# NOTICES OF FINAL RULEMAKING

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

## NOTICE OF FINAL RULEMAKING

### TITLE 12. NATURAL RESOURCES

### CHAPTER 1. RADIATION REGULATORY AGENCY

### PREAMBLE

| 1. Sections Affected | Rulemaking Action |
|---|---|
| R12-1-102 | Amend |
| R12-1-202 | Amend |
| R12-1-206 | Amend |
| Appendix A | Repeal |
| Appendix A | New Section |
| R12-1-303 | Amend |
| R12-1-401 | Amend |
| R12-1-402 | Amend |
| R12-1-403 | Amend |
| R12-1-404 | Amend |
| R12-1-405 | Amend |
| R12-1-406 | Amend |
| R12-1-407 | Amend |
| R12-1-408 | Amend |
| R12-1-409 | Amend |
| R12-1-410 | Amend |
| R12-1-411 | Amend |
| R12-1-412 | Amend |
| R12-1-413 | Amend |
| R12-1-415 | Amend |
| R12-1-416 | Amend |
| R12-1-417 | Amend |
| R12-1-418 | Amend |
| R12-1-419 | Amend |
| R12-1-420 | Amend |
| R12-1-421 | Amend |
| R12-1-422 | Amend |
| R12-1-423 | Amend |
| R12-1-424 | Amend |
| R12-1-425 | Amend |
| R12-1-426 | Amend |
| R12-1-427 | Amend |
| R12-1-428 | Amend |
| R12-1-429 | Amend |
| R12-1-430 | Amend |
| R12-1-431 | Amend |
| R12-1-432 | Amend |
| R12-1-433 | Amend |
| R12-1-434 | Amend |
| R12-1-435 | Amend |
| R12-1-436 | Amend |
| R12-1-437 | Amend |
| R12-1-438 | Amend |
| R12-1-439 | Amend |
| R12-1-440 | Amend |

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|---|---|
| R12-1-441 | Amend |
| R12-1-442 | Amend |
| R12-1-443 | Amend |
| R12-1-444 | Amend |
| R12-1-445 | Amend |
| R12-1-446 | Amend |
| R12-1-447 | Amend |
| R12-1-448 | Amend |
| R12-1-449 | Amend |
| R12-1-450 | Amend |
| Article 5 | Amend |
| R12-1-501 | Amend |
| R12-1-502 | Amend |
| R12-1-504 | Amend |
| R12-1-505 | Amend |
| R12-1-507 | Amend |
| R12-1-508 | Amend |
| R12-1-509 | Amend |
| R12-1-510 | Amend |
| R12-1-511 | Amend |
| R12-1-512 | New Section |
| R12-1-521 | Amend |
| R12-1-522 | Amend |
| R12-1-523 | Amend |
| R12-1-524 | Amend |
| R12-1-531 | Amend |
| R12-1-533 | Amend |
| R12-1-534 | Amend |
| R12-1-541 | Amend |
| R12-1-612 | Repeal |
| R12-1-612 | New Section |
| R12-1-702 | Amend |
| R12-1-720 | New Section |
| Article 9 | Amend |
| R12-1-904 | Amend |
| R12-1-905 | New Section |
| R12-1-911 | Amend |
| R12-1-912 | Repeal |
| R12-1-913 | New Section |
| R12-1-914 | New Section |
| R12-1-1209 | Amend |

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

General authority: A.R.S. § 30-654(B)

Specific authority: A.R.S. §§ 30-657(A), 30-671(B), 30-672.01, 30-673, 30-681, 30-683(C), 30-687(A), and 30-688(A)

**3. The effective date of the rules:**

June 8, 2001

**4. A list of all previous notices appearing in the Register addressing the proposed rules:**

Notice of Rulemaking Docket Opening: 5 A.R.R. 2880, August 20, 1999

Notice of Rulemaking Docket Opening: 6 A.R.R. 1580, April 28, 2000

Notice of Proposed Rulemaking: 6 A.R.R. 2227, June 23, 2000

Notice of Public Information: 6 A.R.R. 4615, December 8, 2000

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

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**6. An explanation of the rules, including the agency's reasons for initiating the rules:**

Introductory Statement: The majority of the changes are the result of a Five-Year Review of the rules contained in Article 4, completed in June 1999, and Article 5 which was completed in the fall of 1998. Many other changes are being made to remain compatible with Nuclear Regulatory Commission (NRC) standards and Conference of Radiation Control Program Directors (CRCPD) suggested rules, incorporate regulatory requirements that were previously addressed in license conditions, and make other changes to improve understanding of existing rules. The following is a summary of the NRC and CRCPD influenced changes, incorporated license conditions, and clarifications.

Article 1: A new definition for "Annual" is added. This word is used frequently throughout the rules. The definition for "Eye dose equivalent" is replaced with "Lens dose equivalent". The definitions for "High radiation area" and "Individual monitoring device" are amended for clarification purposes. The definition for "Quarter" is deleted because it is in conflict with the definition for "Calendar quarter".

Article 2: In R12-1-202 a specific deadline is listed for applying for registration of a radiation producing machine. The contents of the application will contain the newly tabulated requested information in Appendix A at the end of the Article, instead of listing specific application forms. R12-1-206 is amended to clarify the requirements contained in subsection (A), and a new subsection (B) is added that requires registrants to notify the Agency within 15 days of any radiation machine being taken out of service. Other minor changes are made to R12-1-202 and R12-1-206 for clarification purposes.

Article 3: R12-1-303 is amended to prevent users of smaller sealed sources that are exempt from specific licensing requirements, from bundling the smaller sources to create a larger radiation source. Bundling would circumvent the specific licensing requirements associated with some larger sources and compromise the radiation safety inherent in the smaller sources, which was the basis for granting an exemption.

Article 4: In various rules referencing organ dose, "eye" dose is changed to "lens" dose to ensure that compatibility is maintained with NRC regulations. The organ of concern, when considering radiation exposure in the eye, is the lens. In R12-1-431 specific labeling requirements are listed for syringe and vial shields used to protect handlers from radiopharmaceutical radiation. R12-1-438 will authorize licensees to hold radioactive waste with a half-life of 120 days or less, for decay, provided the radioactive waste is held for 10 half-lives and is surveyed prior to disposal. In R12-1-449 users of pocket dosimeters, used to show compliance with Article 4, will be required to maintain them in proper operating condition. R12-1-450 is amended to require users of licensed and sealed radioactive sources to use sources manufactured in accordance with a specific license for their manufacture and to use the sources as intended by the manufacturer. Radioactive sealed sources shall not be opened, unless authorized by the Agency. The described changes to R12-1-438, R12-1-449, and R12-1-450 are made to incorporate license conditions that affect all similarly licensed radioactive material users in rule. Numerous other changes are made throughout the rules in Article 4 that improve clarity, understandability, and incorporated references.

Article 5: R12-1-505 is being amended to require industrial radiographers, using a camera with depleted uranium as shielding, to test the camera for leakage of depleted uranium from the camera housing, as well as leakage from the radioactive source housed in the camera. R12-1-512 is added as a new rule. It requires radiography licensees to have a qualified radiation safety officer. The rule specifies the duties of the radiation safety officer and the deadline for compliance with this new rule. R12-1-521 requires industrial radiographers to pass an exam that will qualify them as being certified. The exam will be given at the Agency and will cost approximately $60. Numerous other changes are made throughout the rules in Article 5 that improve clarity, understandability, and incorporated references.

Article 6: For clarification purposes the contents of R12-1-612 are moved to R12-1-905, because Article 9 addresses concerns associated with high energy x-rays used in particle accelerators. New requirements affecting computerized tomographic (CT) system users will now be listed under R12-1-612. The proposed standards of operation are from suggested state regulations made available to state programs by the CRCPD. Some language has been incorporated from the Illinois CT regulations.

Article 7: In R12-1-702 the definition of "misadministration" is modified to bring its content into alignment with the definition used by the NRC. It was the intent of the Agency to follow the NRC when the rule went into effect in May, however, the definition was incorrectly worded at that time. R12-1-720 is added to clarify the procedure that must be followed when radioactive waste is held for decay in storage. This authorization was previously addressed by license condition.

Article 9: As noted under Article 6, R12-1-905 will contain the requirements for users of high energy x-rays that were formerly located in R12-1-612. They are moved to Article 9 to improve the organization of the rules contained in Title 12. R12-1-912 is amended to inform registrants that release of radioactive material through a ventilation system cannot exceed the limits for radioactive material listed in Article 4. R12-1-913 is added to ensure that registrants notify the Agency and affected patients of any misadministration that occurs as a result of improper use of a particle accelerator. The radiation exposure action levels are associated with the standards in similar federal regulations. R12-1-914 is added for clarification purposes. The requirement to have an Agency representative inspect a new particle accelerator facility prior to the initiation of patient treatments is presently located in R12-1-904(G).

Article 12: R12-1-1209 is reformatted to improve conciseness and for clarification purposes. The Agency should not be required to list civil penalty amounts in correspondence to the radiation user following an inspection, if the Agency has no intention of imposing a civil penalty.

**7. A reference to any study that the Agency relies on in its evaluation of or justification for the final rules and where the public may obtain or review the study, all data underlying each study, any analysis of the study, and other supporting material:**

None

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

Not applicable

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

The changes to Article 2 should not pose a financial burden on radiation-producing machine users. The requirement to provide information concerning the use of radiation is already being imposed on radioactive material users. It is believed, however, that the Agency will see an increase in Agency administrative duties for processing the additional registration paperwork.

The prohibition of radioactive source bundling in Article 3 should effect few users in Arizona. At this time only one company is suspected of this activity. The company would have to acquire a quantity and form of radioactive material requiring a specific license and pay the associated licensing fee. The fee for an Arizona license is $1750 annually. The cost of the source that requires specific licensing must be balanced with the safety issues circumvented by using bundled, exempt radioactive sources.

The change in the disposal action level listed in R12-1-438 should actually save radioactive material users money because they will be allowed to store radioactive waste for decay, waste that is currently sent to a disposal site or waste broker. The estimated current charge is approximately $100 to $400 per cubic foot. The changes to R12-1-449 and R12-1-450 should not present any additional costs to the affected radiation users because the requirements are already being applied to them through license conditions. However, the maintenance of pocket dosimeters will affect registrants, but will impose no additional use conditions. The resulting additional cost for annual calibration is $50 per dosimeter.

The changes to Article 5 will mean additional costs to industrial radiography users. Radiography involves possessing radiography cameras with depleted uranium shielding that will have to be leak tested along with the radioactive source in the camera. The additional cost should be less than $15 for each additional leak test sample. The test will normally be performed twice each year. In R12-1-512 a Radiation Safety Officer (RSO) candidate will have to meet a higher training standard before the candidate will be authorized to oversee a radiography operation. The stricter standard may present some additional future cost to licensees and registrants. Current Radiation Safety Officers will not be asked to meet the new standard, but it will affect future candidates. The future cost of the proposed additional training and experience is unknown at this time. The last additional cost affecting radiography concerns is the requirement to employ only certified radiographers. In a separate rulemaking the Agency will assess a $60 fee for the radiography certification exam. The moneys collected will go directly to the CRCPD for the cost of the test. A fee is not collected by the Agency for proctoring the exam. As a final note, there are five radiography licensees in Arizona employing less than 75 radiographers and radiography assistants.

Recently, there has been concern for patient safety, because of the potential for a large radiation dose given to patients under-going a computerized tomography (CT) x-ray examination. In an attempt to minimize the hazard, the Agency has developed CT rules in R12-1-612, modeled after the CRCPD suggested regulations. The addition of R12-1-612 may result in an additional cost to the registrant, if a physics expert based quality assurance program is not in place.

At this time the driving force for a CT system regulation is the accreditation requirement placed on registrants by insurance providers. Because most medical institutions and major outpatient clinics are dependent on a portion of their income from insurance providers, they are maintaining their systems adequately. Reportedly, some outlying hospitals, small clinics, and some doctor's offices are not maintaining their CT's adequately. An interview of physics consultants servicing x-ray equipment in Arizona has determined that a CT "dosimetry survey" meeting the requirements in R12-1-612 would cost a registrant between $200 and $600. The "dosimetry survey" would include CT calibration and other quality assurance procedures performed between the physics expert's reviews, at intervals established by the physics expert.

It would appear the facility requirements contained in R12-1-612(B) would result in an additional expenditure by a CT registrant, however, most facilities are being constructed with communication and viewing systems. Their presence is being verified during Agency CT facility inspections being performed at this time. The review of the physicist's reports should not result in any additional cost to the Agency, however, the need to supply each inspector with appropriate equipment to perform a minimal verification dosimetry survey will cost the Agency approximately $2,000.

**10. A description of the changes between the proposed rules, including supplemental notices, and final rules:**

The changes described here are not substantive in nature. Therefore, it was not necessary to issue a supplemental notice describing these changes.

Format: Comment that initiated the change, rule change, followed by the Agency's response to the comment.

Article 4:

1. R12-1-431(D)

Comment: Clarify the labeling of syringe requirement.

(New)

**D.** A licensee shall label each syringe and each vial that contains a radiopharmaceutical, used in the practice of medicine, to identify its radiopharmaceutical content. Each syringe shield and vial shield shall also be labeled, unless the label on the syringe or vial is visible when shielded. The label shall indicate the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the name of the person being administered the radiopharmaceutical. Color-coding syringe shields and vial shields does not meet the labeling requirement.

(Old)

**D.** A licensee shall label each syringe and each vial, that contains a radiopharmaceutical, used in the practice of medicine, to identify its radiopharmaceutical content. Each syringe shield and vial shield shall also be labeled, unless the label on the syringe or vial is visible when shielded. Color-coding syringe shields and vial shields does not meet the labeling requirement.

Response: The Agency agrees there may be some difficulty in understanding what constitutes an adequate label. The language that is added specifies what is acceptable on the label. The description is taken directly from 10 CFR 35.60.

Article 6:

1. R12-1-612(B)(2)

Comment: The requirement to have two viewing systems, if the primary is electronic, is cost prohibitive.

A registrant shall ensure that a CT facility has:

(New)

2. A viewing system that will allow the operator to continuously view the patient from the control panel during each examination. If the viewing system malfunctions the CT shall not be used until the viewing system is repaired.

(Old)

2. A viewing system that will allow the operator to continuously view the patient from the control panel during each examination. If the primary viewing system is by electronic, each CT room shall have a secondary viewing system.

Response: The Agency agrees the initial cost may be high, and the maintenance of a second system would add to the cost of maintaining the facility. Also, this is not a therapy procedure. The dose to the patient is considerably lower. It would present little radiation hazard to the patient if a CT scan is completed

2. R12-1-612(C)(7)

Comment: A CT does not emit any radiation when it is not in operation. The language is very confusing in this regard.

(New)

7. Radiation exposure does not exceed 100 mR in one hour at one meter in any direction from the tube port of an operating CT, except in those cases where the x-ray tubes are designed to move, in which case, the maximum dose and associated tube position shall be evaluated according to manufacturer recommendations.

(Old)

7. If the CT is not in use, the radiation one meter in any direction from the tube port does not exceed 100 mR in one hour.

Response: The Agency agrees there is some confusion associated with this subsection. It should not imply there is radiation emitted when the CT is not operating. The operating radiation level is the only concern. The language is changed to better state this concern.

3. R12-1-612(D)

Comment: The medical physicist that maintains a CT, performs an evaluation of the CT's operation not a calibration.

(New)

**D.** Operating Procedures. A registrant shall ensure that:

1. Operating procedures are available at the control panel, or by electronic means, regarding the operation of a CT and evaluation of a CT's operation.
2. The operating procedures contain the following information:
   a. A copy of the latest evaluation of the CT's operation performed by a qualified expert;

b. Instructions on the use of the CT performance phantom by the qualified expert, a schedule of quality control tests with the results of the most recent quality control test, and the allowable variations for the indicated parameters;
c. The distance in millimeters between the tomographic plane and the reference plane if a reference plane is used; and
d. A current technique chart containing the CT's operating parameters, if applicable, and a procedure for determining whether a CT has been performed according to instructions of a physician.

3. If the evaluation of the CT's operation or quality control test identifies a parameter exceeding the tolerance established by a qualified expert, the use of a CT for patient examination is limited to those uses established in written instructions from the qualified expert.

(Old)

**D.** Operating Procedures. A registrant shall ensure that:

1. Operating procedures are available at the control panel regarding the operation and calibration of the system.
2. The operating procedures contain the following information:
   a. A copy of the latest calibration;
   b. Instructions on the use of the CT dosimetry phantom, a schedule of spot checks with the results of the most recent spot check, and the allowable variations for the indicated parameters;
   c. The distance in millimeters between the tomographic plane and the reference plane if a reference plane is used; and
   d. A current technique chart containing the CT's operating parameters, if applicable, and a procedure for determining the number of scans per patient examination.
3. If the calibration or spot check identifies a parameter exceeding the tolerance established by a qualified expert, the use of a CT for patient examination is limited to those uses established in written instructions from the qualified expert.

Response: The Agency agrees with the contention that an engineer performs a calibration after the qualified expert has determined that the CT is delivering more radiation than is necessary to produce diagnostic images.

Note: the word "calibration" will be replaced by the same language in R12-1-612(E) and (F), formerly (F) and (G) in the proposed rules. The requirement to do surveys, formerly (E), has been deleted.

4. R12-1-612(E), also, see (D) above for changes involving this recommended change.

Comment: "Spot check" should not be used because it is commonly used in reference to therapy systems. Note: "noise" has been deleted.

(New)

**E.** Quality control tests. A registrant shall have a written quality control test procedure, developed by a qualified expert, and ensure that the quality control test procedure:

1. Incorporate the use of a CT dosimetry phantom that indicates:
   a. Contrast scale;
   b. Nominal tomographic section thickness;
   c. Resolution capability of the system for low and high contrast objects; and
   d. The mean CTN for water or other reference materials;
2. Is included in the evaluation of the CT's operation and that the interval and system conditions are specified by the registrant's qualified expert.
3. Includes obtaining quality control test images with the CT performance phantom using the same processing mode and CT conditions of operation that are used to perform the evaluation of the CT's operation.
4. Requires that images obtained under subsection (E)(3) be retained until a new evaluation of the CT's operation is performed.
5. Requires the quality control test procedure and records of quality control tests performed be maintained for three years for Agency inspection.

(Old)

**E.** Spot checks. A registrant shall have a written spot check procedure, developed by a qualified expert, and ensure that the spot check procedure:

1. Incorporate the use of a CT dosimetry phantom that indicates:
   a. Contrast scale;
   b. Noise;
   c. Nominal tomographic section thickness;
   d. Resolution capability of the system for low and high contrast objects; and
   e. The mean CTN for water or other reference materials;
2. Is included in the CT calibration and that the interval and system conditions are specified by the registrant's qualified expert.

