall be~~ designed in such a way that excessive radiation will not strike the operator. Particular attention shall ~~should~~ be given to viewing devices, in order to ascertain that lenses and other transparent components attenuate the beam to an acceptable level.

D. A registrant shall provide an ~~An~~ interlock device which prevents entry of any portion of an individual's body ~~limbs, fingers, hands, wrists, etc~~. into the primary beam or causes the primary beam to be shut off upon entry into its path shall be provided on all open-beam x-ray systems. A registrant may apply to the Agency for an exemption from the requirements of a safety device. An application for exemption shall include:

1. A description of the various safety devices that have been evaluated;
2. The reason each device cannot be used; and
3. A description of the alternative methods that will be used to minimize accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.; ~~shall be utilized whenever feasible. When such a device is not feasible, alternate methods shall be provided to minimize the possibility of accidental exposure to the primary beam.~~

E. On open-beam configurations installed after the effective date August 8, 1996, of these rules ~~regulations~~, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

F. A registrant shall equip each ~~Each~~ x-ray tube housing ~~shall be~~ with an interlock that shuts off the tube if the tube is removed from the housing or if the housing is disassembled. ~~so constructed that with all shutters closed, the leakage radiation measured at a distance of 2 in. (5 cm) from its surface is not capable of producing a dose equivalent in excess of 2.5 mrem (25 uSv) in one hour at any specified tube rating.~~

G. A registrant shall supply each ~~Each~~ x-ray generator ~~shall be supplied~~ with a protective cabinet which limits leakage radiation measured at a distance of 5 cm (2 in) ~~(2) in. (5 cm)~~ from its surface so ~~such~~ that it is not capable of producing a dose equivalent in excess of 25 µSv (2.5 mrem).~~25 mrem (2.5 uSv)~~ in 1 ~~one~~ hour.

H. A registrant shall ensure that the ~~The~~ local components of an analytical x-ray system are ~~shall be~~ located and arranged and have ~~shall include~~ sufficient shielding or access control so ~~such~~ that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present in the areas surrounding the local components, ~~therein~~ in excess of the dose limits ~~given~~ in R12-1-416 ~~R12-1-405~~ of this Chapter. For systems utilizing x-ray tubes, these limits ~~levels~~ shall be met at any specified tube rating.

I. A registrant shall perform a radiation survey of the local component group of each analytical x-ray system sufficient to demonstrate compliance with subsection (H). The survey shall be performed following installation, change in configuration, or maintenance, effecting the radiation levels in the areas surrounding the local component group. Records of surveys shall be maintained for 3 years or until the analytical x-ray system is decommissioned, which ever is shorter.

R12-1-805. Administrative Responsibilities ~~responsibilities~~

A. A registrant shall designate an ~~An~~ individual at each facility who is ~~shall be designated to be~~ responsible for maintaining radiation safety. This individual, designated the ~~Radiation Protection Supervisor or~~ Radiation Safety Officer, shall ~~be responsible for the following~~:

1. Establish and maintain ~~Establishing and maintaining~~ operational procedures so that the radiation exposure of each worker is kept as far below the maximum permissible dose as is practical;
2. Instruct ~~Instructing~~ all personnel who work with or near radiation producing machines in safety practices;
3. Maintain ~~Maintaining~~ a system of personnel monitoring;
4. Establish ~~Arranging for establishment of~~ radiation control areas, including placement of appropriate radiation warning signs or ~~and/or~~ devices;
5. Provide a ~~Providing for~~ radiation safety inspection of radiation producing machines on a routine basis;
6. Review ~~Reviewing~~ modifications to x-ray systems ~~apparatus~~, including x-ray tube housing, cameras, diffractometers, shielding, and safety interlocks;
7. Investigate and report ~~Investigating and reporting~~ to proper authorities any case of excessive exposure to personnel and take ~~taking~~ remedial action; and,
8. Be ~~Being~~ familiar with all applicable rules ~~regulations~~ for control of ionizing radiation.

B. An individual shall not be permitted to operate or maintain an open beam analytical x-ray system unless the individual has received instruction in and demonstrated competence in all of the following:

1. Identification of radiation hazards associated with the use of the equipment;
2. Significance of all radiation warning and safety devices, interlocks incorporated into the equipment, or the reasons that devices or interlocks have not been installed on certain pieces of equipment and the extra precautions required in lieu of these precautions;
3. Proper operating procedures for the equipment;
4. Recognition of symptoms of acute localized radiation exposure;
5. Proper procedure for reporting an actual or suspected exposure; and

C. A registrant shall maintain records of instruction and competence for Agency inspection for 3 years from the date of course completion or demonstration.

~~No individual shall be permitted to act as an operator of a particular machine until such individual has received an acceptable amount of training in radiation safety as it applies~~

~~to that machine and is approved by the Radiation Protection Supervisor or Radiation Safety Officer. Operators shall be responsible for:~~

~~1. Keeping radiation exposure to himself and to others as low as is practical;~~

~~2. Being familiar with safety procedures as they apply to each machine;~~

~~3. Wearing of personnel monitoring devices, if applicable; and;~~

~~4. Notifying the Radiation Protection Supervisor or Radiation Safety Officer of known or suspected excessive radiation exposures to himself or others.~~

R12-1-806. Operating Requirements ~~procedures~~

A. A Radiation Safety Officer shall establish written ~~Written~~ emergency procedures pertaining to radiation safety ~~shall be established~~ for each analytical x-ray system and post the procedures ~~x-ray producing apparatus by the Radiation Protection Supervisor and posted~~ in a conspicuous location. The procedures shall include ~~These shall list~~ the telephone number ~~number(s)~~ of the Radiation Safety Officer. A registrant shall notify the Radiation Safety Officer ~~Protection Supervisor and shall include the following actions to be taken~~ in case of a known~~, or suspected,~~ or suspected radiation exposure accident and arrange for medical examination for the exposed ~~individual. accident involving radiation exposure:~~

~~1. Notify Radiation Protection Supervisor, and~~

~~2. Arrange for medical examination.~~

B. A registrant shall provide normal operating procedures to all analytical x-ray equipment workers. An individual shall not operate analytical x-ray equipment in any manner other than that specified in the procedures unless the individual has obtained the Radiation Safety Officer's written approval. ~~Personnel shall not expose any part of their body to the primary beam.~~

C. An individual shall not bypass a safety device or interlock unless the individual has obtained Radiation Safety Officer approval. The approval shall be for a specific period of time. When a safety device or interlock has been bypassed, the Radiation Safety Officer shall place a readily discernable sign on the radiation source housing, warning the reader of the unsafe condition. A registrant shall maintain the written record of the bypass approval for 3 years after the approval expires. ~~Only properly trained maintenance personnel shall be permitted to install, repair, or make other than routine modifications to the x-ray generating apparatus and the tube housing apparatus complex.~~

D. Except as authorized in subsection (C), an individual shall not perform an operation involving removal of covers, shielding materials or tube housings or modification of shutters, collimators, or beam stops without ascertaining that the tube is off and that it will remain off until all protective devices have been restored to the normal operating condition. An individual repairing analytical x-ray equipment shall use the main switch, rather than interlocks, for routine shutdown in preparation for repairs. ~~Whenever possible, x-ray diffraction and spectrographic equipment should be placed in a room separate from other work areas.~~

E. The registrant shall secure unused ports on radiation source housings in the closed position, preventing unauthorized access to the radiation source.

F. Finger or wrist personnel monitoring devices shall be used by:

1. Operators of open beam analytical x-ray equipment, not equipped with a safety device; and
2. Personnel performing maintenance procedures that require the presence of a primary x-ray beam when any local component is disassembled or removed.

G. The registrant shall test safety devices and warning devices for proper operation at intervals not to exceed 1 month. Records of tests shall be maintained for Agency inspection for 3 years following the completion of each test.

~~**E.** If, for any reason, it is necessary to temporarily intentionally alter safety devices, such as bypassing interlocks or removing shielding, such action shall be:~~

~~1. Specified in writing and posted near the x-ray tube housing so that other persons will know the existing status of the machine; and~~

~~2. Terminated as soon as possible.~~

~~**F.** Unused tube head ports shall be secured in the closed position; these shall be checked prior to use when the machine has been left unattended.~~

~~**G.** Personnel film badges or other monitoring devices shall be worn on the finger or wrist, rather than on the body.~~

~~**H.** Analytical x-ray equipment shall not be left unattended while the tube is energized unless:~~

~~1. An interlock device is provided to prevent accidental entry into the primary beam, and~~

~~2. The stray radiation at any accessible point at a distance of 10 inches from the tube housing or its containment, as measured with a monitoring instrument appropriate for the energy range generated, is no greater than 2 mR per hour.~~

~~**I.** Safety devices should be tested at least once per week and shall be tested at intervals not to exceed one month.~~

~~**J.** Records of personnel monitoring results and safety device tests shall be maintained for inspection by the Arizona Atomic Energy Commission.~~

ARTICLE 9. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

R12-1-902. Reserved ~~Registration Requirements~~

~~No person shall receive, possess, use, transfer, or acquire a particle accelerator except as authorized in a registration issued pursuant to these Rules or as otherwise provided for in these Rules. The general procedures for registration of particle accelerator facilities are included in Article 2 of these Rules.~~

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

A. The requirements in this section supplement the registration requirements in 12 A.A.C. 1, Article 2.

B. ~~In addition to the requirements of Article 2, a~~ The Agency shall approve a registration application for use of a particle accelerator ~~will be approved~~ only if the Agency determines that:

1. The applicant is qualified by ~~reason of~~ training and experience to use the accelerator ~~in question~~ for the purpose requested to this Article, ~~in accordance with this Article and~~ Articles 4, and 10 of these rules ~~regulations in such a manner as~~ to minimize danger to public health ~~and safety~~ or property;
2. No change.
3. The issuance of the registration will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in R12-1-904 ~~of these Rules~~;
4. No change.
5. The applicant's staff has substantial experience in the use of particle accelerators for the intended uses; and

~~6. If the applicant is a medical institution having an existing radiation safety committee, the committee shall be responsible for approving, in advance, proposals for uses of particle accelerators (For purposes of this rule a medical institution is defined as any organization dedicated to providing medical and surgical care for the sick on an over-night basis); and~~

~~6.~~7. The applicant has an adequate training program for particle accelerator operators.