3. Includes obtaining spot check images with the CT dosimetry phantom using the same processing mode and CT conditions of operation that are used to perform the CT calibration.
4. Requires that images obtained under subsection (F)(3) be retained until a new CT calibration is performed in the following two forms:
   a. Photographic copies obtained from the image display device; and
   b. A digital form on a storage medium compatible with the CT x-ray system.
5. Requires the spot check procedure and written records of spot checks performed be maintained for Agency inspection.

Response: "Spot check" is in subsection (E), formerly (F). Note: "calibration" is replaced with "evaluation of the CT's operation". The Agency agrees that the use of terminology similar to that used when testing therapy equipment may be confusing.

The following are changes made to R12-1-612(F), formerly (G) involving changes noted above and the following comments.

Comment: Would it be acceptable to allow a two month window for performance of the evaluation of CT operation as is allowed with mammography equipment? Also, would changing an x-ray tube require the repeat evaluation of the CT's operation? Because there are so many types of CT exams it would be difficult to provide the expected dose associated with each one. The use of a dose profile is not applicable when assessing the radiation doses delivered by a CT system.

(New)

**F.** Evaluation of a CT's operation. A registrant shall ensure that:
1. The evaluation of a CT's operation is performed by, or under the direct supervision of, a qualified expert who is physically present at the facility during the evaluation of the CT's operation.
2. The evaluation of a CT's operation:
   a. Is performed before initial patient use and annually (within two months of the annual due date) and after any change or replacement of components that could, in the opinion of the qualified expert, cause a change in radiation output; and
   b. Shall measure the CTDI in a dosimetry phantom along the two axes specified in subsection (F)(4)(b).
3. The evaluation of a CT's x-ray system is performed with a calibrated dosimetry system that:
   a. Has been calibrated using a method that is traceable to the National Institute of Standards and Technology (NIST), and
   b. Has been calibrated within the preceding two years.
4. CT dosimetry phantoms used in determining radiation output meet the requirements specified by the CT manufacturer or a qualified expert who is responsible for maintaining proper operation and:
   a. Are constructed in a way that the parameters used to image the most commonly imaged parts of the human body are evaluated; and
   b. At a minimum, provide means for placement of a dosimeter along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom.
5. Any effects on the measured dose due to the removal of phantom material to accommodate the dosimeter are accounted for in the reported data or included in the statement of maximum deviation for the measured values.

(Old)

**F.** Calibration of radiation output. A registrant shall ensure that:
1. The calibration of a CT is performed by, or under the direct supervision of, a qualified expert who is physically present at the facility during the CT calibration.
2. The calibration of a CT:
   a. Is performed annually and after any change or replacement of components that could, in the opinion of the qualified expert, cause a change in radiation output;
   b. Is performed so that radiation output for each type of head, body, or whole body scan performed is evaluated; and
   c. Includes:
      i. A dose profile that is performed with a CT dosimetry phantom placed on the patient couch or support device without additional materials present;
      ii. A dose profile measured along the center axis of the CT dosimetry phantom for each nominal tomographic section thickness used by the registrant; and
      iii. Measurement of the CTDI along the two axes specified in subsection (G)(4)(b).
3. The calibration of a CT x-ray system is performed with a calibrated dosimetry system that:
   a. Is traceable to a national standard, and
   b. Has been calibrated within the preceding two years.
4. CT dosimetry phantoms used in determining radiation output meet the requirements specified by the CT manufacturer or a qualified expert who is responsible for maintaining proper operation and:

a. Are constructed in such a way that the parameters used to image the most commonly imaged parts of the human body are evaluated; and
b. At a minimum, provide means for placement of a dosimeter along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom.

5. Any effects on the measured dose due to the removal of phantom material to accommodate the dosimeter are accounted for in the reported data or included in the statement of maximum deviation for the measured values.

Response: The Agency agrees that this is an acceptable time-frame for performing the required testing. In regard to retesting a CT system, as part of operation evaluation after a component change or failure, it should be left to the qualified expert. A change of an x-ray tube may require a retest. Therefore, the language in this rule is not changed. Subsection (F)(2)(b) is deleted because it would be difficult to create a complete list of all scan types performed on a CT system, and subsections (F)(2)(c)(i) and (ii) are deleted because the Agency agrees that a dose profile is not applicable when evaluating the dose to a patient.

Article 9:

1. Comment: Not all old wedges are marked with the information required in R12-1-905(A)(3)(e).

(New)

e. Each filter that is removable from the system shall be clearly identified as to that filter's material of construction, thickness, and the nominal wedge angle for wedge filters or a record tracing these factors for each filter shall be maintained at the system console, and

(Old)

e. Each filter which is removable from the system shall be clearly identified as to that filter's material of construction, thickness, and the nominal wedge angle for wedge filters; and

Response: The Agency agrees the older units could present a compliance problem. The staff feels the intent of the rule could be met by a record of traceability listing all of the important factors for each wedge. The suggested language is not substantive because the registrants using filters that are not clearly marked can continue to use them if a suitable record is easily accessible at the console.

2. R12-1-905(A)(5)

Comment: Timers are not used in accelerators that are solely controlled by the setting of monitor units.

(New)

5. Beam monitoring system. All accelerator systems shall be provided with a beam monitoring system in the radiation head capable monitoring and terminating irradiation.
   a. Each beam monitoring system shall have a display at the treatment control panel that registers the accumulated monitor units.
   b. The beam monitoring system shall terminate irradiation if the preselected number of monitor units has been detected by the system.
   c. For units with a secondary beam monitoring system, the primary beam monitoring system shall terminate irradiation if the preselected number of monitor units has been detected. The secondary beam monitoring system shall terminate irradiation if the primary system fails.
   d. In the event of a power failure, the display information required in subsection (A)(5)(a) shall be retained in at least one system following the power failure.
   e. An interlock device shall prevent irradiation if any beam monitoring system is inoperable.
   f. For purposes of this rule:
      i. "Beam monitoring system" means a system of devices that will monitor the useful beam during irradiation and will terminate irradiation if a preselected number of monitor units is accumulated.
      ii. "Monitor unit" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

(Old)

5. Timer. A timer shall be provided and shall meet all of the following requirements:
   a. The timer shall have a display at the treatment control panel and shall have a preset time selector and an elapsed time indicator.
   b. The timer shall be a cumulative timer which switches on and off with the radiation and retains its reading after irradiation is interrupted or terminated. It shall be necessary to zero and subsequently reset the elapsed time indicator and the preset time selector after irradiation is terminated before further irradiation is possible.
   c. The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems fail to do so.

Response: The Agency agrees with this finding, after comparing similar regulations from the state of Illinois. Illinois regulates the monitoring of absorbed dose by requiring the particle accelerator to have a beam monitoring system rather than a timer. Also, a Good Samaritan Medical Center Medical Physicist was contacted about the inappropriate

use of timers in this rule. He agrees that the use of timers is inappropriate for particle accelerators and that timers are used to monitor absorbed dose delivered to a patient treated with a teletherapy system.

3. R12-1-905(B)(3)(d)(ii)

Comment: The language does not accommodate registrants that do not have access to both types of testing, air and water. Air determinations are not commonly performed.

(New)

ii. The exposure rate or dose rate in air or at various depths of water for the range of field sizes used for each effective energy, and for each treatment distance used for radiation therapy;

(Old)

ii. The exposure rate or dose rate in air and at various depths of water for the range of field sizes used for each effective energy, and for each treatment distance used for radiation therapy;

Response: Registrants should be allowed to choose one of the methods. The Agency agrees that in-air calibrations are not commonly used, however, it should remain available to those who want to use it. With the use of the word "or" the authorization will remain in the rule without both tests being required.

4. R12-1-913(A)

Comment: The action level listed under this rule is inappropriate for beam therapy because it is often fractionally administered to the patient.

(New)

**A.** For purposes of this rule "misadministration" means:
1. A therapeutic radiation dose from a machine:
   a. Delivered to the wrong patient;
   b. Delivered using the wrong mode of treatment;
   c. Delivered to the wrong treatment site; or
   d. Delivered in one week to the correct patient, using the correct mode, to the correct therapy site, but greater than 130% of the prescribed weekly dose; or
2. A therapeutic radiation dose from a machine with errors in the calibration, time of exposure, or treatment geometry that result in a calculated total treatment dose differing from the final, prescribed total treatment dose by more than 20%, except for treatments given in 1 to 3 fractions, in which case a difference of more than 10% constitutes a misadministration.

(Old)

**A.** For purposes of this rule "misadministration" means:
1. The administration of radiation from a machine, for therapy purposes involving:
   a. The wrong energy;
   b. The wrong modality;
   c. The wrong patient; or
   d. A dose to an individual from a single application that differs from the prescribed dose by 20%; or
2. A therapeutic radiation dose from a machine such that errors in the calibration, time of exposure, or treatment geometry result in a calculated total treatment dose differing from the final, prescribed total treatment dose by more than 10%.

Response: The Agency agrees the listed action levels are better suited to radiopharmaceuticals. Also, a comparison of these levels to those used by the NRC disclosed that these levels are too restrictive. The Agency will adopt the action levels used by the federal government. This change is not substantive in nature.

**11. A summary of the principal comments and the Agency response to them:**

Article 2:

Comment: In reference to Application Form 1090, what is device cycle time? When is the principal frequency not applicable?

Response: A response to these questions is unnecessary because the requested information concerning MRI systems has been deleted from the list. Licensing of MRI systems will be discontinued in the next rulemaking package, as will all reference to MRI safety in Chapter 1.

Article 4:

1. Comment: In reference to R12-1-419, can an RSO badge a new individual even though it is unlikely that the person will receive 10% of the approved limit?

Will the employer have to get a prior exposure history for this employee that will not be exposed to radiation in excess of the 10% action level?

Is the employer required to attempt to get a complete exposure history?

Response: A RSO can badge any employee at the discretion of the employer. An exposure history is not required if the individual is badged for non-regulatory purposes. When an employer is providing personnel monitoring for regulatory purposes an attempt must be made to get a complete exposure history. What constitutes an adequate attempt is not specified in rule. It should be noted, that a complete history is required if the employee is going to participate in a planned special exposure.

2. R12-1-449(F)(1)

Comment: Electronic pocket dosimeters should be exempted from the leakage test because they cannot drift. Also, the type which does drift cannot be affected by drift that occurs over a 24 hour period because they are never worn for long periods of time and are read as soon as the user leaves the radiation area. The next user is instructed to recharge it before use.

Response: Electronic dosimeters will be exempted from the leakage test. The Agency disagrees with the comment concerning the duration of the drift test. A dosimeter could be worn for longer periods of time. The test should cover the longest time that the dosimeter could be worn. The change will not be made as requested.

3. Comment: Isn't there an acceptable activity level in a sealed source, below which the source would not have to be included in an inventory?

Response: The Agency cannot use the exempt quantities in Exhibit B of Article 3 as the action level for performing the required inventory. When a specific license is obtained from the Agency, all radioactive material possessed by the licensee must be handled in accordance with the license. Although the requested change cannot be made, R12-1-450 will be restructured to clarify its contents.

Article 5:

1. Comment: In reference to R12-1-521, why is it necessary to eliminate the radiography assistant position? The Agency cannot justify putting people out of work if they are doing their job safely. The Agency is eliminating this position in exchange for a trainee/radiographer program that would essentially mean the two workers required at a radiography job site would be radiographers. The Nuclear Regulatory Commission (NRC) does not prevent Agreement states from allowing radiography companies from using assistants. The second concern deals with the short time of one year that an employee is allowed to be a trainee.

Response: After further review, the Agency agrees with these concerns. It cannot be demonstrated in Arizona that assistants are a hazard to fellow workers, themselves, or the public. They should not be put out of work if they do not want to advance to a radiography position or cannot pass the tests to be a radiographer. The Agency has decided to abandon the adoption of a time-limited trainee category and continue the radiographers' assistant category and associated training program.

2. Comment: A minimum amount of training time for training a radiography trainee has not been established in R12-1-521(F). The NRC requires a minimum of two months before an individual can qualify for a radiography position.

Response: The intent was to make the one year training period the maximum length a candidate could be in a training position. After one year, if the tests were not passed, the trainee would no longer be allowed to act as a trainee. It was decided by the Board in the oral proceedings that occurred on July 25, 2000, that the Agency should not be putting a trainee out of employment because the trainee was unable to pass the radiographer qualifying test. The individual may be very capable of acting in the capacity of an assistant, as is currently authorized in the rules. The duration of training will be addressed during the application process, which is the current procedure followed when evaluating levels of adequate training. Suggested time-frames for classroom and field training are listed in NRC Regulation Guide 10.6. These training time-frames are currently accepted by the Agency when approving an applicant's training program.

3. Comment: Does a calibration label meet the requirements for a record of calibration for a survey meter in R12-1-534(6)?

Response: A label would be acceptable to the Agency if the label is legible and contains the necessary information as to how it is performing during a radiation survey.

Article 6:

1. Comment: Why did the Agency chose to develop computerized tomography (CT) rules? It is believed there should be some reference material available to the public at the Agency, indicating a need for CT regulations.

Response: The Agency works very closely with the Conference of Radiation Control Program Directors (CRCPD), a nationally recognized body that is concerned with the safety issues associated with the use of ionizing and nonionizing radiation. The CRCPD develops and makes available to Agreement States, like Arizona, suggested regulations focusing on the radiation uses that are potentially hazardous to patients, the public, and the users of the radiation. The CT rules offered for review are modeled after the CRCPD's suggested regulations.

Prominent medical organizations are able to stay abreast of the many safety concerns associated with the operation of a major clinic. However, there are a number of very small diagnostic imaging operations, some even in shopping malls, that do not have the resources to maintain their diagnostic equipment, which is often older and more often than not, purchased used. In a document issued by the CRCPD, after a study was conducted at a major U.S. medical facility, it was stated that 35% of the collective effective dose (CED) to the patient population was from the CT body exam. At this time the Agency has no rules to ensure that this dose is kept to a minimum. After considerable review the Agency has determined that CT regulations are necessary to protect the health and safety of the public.

2. Comment: Is there a scientific basis for the CT rules?

Response: There are accepted ranges for patient radiation dose associated with radiography, nuclear medicine, and therapy that the medical community and the Agency recognizes. Additionally, because the application of radiation to a patient is considered a part of the practice of medicine the Agency has not set patient radiation levels that cannot be exceeded. However, the Agency is increasingly involved in how the business of radiation use is conducted so that the physician prescribing the use of radiation can be assured that the radiation prescribed is, in fact, the radiation administered to the patient.

3. Comment: The proposed rules in R12-1-612 do not provide sufficient criteria for registrants to maintain their CT units.

Response: This rule was purposely written in a general manner to allow the registrant's qualified expert to establish a suitable quality assurance program for each CT unit. Flexibility in the rule accommodates the many different manufacturers and many different types of CT's currently in use. The procedures established by the qualified expert will become a condition of the registration as is the case under a radioactive material license.

4. Comment: Eliminate any reference to a dosimetry phantom in R12-1-612(D)(2)(b), and (F)(1). Also, this phantom should be only used by a qualified expert.

Response: The Agency agrees there is a distinct difference in the two phantoms used to maintain CT's, and that the dosimetry phantom should only be used by a physicist and should not be referred to when listing the requirements associated with quality control testing. This concern has resulted in "dosimetry phantom" being replaced with "performance phantom" in R12-1-612 subsections regulating CT quality assurance activities.

5. Comments:

What is meant by calibration of a CT system?

Is electronic recordkeeping acceptable?

What is meant by "dosimetry phantom" and "spot check"?

What kind of information is to be gained by recording the number of scans obtained during a specific CT procedure?

What is meant by number of scans?

Response: Any reference to a calibration procedure has been deleted. The "the evaluation of a CT's operation" is used in its place. Electronic recordkeeping is acceptable. A dosimetry phantom is used by a qualified expert to determine the doses received by patients during a CT imaging procedure. The term "dosimetry phantom" was incorrectly used in place of the "CT performance phantom," as noted above. The term "spot check" refers to a series of tests that are listed under quality assurance testing. The term has been deleted in favor of "quality control tests" because a "spot check" is performed when maintaining therapy systems. The Agency agrees that the rule does not define the information gained from determining the number of scans. The actual concern is with the amount of radiation dose to the patient. Because patient dose is directly related to the procedure ordered by the physician, the language will be amended to include a statement that the procedure has been approved by a physician. The number of scans means the number of slices per patient. The value has been discussed above, and there should be no problem with recording the required information.

Article 9:

Comment: Is the machine vendor allowed to make x-ray and neutron measurements?

Response: Yes, under the supervision of the registrant and if properly qualified by the Agency.

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

Many of the rules in Article 4 and 5 must be compatible with the Nuclear Regulatory Commission Regulations. The Agency is bound to these considerations by the Agreement between the Federal Government and the state of Arizona.

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

| Rule | Incorporation |
|---|---|
| R12-1-206(C) | 21 CFR 1020.30(d) |
| R12-1-403 | ICRP Publication 23, "Reference Man" |
| R12-1-416(C) | 40 CFR 190 |
| R12-1-418(B)(1) | NIST Handbooks 150 and 150-4 |
| R12-1-432(4) | 49 CFR 172.403 and 172.436 through 172.440 |
| | 49 CFR 173. 403 and 173.421 through 173.424 |
| R12-1-433(A) | 10 CFR 71.4 |
| R12-1-433(B) | 49 CFR 172.403 and 172.436 through 172.440 |
| R12-1-444(A)(4) | 40 CFR 190 |
| R12-1-502(D)(1) | ANSI Pub. N43.9-1991 |
| R12-1-502(D)(2)(c) | 10CFR 71.51 |
| R12-1-523(B)(1)(a) | ANSI Pub. N13.5-1972 |

**14. Were the rules previously adopted as emergency rules?**

No

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

## TITLE 12. NATURAL RESOURCES

## CHAPTER 1. RADIATION REGULATORY AGENCY

### ARTICLE 1. GENERAL PROVISIONS

Section
R12-1-102. Definitions

### ARTICLE 2. RADIATION MACHINE FACILITY REGISTRATION OR LICENSING, INSTALLATION AND SERVICE REGISTRATION, AND MAMMOGRAPHIC FACILITY CERTIFICATION

Section
R12-1-202. ~~Application Requirements for~~ Registration, ~~or~~ Certification, and Licensing of Ionizing and Nonionizing Radiation Machine Facilities; Notification
R12-1-206. ~~Assembler and/or transfer obligation~~ Assembly, Installation. Removal from Service, and Transfer
~~Appendix A. Registration and Licensing Forms (Excluding Radioactive Material)~~
Appendix A. Application Information

### ARTICLE 3. RADIOACTIVE MATERIAL LICENSING

Section
R12-1-303. Radioactive Material Other than Source Material; Exemptions

### ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

Section
R12-1-401. Purpose
R12-1-402. Scope
R12-1-403. Definitions
R12-1-404. Units and Quantities
R12-1-405. Form of Records
R12-1-406. Implementation
R12-1-407. Radiation Protection Programs
R12-1-408. Occupational Dose Amounts for Adults
R12-1-409. Summation of External and Internal Doses
R12-1-410. Determination of External Dose from Airborne Radioactive Material
R12-1-411. Determination of Internal Exposure
R12-1-412. Determination of Prior Occupational Dose

**ARTICLE 5. ~~RADIATION SAFETY REQUIREMENTS FOR~~ INDUSTRIAL RADIOGRAPHIC OPERATIONS**

**ARTICLE 1. GENERAL PROVISIONS**

**R12-1-102. Definitions**

Terms defined in A.R.S. § 30-651 have the same meanings when used in this Chapter. The following terms have the definitions set forth below. Additional definitions used only in a certain Article will be found in that Article.

"$A_1$" 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 "ARRA" No change.
"Agreement State" No change.
"Airborne radioactive material" No change.
"Airborne radioactivity area" No change.
"ALARA" No change.
"Analytical x-ray equipment" No change.
"Analytical x-ray system" No change.
"Annual" means done or performed yearly. For purposes of Chapter 1 any required activity done or performed within plus or minus two weeks of the annual due date is considered done or performed in a timely manner.
"Background radiation" No change.
"Becquerel" No change.
"Bioassay" No change.
"Brachytherapy" No change.
"By-product material" No change.
"Calendar quarter" No change.
"Calibration" No change.
"Certifiable cabinet x-ray system" No change.
"Certified cabinet x-ray system" No change.
"CFR" No change.
"Chelating agent" No change.
"Civil penalty" No change.
"Collective dose" No change.
"Committed dose equivalent" No change.
"Committed effective dose equivalent" No change.

"Curie" No change.
"Current license" 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" No change.
"Explosive material" No change.
"Exposure" No change.
"Exposure rate" No change.
"External dose" No change.
"Extremity" No change.
~~"Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeters (300 mg/cm2).~~
"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" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in one hour at 30 centimeters from the ~~any source of~~ radiation source or 30 centimeters from any surface that the radiation penetrates ~~or from any surface that the radiation penetrates~~.
"Human use" No change.
"Impound" No change.
"Individual" No change.
"Individual monitoring" No change.
"Individual monitoring device ~~devices~~" or "individual monitoring equipment" means an instrument ~~devices~~ designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these rules, "dosimeter", "personnel dosimeter", and "personnel monitoring equipment" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.
"Industrial radiography" No change.
"Injection tool" No change.
"Inspection" No change.
"Interlock" No change.
"Internal dose" No change.
"Irradiate" No change.
"Laser" No change.
"Lens dose equivalent" (LDE) means the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeters (300 mg/cm2).
"License" 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" (see calendar quarter) ~~means a period of time equal to 1/4 of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.~~
"Rad" No change.
"Radiation" No change.
"Radiation area" No change.
"Radiation dose" No change.
"Radiation machine" means any device capable of producing radiation except those devices with radioactive material as the only source of radiation.
"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" or "source" No change.
"Special form radioactive material" No change.
"Special nuclear material in quantities not sufficient to form a critical mass" No change.
"Storage area" No change.
"Storage container" No change.
"Subsurface tracer study" No change.
"Survey" No change.
"TEDE" No change.
"Teletherapy" No change.
"Temporary job site" No change.
"Test" No change.
"These rules" No change.
"Total Effective Dose Equivalent" (TEDE) No change
"Total Organ Dose Equivalent" (TODE) No change.
"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" No change.
"Year" No change.

## ARTICLE 2. RADIATION MACHINE FACILITY REGISTRATION OR LICENSING, INSTALLATION AND SERVICE REGISTRATION, AND MAMMOGRAPHIC FACILITY CERTIFICATION

**R12-1-202. ~~Application Requirements for~~ Registration, ~~or~~ Certification, and Licensing of Ionizing and Nonionizing Radiation Machine Facilities; Notification**

**A.** A person shall not use ~~receive, possess, use, or transfer~~ a radiation machine except as authorized in this Article.

**B.** A person ~~The owner or persons~~ possessing a ~~an~~y nonexempt radiation machine shall apply for registration of the machine with the Agency within 30 days after its installation ~~acquisition~~. The person applying for registration of a radiation-producing machine shall use the application forms provided by the Agency. The applicant shall provide the information identified in Appendix A of this Article ~~the appropriate form in Appendix A of this Article~~.

**C.** No change.

**D.** No change.

**E.** With the application form for registration of a radiation machine ~~forms for registration of radiation machines~~, except dental, bone mineral analyzer, and mammography facilities, the applicant shall provide a scale drawing of the room in which a stationary x-ray system is located, or provide measurements from the radiation source to the surrounding barrier surfaces. 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 (for example: hallways, offices, parking lots, and lavatories). Estimates of workload shall also be provided with the drawing.

**F.** An applicant proposing to use a particle accelerator for medical purposes shall not use the particle accelerator until the Agency inspection required in R12-1-914 has been completed.

**R12-1-206. ~~Assembler and/or transfer obligation~~ Assembly, Installation, Removal from Service, and Transfer**

**A.** Any person who ~~sells, leases, transfers, lends, disposes,~~ assembles~~,~~ or installs radiation machines in this state shall notify the Agency in writing within 15 days of:

1. The name and address of the person possessing the machine that was assembled or installed ~~persons who have received these machines~~;
2. The manufacturer, model, and serial number of each radiation machine with the tube housing model number and serial number, maximum kVp, and maximum mA, assembled or installed ~~transferred~~; and
3. The date each machine was assembled, installed, or the first clinical procedure is performed ~~of transfer of each radiation machine~~.

**B.** Any person who possesses a radiation machine registered by the Agency shall notify the Agency within 15 days of the machine being taken out of service. The written notification shall contain the name and address of the person receiving the machine, if it is sold, leased, or transferred to another person; the manufacturer, model, and serial number of the machine; and the date the machine was taken out of service.

**C.~~B.~~** In the case of diagnostic x-ray ~~X-ray~~ systems which contain certified components, an assembler shall submit to the Agency a copy of the assembler's report (FDA Report No. 2579) prepared in compliance with requirements in ~~of the Federal Diagnostic X-ray Standard,~~ 21 CFR 1020.30(d), 2000 Edition, published April 1, 2000 by the Office of the Federal Register, National Archives and Records Administration ~~revised as of April 1, 1987~~, incorporated ~~herein~~ by reference and on file with the Agency and ~~in~~ the Office of the Secretary of State, containing no future editions or amendments, ~~shall be submitted to the Agency~~ within 15 days following completion of the assembly. The ~~Such~~ report shall suffice in lieu of any other report by the assembler, when it contains the information required in subsection (A)(2).

**D.~~C.~~** A person shall not ~~No person shall~~ make, sell, lease, transfer, lend, assemble, service, or install radiation machines or the supplies used in connection with radiation machines ~~such machines~~ unless the ~~such~~ supplies and equipment when properly placed in operation and used, ~~shall~~ meet the requirements of these rules.

~~**Appendix A. Registration and Licensing Forms (Excluding Radioactive Material)**~~ **Repealed**

**ARRA-4**
Rev. 04/11/96

ARIZONA RADIATION REGULATORY AGENCY
APPLICATION FOR REGISTRATION OR LICENSING OR SOURCES OF RADIATION
(Excluding Radioactive Material)
(See Instructions on Attached Sheet)

THIS APPLICATION FOR A REGISTRATION/LICENSE: NEW __ RENEWAL __ AMENDMENT __

**FACILITY INFORMATION**

| 1. BUSINESS NAME OF POSSESSOR (Individual, Partnership, Corporation, etc.); | 2. BUSINESS AREA CODE - TELEPHONE # |
|---|---|
| | |

3. BUSINESS MAILING ADDRESS: NO. AND STREET CITY AND STATE ZIP CODE

4. ADDRESS AND TELEPHONE NUMBER AT WHICH SOURCES WILL BE USED, IF DIFFERENT FROM ITEMS 2 AND 3.

5. THIS IS AN APPLICATION FOR (CHOOSE ONE ONLY): SUBMIT A SEPARATE ARRA-4 FORM FOR EACH TYPE OF FACILITY, AS APPLICABLE.

X-RAY FACILITY __ PARTICLE ACCELERATOR FACILITY __ NON-IONIZING RADIATION FACILITY__

6. FACILTY SUBTYPE:

HOSPTIAL __ DENTAL __ PODIATRY __ MAMMOGRAPHY __ CHIROPRACTIC __ MEDICAL CLINIC __
PRIVATE MEDICAL PRACTICE __ EDUCATIONAL __ INDUSTRIAL RADIOGRAPHY__ INDUSTRIAL __ VETERINARIAN__
OTHER __ If Other, explain: _____

7. INDIVIDUAL RESPONSIBLE FOR RADIATION PROTECTION AT THIS FACILITY

NAME TITLE

~~**Appendix A. Registration and Licensing Forms *Continued***~~ **Repealed**

**ARRA-4**

Rev. 04/11/96

8. LEGAL STRUCTURE OF APPLICANT

An Individual __ A Partnership __ A Limited Liability Corporation __ A Corporation __

An Unicorporated Association __ City/County/State Government __

A Partnership
Please provide the name and address of each individual or legal entity owning a partnership interest in the applicant.

Please state the percentage ownership of the applicant partnership held by each of the individuals or legal entities listed above.

A Limited Liability Corporation

Memberships Ownerships

A Corporation

STOCK OF APPLICANT CORPORATION

| # AUTHORIZED SHARES | # ISSUED SHARES | # SUBSCRIBED SHARES | TOTAL STOCKHOLDERS | TOTAL SUBSCRIBERS |
|---|---|---|---|---|
| | | | | |

Is the applicant corporation directly or indirectly controlled by another corporation or other legal entity?
If "yes" give name and address of other corporation or legal entity and describe how such control exists and the extent of the control.

For all entities, please identify the State, District, or Territory under the laws of which the applicant is organized. Include the name and address of any Arizona agent for the applicant.

**SEE ATTACHED SHEET FOR LIST OF ATTACHMENTS TO BE INCLUDED WITH THIS APPLICATION**

9. The applicant or any official executing this application on behalf of the applicant certifies that this application has been prepared in accordance with Arizona Administrative Code, Title 12, Chapter 1, and all information contained on this form, including any supplements and attachments, is true and correct to the best of his or her knowledge and belief.

DATE APPLICANT (ITEM 1) BY TITLE

_____ _____ _____ _____

# RETAIN A COPY FOR YOUR RECORDS

~~**Appendix A. Registration and Licensing Forms *Continued***~~ **Repealed**

**ARRA-4**

Rev. 04/11/96

## INSTRUCTIONS

Amendments to Form ARRA-4 should be submitted on Form ARRA-4. Changes to the attachments do not require a Form ARRA-4, but only submit the attachment form as applicable.

Items 1-3, are self-explanatory. Be sure to include area code and all ZIP codes.

Item 4, list address(es) at which a source of radiation may be used other than the address listed in item 3. If statewide, county wide, or citywide, please so designate. Leave blank if the same as item 3.

Item 5, please classify the facility according to the usage for which this application is being filed. If more than 1 usage of sources of radiation occurs at this facility a separate application should be filed for each usage. You may make copies of the front of this form, if necessary.

Item 6, choose a facility subtype that best describes your facility.

Item 7, list the name and telephone number of the individual who is delegated responsibility for radiation control for the facility. If a committee has this responsibility, list the chairman and attach a list of the committee membership. In any case, an individual usually designated as the Radiation Safety Officer will have the day to day responsibility for the administration of the Radiation Safety Program of the facility. Changes to the Committee Membership of the Radiation Safety Officer may be sent to the Agency by letter or FAX.

Item 8, please indicate the legal structure of the applicant. **NOTE**: for all cases indicate the State, etc., under which the entity is organized and any Arizona Agent representing the entity.

Item 9, please sign and date the application. Send application to: ARRA; 4814 South 40th Street; Phoenix, AZ 85040.

If you have any questions, please write to the above address or call 602-255-4845 ex. 3 FAX 602-437-0705.

**PLEASE NOTE AN APPLICATION FOR A NEW RADIATION MACHINE FACILITY (NEVER REGISTERED/LICENSED BY THE APPLICANT) CANNOT BE PROCESSED UNTIL THE APPROPRIATE APPLICATION FEE IS RECEIVED. IN ACCORDANCE WITH R12-1-202 (C), THE APPLICANT OF AN EXISTING REGISTERED OR LICENSED FACILITY IS NOT TO POSSESS OR USE UNREGISTERED/UNLICENSED EQUIPMENT FOR MORE THAN 30 DAYS. (NOTE: A SCHEDULE OF APPLICATION FEES CAN BE FOUND IN R12-1-1306.)**

No registration is complete unless the appropriate forms listing the equipment to be registered/licensed accompany this application. The following is a list of the appropriate forms to use when registering equipment.

| TYPE EQUIPMENT | ATTACHMENTS TO ARRA-4 APPLICATION |
|---|---|
| Medical/Dental Diagnostic X-Ray units | ARRA-4X |
| Medical Therapy X-Ray (<1Mev) | ARRA-4XT |
| Medical Therapy X-Ray ( ≥ 1Mev) | ARRA-4PAT |
| Industrial Gauge | ARRA-4IG |
| Industrial Radiography (< 1,000 kVp) | ARRA-4IR |
| Industrial Radiography ( ≥ 1Mev) | ARRA-4PAR |
| All other Particle Accelerators | ARRA-4PA |
| Mammography | ARRA-13 |
| Non-Ionizing Application | ARRA-1004 |
| Tanning | ARRA-1005 |
| Radio Frequency | ARRA-1030 |
| Nonionizing User | ARRA-1050 |
| Laser | ARRA-1070 |
| MRI | ARRA-1090 |

~~**Appendix A. Registration and Licensing Forms *Continued***~~ **Repealed**

**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)<br>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 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***~~ **Repealed**

**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)<br><br>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 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***~~ **Repealed**

**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)<br><br>DATE |
|---|---|

**CLASSIFICATION OF PROFESSIONAL IN CHARGE OF MACHINE**

General Practitioner ____ Health Physicist ____ Registered X-Ray Technologist ____
Radiologist ____ Medical Physicist _____ Osteopath ____ Other ____

**PARTICLE ACCELERATOR INFORMATION**

Betatron____ Cyclotron ____ Van de Graaff ____ Other Medical therapy___ medical LINAC____

**EQUIPMENT**

| | MANUFACTURER / MODEL NO. | SERIAL NO. | MAX. Mev | MU/min or MAX. MA. | PHYSICAL LOCATION |
|---|---|---|---|---|---|
| Photons | | | | | |
| Electrons | | | | | |
| Neutrons | | | | | |

**ADDITIONAL 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***~~ **Repealed**

**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)<br><br>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 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***~~ **Repealed**

**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)<br><br>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 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***~~ **Repealed**

**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)<br><br>DATE |
|---|---|

**CLASSIFICATION OF PERSONNEL IN CHARGE OF MACHINE**

Health Physicist ____ Radiographer ____ Other ____

**MACHINE INFORMATION**

Betatron____ Cyclotron ____ Van de Graaff ____ Linear ____ Other ____

This Machine is Mobile ____ or Fixed ____

**EQUIPMENT**

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

**ADDITIONAL REQUESTED 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***~~ **Repealed**

**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)<br><br>DATE |
|---|---|

**CLASSIFICATION OF PERSONNEL IN CHARGE OF MACHINE**

Health Physicist ____ Operator ____ Other ____

**MACHINE INFORMATION**

Betatron____ Cyclotron ____ Van de Graaff ____ Linear ____ Other ____

This Machine is Mobile ____ or Fixed ____

**EQUIPMENT**

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

**ADDITIONAL 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.

# RETAIN A COPY FOR YOUR RECORDS

~~**Appendix A. Registration and Licensing Forms *Continued***~~ **Repealed**

**ARRA-13**
Rev. Nov. 1993

**ARIZONA RADIATION REGULATORY AGENCY**

# APPLICATION FOR MAMMOGRAPHY FACILITY CERTIFICATION

INSTRUCTIONS - Complete all items in this application for Certification of Mammography Facility or for renewal of a Certification. Use supplemental sheet where necessary. Item 11 must be complete on all applications. Prepare two copies of this application and all associated supplements or attachments. Mail original to Arizona Radiation Regulatory Agency; 4814 South 40th Street; Phoenix, AZ 85040. Upon approval of this application the applicant will receive a Certificate issued in accordance with A.R.S. § 32-2843 and 30-672.J.

<table>
<tr><td colspan="2">1A. Name and address of applicant, include ZIP Code.</td><td colspan="2">1B. Street address for Mammography Operations, if different from 1A.</td></tr>
<tr><td colspan="2">2. Person to contact regarding this application.</td><td colspan="2">Telephone No.</td></tr>
<tr><td colspan="4">3. Application for: [ ] New Certification [ ] Renewal Certification [ ] Screening Mammography [ ] Non-Screening Mammography</td></tr>
<tr><td colspan="2">4A. Radiation Safety Officer (RSO).</td><td colspan="2">4B. Radiation Physicist, Training, and Duties.</td></tr>
<tr><td>5. Control Manufacturer.</td><td>6. Control Model #.</td><td>7A. Control Serial #.</td><td>7B. Tube Manuf. and Model #.</td></tr>
<tr><td colspan="2">8. Address of Darkroom. (If not on site, ref § 32-2843 A.R.S.)</td><td colspan="2">9. For Screening Mammography, attach a copy of:<br>a. The physician approved guide for accepting patients.<br>b. The facility’s quality assurance program.<br>c. The Medical Physicist Evaluation of the Facility.</td></tr>
<tr><td colspan="4">10. Physicians to read or interpret mammography images, enclose certification from the Arizona Board of Medical or Osteopathic Examiners.</td></tr>
</table>

11. The applicant or any official executing this application on behalf of the applicant certifies that this application has been prepared in accordance with Arizona Administrative Code, Title 12, Chapter 1, and all information contained on the form, including any supplements and attachments, is true and correct to the best of his or her knowledge and belief.