R12-1-904. Special Registration Requirements for Medical ~~Human~~ Use of Particle Accelerators

~~In addition to the requirements set forth in Article 2, a registration for use of a particle accelerator in the healing arts will be issued only if:~~

A. The requirements in this section supplement the registration requirements in R12-1-903.

B. An applicant that is a "medical institution", as defined in 12 A.A.C. 1, Article 7, and performing human research shall appoint a radiation safety committee ~~1. Whenever deemed necessary by the Agency, the applicant has appointed a medical committee~~ of at least 3 ~~three~~ members to evaluate all proposals for research~~, diagnostic, and therapeutic use of a particle accelerator~~. Membership of the committee shall include expert physicians ~~expert~~ in internal medicine, hematology, therapeutic radiology, and a person experienced in depth dose calculations and protection against radiation.~~;~~

C. The applicant shall ensure that an individual designated as an authorized user on the application is an Arizona licensed physician; is approved by the radiation safety committee, if applicable; and is:

1. Certified in:
   a. Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; or
   b. Radiation oncology by the American Osteopathic Board of Radiology; or
   c. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
   d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
2. Engaged in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic techniques applicable to the use of a particle accelerator, 500 hours of supervised work experience, and a minimum of 3 years of supervised clinical experience.
   a. To satisfy the requirement for instruction, the classroom and laboratory training shall include all of the following subjects.
      i. Radiation physics and instrumentation;
      ii. Radiation protection;
      iii. Mathematics pertaining to the use and measurement of radiotherapy; and
      iv. Radiation biology.
   b. To satisfy the requirement for supervised work experience, training shall occur under the supervision of an authorized user at a medical institution and shall include:
      i. Reviewing of the full calibration measurements and periodic spot checks;
      ii. Preparing treatment plans and calculating treatment times;
      iii. Using administrative controls to prevent misadministration;
      iv. Implementing emergency procedures to be followed in the event of the abnormal operation of a particle accelerator; and
      v. Checking and using survey meters.
   c. To satisfy the requirement for a period of supervised clinical experience, training shall include 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:
      i. Examining individuals and reviewing their case histories to determine their suitability for treatment, noting any limitations or contraindications;
      ii. Selecting the proper dose and how it is to be administered;
      iii. Calculating the therapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses, as warranted by patients' or human research subjects' reaction to radiation; and
      iv. Post-administration follow up and review of case histories.

~~2. The individuals designated on the application as the users have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans;~~ ~~and~~

~~3. The individual designated on the application as the user is a physician.~~

D. With the application the applicant shall provide the name of each authorized user, and the training and experience that satisfies the requirements in subsection(C).

E. Each licensee shall establish and maintain a written quality management program to provide high confidence the radiation produced by the particle accelerator will be administered as directed by an authorized user. The quality management program shall include written policies and procedures to meet the specific patient safety objectives established by the Radiation Safety Officer or Radiation Safety Committee; if applicable.

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

G. The Agency shall inspect a particle accelerator before it is used to treat a human.

R12-1-911. Radiation Survey ~~monitoring~~ Requirements

A. The registrant shall ensure that a portable survey instrument is available at all times in a particle accelerator facility.

~~There shall be available at each particle accelerator facility, appropriate portable monitoring equipment which is operable and has been calibrated for the appropriate radiations being produced at the facility. Such equipment shall be tested for proper operation daily and calibrated at intervals not to exceed one year, and after each servicing and repair.~~

B. A person experienced in the principles of radiation protection and installation design shall:

1. Check operation of the portable survey instrument using a known radiation source prior to its use;
2. Perform and document a radiation protection survey when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas;
3. Perform periodic surveys to determine the amount of airborne particulate radioactivity present in areas of airborne hazards;
4. Perform periodic smear surveys to determine the degree of contamination in target and adjoining areas when the conditions described in subsection (B)(3) exist
5. Perform surveys as prescribed in the written procedures established by the Radiation Safety Officer of the particle accelerator facility.

C. The registrant shall retain the following records:
1. Records of the radiation protection survey required in subsection (B), and an associated facility description, required in R12-1-202(E), until the registration is terminated.
2. Records of particle accelerator calibration, spot checks, personnel radiation safety system tests, and periodic radiation protection surveys until the registration is terminated.

~~B. A radiation protection survey shall be performed and documented by a person experienced in the principles of radiation protection and installation design when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.~~

~~C. All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair.~~

~~D. Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present in areas of airborne hazards.~~

~~E. Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination in target and other pertinent areas.~~

~~F. All surveys shall be made in accordance with the written procedures established by the Radiation Safety Officer of the particle accelerator facility.~~

~~G. Records of all radiation protection surveys, calibration results, instrumentation tests, and smear results shall be kept current and on file at each accelerator facility.~~

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

R12-1-1001. Purpose and Scope ~~scope~~

This Article establishes requirements for notices, instructions, and reports by licensees or registrants to individuals working for a licensee or registrant. The Article explains the ~~engaged in work under a license or registration and.~~ options available to these ~~such~~ individuals in connection with ARRA ~~AAEC~~ inspections of licensees or registrants ~~to ascertain compliance with the provisions of the Act and regulations, registrations and licenses issued thereunder~~ regarding radiological working conditions. The rules ~~regulations~~ in this Article apply to all persons who receive, possess, use, own, or transfer sources of radiation licensed ~~by~~ or registered by ~~with~~ the ARRA. ~~AAEC pursuant to the regulations in Article 2 and Article 3.~~

R12-1-1002. Posting ~~of~~ Notices for Workers ~~notices to workers~~

A. Each licensee or registrant shall post current copies of the following documents:
1. The rules ~~regulations~~ in this Chapter;
2. The license, certificate of registration, conditions or documents incorporated into the license or registration by reference, and any amendments to the license or registration ~~thereto~~;
3. No change.
4. Any notice of violation involving radiological working conditions, proposed imposition of a civil penalty, or order issued under ~~pursuant to~~ 12 A.A.C. 1, Article 12 ~~1~~, and any response from the licensee or registrant.

B. If posting of a document specified in subsections (A)(1), (2), and (3), ~~R12-1-1002(A)(1), (2) or (3)~~ is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

C. No change.

D. Each licensee or registrant shall post documents ~~Documents~~, notices, or forms ~~posted~~, as required by this Section, so that they are conspicuous and ~~pursuant to this Section shall~~ appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies~~, shall be conspicuous,~~ and shall replace any document if it is ~~be replaced if~~ defaced or altered.

E. Agency documents posted as required in ~~pursuant to~~ subsection (A)(4) ~~R12-1-1002(A)(4)~~ shall be posted within 2 ~~two~~ working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted within 2 ~~two~~ working days after dispatch from the licensee or registrant. The ~~Such~~ documents shall remain posted for a minimum of 5 ~~five~~ working days or until action correcting the violation has been completed, whichever is later.

R12-1-1003. Instructions to Workers ~~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 ~~such portions of~~ the restricted area and the health protection problems associated with exposure to ~~such~~ radioactive material or radiation;
2. No change.
3. The applicable provisions of Agency rules ~~regulations~~ and licenses for the protection of personnel from exposures to radiation or radioactive material occurring in each restricted area ~~such areas~~;
4. Their responsibility to report promptly to the licensee or registrant any condition which may lead to or cause a violation of Agency rules ~~regulations~~ 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 ~~pursuant to~~ R12-1-1004.

B. No change.

R12-1-1004. Notifications and Reports to Individuals

A. A licensee or registrant shall report radiation ~~Radiation~~ exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body ~~of an individual shall be reported~~ to the individual as specified in this Section. The information reported shall include data and results obtained under ~~pursuant to~~ Agency rules ~~regulations~~, orders, or license conditions, as shown in records maintained by the licensee or registrant ~~pursuant to Agency regulations~~. Each notification

and report shall be in writing;~~,~~ include appropriate identifying data, such as the name of the licensee or registrant, the name of the individual, and the individual's social security number;~~,~~ include the individual's exposure information; and contain the following statement:

"This report is furnished to you under the provisions of 12 A.A.C. 1. ~~the Arizona Radiation Regulatory Agency rules entitled 'Rules for the Control of Ionizing Radiation'~~. You should preserve this report for future reference".