_____ By:_____
(Type or print name of Certifying Official) (Signature)

_____ Date:_____
(Title of Certifying Official)

RETAIN A COPY FOR YOUR RECORDS

~~**Appendix A. Registration and Licensing Forms *Continued***~~ **Repealed**

**ARRA-1004**

May 1994

**ARIZONA RADIATION REGULATORY AGENCY**

# NONIONIZING RADIATION LICENSE APPLICATION

INSTRUCTIONS - Complete all items in this application for a new license or the renewal of an existing license. Use the provided data forms and supplemental sheets where necessary. Retain a copy of this application for your records. Mail the original to: Arizona Radiation Regulatory Agency, 4814 South 40th Street, Phoenix, Arizona 85040. Upon approval of this application, the applicant will receive a Nonionizing Radiation License issued in accordance with the requirements contained in the Arizona Administrative Code.

| 1. NAME AND ADDRESS OF LICENSEE:<br><br>TELEPHONE NUMBER: | 2. ADDRESS AT WHICH DEVICE(S) WILL BE USED: |
|---|---|
| 3. PERSON TO CONTACT REGARDING THIS APPLICATION<br><br>TELEPHONE NUMBER: | 4. THIS IS AN APPLICATION FOR: (Check appropriate item)<br>❑ NEW LICENSE<br>❑ RENEWAL OF LICENSE NO. _____<br>❑ AMEMDMENT TO LICENSE NO. _____ |

5. THIS APPLICATION IS FOR: (Check appropriate item)

| | | |
|---|---|---|
| [ ] TANNING FACILITY | number of devices _____ | Attach Tanning Data Forms and Nonionizing Radiation User Applications |
| [ ] INDUSTRIAL LASER FACILITY | number of devices _____ | Attach Laser Facility Data Forms and Nonionizing Radiation User Applications |
| [ ] MEDICAL LASER FACILITY | number of devices _____ | Attach Laser Facility Data Forms and Nonionizing Radiation User Applications |
| [ ] LASER LIGHT SHOW | variance number _____ | Attach Variance and Nonionizing Radiation User Applications |
| [ ] MEDICAL RF DEVICE FACILITY | number of devices _____ | Attach RF Data Forms and Nonionizing Radiation User Applications |
| [ ] MEDICAL IMAGING FACILITY | number of devices _____ | Attach Imaging Data Forms and Nonionizing Radiation User Applications |
| [ ] INDUSTRIAL RF FACILITY | number of devices _____ | Attach RF Data Forms and Nonionizing Radiation User Applications |
| [ ] OTHER RADIATION MACHINES | Contact the Agency | |

The Applicant or any official executing this certificate on behalf of the applicant named in item 1, certifies that this application is prepared in conformity with Arizona Administrative Code, Title 12, Chapter 1, and that all information contained on the form, including any attachments, is true and correct to the best of his or her knowledge and belief. Further, the Applicant or any official executing this certificate on behalf of the applicant agrees to conform to the Statutory and Administrative requirements of the State of Arizona and the Arizona Radiation Regulatory Agency.

_____ BY:_____
(TYPE OR PRINT NAME OF CERTIFYING OFFICIAL) (SIGNATURE)

_____ DATE:_____
(TITLE OF CERTIFYING OFFICIAL)

RETAIN A COPY FOR YOUR RECORDS

~~**Appendix A. Registration and Licensing Forms *Continued***~~ **Repealed**

**ARRA-1005**
May 1994

**ARIZONA RADIATION REGULATORY AGENCY**

# TANNING DATA FORM

INSTRUCTIONS - Complete all items in this data sheet for licensing a new facility or the renewal or amendment of an existing license. Use one data form for each Tanning Device. Retain a copy of this data sheet for your records. Attach this data sheet to your NONIONIZING RADIATION LICENSE APPLICATION and mail to: Arizona Radiation Regulatory Agency, 4814 South 40th Street, Phoenix, Arizona 85040. Upon approval of this application, the applicant will receive a Nonionizing Radiation License issued in accordance with the requirements contained in the Arizona Administrative Code. This data form is for use by Tanning device facilities. Other facility types are required to use forms provided by the Agency.

| | |
|---|---|
| 1. NAME AND ADDRESS OF LICENSEE:<br><br>TELEPHONE NUMBER: | 2. ADDRESS AT WHICH DEVICE(S) WILL BE USED: |
| 3. PERSON TO CONTACT REGARDING THIS DATA FORM<br><br>TELEPHONE NUMBER: | 4. THIS IS AN APPLICATION FOR: (Check appropriate item)<br>❑ NEW LICENSE<br>❑ RENEWAL OF LICENSE NO. _____<br>❑ AMEMDMENT TO LICENSE NO. _____ |
| 5. TANNING DEVICE IDENTIFYING INFORMATION:<br><br>MANUFACTURER: _____<br>MODEL NUMBER: _____<br>DATE OF MANUFACTURE: _____<br>TYPE OF LAMPS USED: ❑ UVA ❑ UVB ❑ UVA/UVB | 6. TIMER TYPE AND INDENTIFYING INFORMATION:<br>❑ ORIGINAL CERTIFIED TIMER<br>❑ AFTERMARKET ELECTRONIC<br>❑ AFTERMARKET MECHANICAL<br>MAXIMUM TANNING TIME SETTING: _____<br>USER ABLE TO TERMINATE EXPOSURE LOCALLY: ❑ YES ❑ NO |

The Applicant or any official executing this certificate on behalf of the applicant named in item 1, certifies that this application is prepared in conformity with Arizona Administrative Code, Title 12, Chapter 1, and that all information contained on the form, including any attachments, is true and correct to the best of his or her knowledge and belief. Further, the Applicant or any official executing this certificate on behalf of the applicant agrees to conform to the Statutory and Administrative requirements of the State of Arizona and the Arizona Radiation Regulatory Agency.

_____ BY:_____
(TYPE OR PRINT NAME OF CERTIFYING OFFICIAL) (SIGNATURE)

_____ DATE:_____
(TITLE OF CERTIFYING OFFICIAL)

RETAIN A COPY FOR YOUR RECORDS

~~**Appendix A. Registration and Licensing Forms *Continued***~~ **Repealed**

**ARRA-1030**
May 1994

**ARIZONA RADIATION REGULATORY AGENCY**

# RF DATA FORM

INSTRUCTIONS - Complete all items in this data sheet for licensing a new facility or the renewal of an existing license. Use one data form for each RF Device. Retain a copy of this data sheet for your records. Attach this data sheet to your NONIONIZING RADIATION LICENSE APPLICATION and mail to: Arizona Radiation Regulatory Agency, 4814 South 40th Street, Phoenix, Arizona 85040. Upon approval of this application, the applicant will receive a Nonionizing Radiation License issued in accordance with the requirements contained in the Arizona Administrative Code. This data form is for use by RF device facilities. Other facility types are required to use forms provided by the Agency.

| | |
|---|---|
| 1. NAME AND ADDRESS OF LICENSEE:<br><br>TELEPHONE NUMBER: | 2. ADDRESS AT WHICH DEVICE(S) WILL BE USED: |
| 3. PERSON TO CONTACT REGARDING THIS DATA FORM<br><br>TELEPHONE NUMBER: | 4. THIS IS DATA FOR AN APPLICATION FOR: (Check appropriate item)<br>❑ NEW LICENSE<br>❑ RENEWAL OF LICENSE NO. _____<br>❑ AMEMDMENT TO LICENSE NO. _____ |
| 5. RF DEVICE INDENTIFYING INFORMATION:<br><br>MANUFACTURER: _____<br>MODEL NUMBER:_____<br>SERIAL NUMBER: _____ | 6. RF DEVICE STRENGTH AND TYPE:<br><br>DEVICE OUTPUT POWER:_____<br>DUTY CYCLE:_____<br>PRINCIPAL FREQUENCY:_____ |

The Applicant or any official executing this certificate on behalf of the applicant named in item 1, certifies that this application is prepared in conformity with Arizona Administrative Code, Title 12, Chapter 1, and that all information contained on the form, including any attachments, is true and correct to the best of his or her knowledge and belief. Further, the Applicant or any official executing this certificate on behalf of the applicant agrees to conform to the Statutory and Administrative requirements of the State of Arizona and the Arizona Radiation Regulatory Agency.

_____ BY_____
(TYPE OR PRINT NAME OF CERTIFYING OFFICIAL) (SIGNATURE)

_____ DATE_____
(TITLE OF CERTIFYING OFFICIAL)

RETAIN A COPY FOR YOUR RECORDS

~~**Appendix A. Registration and Licensing Forms *Continued***~~ **Repealed**

**ARRA-1050**
May 1994

**ARIZONA RADIATION REGULATORY AGENCY**

# NONIONIZING RADIATION USER APPLICATION

INSTRUCTIONS - Complete one of these applications, to be included with a NONIONIZING RADIATION LICENSE APPLICATION, for each user to be authorized use on a new license or the renewal of an existing license. Use supplemental sheets where necessary. Retain a copy of this application for your records. Mail the original to: Arizona Radiation Regulatory Agency, 4814 South 40th Street, Phoenix, Arizona 85040.

| 1. NAME AND ADDRESS OF LICENSEE<br><br>TELEPHONE NUMBER: | 2. ADDRESS AT WHICH DEVICE(S) WILL BE USED |
|---|---|
| 3. PERSON TO CONTACT REGARDING THIS APPLICATION<br><br>TELEPHONE NUMBER: | 4. THIS APPLICATION IS PART OF A(N): (Check appropriate item)<br>❑ NEW LICENSE<br>☑ RENEWAL OF LICENSE NO. _____<br>❑ AMEMDMENT TO LICENSE NO. _____ |

The operator has been trained and demonstrated competence in the safe use of this equipment.
A copy of safety rules has been provided to the operator.

The operator has been made aware of any restrictions in operating techniques required for the safe use of the devices.

A copy of the Arizona Administrative Code, Title 12, Chapter 1 is available for review by the operator, and the requirements of the applicable portions of the same have been reviewed with the operator.

Job Title of Operator: _____ Job Title of Supervisor of Operator: _____

Name of Operator: _____ Name of Safety Officer: _____

The Use Applicant or the Official executing this certificate on behalf of the License Applicant named in item 1, certifies that this application is prepared in conformity with Arizona Administrative Code, Title 12, Chapter 1, and that all information contained on the form, including any attachments, is true and correct to the best of his or her knowledge and belief. Further, the User Applicant or any official executing this certificate on behalf of the applicant agrees to conform to the Statutory and Administrative requirements of the State of Arizona and the Arizona Radiation Regulatory Agency.

_____ BY:_____
(TYPE OR PRINT NAME OF OPERATOR) (SIGNATURE OF OPERATOR)

_____ DATE:_____
(TITLE OF OPERATOR)

_____ BY:_____
(TYPE OR PRINT NAME OF CERTIFYING OFFICIAL) (SIGNATURE OF CERTIFYING OFFICIAL)

_____ DATE:_____
(TITLE OF CERTIFYING OFFICIAL)

RETAIN A COPY FOR YOUR RECORDS

~~**Appendix A. Registration and Licensing Forms *Continued***~~ **Repealed**

**ARRA-1070**
May 1994

**ARIZONA RADIATION REGULATORY AGENCY**

# LASER DATA FORM

INSTRUCTIONS - Complete all items in this data sheet for licensing a new facility or the renewal or amendment of an existing license. Use one data form for each regulated LASER. Retain a copy of this data sheet for your records. Attach this sheet to your NONIONIZING RADIATION LICENSE APPLICATION and mail to: Arizona Radiation Regulatory Agency, 4814 South 40th Street, Phoenix, Arizona 85040. Upon approval of this application, the applicant will receive a Nonionizing Radiation License issued in accordance with the requirements contained in the Arizona Administrative Code. This data form is for use by Laser facilities. Other facility types are required to use forms provided by the Agency.

| | |
|---|---|
| 1. NAME AND ADDRESS OF LICENSEE:<br><br>TELEPHONE NUMBER: | 2. ADDRESS AT WHICH DEVICE(S) WILL BE USED: |
| 3. PERSON TO CONTACT REGARDING THIS DATA FORM<br><br>TELEPHONE NUMBER: | 4. THIS IS DATA FOR AN APPLICATION FOR: (Check appropriate item)<br>❑ NEW LICENSE<br>❑ RENEWAL OF LICENSE NO. _____<br>❑ AMEMDMENT TO LICENSE NO. _____ |
| 5. LASER INDENTIFYING INFORMATION:<br><br>MANUFACTURER: _____<br>MODEL NUMBER: _____<br>SERIAL NUMBER: _____ | 6. LASER CLASS AND TYPE:<br><br>LASER CLASS: _____<br>LASING MEDIUM (i.e., CO2 or YAG):_____<br>PRINCIPAL WAVELENGTH: _____ |

The Applicant or any official executing this certificate on behalf of the applicant named in item 1, certifies that this application is prepared in conformity with Arizona Administrative Code, Title 12, Chapter 1, and that all information contained on the form, including any attachments, is true and correct to the best of his or her knowledge and belief. Further, the Applicant and any official executing this certificate on behalf of the applicants behalf agrees to conform to the Statutory and Administrative requirements of the State of Arizona and the Arizona Radiation Regulatory Agency.

_____
(TYPE OR PRINT NAME OF CERTIFYING OFFICIAL)

BY_____
(SIGNATURE)

_____
(TITLE OF CERTIFYING OFFICIAL)

DATE:_____

RETAIN A COPY FOR YOUR RECORDS

~~**Appendix A. Registration and Licensing Forms *Continued***~~ **Repealed**

**ARRA-1090**
May 1994

**ARIZONA RADIATION REGULATORY AGENCY**

# IMAGING DATA FORM

INSTRUCTIONS - Complete all items in this data sheet for licensing a new facility or the renewal or amendment of an existing license. Use one data form for each Imaging Device. Retain a copy of this data sheet for your records. Attach this data sheet to your NONIONIZING RADIATION LICENSE APPLICATION and mail to: Arizona Radiation Regulatory Agency, 4814 South 40th Street, Phoenix, Arizona 85040. Upon approval of this application, the applicant will receive a Nonionizing Radiation License issued in accordance with the requirements contained in the Arizona Administrative Code. This data form is for use by Imaging device facilities. Other facility types are required to use forms provided by the Agency.

| | |
|---|---|
| 1. NAME AND ADDRESS OF LICENSEE:<br><br>TELEPHONE NUMBER: | 2. ADDRESS AT WHICH DEVICE(S) WILL BE USED: |
| 3. PERSON TO CONTACT REGARDING THIS DATA FORM<br><br>TELEPHONE NUMBER: | 4. THIS IS DATA FOR AN APPLICATION FOR: (Check appropriate item)<br>❑ NEW LICENSE<br>❑ RENEWAL OF LICENSE NO. _____<br>❑ AMEMDMENT TO LICENSE NO. _____ |
| 5. IMAGE DEVICE INDENTIFYING INFORMATION:<br><br>MANUFACTURER: _____<br>MODEL NUMBER: _____<br>SERIAL NUMBER: _____ | 6. IMAGING DEVICE STRENGTH AND TYPE<br><br>DEVICE FIELD STRENGTH: _____<br>DEVICE CYCLE TIME: _____<br>PRINCIPAL FREQUENCY: _____ |

The Applicant or any official executing this certificate on behalf of the applicant named in item 1, certifies that this application is prepared in conformity with Arizona Administrative Code, Title 12, Chapter 1, and that all information contained on the form, including any attachments, is true and correct to the best of his or her knowledge and belief. Further, the Applicant or any official executing this certificate on behalf of the applicants behalf agrees to conform to the Statutory and Administrative requirements of the State of Arizona and the Arizona Radiation Regulatory Agency.

_____ BY_____
(TYPE OR PRINT NAME OF CERTIFYING OFFICIAL) (SIGNATURE)

_____ DATE:_____
(TITLE OF CERTIFYING OFFICIAL)

RETAIN A COPY FOR YOUR RECORDS

**Appendix A.Application Information**

An application shall contain the following information as required in R12-1-202(B), before a registration or license will be issued. The Agency shall provide an application form to an applicant with a guide, if available, or shall assist the applicant to ensure only correct information is provided in the application.

| | |
|---|---|
| Name and mailing address of applicant | Use location |
| Person responsible for radiation safety program | Telephone number |
| Type of facility | Facility subtype |
| Legal structure and ownership | Signature of certifying agent |
| Radiation machine information | Equipment identifiers |
| Shielding information | Scale drawing |
| Equipment operator instructions and restrictions | Physicist name and training, if applicable |
| Classification of professional in charge | |
| Record of calibration for therapy units | Type of request: amendment, new, or renewal |
| Protection survey results, if applicable | |
| Type of industrial radiography program, if applicable | |
| Radiation Safety Officer name, if applicable | Contact person |
| Laser class and type, if applicable | Appropriate fee listed in Article 13 schedule |
| Other licensing and registration requirements listed in Articles 2, 6, 8, 9, and 14 | |

**ARTICLE 3. RADIOACTIVE MATERIAL LICENSING**

**R12-1-303. Radioactive Material Other than Source Material; Exemptions**

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

**B.** No change.
1. No change.
   a. No change.
      i. No change.
      ii. No change.
      iii. No change.
      iv. No change.
      v. No change.
      vi. No change.
      vii. No change.
         (1) No change.
         (2) No change.
         (3) No change.
      viii. No change.
   b. No change.
   c. No change.
   d. No change.
   e. No change.
   f. No change.
   g. No change.
      i. No change.
      ii. No change.
      iii. No change.
      iv. No change.
      v. No change.

vi. No change.
h. No change.
i. No change.
ii. No change.
iii. No change.
iv. No change.
2. No change.
3. No change.
a. No change.
b. No change.
4. No change.
a. No change.
b. No change.

**C.** Exempt quantities
1. No change.
2. No change.
3. No change.
4. Sources containing exempt quantities of radioactive material shall not be bundled or placed in close proximity for the purpose of using the radiation from the combined sources in place of a single source, containing a licensable quantity of radioactive material.
5. Possession and use of bundled or combined sources containing exempt quantities of radioactive material in unregistered devices by persons exempt from licensing is prohibited.

## ARTICLE 4. STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION

### R12-1-401. Purpose

**A.** Article 4 establishes standards for protection against ionizing radiation resulting from activities conducted according ~~pursuant~~ to licenses or registrations issued by the Agency. These rules ~~regulations~~ are issued according ~~pursuant~~ to A.R.S. Title 30, Chapter 4, ~~Arizona Revised Statutes,~~ as amended.

**B.** The requirements of Article 4 are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose equivalent to an individual, including radiation exposure ~~doses~~ resulting from all sources of radiation other than radiation prescribed by a physician in the practice of medicine, radiation received while voluntarily participating in a medical research program, and background radiation, does not exceed the standards for protection against radiation prescribed in this Article ~~Article 4~~. However, this Article does not limit ~~nothing in Article 4 shall be construed as limiting~~ actions that may be necessary to protect health and safety.

### R12-1-402. Scope

Except as specifically provided in other Articles of these rules ~~regulations~~, Article 4 applies to persons licensed or registered by the Agency to receive, possess, use, transfer, or dispose of sources of ionizing radiation. ~~The limits in Article 4 do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs~~.

### R12-1-403. Definitions

~~**A.**~~ "ALI" means annual limit on intake, the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the Reference Man ~~reference man~~ that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Appendix B, Table I, Columns 1 and 2~~, of Appendix B~~.