B. Each licensee or registrant shall provide annual notification of ~~advise such worker annually of the worker's~~ exposure to radiation or radioactive material for each worker, as shown in records maintained by the licensee or registrant under ~~pursuant to~~ R12-1-419(D).

C. At the request of a worker formerly engaged in work controlled by the licensee or the registrant, each licensee or registrant shall furnish to the worker a report of the worker's exposure to radiation or radioactive material. The ~~Such~~ report shall be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the licensee or registrant, whichever is later; and the report shall cover, within the period of time specified in the request, each calendar quarter in which the worker's activities involved exposure to radiation from radioactive material licensed by, or radiation machines registered with the Agency; and the report shall include the dates and locations of work under the license or registration in which the worker participated during this period.

D. Reports to individuals of their exposure to radiation shall be made according to R12-1-446. ~~When a licensee or registrant is required pursuant to R12-1-444, or, for implementing the provisions of R12-1-401, R12-1-413(C), R12-1-445, and Article 12 of this Chapter, to report to the Agency any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on the licensee's or registrant's exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the Agency.~~

R12-1-1005. Licensee, Registrant, and Worker Representation During Agency Inspection ~~Presence of representatives of licensees or registrants and workers during inspection~~

A. No change.

B. No change.

C. A worker authorized to consult with an Agency inspector under to R12-1-1006, may authorize another individual to represent the worker's interests during the Agency inspection. The ~~If, at the time of inspection, an individual has been authorized by the workers to represent them during Agency inspections, the~~ licensee or registrant shall notify the inspectors of the worker's ~~such~~ authorization and ~~shall~~ give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

D. Each workers' representative shall be routinely engaged in work under control of the licensee or registrant or shall have received instructions under ~~as specified in Section~~ R12-1-1003.

E. Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with ~~the conduct of~~ the inspection. However, only one workers' representative at a time may accompany the inspectors.

F. With the approval of the licensee or registrant and the worker's ~~workers'~~ representative an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany Agency inspectors during the inspection of physical working conditions.

G. Notwithstanding the other provisions of this Section, Agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information the worker's ~~workers'~~ representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, any individual who accompanies an inspector may have access to such information only if authorized ~~otherwise so authorized,~~ by the classifying agency.

R12-1-1006. Consultation with Workers During Inspections ~~workers during inspections~~

A. A licensee or registrant shall afford Agency inspectors talking to a licensee or registration representative the opportunity to ~~Agency inspectors may~~ consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Agency rules ~~regulations~~ and licenses to the extent the inspectors deem consultation necessary for conducting ~~the conduct of~~ an effective and thorough inspection.

B. During the course of an inspection, any worker may privately bring ~~privately~~ to the attention of the inspectors, either orally or in writing, any past or present condition which the worker ~~he~~ has reason to believe may have contributed to or caused any violation of the Act, these rules ~~regulations~~, or license condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material or a registered radiation machine under the licensee's or registrant's control. If this notification is in writing, the worker ~~Any such notice in writing~~ shall comply with the requirements of R12-1-1007(A).

C. The provisions of R12-1-1006(B) ~~R12-1006(B)~~ shall not be interpreted as authorization to disregard instructions required by ~~pursuant to Section~~ R12-1-1003.

R12-1-1007. Requests by Workers for Inspections ~~workers for inspection~~

A. Any worker or representative of workers who believes that a violation of the Act, these rules ~~regulations~~ or license conditions exists or has occurred with regard to radiological working conditions in which the worker is engaged, may request an inspection of the facility by the Agency. Any ~~such~~ request shall be in writing, addressed to the Director, ~~and shall~~ set forth the specific grounds for the request and ~~shall~~ be signed by the worker or representative of the workers. The Agency shall provide a ~~A~~ copy ~~shall be provided~~ to the licensee or registrant ~~by the Agency~~ no later than at the time of inspection except that, upon the request of the worker, the Agency shall protect the worker's ~~his~~ name and the name of individuals referred to in the request ~~therein shall be protected by the Agency~~ to the extent authorized by law, except for good cause shown.

B. If, upon receipt of a request for inspection ~~such notice~~, the Agency's Director determines that there are reasonable grounds to believe that the alleged violation exists or has occurred, the Director ~~he~~ shall initiate an inspection ~~cause an inspection to be made~~ as soon as practicable, to determine if the ~~such~~ alleged violation exists or has occurred. Inspections

performed under ~~pursuant to~~ this subsection need not be limited to matters referred to in the complaint.

C. A ~~No~~ licensee or registrant shall not discharge or in any manner discriminate against any worker because the ~~such~~ worker has filed any complaint or caused to be instituted any proceeding under these rules ~~regulations~~ or has testified or is about to testify in the instituted ~~any such~~ proceeding or because the worker exercises, ~~of the exercise by such worker~~ on behalf of the worker ~~himself~~ or others, ~~of~~ any option afforded by this Article.

R12-1-1008. Inspections not Warranted; Review ~~warranted; review~~

If the Agency determines, with respect to a complaint under R12-1-1007, that an inspection is not warranted or there are no reasonable grounds to believe that a violation exists or has occurred, the Agency shall notify the complainant in writing of the ~~such~~ determination. The complainant may obtain review of the ~~such~~ determination by submitting a written request for hearing to the Agency. The Agency ~~, who~~ will provide for a hearing before the Radiation Regulatory Hearing Board under 12 A.A.C. 1, Article 12 ~~in accordance with Article 12 of this Chapter~~ and A.R.S. Title 41, Chapter 6, Article 1.

Exhibit A.Form ARRA-6 (1993) Notice to Employees. No change.

ARTICLE 12. ADMINISTRATIVE PROVISIONS

R12-1-1209. Notice of Violation

A. No change

B. No change

C. The notice shall also specify the License or Registration Division, any proposed sanction and the amount of any proposed civil penalty, unless the civil penalty is ~~proposed to be~~ waived as authorized in ~~pursuant to~~ R12-1-1216(C).

R12-1-1210. Response to Notice of Violation

A. Except as provided in subsection (D), within 30 calendar days of the date of the notice, or other time specified in the notice ~~therein~~, the person charged with the violation shall submit a written response which includes a description of:
   1. The actions taken to achieve compliance and the results of the actions ~~therein~~; or
   2. No change.
   3. No change.

B. If the person charged with a violation submits a timely response, the Director, in consideration of the answer and the severity level of the violation, shall do 1 ~~one~~ of the following:
   1. Issue an order conditionally imposing the full amount of the proposed civil penalty and any other sanctions proposed;
   2. Issue an order conditionally mitigating or waiving the proposed civil penalty under ~~pursuant to~~ R12-1-1214(B) ~~R12-1-1214(C)~~;
   3. Waive the penalty as authorized under ~~pursuant to~~ R12-1-1216(C);
   4. Enter into a consent agreement as authorized under ~~pursuant to~~ R12-1-1222 ~~R12-1-1221~~.

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

D. No change

R12-1-1211. Initial Orders

A. Initial orders are ~~shall be~~ valid for 30 ~~20~~ calendar days after the date of the order, or until the ~~such other~~ time specified in the order, during which time the person charged may:
   1. Pay the civil penalty proposed and accept any proposed sanction, or
   2. Request a hearing before the Board.

B. No change

R12-1-1212. Request for Hearing in Response to an Initial Order

A. In a request for a hearing, a person charged with a violation shall include a statement of the issues and the explanations and the arguments supporting denial of the violation or demonstrating extenuating circumstances, errors in notice, or any other reasons for not imposing the civil penalty, sanction, or both. ~~A request for a hearing shall include a statement of the issues relied on by the person charged and whatever explanations and arguments the person charged may have to support a denial of the violation charged or demonstrate extenuating circumstances, errors in the notice, or other reason why the civil penalty and/or sanctions should not be imposed.~~

B. The statement shall identify all issues. The failure to include an issue may, at the option of the Board ~~board~~, foreclose consideration of that issue. If a statement is not provided or is insufficient the Board may summarily determine the issues.

C. No change

D. No change

R12-1-1213. Severity Levels of Violations

A. The following violations are classified as severity level I violations:
   1. Any failure, malfunction, or insufficiency of a safety system which may result in
      a. An individual exposure,
      b. A concentration of radionuclides, or
      c. A radiation level,

      in excess of 10 times the limits specified in 12A.A.C.1, or 10 times the prescribed patient dose: ~~resulting in an individual exposure, concentration of radionuclides, radiation level or loss of control over a radiation source which may result in a radiation level in excess of ten times the limits specified in this Chapter, or ten times the prescribed patient dose.~~
   2. ~~Inaccurate or incomplete information~~
      ~~a.~~ Any inaccurate or incomplete information that is intentionally provided by a licensee or registrant official ~~to the Agency deliberately with the knowledge of a licensee or registrant official~~, and if the information had been complete and accurate at the time it was provided, ~~that the information is incomplete or inaccurate, or~~
      ~~b.~~ ~~If the information, had it been complete and accurate at the time provided,~~ would have likely resulted in action such as an immediate order required to protect the public health and safety.
   3. ~~False information~~
      ~~a.~~ Any information that the Agency requires be kept by a licensee or registrant that is incomplete or inaccurate because of falsification by or with the knowledge of a licensee or registrant official, and if the information had been complete and accurate at the time it was ~~or~~
      ~~b.~~ ~~If the information, had it been complete and accurate when~~ reviewed by the Agency, would have

likely resulted in action such as an immediate order required to protect the public health and safety.