~~**B.**~~ "Class" means a classification scheme for inhaled material according to the material's ~~its~~ rate of clearance from the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, days ~~Days~~, of less than 10 days, for Class W, weeks ~~Weeks~~, from 10 to 100 days, and for Class Y, years ~~Years~~, of greater than 100 days (See Introduction, Appendix B). For purposes of these rules ~~regulations~~, "lung class" and "inhalation class" are equivalent terms.

~~**C.**~~ "DAC" means derived air concentration, the concentration of a given radionuclide in air which, if breathed by Reference Man ~~the reference man~~ for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these rules ~~regulations~~, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Appendix B, Table I, Column 3~~, of Appendix B~~.

~~**D.**~~ "DAC-hour" means derived air concentration-hour, the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee or registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

~~E.~~ "Declared pregnant woman" means a woman who has voluntarily informed the licensee or registrant in writing of the pregnancy and the estimated date of conception. ~~her employer, in writing, of her pregnancy and the estimated date of conception.~~

~~F.~~ "Deterministic effect" [see "Nonstochastic effect"].

~~G.~~ "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

~~H.~~ "Inhalation class" [see "Class"].

~~I.~~ "Lung class" [see "Class"].

~~J.~~ "Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these rules ~~regulations~~, "deterministic effect" is an equivalent term and "threshold" means that which if not exceeded, poses no risk or likelihood of an effect to occur.

~~K.~~ "Planned special exposure" means an infrequent exposure to radiation received while employed, but separate from and in addition to the annual occupational dose limits.

~~L.~~ "Probabilistic effect" [see "Stochastic effect"].

~~M.~~ "Reference Man" means a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base. A description of ~~the~~ Reference Man is contained in the International Commission on Radiological Protection report, ICRP Publication 23, "Report of the Task Group on Reference Man," published in 1975 by Pergammon Press, incorporated ~~herein~~ by reference and on file with the Agency and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments.

~~N.~~ "Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

~~O.~~ "Sanitary Sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

~~P.~~ "Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without a threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these rules ~~regulations~~, "probabilistic effect" is an equivalent term.

~~Q.~~ "Very-high ~~Very high~~ radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rad) in one hour at one meter from a radiation source ~~of radiation~~ or one meter from any surface that the radiation penetrates. (At very high doses received at high dose rates, units of absorbed dose, the gray and rad should be used, ~~gray and rad, are appropriate,~~ rather than units of dose equivalent, the sievert and rem)

~~R.~~ "Weighting factor" $w_T$ for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of $w_T$ are:

| **ORGAN DOSE WEIGHTING FACTORS** | |
|---|---|
| **Organ or Tissue** | **$w_T$** |
| Gonads | 0.25 |
| Breast | 0.15 |
| Red bone marrow | 0.12 |
| Lung | 0.12 |

| | |
|---|---|
| Thyroid | 0.03 |
| Bone surfaces | 0.03 |
| Remainder | 0.30[a] |
| Whole Body | 1.00[b] |

[a] 0.30 results from 0.06 for each of five "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

[b] For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved by the Agency on a case-by-case basis ~~until such time as specific guidance is issued~~.

**R12-1-404. Units and Quantities**

**A.** Each licensee or registrant shall use the Standard International (SI) ~~SI~~ units becquerel, gray, sievert, and coulomb per kilogram, or the special units curie, rad, rem, and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this Article ~~4~~.

**B.** The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this Article ~~4~~, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens ~~eye~~ dose equivalent, deep dose equivalent, or committed effective dose equivalent.

**R12-1-405. Form of Records**

A licensee or registrant shall ensure that each ~~Each~~ record required by this Article is ~~4~~ ~~shall be~~ legible throughout the specified retention period. The record shall be the original, ~~or~~ a reproduced copy, or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. As an alternative the record may be stored in electronic media capable of ~~with the capability for~~ producing legible~~, accurate, and complete~~ records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. A licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

**R12-1-406. Implementation**

~~**A.**~~ Any existing license or registration condition that is more restrictive than this Article ~~4~~ remains in force until amendment or renewal of the license or registration.

~~**B.** If a license or registration condition exempts a licensee or registrant from a provision of Article 4 in effect on or before January 1, 1994, it also exempts the licensee or registrant from the corresponding provision of Article 4., until an amendment or renewal of the license or registration modifies or removes this condition.~~

~~**C.** If a license or registration condition cites provisions of Article 4 in effect prior to January 1, 1994, which do not correspond to any provisions of Article 4, the license or registration condition remains in force until an amendment or renewal of the license or registration modifies or removes this condition.~~

**R12-1-407. Radiation Protection Programs**

**A.** No change.

**B.** The licensee or registrant shall use, to the extent practical ~~practicable~~, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

**C.** No change.

**D.** No change.

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

**R12-1-408. Occupational Dose Amounts for Adults**

**A.** Each ~~The~~ licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures required in ~~pursuant to~~ R12-1-413, to the following dose limits:

1. No change.
   a. No change.

b. No change.
2. The annual limits to the lens of the eye, to the skin, and to the extremities which are:
   a. A lens ~~An eye~~ dose equivalent of 0.15 Sv (15 rem), and
   b. No change.

**B.** No change.

**C.** The assigned deep dose equivalent and shallow dose equivalent is for the portion of the body receiving the highest exposure determined as follows:
1. The deep dose equivalent, lens ~~eye~~ dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.
2. If ~~When~~ a protective apron is worn and monitoring is conducted as specified in R12-1-419(B), the effective dose equivalent for external radiation shall be determined as follows:
   a. If ~~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% ~~percent~~ of the limit specified in R12-1-408(A), the reported deep dose equivalent value multiplied by 0.3 is the effective dose equivalent for external radiation; or
   b. No change.

**D.** No change.

**E.** No change.

**F.** No change.

**R12-1-409. Summation of External and Internal Doses**

**A.** If a ~~the~~ licensee or registrant is required to monitor according to R12-1-419(B) and (C), the licensee or registrant shall add 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 to R12-1-419(B) or only according to R12-1-419(C), summation is not required to demonstrate compliance with dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses according to subsections (B), (C), and (D). 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.** 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 (1 ~~one~~):
1. The sum of the fractions of the inhalation ALI for each radionuclide, or
2. The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or
3. The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using applicable ~~appropriate~~ biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, $w_T$, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10% of the maximum weighted value of $H_{T,50}$, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

**C.** 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.** 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 according ~~pursuant~~ to this subsection.

**R12-1-410. Determination of External Dose from Airborne Radioactive Material**

**A.** Each licensee ~~Licensees or registrants~~ shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, lens ~~eye~~ dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See Appendix B, footnotes 1 and 2.

**B.** No change.

**R12-1-411. Determination of Internal Exposure**

**A.** For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, each ~~the~~ licensee or registrant shall, when required according ~~pursuant~~ to R12-1-419, take suitable and timely measurements of:
1. Concentrations of radioactive materials in air in work areas;
2. Quantities of radionuclides in the body;
3. Quantities of radionuclides excreted from the body; or
4. Combinations of these measurements.

**B.** No change.

**C.** No change.

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

**D.** No change.

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

**F.** No change.

**G.** If ~~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 compliance with the dose limits in R12-1-408 and complies ~~to comply~~ with the monitoring requirements in R12-1-419, ~~and~~
2. The concentration of any radionuclide disregarded is less than 10% of its DAC, and
3. The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30%.

**H.** When determining the committed effective dose equivalent, the following information may be considered:
1. In order to calculate the committed effective dose equivalent, the licensee ~~or registrant~~ may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.
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 Appendix B, Table I. The licensee ~~or registrant~~ may, as a simplifying ~~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) is met.

**R12-1-412. Determination of Prior Occupational Dose**

**A.** For each individual who may enter a ~~the~~ licensee's or registrant's restricted area and is likely to receive, in a year, an occupational dose requiring monitoring according ~~pursuant to~~ R12-1-419, the licensee or registrant shall:
1. Determine the occupational radiation dose received during the current year; and
2. Attempt to obtain the records of lifetime cumulative occupational radiation dose.

**B.** Before ~~Prior to~~ permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:
1. No change.
2. All doses in excess of the limits received during the lifetime of the individual, including doses received during accidents and emergencies~~, received during the lifetime of the individual~~; and
3. All lifetime, cumulative, occupational radiation doses.

**C.** In complying with the requirements of subsection (A) ~~above~~, a licensee or registrant shall ~~may~~:
1. Accept, as a record of the occupational dose that the individual received during the current year, a written and signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and
2. No change.
3. No change.

**D.** No change.
1. The licensee or registrant shall record the exposure history, as required by subsection (A) ~~above,~~ on Agency Form Y (available from the Agency) or a similar ~~other~~ clear and legible record~~,~~ of all the information required by this subsection. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report for ~~in~~ preparing Agency Form Y or its equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on Agency Form Y or its equivalent indicating each period ~~the periods~~ of time for which there is no data ~~are not available~~.
2. The licensee or registrant is ~~Licensees or registrants are~~ not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed according ~~pursuant~~ to the rules ~~regulations~~ in Article 4 in effect before January 1, 1994. Occupational ~~Further, occupational~~ exposure histories obtained and recorded on Agency Form Y or its equivalent before January 1, 1994, would not have included effective dose equivalent but may be used in the absence of specific information on the intake of radionuclides by the individual.
3. If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall ~~assume~~:

a. In establishing administrative controls under ~~pursuant to~~ R12-1-408(F) for the current year, reduce ~~that~~ the allowable dose limit for the individual ~~is reduced~~ by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and
b. Not subject ~~That~~ the individual to ~~is not available for~~ planned special exposures.

4. The licensee or registrant shall retain current and prior records on Agency Form Y or its equivalent for three years after the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Agency Form Y or its equivalent for three years after the record is made.

**R12-1-413. Planned Special Exposures**

**A.** A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in R12-1-408, provided that each of the following conditions is satisfied:

1. No change.
2. No change.
3. No change.
   a. Informed in writing of the purpose of the planned special exposure; ~~operation; and~~
   b. Informed in writing of the estimated doses, ~~and~~ associated potential risks, and specific radiation levels or other conditions that might be involved in performing the task; and
   c. Instructed in the measures to be taken to keep the dose ALARA ~~in accordance with R12-1-407(B)~~, considering other risks that may be present.
4. Before ~~Prior to~~ permitting an individual to participate in a planned special exposure, the licensee or registrant shall ascertain ~~ascertains~~ prior doses as required by R12-1-412(B) ~~during the lifetime of the individual~~ for each individual involved.
5. Subject to R12-1-408(B), the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses that exceed ~~in excess of the limits to exceed~~:
   a. No change.
   b. No change.
6. The licensee or registrant shall maintain ~~maintains~~ records ~~of the conduct~~ of a planned special exposure in accordance with subsections (B) and (C) ~~below~~ and submit ~~submits~~ a written report to the Agency within 30 days after the date of ~~following~~ any planned special exposure conducted in accordance with this Section, informing the Agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by subsection (B) ~~below~~.
7. The licensee or registrant shall record ~~records~~ the best estimate of the dose resulting from the planned special exposure in the individual's record and inform ~~informs~~ the individual, in writing, of the dose within 30 days after ~~from~~ the date of the planned special exposure. The dose from a planned special exposure ~~exposures~~ shall not be considered in controlling future occupational dose of the individual according ~~pursuant~~ to R12-1-408(A) but shall be included in evaluations required by subsections (A)(4) and (A)(5) ~~paragraphs A.4. and 5, above~~.

**B.** No change.

1. For each ~~use of~~ planned special exposure ~~exposures~~, the licensee or registrant shall maintain records that describe:
   a. No change.
   b. No change.
   c. No change.
   d. No change.
   e. What precautions were taken to assure that doses were minimized ~~maintained~~ in accordance with R12-1-407(B),
   f. What individual and collective doses were expected ~~to result~~,
   g. No change.
   h. The process through which ~~That~~ the employee involved in the planned special exposure has been informed in writing of the information contained in subsection (A)(3) ~~paragraph (A)(3), above~~.
2. The licensee or registrant shall retain the records for three years after the Agency terminates each pertinent license or registration ~~requiring these records~~.

**R12-1-414. Occupational Dose Limits for Minors**

The annual occupational dose limits for minors are 10% of the annual occupational dose limits specified for adult workers in R12-1-408.

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

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

**B.** No change.

**C.** The dose equivalent to an embryo or fetus is the sum of:
1. The deep dose equivalent to the declared pregnant woman; and
2. The dose equivalent to the embryo or fetus from radionuclides in the embryo or fetus ~~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 equivalent to the embryo or fetus has exceeded 4.5 mSv (0.45 rem), the licensee or registrant is deemed to be in compliance with subsection (A), if the additional dose equivalent to the embryo or fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

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

**R12-1-416. Dose Limits for Individual Members of the Public**

**A.** Each licensee or registrant shall conduct operations so that:
1. The total effective dose equivalent to any individual member ~~members~~ of the public from the licensed or registered operation does not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose contribution from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with R12-1-436; and
2. ~~Registrants shall not be required to retrofit locations within facilities where only radiation machines exist prior to the effective date of these rules and met the previous requirement of (0.5 rem) in a year; and~~
2.~~3.~~ The dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour.

**B.** Registrants possessing radiation machines in operation before August 10, 1994, are exempt from the requirement in subsection (A)(1). Operation of these machines shall be conducted so that the total effective dose equivalent to any individual member of the public does not exceed 5 mSv (0.5 rem) in a year.

**C.~~B.~~** A licensee, registrant, or an applicant for a license or registration may apply for ~~prior~~ Agency authorization to operate with an ~~up to an~~ annual dose limit of 5 mSv (0.5 rem) for an individual member of the public ~~of 5 mSv (0.5 rem)~~. The ~~This~~ application shall include the following information:
1. An explanation ~~Demonstration~~ of the need for and the expected duration of operations in excess of the limit in subsection (A) ~~above~~, and.
2. No change.
3. No change.

**D.~~C.~~** A ~~In addition to the requirements of Article 4, a~~ licensee or registrant shall comply with ~~subject to the provisions of~~ the U.S. Environmental Protection Agency's applicable environmental radiation protection standards in 40 CFR 190, 1999 Edition, published July 1, 1999 by the Office of Federal Register, National Archives and Records Administration, incorporated by reference and on file with the Agency and the Office of the Secretary of State, containing no future editions or amendments. ~~U.S. Environmental Protection Agency's generally applicable environmental radiation standards in Title 40, Code of Federal Regulations, Part 190, 1992 Edition, published July 1, 1992, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Office of Secretary of State, shall comply with those standards.~~

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

**F.~~E.~~** Each licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted areas and radioactive materials contained in effluents released to unrestricted areas ~~to demonstrate compliance with the dose limits for individual members of the public listed above~~.

**G.~~F.~~** Each licensee or registrant shall ~~show compliance with the annual dose limit listed above by~~:
1. Demonstrate by measurement ~~Demonstrating by measurement~~ or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or
2. Demonstrate ~~Demonstrating~~ that:
   a. The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Appendix B, Table II ~~of Appendix B~~; and
   b. No change.

**H.~~G.~~** No change.

**I.~~H.~~** ~~Records.~~ Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public; and shall retain the records for three years after the Agency terminates each pertinent license or registration ~~requiring the record~~.

**R12-1-417. Testing for Leakage or Contamination of Sealed Sources**

**A.** A ~~The~~ licensee in possession of any sealed source shall ensure ~~assure~~ that:
1. Each sealed source, except as specified in subsection (B) ~~below~~, is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the licensee or registrant.
2. Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six months or at alternative intervals approved by the Agency, after evaluation of information specified by

R12-1-311 (D)(2) and (D)(3) ~~of these regulations~~, or equivalent information specified by an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.

3. Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three months or at alternative intervals approved by the Agency, after evaluation of information specified by R12-1-311 (D)(2) and (D)(3). ~~of these regulations~~, or equivalent information specified by an Agreement State, a Licensing State, or the Nuclear Regulatory Commission.
4. Each ~~For each~~ sealed source suspected of damage or leakage is ~~that is required to be~~ tested for leakage or contamination~~, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee or registrant shall assure that the sealed source is tested for leakage or contamination~~ before further use.
5. Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, are ~~shall be~~ capable of detecting the presence of 185 Bq (0.005 µCi) of radioactive material on a test sample. The person conducting the test shall take test ~~Test~~ samples ~~shall be taken~~ from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which ~~one might expect~~ contamination could ~~to~~ accumulate. For a sealed source contained in a device, the person conducting the test shall obtain test samples ~~are obtained~~ when the source is in the "off" position.
6. The test for leakage from ~~for~~ brachytherapy sources containing radium ~~manufactured to contain~~ ~~Radium~~ is ~~shall be~~ capable of detecting an absolute leakage rate of 37 Bq (0.001 µCi) of Radon-222 in a 24-hour ~~24 hour~~ period when the collection efficiency for Radon-222 and its daughters has been determined with respect to collection method, volume, and time.
7. Tests for contamination from radium ~~Radium~~ daughters are ~~shall be~~ taken on the interior surface of brachytherapy source storage containers and are ~~shall be~~ capable of detecting the presence of 185 Bq (0.005 µCi) of a radium ~~Radium~~ daughter which has a half-life greater than four days.

**B.** A licensee ~~or registrant~~ need not perform tests ~~test~~ for leakage or contamination on the following sealed sources:

1. No change.
2. No change.
3. No change.
4. No change.
5. No change.
6. Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used, and identified as in storage. The licensee ~~or registrant~~ shall, ~~however~~, test each ~~such~~ sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within six months before the date of use or transfer.

**C.** Persons specifically authorized by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission shall perform tests for leakage or contamination from sealed sources. ~~Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.~~

**D.** A licensee shall maintain for Agency inspection test ~~Test~~ results ~~shall be kept~~ in units of becquerel or microcurie ~~and maintained for inspection by the Agency~~.

**E.** The following is ~~shall be~~ considered evidence that a sealed source is leaking:

1. No change.
2. No change.
3. The presence of removable contamination resulting from the decay of 185 Bq (0.005 µCi) or more of radium. ~~Radium.~~

**F.** A ~~The~~ licensee ~~or registrant~~ shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this Article ~~Article 4~~.

**G.** ~~Reports.~~ A ~~The~~ licensee shall file a report with the Agency within five days ~~with the Agency~~ if the test for leakage or contamination indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results, and the corrective action taken.

**H.** A licensee shall maintain records of the tests for leakage required in subsection (A) ~~Records: Records of tests for leakage or contamination of sealed sources shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency~~ for three years after the records are made.

**R12-1-418. Surveys and Monitoring**

**A.** No change.

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

**B.** No change.
1. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology, according ~~pursuant~~ to NVLAP procedures ~~Procedures~~ published March 1994 as NIST Handbook 150, and NIST Handbook 150-4 published August 1994, ~~November 1990 as Edition NISTIR-4493~~ by the U.S. Department of Commerce, incorporated ~~herein~~ by reference and on file with the Agency and the Office of the Secretary of State, containing no future editions or amendments; and
2. No change.