4. Any concealment or attempted concealment of a severity level I violation of the Act, 12A.A.C.1 ~~this Chapter~~ or a license condition. This is ~~shall be~~ a separate violation ~~and~~ in addition to the original violation.
5. Any concealment or attempted concealment of a severity level II violation of the Act, 12A.A.C.1 ~~this Chapter~~ or a license condition. This violation shall ~~be expressed as an~~ increase ~~of~~ the severity level of the original violation by 1 level.
6. For ~~the purposes of subsections (2) and (3) above~~ the term "licensee or registrant official" means the owner, a partner, a corporate officer, a radiation safety officer, the individual signing an application for a license or registration, or the chairman of any radiation safety committee supervising the radiation safety program of the licensee or registrant.

B. The following violations are classified as severity level II violations:

1. Any failure, malfunction, or insufficiency of a safety system which may result in
   a. An individual exposure,
   b. A concentration of radionuclides, or
   c. A radiation level,

   in excess of 2 times the limits specified in 12A.A.C.1, or 2 times the prescribed patient dose ~~resulting in an individual exposure, concentration of radionuclides, radiation level or loss of control over a radiation source which may result in a radiation level in excess of two times the limits specified in this Chapter, or two times a prescribed therapeutic patient dose or three times a diagnostic patient dose.~~
2. No change.
3. Any concealment or attempted concealment of a severity level III violation of the Act, 12 A.A.C.1 ~~this Chapter~~ or a license condition by a licensee or registrant official as defined in subsection (A)(6) ~~above~~. This violation shall ~~be expressed as an~~ increase ~~of~~ the severity level of the original violation by 1 level.
4. No change.

C. The following violations are classified as severity level III violations:

1. Any failure, malfunction, or insufficiency of a safety system which may result in
   a. An individual exposure,
   b. A concentration of radionuclides, or
   c. A radiation level,

   in excess of the limits specified in 12A.A.C.1, or 20% of a prescribed therapeutic patient dose ~~resulting: in an individual exposure, concentration of radionuclides, radiation level or loss of control over a radiation source which may result in a radiation level in excess of the limits specified in this Chapter, or greater than 20% of a prescribed therapeutic patient dose.~~
2. Any concealment or attempted concealment of a severity level IV or V violation of the Act, 12A.A.C. ~~this Chapter~~ or a license condition. This violation shall ~~be expressed as an~~ increase ~~of~~ the severity level of the original violation by 1 level.
3. Any violation of the safety requirements for the use, storage, disposal or the preparation for transportation of sources of radiation, as prescribed in the Act, this Chapter or in a license condition, provided the violation does not meet the criteria for a severity level I or II violation and the licensee does not maintain a radiation safety quality assurance program meeting the requirements of R12-1-407 ~~R12-1-1214(A)~~.
4. Any factually incorrect statement~~, except an accidental misstatement as described in R12-1-1214(B)~~, upon which the Agency relied or would have relied in consideration of any action.
5. Any attempt to interfere with the progress of an inspection by the Agency.
6. The acquisition of any source of radiation without the applicable current registration or license, unless otherwise authorized by these rules; or use of the source outside the scope of the current registration or license.
7. No change.

D. The following violations are classified as severity level IV violations.

1. No change.
2. Any violation of the safety requirements for the use, storage, disposal, or preparation for transportation of sources of radiation, prescribed in the Act, 12A.A.C.1, or in a license or registration condition, provided the violation does not meet the criteria for a severity level I, II or III violation;
3. Failure to maintain records of mammography quality control tests, listed in Appendix B of 12 A.A.C.1, Article 6.
2. ~~Any failure of a registrant or licensee to comply with the record keeping or reporting requirements in the Act, rules or any license condition, if as a result of the failure, compliance with a safety requirement cannot be demonstrated.~~
4. Any failure to comply with the reporting requirements in the Act or 12A.A.C.1.

E. The following violations are classified as severity level V violations:

1. Failure of a registrant or a licensee to comply with the record keeping requirements of:
   a. The Act,
   b. 12A.A.C.1; or
   c. A registration or facility certification, or license condition, provided that all safety requirements prescribed in the Act, 12A.A.C.1, or in a license or registration condition are met or otherwise demonstrated.
2. If compliance with all safety requirements cannot be demonstrated by the registrant or licensee the failure to comply with the record keeping requirements is classified as a level IV violation.

~~**E.** The following violations are classified as severity level V.~~

~~1. Any violation of the safety requirements for the use, storage, disposal or the preparation for transportation of sources of radiation, as prescribed in the Act, this Chapter or in a license condition, provided the violation does not meet the criteria for a severity level I or II violation and the licensee or registrant maintains a radiation safety program meeting the mitigating factors of R12-1-1214(A).~~

~~2. A failure of a registrant or licensee to comply with the record keeping or reporting requirements in the Act, this Chapter or any license condition, if compliance with all safety requirements can be otherwise demonstrated.~~

R12-1-1214. Mitigating Factors

~~**A.** The Agency may refrain from issuing a Notice of Violation for a Severity Level V violation that is documented in an inspection report provided the report includes a brief descrip-~~

~~tion of the corrective action and that the violation meets all of the following:~~

~~1. It was not a violation that could reasonably be expected to have been prevented by the licensee's or registrant's corrective action for a previous violation or a previous licensee or registrant finding;~~

~~2. It was or will be corrected within the time given for correction, by specific corrective action committed to by the licensee or registrant by the end of the inspection, including immediate corrective action and comprehensive corrective action to prevent recurrence;~~

~~3. It was not a willful violation.~~

~~B.~~A. The Agency may refrain from issuing a Notice of Violation for Severity level IV or V violations identified by the registrant or licensee provided the severity level IV or V violations are identified in an inspection report, ~~and~~ the report includes a brief description of the corrective action, and ~~that~~ the violation meets all of the following criteria:

1. It was identified by the licensee, as a result of an event discovered by the licensee or registrant;
2. It was not a violation that could reasonably be expected to have been prevented

by the licensee's or registrant's corrective action for a previous violation or a previous licensee or registrant finding;

3. It was or will be corrected within a reasonable time, by specific corrective action committed to by the registrant or licensee ~~or registrant~~ by the end of the inspection. The corrective action shall include comprehensive measures that will prevent reoccurrence; ~~including immediate corrective action and comprehensive corrective action to prevent recurrence;~~
4. It was not a willful violation or if it was willful;
   a. The violation was reported to the Agency;
   b. The violation appears to be the isolated action of an employee without management involvement and the violation was not caused by lack of management oversight;
   c. Significant remedial action was taken by the licensee or registrant, demonstrating ~~such that it demonstrates~~ the seriousness of the violation to all affected personnel.

B.~~C.~~ The Director may ~~shall~~:

1. Reduce the scheduled civil penalty, including any augmentation, by 50% for the discovery, remedy, and voluntary reporting of a severity level I or II ~~severity level I, II or III~~ violation by the registrant or licensee; or ~~.~~
2. Waive the scheduled civil penalty, including augmented civil penalties, for the discovery, remedy, and voluntary reporting of a severity level III, IV, or V ~~severity level IV, or V~~ violation by the registrant or licensee. For the purposes of this rule," voluntary reporting" means that the registrant or licensee has notified the Agency of a violation, the reporting of which, may or may not be required under 12A.A.C.1

R12-1-1215. License and Registration Divisions

A. Each registrant or license type is ~~shall be~~ classified into 1 ~~one~~ of 3 ~~three~~ administrative sanction divisions.

1. Division I licenses and registrations:

Broad Academic Class A	Major Accelerator Facility
Broad Academic Class B	Medical Materials Class A
Broad Academic Class C	Medical Teletherapy
Broad Industrial Class A	Nuclear Laundry
Broad Medical	Nuclear Pharmacy
Distribution	Open Field Irradiator
Class C Laser Facility	Secondary Uranium Recovery
Fixed Gauge Class A	Waste Processor Class A
Industrial Radiography Class A	Well Logging
Low Level Radioactive Waste Disposal Site	X-Ray Machine Class A
NORM Commercial Disposal Site	

2. Division II licenses and registrations:

Broad Industrial Class B	Laser Light Show
Broad Industrial Class C	Limited Academic
Class B Industrial Radiofrequency Facility	Medical Imaging Facility
Class B Laser Facility	Medical Laser
Class C Industrial Radiofrequency Facility	Medical Materials Class B
Fixed Gauge Class B	Medical Radiofrequency Device Facility
Health Physics Class A	Research and Development Self Shielded Irradiator
Industrial Radiation Machine	Tanning Facility
Industrial Radiography Class B	Waste Processor Class B
NORM Commercial Disposal Site	X-Ray Machine Class B

3. Division III licenses and registrations:

Class A Laser Facility	Leak Detector
Class A Industrial Radiofrequency Facility	Limited Industrial
Depleted Uranium	Medical Materials Class C
Gas Chromatograph	Other Radiation Machine
General Depleted Uranium	Portable Gauge
General Industrial	Possession Only
General Medical	Unclassified
General Veterinary Medicine	Veterinary Medicine
Health Physics Class B	X-ray Machine Class C
Laboratory	Reciprical
Radioactive waste transfer-for-disposal	

~~1. Division I licenses and registrations shall be Broad Academic Class A; Broad Academic Class B; Broad Academic Class C; Broad Medical; Medical Materials Class A; Medical Teletherapy; Broad Industrial Class A; Fixed Gauge Class A; Industrial Radiography Class A; Open Field Irradiator; Well Logging; Distribution; Nuclear pharmacy; Nuclear Laundry; Secondary Uranium Recovery; Low Level Radioactive Waste Disposal Site; Waste Processor Class A; X-ray Machine Class A; Major Accelerator Facility; Class C Laser Facility;~~

~~2. Division II licenses and registrations shall be Limited Academic; Medical Materials Class B; Broad Industrial Class B; Broad Industrial Class C; Fixed Gauge Class B; Industrial Radiography Class B; Self Shielded Irradiator; Health Physics Class A; Waste Processor Class B; X-ray Machine Class B; Industrial Radiation Machine;~~

~~Tanning Facility; Class B Laser Facility; Medical Laser Facility; Medical Radiofrequency Device Facility; Laser Light Show; Medical Imaging Facility; Class B Industrial Radiofrequency facility; Class C Radiofrequency Facility.~~

~~3. Division III licenses and registrations shall be Medical Materials Class C; General Medical; Limited Industrial; Portable Gauge; Leak Detector; Gas Chromatograph; General Industrial; Depleted Uranium; General Depleted Uranium; Veterinary Medicine; General Veterinary Medicine; Health Physics Class B; Possession Only; X-ray Machine Class C; Class A Laser Facility; Class A Radiofrequency Facility; Other Radiation Machine; Unclassified.~~

B. Any person required by the Act to register the use of a general license with the Agency, or to obtain a specific license from the Agency, is ~~shall be~~ considered a licensee of the appropriate type notwithstanding the failure of the person to register or obtain a license.

C. Out-of-state licensees issued a general license for reciprocal recognition under ~~pursuant to~~ R12-1-321 are ~~shall be~~ classified in accordance with an appropriate specific license type defined in R12-1-1302.

D. For administrative purposes, the following individuals are classified with the Division III licensees and registrants in subsection (A)(3):

1. Any individual not required to register the use of a general license;
2. Any individual not required to obtain a specific license;
3. Any individual not required to register a source of radiation who violates the Act or 12A.A.C.1; and
4. Any x-ray machine servicing registrant.

~~For the purposes of this Article, an individual who is not required to register the use of a general license or to obtain a specific license shall be classified as a Division III licensee.~~

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

A. Except as augmented by R12-1-1217, the schedule of civil penalties is ~~shall be~~ as follows:

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

B. Payment of civil penalties for severity level I and severity level II violations may not be avoided merely by rectifying the condition; however, Board may mitigate or waive the penalty upon determining a violation meets all of the following:

1. It was not a violation that could reasonably be expected to have been prevented by the licensee's or registrant's corrective action for a previous violation or a previous licensee or registrant finding;
2. It was or will be corrected within the time given for corrections, by specific corrective action committed to by the licensee or registrant by the end of the inspection, which includes ~~including~~ immediate ~~corrective action~~ and comprehensive measures ~~corrective action~~ to prevent recurrence;
3. It was not a willful violation.

C. The Director or Board shall waive payment ~~Payment~~ of penalties for severity level ~~levels~~ III through severity level V violations ~~will be waived by the Director or the Board~~ provided:

1. The violation is not subject to augmentation under ~~pursuant to~~ R12-1-1217, and
2. The registrant or licensee submits a timely and adequate response to the notice, rectifies the conditions which appear to have caused the violation, and ~~otherwise~~ complies with the Act, 12A.A.C.1, registration, ~~this Chapter~~, and license conditions, ~~, or takes steps acceptable to the Director to ensure compliance.~~

R12-1-1217. Augmentation of Civil Penalties

A. A continuing violation is ~~shall~~, for the purposes of calculating the proposed civil penalty, ~~be~~ considered a separate violation for each day it continues ~~of its continuance~~. The second (or successive) day of a continuing violation is not ~~shall not be~~ considered a repeat violation of the violation occurring on the 1st ~~first~~ day.

B. If a second severity level I violation is committed within 5 ~~five~~ years, the Agency shall increase the base scheduled civil penalty ~~shall be increased~~ by 100%, provided the license is not revoked under ~~pursuant to~~ R12-1-1219.

C. If a 2nd ~~second~~ severity level II violation is committed within a period of5 ~~five~~ years, the Agency shall increase the base scheduled civil penalty by ~~shall be increased~~ 50%, provided the registration or license is not revoked under ~~pursuant to~~ R12-1-1219.

D. If a severity level III violation is repeated within 5 ~~five~~ years, the Agency shall increase the base scheduled civil penalty by ~~shall be increased~~ 50%. ~~The penalty may not be avoided merely by achieving compliance.~~ If the same severity level III violation is repeated a 2nd ~~second~~ time within 5 ~~five~~ years, the base scheduled civil penalty shall be increased by 100%, provided the registration or license is not revoked under ~~pursuant to~~ R12-1-1219.

E. If a severity level IV violation is repeated within 5 ~~five~~ years, the Agency shall propose the base scheduled civil penalty ~~shall be proposed~~. ~~The penalty may not be avoided merely by achieving compliance.~~

1. If the same violation occurs 3 times ~~is repeated a second time~~ within 5 ~~five~~ years, the Agency shall increase the base scheduled civil penalty ~~shall be increased~~ by 50%. ~~The penalty may not be avoided merely by achieving compliance~~.
2. If the same violation occurs 4 times ~~is repeated a third time~~ within 5 ~~five~~ years, the Agency shall increase the base scheduled civil penalty ~~shall be increased~~ by 100%, provided the registration or license is not revoked under ~~pursuant to~~ R12-1-1219.

~~F. If a severity level V violation is repeated within five years, the base scheduled amount of the civil penalty shall be proposed. The penalty may be avoided by prompt and effective actions to achieve compliance. If the violation is repeated more than once within five years, the scheduled amount of~~

~~the civil penalty shall be increased by 50% for each subsequent violation and may not be avoided merely by achieving compliance.~~

F. If greater than 3 severity level V violations are observed during 2 consecutive inspections, the Agency shall impose a civil penalty each violation. The base civil penalty for each violation is the base scheduled civil penalty assessed for a severity level V violation. If the inspection shows repetition of a violation the base civil penalty for each repeat violation is the base scheduled civil penalty assessed for a severity level IV violation. Subsection (E) does not apply to penalties under this section.

G. Other rights and procedures are not ~~shall not be~~ affected by the repeat nature of a ~~the~~ violation. ~~In no case shall a civil penalty be proposed which exceeds the limits specified in A.R.S. § 30-687(C).~~

H. A person may avoid the ~~The~~ penalties in subsections (D),~~(E) and (F)~~ and (E) ~~above~~, ~~may be avoided by~~ demonstrating ~~showing~~ to the Director in the response to the ~~to proposed civil~~ penalty that the violation meets all of the following criteria:

1. It was not a violation that could reasonably be expected to have been prevented by the licensee's or registrant's corrective action for a previous violation or a previous licensee or registrant finding;
2. It was or will be corrected within the time given for correction, by specific corrective action committed to by the licensee or registrant by the end of the inspection, which includes ~~including~~ immediate ~~corrective action~~ and comprehensive measures ~~corrective action~~ to prevent recurrence;
3. It was not a willful violation.

I. Notwithstanding any other provision of this section, the Agency shall not impose a ~~no~~ penalty that exceeds ~~shall exceed~~ a maximum of $5,000 ~~five thousand dollars~~ for each violation for each day up to a maximum of $25,000 for any 30 day ~~twenty-five thousand dollars for any thirty day~~ period.

R12-1-1218. Payment of Civil Penalties

A. A person shall pay ~~Payment of~~ civil penalties imposed under this Article ~~shall be made~~ by certified check or money order payable to the Agency, and mailed or delivered to the Agency at the address shown on the notice of violation.

B. Payment of a civil penalty is ~~Payment shall be~~ due 30 calendar days after the effective date of the final order imposing the civil penalties, unless an alternate payment schedule is agreed upon before that date. A ~~No~~ payment schedule shall not extend beyond 1 ~~one~~ year after the due date.

R12-1-1219. Additional Sanctions - Show Cause

A. If a severity level I violation is repeated or if any 2nd ~~second~~ severity level I violation is committed within 10 ~~ten~~ years, the Agency shall require the registrant or licensee ~~shall be required~~ to show cause why the license should not be suspended or revoked.

B. If any 2nd ~~second~~ severity level II violation is committed within 5 ~~five~~ years, or if a severity level II violation involving radioactive effluent releases, excessive radiation levels or radiation overexposure to an individual is committed within 5 ~~five~~ years of a similar severity level I violation, the Agency shall require the registrant or licensee ~~shall be required~~ to show cause why the license should not be suspended or revoked.