**C.** No change.

**D.** No change.
1. No change.
2. The licensee or registrant shall retain each of the following records for three years after the Agency terminates the ~~each pertinent~~ license or registration ~~requiring the record~~:
   a. Records of the survey results used ~~results of surveys~~ to determine the dose from external sources of radiation ~~used~~, in the absence of or in combination with individual monitoring data, and provide an ~~in the~~ assessment of individual dose equivalents;
   b. Records of the measurement and calculation results ~~results of measurements and calculations~~ used to determine individual intakes of radioactive material and used in the assessment of internal dose;
   c. Records showing the results of air sampling, surveys, and bioassays required according ~~pursuant~~ to R12-1-425(A)(3)(a) and (b); and
   d. Records of the measurement and calculation results ~~results of measurements and calculations~~ used to evaluate the release of radioactive effluents to the environment.

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

**A.** No change.

**B.** No change.
1. No change.
2. No change.
3. No change.
4. No change.
   a. No change.
   b. An individual monitoring device used for lens ~~eye~~ dose equivalent shall be located at the neck, or an unshielded location closer to the eye, outside the protective apron.
   c. No change.

**C.** No change.
1. Adults likely to receive, in one year, an intake in excess of 10% of the applicable ALI in Table I, Columns 1 and 2, of Appendix B; and
2. No change.

**D.** No change.
1. No change.
   a. The deep dose equivalent to the whole body, lens ~~eye~~ dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;
   b. No change.
   c. No change.
   d. No change.
   e. No change.
   f. No change.
2. No change.
3. No change.
4. No change.
5. No change.

**R12-1-420. Control of Access to High Radiation Areas**

**A.** A ~~The~~ licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:
1. A control device that, upon entry into the area, causes the level of radiation to be reduced below the ~~that~~ level at which an individual might receive a deep-dose equivalent of 1 mSv (0.1 rem) in one hour at 30 centimeters from the source ~~of radiation~~ from any surface that the radiation penetrates;
2. No change.
3. No change.

**B.** No change.

**C.** No change.
**D.** The licensee or registrant shall establish the controls required by subsections ~~subsection~~ (A) and (C) ~~above~~ in a way that does not prevent individuals from leaving a high radiation area.
**E.** No change.
1. No change.
2. No change.

**F.** The licensee or registrant is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in Article 4 and ~~to~~ operate in accordance with R12-1-407(B) and the provisions of the licensee's or registrant's radiation protection program.
**G.** The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area ~~as described in this Section~~ if the registrant has met all the specific requirements for access and control specified in other applicable Articles of these rules ~~regulations~~, such as, Article 5 for industrial radiography, Article 6 for x-rays in the healing arts, and Article 9 ~~8~~ for particle accelerators.

**R12-1-421. Control of Access to Very-high Radiation Areas**
**A.** In addition to the requirements in R12-1-420, a ~~the~~ licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 5 Gy (500 rad) or more in one hour at one meter from a source ~~of radiation~~ or from any surface that ~~through which~~ the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation~~,~~ or ~~to~~ non-self-shielded irradiators.
**B.** The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area, ~~as~~ described in subsection (A) ~~above~~, if the registrant has met all ~~the specific~~ requirements for access and control specified in other applicable Articles of these rules ~~regulations~~, such as, Article 5 for industrial radiography, Article 6 for x rays in the healing arts, and Article 9 ~~8~~ for particle accelerators.
**C.** Each licensee or registrant shall maintain records of tests made according ~~pursuant~~ to R12-1-422(B)(9) on entry control devices for very-high ~~very high~~ radiation areas. These records shall include the date, time, and results of each ~~such~~ test of function.
**D.** No change.

**R12-1-422. Control of Access to Irradiators (Very-high Radiation Areas)**
**A.** This Section applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. This Section does not apply to sources of radiation that are used in teletherapy, ~~in~~ industrial radiography, or ~~in~~ completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.
**B.** A licensee or registrant shall ensure that each ~~Each~~ area in which ~~there may exist~~ radiation levels may exceed ~~in excess of~~ 5 Gy (500 rad) in one hour at one meter from a source ~~of radiation~~ that is used to irradiate materials meets ~~shall meet~~ the following requirements:
1. Each entrance or access point shall be equipped with entry control devices that ~~which~~:
   a. No changes.
   b. No changes.
   c. No changes.
2. If the control devices required in subsection (B)(1) fail to function, additional control devices shall be provided so that: ~~Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by subsection (B)(1) above:~~
   a. No changes.
   b. Conspicuous visible and audible alarm signals are generated so that an ~~to make an~~ individual entering ~~attempting to enter~~ the area is aware of the hazard. The individual who enters the very-high radiation area after an alarm signals, shall be ~~and at least 1 other authorized individual, who is physically present,~~ familiar with the process ~~activity~~ and equipment. Before entering, the individual shall ensure that a second individual is present and aware of the first person's actions. ~~prepared to render or summon assistance, aware of the failure of the entry control devices~~.
3. No changes.
   a. No changes.
   b. Conspicuous visible and audible alarm signals are generated so that ~~to make~~ potentially affected individuals are aware of the hazard. Potentially affected individuals shall notify the ~~and the~~ licensee or registrant ~~or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware~~ of the failure or removal of the physical barriers ~~barrier~~.

4. No changes.
5. Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of subsections (B)(3) ~~paragraphs (A)(3)~~ and (B)(4) ~~above~~.
6. The licensee or registrant shall equip each ~~Each~~ area ~~shall be equipped~~ with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, ~~which shall be~~ installed in the area, and which can prevent the source of radiation from being put into operation.
7. The licensee or registrant shall control each ~~Each~~ area ~~shall be controlled~~ by use of ~~such~~ administrative procedures and ~~such~~ devices ~~as are~~ necessary to ensure that the area is cleared of personnel before ~~prior to~~ each use of the source of radiation.
8. The licensee or registrant shall check each ~~Each~~ area ~~shall be checked~~ by ~~a~~ radiation measurement to ensure that, before ~~prior to~~ the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of 1 mSv (0.1 rem) in one hour.
9. The licensee or registrant shall test the entry control devices required in subsection ~~paragraph~~ (B)(1) ~~above shall be tested~~ for proper functioning and keep records according to ~~. Record keeping shall be in accordance with~~ R12-1-421.
   a. Testing shall be conducted before ~~prior to~~ initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day;
   b. Testing shall be conducted before ~~prior to~~ resumption of operation of the source of radiation after any unintentional interruption: and
   c. No changes.

10 The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in a safe condition or ~~to~~ effect repairs on controls, unless control devices are functioning properly.

11. The licensee or registrant shall control entry ~~Entry~~ and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, ~~shall be controlled by such~~ with devices and administrative procedures ~~as are~~ necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any uncontained ~~loose~~ radioactive material that is carried toward ~~such~~ an exit and automatically ~~to~~ prevent uncontained ~~loose~~ radioactive material from being carried out of the area.

**C.** A licensee, registrant, or applicant seeking a license or registration for a source of radiation ~~Licensees, registrants, or applicants for licenses or registrations for sources of radiation~~ within the purview of subsection (B) that ~~above which~~ will be used in a variety of positions or in locations, such as open fields or forests, that make it impractical ~~impracticable~~ to comply with certain requirements of subsection (B) ~~above, such as those for the automatic control of radiation levels,~~ may apply to the Agency for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to that ~~those~~ specified in subsection (B) ~~above~~. At least one of the alternative measures shall be ~~include~~ an entry-preventing interlock control, based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where the ~~such~~ sources of radiation are used.

**D.** A licensee or registrant shall provide the ~~The~~ entry control devices required by subsections (B) and (C) ~~above shall be established~~ in such a way that no individual will be prevented from leaving the area.

**E.** No change.

1. Each licensee or registrant shall maintain records of tests made according ~~pursuant~~ to subsection ~~paragraph~~ (B)(9) ~~above~~ on entry control devices for very-high ~~very high~~ radiation areas. These records shall include the date~~, time,~~ and results of each ~~such~~ test of function.
2. The licensee or registrant shall retain the records for three years from the date ~~after~~ the record is made.

**R12-1-423. Use of Process or Other Engineering Controls**

A ~~The~~ licensee or registrant shall use process or other engineering controls, such as~~,~~ containment or ventilation, to control ~~the~~ concentrations of radioactive material in the air and comply with~~, as may be required to meet the requirements of~~ R12-1-407.

**R12-1-424. Use of Other Controls**

When it is not practical ~~practicable~~ to apply process or other engineering controls to control ~~the~~ concentrations of radioactive material in the air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent according to ~~in accordance with~~ R12-1-407(B), increase monitoring and limit intakes by one or more of the following means:

1. Control ~~of~~ access, ~~or~~
2. Limit ~~Limitation of~~ exposure times,
3. Use ~~of~~ respiratory protection equipment, or
4. Use other ~~Other~~ controls.

**R12-1-425. Use of Individual Respiratory Protection Equipment**

**A.** If a ~~the~~ licensee uses respiratory protection equipment to limit intakes according ~~pursuant~~ to R12-1-424:

1. Except as provided in subsection (A)(2) ~~paragraph (A)(2-b) below~~, the licensee shall use only respiratory protection equipment that is tested and certified ~~or had certification extended~~ by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration (NIOSH/MSHA). ~~, using standards in 30 CFR Part 11, 1993 Edition, published July 1, 1993, by the Office of the Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Office of Secretary of State.~~
2. If the licensee wishes to use equipment that has not been tested or certified by (NIOSH/MSHA) ~~the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration has not had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration~~, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of the ~~that~~ equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use~~, as required in 30 CFR, Part 11, referenced in paragraph (A)(1) above~~.
3. No change.
   a. No change.
   b. No change.
   c. Testing of respirators for operability immediately before ~~prior to~~ each use;
   d. No change.
   e. No change.
4. No change.
   a. No change.
   b. No change.
   c. No change.
5. The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require ~~such~~ relief from respirator use.
6. No change.

**B.** When estimating exposure of individuals to airborne radioactive materials, the licensee may take credit for respiratory protection equipment used to limit intakes as allowed in ~~pursuant to~~ R12-1-424, provided that the following conditions, in addition to those in subsection (A) ~~above~~, are satisfied:

1. The licensee selects respiratory protection equipment from Appendix A, that provides a protection factor that will afford the user protection from the peak concentration of airborne radioactive material and requires its use when ~~that provides a protection factor, specified in Appendix A, greater than the multiple by which~~ peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B, Table I, Column 3. However, if the selection of respiratory protection equipment, with a protection factor greater than the peak concentration, is inconsistent with the goal of maintaining the total effective dose equivalent ALARA as specified in R12-1-407(B), a ~~specified in R12-1-424 of keeping the total effective dose equivalent as required in R12-1-407.B., the~~ licensee may select respiratory protection equipment with a lower protection factor, provided the equipment selection and other controls authorized in R12-1-424 result ~~that such a selection would result~~ in a total effective dose equivalent that is ALARA as specified in ~~that meets the requirements in~~ R12-1-407(B). The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in the air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.
2. No change.
   a. No change.
   b. No change.

**C.** In an emergency, the licensee shall use as emergency equipment only respiratory protection equipment that has been specifically certified or has ~~had~~ certification ~~extended~~ for emergency use by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration NIOSH/MSHA.

**D.** ~~Reports.~~ The licensee shall notify the Agency in writing at least 30 days before the date that respiratory protection equipment is first used according to subsections (A) or (B) ~~pursuant to either R12-1-425 (A) or (B)~~

**R12-1-426. Security of Stored Sources of Radiation**

A ~~The~~ licensee or registrant shall secure from unauthorized removal or access licensed or registered sources of radiation that are stored in unrestricted areas.

**R12-1-427. Control of Sources of Radiation Not in Storage**

**A.** A ~~The~~ licensee shall control and maintain constant surveillance of licensed ~~or registered~~ radioactive material that is in an unrestricted area and ~~that is~~ not in storage or in a patient.

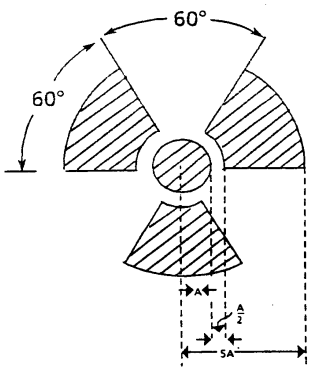
**B.** A ~~The~~ registrant shall maintain control of radiation machines that are in an unrestricted area and ~~that are~~ not in storage.

**R12-1-428. Caution Signs**

**A.** ~~Standard radiation symbol.~~ Unless otherwise authorized by the Agency, a licensee or registrant shall use the symbol prescribed by this Section with ~~shall use~~ the colors magenta, or purple, or black on yellow background as the standard radiation symbol. The symbol prescribed is the three-bladed design as follows:

RADIATION SYMBOL

1. Cross-hatched area is to be magenta, ~~or~~ purple, or black; and
2. The background is to be yellow.




**B.** ~~Exception to color requirements for standard radiation symbol.~~ Notwithstanding the requirements of subsection (A) ~~above~~, licensees or registrants are authorized to label sources of radiation, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols that lack the ~~and without a~~ color scheme required in subsection (A) ~~requirement~~.

**C.** ~~Additional information on signs and labels.~~ In addition to the contents of signs and labels prescribed in this Article ~~4~~, the licensee or registrant shall provide, on or near the required signs and labels, additional information~~, as appropriate,~~ to make individuals aware of potential radiation exposures and to minimize the exposures.

**R12-1-429. Posting ~~Posting Requirements~~**

**A.** A ~~Posting of radiation areas: The~~ licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

**B.** ~~Posting of high radiation areas.~~ The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

**C.** ~~Posting of very high radiation areas.~~ The licensee or registrant shall post each very-high ~~very high~~ radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

**D.** ~~Posting of airborne radioactivity areas.~~ The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

**E.** ~~Posting of areas or rooms in which licensed material is used or stored.~~ The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of licensed ~~such~~ material specified in Appendix C with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

**R12-1-430. Posting Exceptions ~~to Posting Requirements~~**

**A.** No change.

1. The sources of radiation are constantly attended during these periods by an individual who takes ~~the~~ precautions necessary to prevent ~~the~~ exposure of individuals to sources of radiation in excess of ~~the~~ limits established in this Article ~~4~~; and
2. No change.

**B.** A licensee or registrant is not required to post caution signs in rooms ~~Rooms~~ or other areas in hospitals that are occupied by patients that have been administered radioactive material ~~are not required to be posted~~ under ~~with caution signs pursuant to~~ R12-1-429, provided that confinement of the patient is not required by ~~pursuant to~~ a condition of ~~on~~ the radioactive material license.

**C.** A licensee or registrant is not required to post a caution sign in a ~~A~~ room or area ~~is not required to be posted with a caution sign~~ because of the presence of a sealed source, provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.

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

**R12-1-431. Labeling Containers and Radiation Machines**

**A.** A ~~The~~ licensee shall ensure that each container of licensed material is labeled with ~~bears~~ a durable, clearly visible ~~label bearing the~~ radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL". The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the radioactivity ~~activity~~ is estimated, radiation level ~~levels~~, kind of material ~~kinds of materials~~, and mass enrichment, to permit an individual ~~individuals~~ handling or using a container ~~the containers~~, or working in the vicinity of a container ~~the containers~~, to take precautions to avoid or minimize exposure ~~exposures~~.

**B.** Each licensee shall, before ~~prior to~~ removal or disposal of an empty, uncontaminated container ~~containers~~ to an unrestricted area ~~areas~~, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

**C.** Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner to caution an individual ~~which cautions individuals~~ that radiation is produced when it is energized.

**D.** A licensee shall label each syringe and each vial that contains a radiopharmaceutical, used in the practice of medicine, to identify its radiopharmaceutical content. Each syringe shield and vial shield shall also be labeled, unless the label on the syringe or vial is visible when shielded. The label shall indicate the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the name of the person being administered the radiopharmaceutical. Color-coding syringe shields and vial shields does not meet the labeling requirement.

**R12-1-432. Labeling Exemptions ~~to Labeling Requirements~~**

A licensee is not required to label:

1. No change.
2. No change.
3. Containers attended by an individual who takes ~~the~~ precautions necessary to prevent ~~the~~ exposure of individuals to radiation in excess of the limits established in this ~~by~~ Article ~~4~~;
4. Containers holding ~~which contain~~ radioactive material that does not exceed the limits for excepted quantity or article as defined and limited in 49 CFR ~~by the U.S. Department of Transportation (USDOT) regulations 49 CFR §§~~ 173.403~~(m) and (w)~~, and 173.421 through 173.424 ~~424~~, and are transported, packaged, and labeled ~~in transport and packaged and labeled~~ in accordance with 49 CFR ~~§§ 172.403 and~~ 172.436 through 172.440 ~~440~~, 1999 Edition, published October 1, 1999 by the Office of Federal Register National Archives and Records Administration, incorporated by reference and on file with the Agency and Office of Secretary of State. This incorporation by reference contains no future editions or amendments ~~of the U.S. Department of Transportation, 1992 Edition, published October 1, 1992 by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Office of Secretary of State~~;
5. Containers that are accessible only to individuals authorized to handle, ~~or~~ use ~~them~~, or ~~to~~ work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. A licensee shall retain the ~~The~~ record ~~shall be retained~~ as long as the containers are in use for the purpose indicated on the record; or
6. No change.

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

**A.** Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in 10 CFR 71.4, 2000 Edition, published January 1, 2000 by the Office of the Federal Register, National Archives and Records Administration, incorporated by reference and on file with the Agency and the Office of the Secretary of State, containing no future editions or amendments ~~10 CFR § 71.4, 1993 Edition, published January 1, 1993, by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file with the Office of Secretary of State~~, shall make arrangements to receive:

1. No change.
2. No change.

**B.** No change.

1. Monitor the external surfaces of a package, labeled with a Radioactive White I, Yellow II, or Yellow III as specified in 49 CFR 172.403 and 172.436 through 172.440, 1999 Edition, published October 1, 1999 by the Office of Federal Register, National Archives and Records Administration, incorporated by reference and on file with the Agency and the Office of the Secretary of State, containing no future editions or amendments ~~49 CFR §§ 172.403 and 172.436 through 440, 1992 Edition, published October 1, 1992 by the Office of Federal Register National Archives and Records Administration, incorporated herein by reference and on file at the Office of Secretary of State~~, for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in R12-1-102 ~~of these rules~~; and
2. Monitor the external surfaces of a package, labeled with a Radioactive White I, Yellow II, or Yellow III as specified ~~in 49 CFR §§ 172.403 and 172.436 through 440, reference~~ in subsection (B)(1) ~~paragraph (B)(1) above~~, for radiation

levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, ~~as~~ defined in 10 CFR~~, Part~~ 71, and referenced in subsection (A) ~~above~~; and

3. No change.

**C.** The licensee shall perform the monitoring required by subsection (B) ~~above~~ as soon as practical ~~practicable~~ after receipt of the package, but not later than three hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than three hours from the beginning of the next working day if it is received after working hours.