C. If repeated or different severity level III violations are committed on 3 ~~three~~ separate occasions within any 5 ~~five~~ year period, the Agency may require the registrant or licensee ~~shall be required~~ to show cause why the license should not be suspended or revoked.

R12-1-1220. Escalated Enforcement

A. The Director may issue an order to suspend or modify a registration or license, or impound a radiation source for ~~impounding the radiation source or suspending or modifying the registration or license at the same time as or prior to issuing a notice of violation for:~~

1. Any severity level I violation, or
2. Any of the following occurring within a 5 ~~five~~ year period:
   a. A repeat severity level II violation,
   b. A different 2nd ~~second~~ severity level II violation, or
   c. A severity level II violation after a severity level I violation.

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

C. The Agency shall hold hearings according to ~~Hearings shall be held in accordance with~~ A.R.S. § 30-688.

D. An order of impoundment or registration/license suspension or modification shall remain in effect until the order is suspended or modified by the Board pursuant to A.R.S. § 30-688.

R12-1-1222. Enforcement Conferences

A. An enforcement conference for purpose of establishing a consent agreement consists ~~shall consist~~ of a meeting in person between management personnel of the registrant or licensee and the Agency.

B. The enforcement conference ~~shall be~~ informal, however the Agency shall make a record of items discussed and decisions reached ~~shall be made~~. Statements made at the conference shall not be introduced in evidence at a formal hearing unless all parties have consented.

C. Based on the results of the conference, the Agency may:

1. Dismiss the notice of violation; ~~, or;~~
2. Enter into a consent agreement; or
3.~~2.~~ Continue with, or initiate, formal proceedings.

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

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

B. If an applicant fails to respond to a written notification of deficiencies within the time-frame specified in R12-1-1309, the Agency shall consider the application abandoned.

Table A. Registration and Licensing Time-frames

Table A

REGISTRATION AND LICENSING TIME-FRAMES

License or Registration category in R12-1-1306	Administrative Completeness Review Time Frame, in days	Substantive Review Time Frame, in days	Overall Time Frame, In days
A1	30	90	120
A2	30	90	120
A3	30	90	120
A4	30	90	90
B1	30	90	120
B2	30	90	120
B3	30	90	120
B4	30	90	120
B5	30	90	120
B6	30	30	60
C1	30	60	90
C2	30	60	90
C3	30	60	90
C4	30	60	90
C5	30	60	90
C6	30	60	90
C7	30	60	90
C8	30	90	120
C9	30	60	90
C10	30	30	60
C11	30	90	120
C12	30	90	120
C13	30	90	120
C14	30	90	120

C15	30	90	120
C16 C17 D1	30 30 30	90 90 90	120 120 120
D2	30	90	120
D3	30	90	120
D4	30	30	60
D5	30	30	60
D6	30	90	120
D7	30	30	60
D8	30	60	90
D9	30	90	120
D10	30	90	120
D11	365	1,095	1,460
D12	180	730	910
D13	90	365	455
D14	30	90	120
D15	30	30	60
D16	15	15	30
D17	30	30	60
D18	30	90	120
D19	120	365	485
E1	30	30	60
E2	30	30	60
E3	30	30	60
E4	30	30	60
E5	30	90	120
E6	30	30	60
E7	30	30	60
E8	30	30	60
E9	30	30	60

E10	15	15	30
E11	30	30	60
E12	30	30	60
E13	30	30	60
E14	30	30	60
E15	30	30	60
E16	30	30	60
E17	30	90	120

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

ARTICLE 13. LICENSE AND REGISTRATION FEES

R12-1-1301. Definition

"Combined" means the Agency has granted authorized activities ~~granting of the authorities~~ contained in 2 ~~two~~ or more license types in a single license document, ~~and~~ requiring the payment ~~only~~ of a single license fee for the more expensive license of the planned combination ~~license of the highest cost type of licenses combined~~.

R12-1-1302. Types of Licenses and Registrations

A. Category A licenses are ~~shall be~~ those specific licenses which authorize a school, college, university, or other teaching facility to possess and use radioactive materials for instructional or research purposes. ~~A category A license may not be combined with any other type of license.~~
   1. A broad academic class A license is any category A license which meets the specifications of R12-1-310(A)(1) ~~R12-1-310(G)(1)~~.
   2. A broad academic class B license is any category A license other than a broad academic class A license which meets the specifications of R12-1-310(A)(2) ~~R12-1-310(G)(2)~~.
   3. A broad academic class C license is any category A license other than a broad academic class A or B license which meets the specifications of R12-1-310(A)(3) ~~R12-1-310(G)(3)~~.
   4. A limited academic license is any category A license which authorizes only those radioisotopes, forms, and quantities individually specified in the license.

B. Category B licenses are those ~~shall consist of~~ specific or general licenses which authorize the application of radioactive material or the radiation from it ~~therefrom~~ to a human being for medical diagnostic, therapeutic, or research purposes, or the use of radioactive material in medical laboratory testing. Except for a type B6, general medical license, the Agency shall not combine a category B license may not be combined with a license of any other category.
   1. A broad medical license is any category B license which meets the specifications of R12-1-310(A)(1) ~~R12-1-310(G)(1)~~ and meets the requirements of 12 A.A.C. 1, Article 7 ~~rather than the requirements of R12-1-310(G)(2)~~. A broad medical license may authorize any medical use other than teletherapy.
   2. A medical materials class A license is any specific category B license, other than a broad medical license, which authorizes the use of radiopharmaceuticals and sealed sources containing radioactive materials for a therapeutic purpose in quantities which require hospitalization of the patient for radiation safety purposes. The license may authorize other radioactive materials and other medical uses, except teletherapy~~, in addition to the above~~.
   3. No change.
   4. No change.
   5. A medical teletherapy license is a specific category B license which solely authorizes radioisotopes in the form of multi-curie sealed sources for use in external beam therapy. The Agency shall not combine a ~~A~~ medical teletherapy license ~~may not be combined~~ with any other type of category B license.
   6. No change.

C. Category C licenses are those ~~shall consist of~~ specific or general licenses authorizing the use of radioactive materials in any activity other than those authorized by a category A, B, or D license. Except as specifically authorized in this Section, The Agency shall not combine a category C license ~~may not be combined~~ with any other type of license.
   1. A broad industrial class A license is any category C license which meets the specifications of R12-1-310(A)(1) ~~R12-1-310(G)(1)~~. The Agency may combine a ~~A~~ broad industrial class A license ~~may be combined~~ with any other category C license except industrial radiography, open field irradiator, or well logging licenses.
   2. A broad industrial class B license is any category C license other than a broad industrial class A license which meets the specifications of R12-1-310(A)(2) ~~R12-1-310(G)(2)~~. A broad industrial class B license may be combined with any other category C license except industrial radiography, open field irradiator, or well logging licenses.
   3. A broad industrial class C license is any category C license other than a broad industrial class A or B license which meets the specifications of R12-1-310(A)(3) ~~R12-1-310(G)(3)~~. The Agency may combine ~~A~~ broad industrial class C license ~~may be combined~~ with any other category C license except industrial radiography, open field irradiator, or well logging licenses.
   4. No change.
   5. A portable gauge license is a specific category C license which authorizes radioactive materials in the form of sealed sources for use in measuring or gauging devices

designed and manufactured to be transported to the location of use. The Agency may combine a ~~A~~ portable gauge license ~~may be combined~~ with any broad scope industrial license or a fixed gauge class A license.

6. A fixed gauge class A license is a specific category C license which authorizes the possession of 50 or more measuring or gauging devices containing radioactive materials, ~~and~~ where each device is permanently mounted for use at a single location.
7. A fixed gauge class B license is a specific category C license which authorizes the possession of 1 through 49 measuring or gauging devices containing radioactive materials, ~~and~~ where each device is permanently mounted for use at a single location.
8. No change.
9. No change.
10. No change.
11. No change.
12. No change.
13. No change.
14. A self-shielded irradiator license is a specific category C license authorizing the use radioisotopes in the form of sealed sources for irradiation of materials in a shielding device from which the sources are not removed during irradiation. The Agency may combine a ~~A~~ self-shielded irradiator license ~~may be combined~~ with any broad industrial ~~broad~~ license.
15. No change.
16. A research and development license is a specific category C license which authorizes a licensee to utilize radioactive material in unsealed and sealed form for industrial, scientific, or biomedical research, not including administration of radiation or radioactive material to human beings.
17. A laboratory license is a specific category C license which authorizes a licensee to perform specific in-vitro or in-vivo medical or veterinary testing, while possessing quantities of radioactive material greater than the general license quantities authorized in R12-1-306.