**D.** No change.

1. No change.
2. No change.

**E.** No change.:

1. Establish, maintain, and retain written procedures for safely opening packages that contain ~~in which~~ radioactive material ~~is received~~, and
2. No change.

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

**R12-1-434. General Requirements for Waste Disposal**

**A.** No change.

1. By transfer to an authorized recipient as provided in R12-1-439 or in Article 3 of these rules ~~regulations~~, or to the U.S. Department of Energy;
2. No change.
3. No change.
4. As authorized according ~~pursuant~~ to R12-1-435, R12-1-436, R12-1-437, or R12-1-438.

**B.** No change.

1. No change.
2. No change.
3. No change.
4. Disposal at a land disposal facility licensed according ~~pursuant~~ to Article 3 of these rules ~~regulations~~; or
5. No change.

**R12-1-435. Method for Obtaining Approval of Proposed Disposal Procedures**

A licensee or applicant for a license may apply to the Agency for approval of proposed procedures, not otherwise authorized in this Chapter for disposal ~~these regulations, to dispose~~ of licensed material generated in the licensee's operations. Each application shall include:

1. A description of the waste containing licensed material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation; ~~, and the proposed manner and conditions of waste disposal;~~
2. The proposed manner and conditions of waste disposal;
3. ~~2.~~ An analysis and evaluation of pertinent information on the nature of the environment;
4. ~~3.~~ The nature and location of other potentially affected facilities; and
5. ~~4.~~ An analysis ~~Analyses~~ and procedure ~~procedures~~ to ensure that doses comply ~~are maintained in accordance~~ with R12-1-407(B), and are within the dose limits in this Article ~~4~~.

**R12-1-436. Disposal by Release into Sanitary Sewerage System**

**A.** No change.

1. No change.
2. The quantity of licensed radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee or registrant does not exceed the concentration listed in Appendix B, Table III ~~of Appendix B, ;~~
3. If more than one radionuclide is released, the following conditions shall also be satisfied:
   a. The licensee shall determine the fraction of the limit in Appendix B, Table III ~~of Appendix B~~ represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee or registrant into the sewer by the concentration of that radionuclide listed in Appendix B, Table III ~~of Appendix B, ;~~ and
   b. The sum of the fractions for each radionuclide required by subsection (A)(3)(a) ~~subparagraph (A)(3)(a) above~~, does not exceed unity; and
   c. No change.

**B.** Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in subsection (A) ~~above~~.

**R12-1-437. Treatment or Disposal by Incineration**
A licensee shall ~~may~~ treat or dispose of licensed material by incineration only in the amounts and forms specified in R12-1-438 or as specifically approved by the Agency according ~~pursuant~~ to R12-1-435.

**R12-1-438. Disposal of Specific Wastes**
**A.** No change.
1. No change.
2. No change.
3. 1.85 kBq (0.05µCi), or less, of Iodine-125 per gram of medium used in analyzing in vitro laboratory samples and associated sample holders contaminated during the laboratory procedure.

**B.** A licensee shall not dispose of tissue, contaminated with radioactive material, according ~~pursuant~~ to subsection (A)(2) ~~above~~ in a manner that would permit its use either as food for humans or as animal feed.

**C.** A licensee is authorized to hold radioactive material with a physical half-life of 120 days or less for decay in storage before disposal in ordinary trash, and is exempt from the requirements of R12-1-434, provided:
1. Radioactive material held for disposal is permitted to decay for a minimum period of 10 half-lives;
2. The container of radioactive material is surveyed at its surface with no interposed shielding, before disposal as ordinary trash with a radiation detection survey meter set on its most sensitive scale and appropriate for the type of radiation being detected.
3. The radioactivity of the container, determined by survey, is less than two times background; and
4. All radiation labels are removed or obliterated.

**D.~~C.~~** ~~Records.~~ The licensee shall maintain records in accordance with R12-1-441.

**R12-1-439. Transfer for Disposal and Manifests**
~~**A.** The requirements of this Section are designed to control transfers of low-level radioactive waste intended for disposal at a licensed low-level radioactive waste disposal facility, establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes.~~

**A.~~B.~~** Each shipment of radioactive waste designated for disposal at a licensed low-level radioactive waste disposal facility shall be accompanied by a shipment manifest as specified in subsection (D)(1) ~~paragraph (E)(1) below~~.

**B.~~C.~~** Each shipment manifest shall include a certification by the waste generator as specified in subsection (D)(2) ~~paragraph (E)(2) below~~.

**C.~~D.~~** Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in subsection(D)(3) ~~paragraph (E)(3) below~~.

**D.~~E.~~** Requirements for manifests and transfer of low-level radioactive waste to ~~for disposal at~~ land disposal facilities ~~and manifests~~:
1. ~~Manifest.~~ The shipment manifest shall contain the name, address, and telephone number of the person generating the waste. The manifest shall also include the name, address, and telephone number or the name and U.S. Environmental Protection Agency hazardous waste identification number of the person transporting the waste to the land disposal facility. The manifest shall also indicate: a physical description of the waste, the volume, radionuclide identity and quantity, the total radioactivity, and the principal chemical form. The solidification agent shall be specified. Waste containing more than 0.1% chelating agents by weight shall be identified and the weight percentage of the chelating agent estimated. Wastes classified as Class A, Class B, or Class C in Appendix D, Section I ~~of Appendix D~~ shall be clearly identified by class ~~as such~~ in the manifest. The total quantity of the radionuclides hydrogen-3, carbon-14, technetium-99, and iodine-129 shall be shown. The manifest required by this paragraph may be shipping papers used to meet U.S. Department of Transportation or U.S. Environmental Protection Agency regulations or requirements of the receiver, provided all the required information is included. Copies of manifests required by this Section may be legible carbon copies or legible photocopies.
2. ~~Certification.~~ The waste generator shall include in the shipment manifest a certification that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the U.S. Department of Transportation and the Agency. An authorized representative of the waste generator shall sign and date the manifest.
3. Control and Tracking
   a. Any radioactive waste generator who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in subsections (D)(3)(a)(i) through (viii) ~~subdivision (a)(1) through (viii)~~. Any radioactive waste generator who transfers radioactive waste to a licensed waste processor who treats or repackages waste shall comply with the requirements of subsections (D)(3)(a)(iv) through (vii) ~~subdivision (a)(iv) through (vii)~~. A licensee shall:
      i. Prepare all wastes so that the waste is classified according to Appendix D, Section I ~~of Appendix D~~ and is characterized as required in ~~meets the waste characteristics requirements in~~ Appendix D, Section II ~~of Appendix D~~;

ii. Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with Appendix D, Section III ~~Section I of Appendix D~~;
iii. Conduct a quality control program, including management evaluation of audits, to ensure compliance with Appendix D, Sections ~~Section~~ I and II ~~of Appendix D; the program shall include management evaluation of audits~~;
iv. Prepare shipping manifests to meet the requirements of subsections (D)(1) and (D)(2) ~~Section I and II~~;
v. Forward a copy of the manifest to the intended recipient, at the time of shipment, or deliver the manifest to a collector at the time the waste is collected, obtaining acknowledgment of receipt in the form of a signed copy of the manifest or equivalent documentation from the collector;
vi. No change.
vii. No change.
viii. For any shipment ~~shipments~~ or any portion of a shipment for which acknowledgment of receipt is not ~~has not been~~ received within the times ~~set forth~~ in this Section ~~section~~, conduct an investigation in accordance with subsection (D)(3)(e) ~~Section III. (e)~~.

b. No change.
i. Acknowledge receipt of the waste from the generator within one week of receipt, by returning a signed copy of the manifest or equivalent documentation to the generator;
ii. Prepare a new manifest to reflect consolidated shipments; the new manifest shall serve as a listing or index for the detailed generator manifests. Copies of the generator manifests shall be a part of the new manifest. The waste collector may prepare a new manifest without attaching the generator manifests, provided the new manifest contains for each package the information specified in subsection (D)(1) ~~Section I~~. The collector licensee shall certify that nothing has been done to the waste that would invalidate the generator's certification;
iii. No change.
iv. No change.
v. No change.
vi. For any shipments or any portion of a shipment for which acknowledgment of receipt is not received within the times ~~set forth~~ in this Section ~~section~~, conduct an investigation in accordance with subsection (D)(3)(e) ~~Section III.(e)~~.

c. No change.
i. No change.
ii. Prepare a new manifest that meets the requirements in subsections (D)(1) and (D)(2) ~~of Section I and II~~. Preparation of the new manifest reflects that the processor is responsible for the waste;
iii. Prepare all wastes so that the waste is classified according to Appendix D Section I ~~of Appendix D~~ and meets the waste characteristics requirements in Appendix D Section II ~~of Appendix D~~
iv. Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with Appendix D, Section III ~~Section I and III of Appendix D~~;
v. Conduct a quality control program, including management evaluation of audits, to ensure compliance with Appendix D, Sections ~~Section~~ I and II ~~of Appendix D; the program shall include management evaluation of audits~~;
vi. Forward a copy of the new manifest to the disposal site generator or waste collector at the time of shipment, or deliver the manifest to a collector at the time the waste is collected, obtaining acknowledgment of receipt in the form of a signed copy of the manifest or equivalent documentation by the collector;
vii. No change.
viii. No change.
ix. For any shipment or portion of a shipment for which acknowledgment of receipt is not received within the times ~~set forth~~ in this Section, conduct an investigation in accordance with subsection (D)(3)(e) ~~Section III.(e)~~.

d. No change.
i. No change.
ii. No change.
iii. Notify the shipper, that is, the generator, the collector, or processor, and the Agency when any shipment or portion of a shipment has not arrived within 60 days after the date that the advance manifest was received.

e. Any shipment or portion of a shipment for which acknowledgment is not received within the times ~~set forth~~ in this Section ~~section~~ shall be:
i. Investigated ~~Be investigated~~ by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and
ii. Traced ~~Be traced~~ and reported to the shipper. The investigation shall include tracing the shipment and filing a report with the Agency. Each licensee who conducts a trace investigation shall file a written report with the Agency within two weeks of completion of the investigation.

**R12-1-440. Compliance with Environmental and Health Protection Regulations**
Nothing in R12-1-434, R12-1-435, R12-1-436, R12-1-437, R12-1-438, or R12-1-439 relieves the licensee from complying with other applicable federal, state and local regulations governing any other toxic or hazardous properties of materials that may be disposed of according ~~pursuant~~ to R12-1-434, R12-1-435, R12-1-436, R12-1-437, or R12-1-438 R12-1-439.

**R12-1-441. Records of Waste Disposal**
**A.** Each licensee ~~or registrant~~ shall maintain records of the disposal of licensed ~~or registered~~ materials made in accordance with ~~pursuant to~~ R12-1-435, R12-1-436, R12-1-437, R12-1-438, and disposal by burial in soil, including burials authorized before February 25, 1985.*
**B.** The ~~The licensee or registrant shall retain the~~ records required by subsection (A) shall be maintained for three ~~above for three~~ years after the Agency terminates the applicable ~~each pertinent~~ license or registration ~~requiring the record~~.

**R12-1-442. Agency Inspection of Shipments of Waste**
Each shipment of waste to a disposal facility, licensed under R12-1-1302(D)(11), is subject to inspection by the Agency before ~~prior to~~ shipment or transportation. The waste shipper shall notify the Agency not less than five working days before ~~prior to~~ the scheduled shipment or transportation of waste to a ~~of the intent to transport waste to the~~ licensed ~~land~~ disposal facility.

**R12-1-443. Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation**
**A.** ~~Telephone reports.~~ Each licensee or registrant shall report to the Agency by telephone as follows:
1. Immediately after it becomes known to the licensee that licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C is stolen, lost, or missing under circumstances that indicate ~~it appears~~ to the licensee that an exposure could result to individuals in unrestricted areas;
2. Within 30 days after it becomes known to the licensee that licensed radioactive material in an aggregate quantity greater than 10 times the quantity specified ~~identified~~ in Appendix C is stolen, lost, or missing, and is still missing.
3. No change.

**B.** ~~Written reports.~~ Each licensee or registrant required to make a report according ~~pursuant~~ to subsection (A) ~~above~~ shall, within 30 days after making the telephone report, make a written report to the Agency that contains ~~setting forth~~ the following information:
1. A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model, ~~and~~ serial number, type, and maximum energy of radiation emitted;
2. No change.
3. A statement of disposition, or probable disposition, of the licensed or registered source of radiation ~~involved~~;
4. No change.
5. No change.
6. No change.

**C.** After filing ~~Subsequent to filling~~ the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of the ~~such~~ information.
**D.** The licensee or registrant shall provide the names of individuals who may have received an exposure to radiation as a result of an incident as required in subsection (B). ~~The licensee or registrant shall prepare any report filed with the Agency pursuant to this Section so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.~~

**R12-1-444. Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits**
**A.** ~~Reportable events.~~ In addition to the notification required by R12-1-445, each licensee or registrant shall submit a written report within 30 days after learning of any of the following ~~occurrences~~:
1. No change.
2. No change.
   a. No change.
   b. No change.
   c. The limits for an embryo or fetus ~~embryo/fetus~~ of a declared pregnant woman in R12-1-415;
   d. No change.
   e. Any applicable limit in the license or registration; ~~or~~
3. No change.
   a. No change.
   b. An unrestricted area in excess of 10 times the applicable limit ~~set forth~~ in this Article ~~4~~ or in the license or registration, whether or not this involves an ~~involving~~ exposure of any individual to a dose in excess of the limits in R12-1-416; ~~or~~
4. Radiation levels or concentrations of radioactive material in excess of the standards in ~~For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in~~ 40

CFR 190, 1999 Edition, published July 1, 1999, by the Office of the Federal Register, National Archives and Records Administration, incorporated by reference and on file with the Agency and the Office of Secretary of State, if the licensee is subject to these federal standards, or there is a license condition referencing the 40 CFR 190 standards. This incorporation contains no future editions or amendments. ~~1992 Edition, published July 1, 1992, by the Office of the Federal Register, National Archives and Records Administration, incorporated herein by reference and on file with the Office of Secretary of State, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.~~

**B.** No change.

1. Each report ~~required by this Section~~ shall contain a description of each individual's exposure ~~describe the extent of exposure of individuals~~ to radiation and radioactive material, including~~,~~ as applicable ~~appropriate~~:
   a. No change.
   b. No change.
   c. No change.
   d. No change.
2. Each report filed according ~~pursuant~~ to subsection (A) ~~above~~ shall include for each individual exposed: the name, Social Security Number ~~account number~~, and date of birth. With respect to the limit for the embryo or fetus ~~embryo/fetus~~ in R12-1-415, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

**C.** All licensees or registrants who make reports according ~~pursuant~~ to subsection (A) ~~above~~ shall submit the report in writing to the Agency.

**R12-1-445. Notification of Incidents**

**A.** ~~Immediate notification.~~ Notwithstanding other requirements for notification, each licensee or registrant shall immediately report to the Agency each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

1. No change.
   a. No change.
   b. A lens ~~An eye~~ dose equivalent of 0.75 Sv (75 rem) or more; or
   c. No change.
2. No change.

**B.**~~3.~~ If the Agency's telephone ~~phone~~ does not answer within three minutes, the Duty Officer of the Arizona Department of Public Safety is to be called and advised of:

1. The existing radiation emergency,
2. The need to notify the Radiation Regulatory Agency's Duty Officer,
3. The caller's identity and the name of the affected licensee or registrant,
4. The location of the incident, and
5. A telephone number where the caller can be reached. ~~, "this is a radiation emergency notification" and ask to contact the Radiation Regulatory Agency's Duty Officer. The caller shall identify him or herself and the licensee or registrant, state the location of the incident, and give a phone number at which the caller can be reached.~~

**C.**~~**B.** Twenty-four hour notification.~~ Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Agency each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

1. No change.
   a. No change.
   b. A lens ~~An eye~~ dose equivalent exceeding 0.15 Sv (15 ~~1.5~~ rem); or
   c. No change.
2. No change.

**D.**~~**C.** The licensee or registrant shall prepare each report filed with the Agency according pursuant to this Section so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.~~

**E.**~~**D.** Licensees or registrants shall make the reports required by subsections (A) and (C) (B) above to the Agency by telephone, telegram, mailgram, or facsimile.~~

**F.**~~**E.** The provisions of this Section do not apply to doses that result from planned special exposures, provided the doses from the planned special exposure such doses are within the planned limits for planned special exposures and are reported according pursuant to R12-1-413.~~

**R12-1-446. Notifications and Reports to Individuals**

**A.** Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in R12-1-1004 ~~of these regulations~~.

**B.** Each licensee or registrant shall notify the individual exposed to radiation or radioactive material in the report to the Agency required in R12-1-445. ~~When a licensee or registrant is required pursuant to R12-1-445 to report to the Agency any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual~~. A separate notice to the exposed individual shall be provided no later than the date the report is submitted to the Agency and shall comply with R12-1-1004(A). ~~Such notice shall be transmitted at a time not later than the transmittal to the Agency and shall comply with the provisions of R12-1-1004(A). of these regulations.~~

**R12-1-447. Vacating Premises**

**A.** If a facility has been used for activities involving radioactive material each licensee shall notify the Agency in writing of the intent to vacate the facility no less than 45 days before relinquishing possession or control of the facility. ~~Each specific licensee shall, no less than 45 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of his activities, notify the Agency in writing of intent to vacate. When deemed necessary by the Agency, the licensee shall decontaminate the premises in such a manner as the Agency may specify.~~

**B.** If a facility is contaminated with radioactive material, the licensee vacating the facility shall decontaminate it using Agency-approved procedures.

**C.** The Agency shall inspect a vacated facility to determine whether it is contaminated with radioactive material.

**R12-1-448. Additional Reporting ~~Requirements~~**

**A.** Each licensee shall notify the Agency as soon as possible, but not later than ~~immediately, not later than~~ four hours after the discovery of an event, and take immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed the limits specified in this Chapter or releases of licensed material that could exceed the limits specified in this Chapter. For purposes of this Section ~~section~~, event means a radiation accident involving a fire, explosion, gas release, or similar occurrence.

**B.** No change.
1. No change.
   a. No change.
   b. Involves a quantity of radioactive material greater than five times the lowest annual limit on intake specified in Appendix B of this Article; and
   c. No change.
2. No change.
   a. No change.
   b. No change.
   c. No change.
3. No change.
4. No change.
   a. No change.
   b. No change.

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

**D.** Each licensee who makes a report required by subsections (A) or (B) ~~above~~ shall submit a written follow-up report within 30 days of the initial report. Written reports prepared as required by ~~pursuant to~~ other rules may be submitted to fulfill this requirement if the reports contain all of the required information in this Section ~~section~~. The licensee shall send the written report to the Agency. The report shall include the following:
1. No change.
2. No change.
3. No change.
4. No change.
5. No change.
6. No change.