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

1. A distribution license is one which, ~~except as noted,~~ authorizes the commercial distribution of radioactive materials or radioisotopes in products to persons holding an appropriate general or specific license. The Agency shall ensure that a distribution license does not:
   a. Authorize ~~A distribution license shall not authorize~~ distribution of radiopharmaceuticals or distribution to persons exempt from regulatory control; or
   b. Authorize ~~A distribution license shall not authorize~~ any other use of the radioactive material. An appropriate category C license is ~~shall be~~ required for possession of radioisotopes and their incorporation into products.
2. No change.
3. No change.
4. The Agency may combine ~~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. A depleted uranium license ~~may be combined~~ 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..
5. No change.
6. No change.
7. No change.
8. A health physics class A license is one which authorizes the use of radioactive materials for performing ~~to perform~~ instrument calibrations, ~~the~~ processing ~~of~~ leak test or environmental samples, or providing ~~the provision of~~ radiation dosimetry services.
9. No change.
10. A secondary uranium recovery license is one which authorizes the extraction of natural uranium or thorium from an ore stream or tailing which is being or has been processed primarily for the extraction of another mineral. The Agency shall not combine a ~~A~~ secondary uranium recovery license ~~may not be combined~~ with any other license.
11. A low-level, radioactive waste, ~~land~~ disposal facility license is 1 ~~one~~ which is issued for a "~~land~~ disposal facility" as that term is used in R12-1-439 and R12-1-442 ~~R12-1-430 and R12-1-431~~; is constructed and operated according to the requirements in ~~in accordance with~~ 10 CFR 61, 1998 Edition, published January 1, 1998, incorporated by reference and on file with the Agency and the Office of the Secretary of State, containing no future editions or amendments; and having a closure or long-term care plan meeting the requirements of 10 CFR 61.
12. A waste processor class A license is one authorizing the incineration, compaction, repackaging, or any other treatment or processing of low-level radioactive waste prior to transfer to another person authorized to receive or dispose of the waste. The Agency shall not combine a ~~A~~ waste processor class A license ~~may not be combined~~ with any other license.
13. A waste processor class B license is one which authorizes a waste broker to receive prepackaged, low-level radioactive waste from other licensees; combine the waste into shipments; and transfer the waste without treating or processing the waste in any manner and without repackaging except to place damaged or leaking packages into overpacks. The Agency shall not combine ~~A~~ waste processor class B license ~~may not be combined~~ with any other license.
14. No change.
15. A possession-only license is a license of any other category which authorizes only the possession in storage, but no use of, the authorized materials. A license which has been suspended as an enforcement action is not ~~shall not be~~ considered a possession-only license.
16. No change.
17. A radioactive waste transfer-for-disposal license is an authorization for the generator of radioactive waste to transfer the radioactive waste for disposal at a licensed disposal site under R12-1-439 and R12-1-442. This license is subject to a special fee as provided by R12-1-1307 but is exempt from annual fees.
18. No change.
19. A NORM commercial disposal site license is one that authorizes the receipt of waste material contaminated with naturally occurring radioactive material from other licensees for permanent disposal, provided the concen-

tration of the radioactive material does not exceed 74kBq (2,000 picocuries)/gram.

E. Category E registrations and licenses are those that register the possession of x-ray equipment or license the use of non-ionizing radiation producing equipment ~~a radiation machine~~ under ~~pursuant to~~ 12 A.A.C. 1, Article 2 or 14 ~~of this Chapter~~. The Agency shall not combine Category E registrations or licenses ~~may not be combined~~ with any other registration or license.

1. An X-ray machine class A registration is one authorizing the possession of X-ray machines and particle accelerators in a hospital or other facility offering inpatient care.
2. An X-ray machine class B registration is one authorizing the possession of X-ray machines and particle accelerators in a medical, osteopathic, or chiropractic office or clinic not offering inpatient care; or possession ~~the possession of X-ray machines~~ in a school, college, university, or other teaching facility.
3. No change.
4. No change.
5. No change.
6. No change.
7. A class A laser facility license is one which authorizes the operation of 1 to 10 ~~one to ten~~ laser systems subject to R12-1-1433.
8. No change.
9. No change.
10. No change.
11. No change.
12. No change.
13. No change.
14. A class A industrial radiofrequency device facility license is one authorizing 1 to 5 ~~one to five~~ radiofrequency heat sealers or industrial microwave ovens.
15. No change.
16. No, change.
17. No change.

R12-1-1303. Fee for Initial License and Initial Registration

An applicant shall remit for a new license or new registration ~~An application for a new license or registration shall be accompanied by~~ the appropriate fee as prescribed in R12-1-1306, except that the fee will be prorated on a quarterly basis for applications submitted after March 31.

R12-1-1304. Annual Fees for Licenses and Registrations

A. No change.

B. No change.

C. If a licensee or registrant fails to pay the annual fee by January 1, the license is ~~shall be deemed~~ not current.

D. If a licensee or registrant fails to pay the annual fee by April 1, the Agency shall apply administrative sanction provisions of 12 A.A.C. 1, Article 12 ~~of this Chapter shall be applied~~.

R12-1-1305. Method of Payment

A. An applicant licensee or registrant shall pay fees ~~Payment of fees shall be~~ by check or money order, payable to the "State of Arizona" at the address shown on the application, license, registration, or renewal notice.

B. No change.

R12-1-1306. Table ~~Schedule~~ of Fees

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

Table 13-1

Category	Type	Annual fee
A1.	Broad academic class A	$2,600
A2.	Broad academic class B	$1,500
A3.	Broad academic class C	$1,200
A4.	Limited	$600
B1.	Broad medical	$1,650
B2.	Medical materials class A	$1,400
B3.	Medical materials class B	$1,000
B4.	Medical materials class C	$500
B5.	Medical teletherapy	$1,650
B6.	General medical	$75
C1.	Broad industrial class A	$2,200
C2.	Broad industrial class B	$1,600
C3.	Broad industrial class C	$1,250
C4.	Limited industrial	$500
C5.	Portable gauge	$500
C6.	Fixed gauge class A	$800
C7.	Fixed gauge class B	$500
C8.	Leak detector	$500
C9.	Gas chromatograph	$300
C10.	General industrial	No Fee
C11.	Industrial radiography class A	$1,650
C12.	Industrial radiography class B	$1,500
C13.	Open field irradiator	Full Cost
C14.	Self-shielded irradiator	$600
C15.	Well logging	$1,750
C16.	Research and Development	$750
C17.	Laboratory	$600
D1.	Distribution	$2,150
D2.	Nuclear pharmacy	$2,150
D3.	Nuclear laundry	$2,250
D4.	Depleted uranium	$100
D5.	General depleted uranium	$75
D6.	Veterinary medicine	$500
D7.	General veterinary medicine	$75
D8.	Health Physics class A	$600
D9.	Health physics class B	$450
D10.	Secondary uranium recovery	$4,000
D11.	Low-level radioactive waste Disposal Site	(3) ~~Full Cost~~
D12.	Waste processor class A	$2,250
D13.	Waste processor class B	$500
D14.	Additional facility	(1)
D15.	Possession only	(2)
D16.	Reciprocal	(3)
D17.	Radioactive waste transfer-for-disposal	(3)
D18.	Unclassified	Full Cost
D19.	Norm commercial disposal site	$200,000
E1.	X-ray machine Class A (per tube)	$64
E2.	X-ray machine class B (per tube)	$44
E3.	X-ray machine class C (per tube)	$36
E4.	Industrial radiation machine (per device)	$36
E5.	Major accelerator facility	Full Cost
E6.	Tanning facility (per device)	$24
E7.	Class A laser facility	$150
E8.	Class B laser facility	$350
E9.	Class C laser facility	$600

E10.	Laser light show	$350
E11.	Medical laser facility (per laser system)	$40
E12.	Medical RF device facility (per unit)	$40
E13.	Medical imaging facility (per unit)	$50
E14.	Class A industrial radiofrequency facility	$60
E15.	Class B industrial radiofrequency facility	$180
E16.	Class C industrial radiofrequency facility	$300
E17.	Other radiation machine	Full Cost

Notes: (1) 20% of the base fee for each additional site, not to exceed 100% additional for all sites.
(2) 50% of the annual fee for the license type required for full use of the stored radioactive materials.
(3) See R12-1-1307.

B. The annual fee for a license or registration for which the scheduled fee is "Full Cost" is ~~shall be~~ approximately 18% of the full actual cost to the Agency for the personnel, consultants, facilities, equipment, supplies, and transportation used in evaluating the original application. The cost of all ~~All~~ applications for amendments and all regular inspections during the 5 ~~five~~-year normal life of the license or registration, is calculated as follows:

1. The application fee is ~~shall be~~ based on estimates of the cost which are ~~shall in turn be~~ based on consideration of (in order of preference):
   a. No change.
   b. No change.
   c. No change.
2. Annual fees for the 2nd ~~second~~ through 4th ~~fourth~~ years are ~~shall be~~ determined by recalculation of the estimate made under subsection (B)(1) ~~pursuant to paragraph (1) above~~, considering the actual cost based on experience in previous years and any revision of the estimated future costs.
3. The fee for the 5th ~~fifth~~ year is ~~shall be~~ 22.5% of the total actual cost to the Agency to issue and service the license or registration over the 1st ~~first~~ 4 ~~four~~ years of the license.

R12-1-1307. Special License Fees

A. The fee for a Type D16 license providing reciprocal recognition under R12-1-320 of a radioactive materials license issued by the U.S. NRC or another state is ½ ~~shall be one-half~~ of the annual fee for an Arizona license of the appropriate type. The fee is ~~shall be~~ due and payable at the time reciprocity is requested, and the general license does ~~shall~~ not become current until the fee is paid.

B. The fee for a Type D17 radioactive waste transfer-for-disposal license is ~~any person requiring certification of the packaging of Low-level Radioactive Waste for disposal shall be~~ $2.50 per cubic foot of waste transferred, including packaging.

1. A standard 55-gallon drum waste package is ~~shall be~~ considered to be 7 1/2 cubic feet of waste.
2. The fee is ~~shall be~~ due at the time the waste is shipped, unless a prior written agreement between the licensee and the Agency is in effect. The total fee due shall be paid to the Agency in accordance with R12-1-1305(A).

C. For a low-level radioactive waste disposal site the initial application fee is $3,000,000. The annual fee for the 2nd through 5th years is $3,000,000. The Agency shall promulgate a new fee rule for years subsequent to year 5. Based on data gathered during the first 5 years, the Agency shall set a reasonable fee after consideration of the following factors:

1. Unrecovered costs which the Agency may charge under A.R.S. §30-654(B)(18).
2. Actual costs incurred by the Agency.

R12-1-1308. Fee for Requested Inspections

A. A licensee or registrant may request an inspection of its facility at any time. The Agency shall ~~will~~ bill the licensee or registrant 90% of the full cost of the inspection, based on personnel time for preparation, travel, on-site inspection, review of findings, and preparation of report, charged at $25 per hour and mileage charged at the most current rate established by the Department of Revenue under A.R.S.§30-623 ~~25¢ per mile~~.

B. No change.

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

12-1-1309. Abandonment of License or Registration Application

A. Any license or registration application for which the applicant has been provided a written notification of deficiencies in the application and for which the applicant does not make a written attempt to supply the requested information or request an extension in writing within 90 days of the date of the written notice of deficiencies, shall be considered abandoned and will not be processed.

B. If an applicant does not act in the time frame specified in subsection(A), a new application shall be submitted with the appropriate fee.

NOTICE OF PROPOSED RULEMAKING

TITLE 12. NATURAL RESOURCES

CHAPTER 2. MEDICAL RADIOLOGIC TECHNOLOGY BOARD OF EXAMINERS

PREAMBLE

1. Section Affected	Rule Making Action
Article 3	Repeal
Article 3	New Title
R12-2-301	Repeal
R12-2-301	New Section
R12-2-302	Repeal

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

   General: A.R.S. §§ 32-2803(A), 41-1073 to 1078

   Specific: A.R.S. §§ 32-2803(B) and (C), 32-2804, 32-2812, 32-2813, 32-2814, and 32-2816.

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

   Name: John Gray

   Address: Arizona Radiation Regulatory Agency
   4814 South 40th Street
   Phoenix, Arizona 85040

   Telephone: (602) 255-4845, Ext. 241

   Fax: (602) 437-0705

4. **An explanation of the rule, including the agency's reasons for initiating the rule:**

   Article 3 The article title and sections are repealed. Application processing time-frames for radiologic technology certification and radiologic technology school approval are added as required by the new law A.R.S. § 41-1073.

   R12-2-301 The approved schools of radiologic technology are repealed. Listed are the time-frames for processing applications, and associated requirements that must be met by the Board.

   R12-1-302 Requirements for use of x-rays by radiologic students are repealed.

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

   Not applicable.

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

   With the exception of the Agency, the economic impact to all affected parties should be none to minimal. Failure to comply with the time-frames will result in the Agency having to meet the financial consequences described in § 41-1077.

7. **The name and address of agency personnel with whom persons may communicate with regarding the accuracy of the economic, small business, and consumer impact statement:**

   Name: John Gray, MRTBE Program Manager

   Address: Arizona Radiation Regulatory Agency
   4814 South 40th Street
   Phoenix, Arizona 85040

   Telephone: (602) 255-4845, Ext. 233

   Fax: (602) 437-0705

8. **The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:**

   An oral proceeding is scheduled for October 13, 1998, at 900 A,M. at the address listed below. A person may submit written comments concerning the proposed rules by submitting them no later than 5 P.M. October 13, 1998, to the following person:

   Name: John Gray, MRTBE Program Manager

   Location: Arizona Radiation Regulatory Agency
   4814 South 40th Street
   Phoenix, Arizona 85040

   Telephone: (602) 255-4845

   Fax: (602) 437-0705

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

   Not applicable.

10. **Incorporated by reference and their location in the rules:**

    None.

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

TITLE 12. NATURAL RESOURCES

CHAPTER 2. MEDICAL RADIOLOGIC TECHNOLOGY BOARD OF EXAMINERS

ARTICLE 3. PROCESSING TIME FOR APPLICATIONS

~~Schools of Diagnostic and Therapeutic Radiologic Technology~~

Section
~~R12-2-301.~~ ~~School approval~~ Repeal
R12-2-301. Application Processing Time Frames
~~R12-2-302.~~ ~~Use of x-rays by students~~ Repeal

ARTICLE 3. ~~Schools of Diagnostic and Therapeutic Radiologic Technology~~

Article 3. ~~Schools of Diagnostic and Therapeutic Radiologic Technology~~

~~R12-2-301. School approval~~

~~A. Pursuant to A.R.S. §32-2804, the following schools of radiologic technology in the State of Arizona have been approved by the Board:~~

~~1. Northern Arizona University~~
~~Department of Radiologic Technology~~
~~Box 15075~~
~~Flagstaff, AZ 86001~~

~~2. Maricopa Technical Community College~~
~~Department of Radiologic Technology~~
~~106 E Washington Street~~
~~Phoenix, AZ 85004~~

~~3. Pima Community College~~
~~Radiologic Technology Program~~
~~2202 West Anklam Road~~
~~Tucson, AZ 85709~~

~~B. In approving schools of radiologic technology, pursuant to A.R.S. § 32-2804, the Board shall approve those radiologic technology schools accredited by the Committee on Allied Health Education and Accreditation (CAHEA). A copy the accreditation publication of CAHEA is available for public review at the office of the Board and the Office of the Secretary of State.~~

ARTICLE 3. LICENSING TIME-FRAMES

R12-2-301. Licensing Time-Frames

A. Within 30 days of receiving an initial or a renewal certificate application package, the Board shall notify the applicant of any deficiencies found in the package. The Board shall provide a written comprehensive list of the deficiencies to the applicant. The 30 day time-frame for determining administrative completeness is suspended from the date the deficiency notice is mailed until the date that the Board receives all missing information from the applicant. If an applicant fails to supply the missing information or to request an extension of response time within 90 days from the date of the deficiency notice, The Board shall consider the application abandoned and require a new application with all appropriate fees.

B. The Board shall render a certification decision within 30 days after completion of the administrative completeness review time-frame, unless an extension of 15 days is agreed to by the applicant. If deficiencies are found in the application period, the Board shall make a written comprehensive request for additional information from the applicant. The 30 day time-frame for substantive review is suspended from the date the request is mailed until the date that the Board receives additional information from the applicant. If an applicant fails to respond to the written request or requests an extension of response time within 90 days of the notice, the Board shall consider the application abandoned and require a new application with all appropriate fees.

1. If an applicant is found to be ineligible, the Board shall provide the applicant a written notice of denial explaining:
   a. The reason of the denial with citation of supporting statute or rule;
   b. The applicant's right to seek an appeal of the denial; and
   c. The time periods for appealing the denial.
2. If an applicant is found to be eligible, the applicant shall be notified and provided a certificate number.

C. Within 60 days of receiving a school application package, The Board shall notify the applicant of any deficiencies found in the package. The Board shall provide a written comprehensive list of the deficiencies to the applicant. The 60 day time-frame for determining administrative completeness is suspended from the date the deficiency notice is mailed until the date that the Board receives all of the missing information from the applicant. If an applicant fails to supply the missing information or to request an extension of response time within 90 days from the date of the deficiency notice, the Board shall consider the application abandoned and require a new application with all appropriate fees.

D. The Board shall render a decision regarding school approval within 60 days after the completion of the administrative completeness review time-frame, unless an extension of 30 days is agreed to by the applicant. If deficiencies are found in the application package, the Board shall make a written comprehensive request for additional information from the applicant. The 60 day time-frame for substantive review is suspended from the date the request is mailed until the date that the Board receives all additional information from the applicant. If an applicant fails to respond to the written request or requests an extension of response time within 90 days of the notice, the Board shall consider the application abandoned and require a new application with all appropriate fees.

1. If an applicant is found to be ineligible, the Board shall provide the applicant a written notice of denial explaining:
   a. The reason for the denial with citation to supporting statutes or rules;
   b. The applicant's right to seek an appeal of the denial; and
   c. The time period for appealing the denial.
2. If an applicant is found to be eligible, the applicant shall be notified and the application shall be provided to the Board for approval.

E. For the purposes of A.R.S. Title 41, Chapter 6, Article7.1, the Board establishes the following time-frames in days:

Certification and School Approval Time-frames

Type of Application	Administrative Completeness Review Time	Substantive Review Time-frame	Overall Time-frame
Certification	30	30	60
School Approval	60	60	120

~~R12-2-302. Use of X-ray By Students~~

~~Students may apply radiation to a human body only at the clinical facility of a school or college for the purpose of clinical practice in the use of x-ray equipment. They shall not be assigned to night or weekend experience or otherwise be required to apply radiation except under adequate supervision and then only when they derive sufficient educational benefit from such service.~~