**R12-1-449. Survey Instruments and Pocket Dosimeters**

**A**. No change.

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

**C.** No change.

**D.** No change.
1. No change.
2. No change.

**E.** No change.

**F.** Each licensee or registrant shall ensure that pocket dosimeters used to show compliance with this Article:
1. Have been evaluated, using a procedure acceptable to the Agency, for proper operation annually, and following repair, unless a more frequent evaluation is required by license condition. With the exception of electronic pocket dosimeters, which are exempted from the drift test, the evaluation shall include a check for drift over a 24-hour period, and
2. Meet the performance criteria listed in R12-1-523(B).

**G.** Records of personnel dosimeter operational checks shall be maintained for three years.

**R12-1-450. Sealed Sources ~~Source Requirements~~**

**A.** A licensee shall only receive, possess, and use radioactive materials contained in a sealed source that has been manufactured, labeled, packaged, and distributed in accordance with a specific license for its manufacture and distribution. The license to manufacture and distribute a sealed source shall be issued by the Agency, U.S. Nuclear Regulatory Commission, a Licensing State, or another Agreement State.

**B.~~A.~~** Any licensee who possesses and uses sealed sources containing radioactive material shall follow the radiation safety and handling instructions approved by the Agency; or follow the radiation safety and handling instructions 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. If the handling instructions, leaflet, or brochure is no longer available or a copy cannot be obtained from the manufacturer, the licensee shall notify the Agency that the source information is no longer available.

**C.** Inventories:
1. An inventory shall be conducted at intervals not to exceed six months, unless a shorter interval is specified by license condition.
2. The records of the inventory shall be maintained for three years from the date of the inventory, and shall be available for inspection by the Agency.
3. The information recorded shall include:
   a. The kind and quantity of radioactive material,
   b. The model and serial number of the source or the device in which it is mounted,
   c. The location of the sealed source,
   d. The date of the inventory, and
   e. The signature of the person performing the inventory.

~~**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.~~

**D.~~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.

**E.** Sealed sources, containing radioactive material, shall not be opened unless authorized by license condition.

**F.** Sealed sources and machines, devices, or equipment containing sealed sources shall be used in accordance with procedures described in the manufacturer's instructions and the safety precautions described in the Nuclear Regulatory Commission Sealed Sources and Device Registry, unless the instructions or precautions conflict with these rules or license condition.

## ARTICLE 5. ~~RADIATION SAFETY REQUIREMENTS FOR~~ INDUSTRIAL RADIOGRAPHIC OPERATIONS

**R12-1-501. Limits on Levels of Radiation for Radiographic Exposure Devices and Storage Containers**

**A.** A licensee shall ensure that radiographic ~~Radiographic~~ exposure devices with ~~measuring~~ less than 10 centimeters (4 inches) of space ~~four inches (10 centimeters)~~ from the sealed source storage position to any exterior surface of the device ~~shall~~ have no radiation level in excess of 500 microsievert (50 millirem) per hour at 15 centimeters (6 inches) ~~six inches (15 centimeters)~~ from any exterior surface of the device.

**B.** A licensee shall ensure that radiographic ~~Radiographic~~ exposure devices with ~~measuring~~ 10 centimeters (4 inches) of space ~~four inches (10 centimeters)~~ or more from the sealed source storage position to any exterior surface of the device, and all storage containers for sealed sources or for radiographic exposure devices, ~~shall~~ have no radiation level in excess of 2 ~~two~~ millisievert (200 millirem) per hour at any exterior surface, and 100 microsievert (10 millirem) per hour at one meter (40 inches) ~~40 inches (one meter)~~ from any exterior surface. The radiation levels specified are with the sealed source in the shielded position.

**R12-1-502. Radiographic Equipment Standards and Equipment Failure Notification**

**A.** Each registrant shall ensure that each x-ray machine has ~~Each x-ray machine shall be provided with~~ a lock designed to prevent unauthorized use or accidental production of radiation and is ~~shall be~~ kept locked at all times except when under the direct surveillance of a radiographer or radiographer's assistant.

**B.** ~~1.~~ Exposure devices shall ~~Devices~~:

1. ~~a.~~ Have a ~~A~~ lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from the shielded position; and
2. ~~b.~~ Be ~~Shall be~~ kept locked when not under the direct surveillance of a radiographer or radiographer's assistant unless alternate safety measures approved by the RSO are followed.

**C.** ~~2.~~ Source storage containers and source changers shall: ~~Source Storage Containers and Source Changers~~:

1. ~~a.~~ Have a ~~A~~ lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position; and
2. ~~b.~~ Be ~~Shall be~~ kept locked if they contain ~~when containing~~ sealed sources, unless they are ~~except when~~ under the direct surveillance of a radiographer or a radiographer's assistant.

**D.** ~~C.~~ No change.

1. Each radiographic exposure device, sealed source, and all associated equipment shall meet the requirements specified in American National Standards Institute ~~Standard~~ Publication N43.9-1991 (previously N432-1980) "American National Standard for Gamma Radiography-Specifications for Design and Testing Apparatus ~~Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography~~," 1991 Edition, published October 24, 1991~~,~~ by the American National Standards Institute, 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. The incorporated material may be purchased from the American National Standards Institute, Inc., 1430 Broadway, New York, New York, 10018 ~~incorporated herein by reference and on file with the Office of the Secretary of State~~.
2. In addition to the requirements specified in subsection (D)(1) ~~paragraph (1) of this subsection~~, the following requirements apply to radiographic exposure devices and associated equipment.
   a. The licensee shall have available for review documented proof that each device and associated equipment meets the requirements of R12-1-502(D)(1) ~~aforementioned standard~~;
   b. The licensee shall ensure that each radiographic exposure device has ~~shall have~~ attached to it ~~by the user~~, a durable, legible, clearly visible label bearing the ~~following~~:
      i. Chemical symbol and mass number of the radionuclide in the device~~:~~;
      ii. Activity and the date on which this activity was last measured;
      iii. Model number and serial number of the sealed source~~:~~;
      iv. Manufacturer of the sealed source~~:~~ and
      v. Licensee's name, address, and telephone number.
   c. The licensee shall ensure that radiographic ~~Radiographic~~ exposure devices intended for use as Type B transport containers ~~must~~ meet the applicable requirements of 10 CFR 71.51, 2000 Edition, published January 1, 2000, by the Office of the Federal Register, National Archives and Records Ad ministration, 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 ~~1993 Edition, published January 1, 1993, by the Office of the Federal Register National Archives and Records Ad ministration, incorporated herein by reference and on file with the Office of the Secretary of State.~~
   d. Modification of radiographic ~~my~~ exposure devices and associated equipment is prohibited unless the design of any replacement component, including source holder, source assembly, controls, or guide tubes would not compromise the design safety features of the system.
3. In addition to the requirements specified in subsections (D)(1) and (D)(2) ~~paragraphs (1) and (2) of this subsection~~, the following requirements apply to radiographic exposure devices and associated equipment that allow the source to be moved out of the device for routine radiographic operations ~~operation~~.
   a. The coupling between the source assembly and the control cable shall ~~must~~ be designed so ~~in such a manner~~ that the source assembly will not become disconnected if positioned ~~cranked~~ outside the guide tube. The coupling shall be constructed so that ~~must be such that~~ it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.
   b. The device shall ~~must~~ automatically secure the source assembly when it is retrieved ~~cranked~~ back into the fully shielded position within the device. This securing system shall ~~may~~ only be released by means of a deliberate operation on the exposure device.
   c. The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device shall ~~must~~ be equipped with safety plugs or covers ~~which~~ that shall ~~must~~ be installed during storage and transportation to protect the source assembly from water, mud, sand, or other foreign matter.

d. Each sealed source or source assembly shall ~~must~~ have attached to it or engraved in it, a durable, legible, visible label with the words: "DANGER-RADIOACTIVE". The label shall ~~must~~ not interfere with the safe operation of the exposure device or associated equipment.
e. The guide tube shall ~~must~~ have passed the crushing tests for the control tube as specified in ANSI N43.9-1991 and a kinking resistance test that closely approximates the kinking forces likely to be encountered during use.
f. Guide tubes shall ~~must~~ be used when moving the source out of the device.
g. An exposure head or similar device designed to prevent the source assembly from passing out the end of the guide tube shall ~~must~~ be attached to the outermost end of the guide tube during radiographic operations.
h. The guide tube exposure head connection shall ~~must~~ be able to withstand the tensile test for control units specified in ANSI N43.9-1991.
i. Source changers shall ~~must~~ provide a system of ensuring ~~assuring~~ that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.
j. All newly manufactured radiographic exposure devices and associated equipment acquired by licensees after January 10, 1992, shall ~~must~~ comply with the requirements of this Section.
k. All radiographic exposure devices and associated equipment in use after January 10, 1996, shall ~~must~~ comply with the requirements of this Section.

**E.~~D.~~** In addition to the notification requirements in Article 4, each licensee or registrant shall submit a written report within 30 days to the Agency whenever one or more of the following equipment failures occur ~~failure events occurs~~:
1. No change.
2. A ~~The~~ source assembly is ~~becomes~~ unintentionally disconnected from the drive cable;
3. Any component ~~All components~~ critical to safe operation of the radiographic exposure device fails to properly perform its intended function;
4. No change.
5. Personnel overexposure submitted under R12-1-444, involving failure of safety components of radiography exposure devices, source storage containers, or ~~and~~ source changers.

**F.~~E.~~** Each report required in subsection (E)~~(D)~~ ~~above~~ shall contain the following information:
1. No change
2. No change.
3. Manufacturer and model number of equipment involved in the incident;
4. No change.
5. No change.
6. No change.
7. No change.

**R12-1-504. Radiation Survey Instruments**

**A.** A ~~The~~ licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys ~~as~~ required by this Article and Article 4 of this Chapter. Instrumentation required by this Article shall have a range ~~such~~ that allows 20 microsievert (2 millirem) per hour through 10 millisievert (1 rem) per hour to ~~can~~ be measured.

**B.** No change.
1. Based on the scales and associated energies at which the meter will be used ~~At energies appropriate for use~~ and at intervals not to exceed:
   a. Three months and after each instrument servicing for instruments used in radiographic operations utilizing sealed sources ~~containing radioactive material~~, or
   b. No change.
2. So that ~~Such that~~ accuracy within plus or minus 20% of the calibration source ~~percent~~ can be demonstrated; and
3. For linear scale instruments, at two points located approximately 1/3 and 2/3 of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at three points between 0.02 and 10 mSv (2 and 1000 mRem) per hour. ~~At two or more widely separated points, other than zero, on each scale.~~

**C.** Records of the calibrations shall be retained for three years after the calibration date.

**R12-1-505. Leak Testing, Repair, Tagging, Opening, Modification, and Replacement of Sealed Sources**

**A.** A licensee shall ensure that the ~~The~~ replacement of any sealed source fastened to or contained in ~~permanently mounted in~~ a radiographic exposure device and the leak testing, repair, tagging, opening, or ~~any~~ modification of any sealed source is ~~shall be~~ performed ~~only~~ by persons specifically licensed to do so by the Agency, the U. S. Nuclear Regulatory Commission, or an Agreement or Licensing State.

**B.** Each sealed source shall be tested for leakage at intervals not to exceed six months. In the absence of a certificate from a transferor that a test has been made within the six months before ~~prior to~~ the transfer, the sealed source shall not be used ~~put into use~~ until it is tested.

**C.** The leak test shall be capable of detecting the presence of 185 becquerel (0.005 microcurie) of removable contamination. The leak test for a sealed source in a radiographic exposure device or source changer shall consist of swab testing the exit port using a procedure submitted in detail as part of the license application. Records of leak test results shall be kept in units of microcuries or becquerel and maintained ~~retained~~ for three years after the ~~next required~~ leak test is performed.

**D.** Any leak test that ~~which~~ reveals the presence of removable contamination ~~radioactive material~~ in excess of the amount specified in subsection (C) ~~above~~ shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and decontaminate, repair, or dispose ~~shall cause it to be decontaminated and repaired or to be disposed~~ of it in accordance with this Chapter. The licensee shall file a ~~A~~ report ~~shall be filed~~ with the Agency within five days after ~~of~~ receiving the results of the test, describing the equipment involved, the test results, and the corrective action taken.

**E.** Each radiographic exposure device using depleted uranium (DU) shielding and an "S" tube configuration shall be tested for DU contamination at intervals not to exceed 12 months. The analysis shall be performed in accordance with subsections (A) and (C). Should leak testing reveal the presence of 185 Bq (0.005 microcuries) or more of removable DU contamination, the exposure device shall be removed from service until an evaluation of the wear on the S-tube has been conducted. The exposure device shall not be used if the evaluation reveals that the S-tube is worn through. DU shielded exposure devices do not have to be tested for DU contamination while in storage. However, before using or transferring a radiographic exposure device, the device shall be tested for DU contamination if it has been stored for more than 12 months. Records of the DU leak test shall be maintained in accordance with subsection (C). Licensees will have three months from the effective date of this rule to comply with the DU leak testing requirements in this subsection.

**F.** ~~**E.**~~ A sealed source that ~~which~~ is not fastened to or contained in a radiographic exposure device or source changer shall have permanently attached to it a durable tag at least 2.5 centimeters (1 inch) ~~one inch (2.5 centimeters)~~ square bearing the prescribed radiation caution symbol in conventional colors, magenta or purple on a yellow background, and at least the instructions: "DANGER - RADIOACTIVE MATERIAL - DO NOT HANDLE - NOTIFY CIVIL AUTHORITIES IF FOUND".

**R12-1-507. Utilization Logs ~~logs~~**

Each licensee or registrant shall maintain current logs, which shall be retained for three years from the date of the recorded event and which show ~~shows~~ the following information for each source of radiation:

1. A description, including make, model, and serial number ~~(or make and model number)~~ of each radiographic exposure device ~~source of radiation~~ or storage container in which a source of radiation ~~the sealed source~~ is located;
2. The identity of the radiographer to whom the source of radiation is assigned;
3. Locations where the source of radiation was used and dates of use; and
4. No change.

**R12-1-508. Inspection and Maintenance of Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments**

**A.** Each ~~The~~ licensee shall perform visual and operability checks on radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments ~~check for defects in~~ or damage to ~~radiographic exposure devices, storage containers, and source changers~~ before ~~prior to~~ use each day the equipment is used. Survey instrument operability checks shall performed using a check source.

**B.** Each ~~The~~ licensee shall perform inspection and maintenance on radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments ~~conduct a program for inspection and maintenance of radiographic exposure devices, storage containers and source changers~~ at intervals not to exceed three months and before their initial use to ensure ~~or prior to the first use thereafter to assure~~ proper functioning of components important to safety. All parts shall be maintained in accordance with the licensee's written procedures and manufacturer's specifications. Records of inspection and maintenance shall be retained for three years from the date the record is made.

**C.** If any inspection reveals defects or damage to components critical to radiation safety, the radiographic exposure devices, transport and storage containers, associated equipment, source changers, or survey instruments ~~device~~ shall be removed from service until repairs have been made.

**R12-1-509. Permanent ~~Sealed Source~~ Radiographic Installations**

A licensee or registrant shall ensure that a permanent radiographic installation ~~Permanent radiographic installations with~~ having high radiation area entrance controls of the types described in R12-1-420(A) meets ~~shall also meet~~ the following requirements:

1. Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation shall have both visible and audible warning signals to warn persons of the presence of radiation. The visible signal shall be activated by radiation whenever the source is exposed. The audible signal shall be activated by ~~when~~ an attempt ~~is made~~ to enter the installation while the source is exposed; and
2. The control device or alarm system shall be tested for proper operation at the beginning of each workday the installation is used ~~at the beginning of each use~~. Records of the ~~such~~ tests shall be retained for three years from the date the record is made.

**R12-1-510. Operating Personnel ~~Requirements~~**
Each licensee and registrant shall provide, at least ~~as a minimum~~, two radiographic personnel for each radiographic exposure device in use for any industrial radiography conducted at a location other than at a permanent radiographic installation ~~facility~~ (shielded room, bay, or bunker) meeting the requirements of R12-1-509(1). If one of the personnel is a radiographer's assistant, the other shall be a certified radiographer authorized by the license.

**R12-1-511. License and Registration Application ~~Requirements~~ for Industrial Radiography**
If a licensee has satisfied the licensing requirements ~~set forth~~ in R12-1-309, the Agency shall issue a specific license or registration for industrial radiography if:

1. The applicant has a program to provide the instruction specified in R12-1-521 for radiographers and if applicable, a program to provide instruction to enclosed radiography x-ray machine operators. The applicant shall submit to the Agency a schedule or description of the training program that ~~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 an 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.
3. The applicant has an internal inspection program adequate to ensure ~~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 shall include the internal inspections at intervals not to exceed three months and inspection record retention for two years;
4. No change.
5. The sealed source radiographer applicant who desires to conduct leak tests has established procedures to be followed in leak testing sealed sources for possible leakage and contamination and submits to the Agency a description of the ~~such~~ procedures including:
   a. No change.
   b. No change.
   c. No change.
6. No change.

**R12-1-512. ~~Repealed~~ Radiation Safety Officer**

**A.** Each licensed or registered industrial radiography operation shall have a Radiation Safety Officer. The Radiation Safety Officer (RSO) shall oversee radiation safety activities to ensure they are being performed in accordance with state statutes and rules.

**B.** The minimum qualifications, training, and experience for an industrial radiography RSO are as follows:
   1. Completion of the training and testing requirements in R12-1-521;
   2. Completion of one year (2000 hours) of practical experience as a qualified radiographer in industrial radiographic operations; and
   3. Completion of training approved by the Agency in the establishment and maintenance of a radiation safety program.

**C.** The Agency shall consider a candidate if the candidate has training and experience in the field of ionizing radiation, differing from the training and experience in subsection (B), and has had formal training with respect to the establishment and maintenance of a radiation safety program.

**D.** An RSO shall:
   1. Establish, oversee, and review all operating, emergency, and ALARA procedures as required by R12-1-407;
   2. Oversee and approve all phases of the training program for radiography personnel, ensuring that appropriate and effective radiation protection practices are taught;
   3. Ensure that required radiation surveys and leak tests are performed and documented in accordance with these rules and take corrective measures if levels of radiation exceed established limits;
   4. Ensure that personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by R12-1-444; and
   5. Ensure that operations are conducted safely and institute corrective actions, including cessation of operations when necessary.

**E.** Licensees and registrants have six months from July 1, 2001, to meet the requirements of subsections (B) and (C).

**R12-1-521. ~~Requirements for Radiographers and Radiographer's Assistants~~ Radiographer and Radiographer's Assistant Qualifications, Radiographer Certification, and Audits**

**A.** A ~~The~~ licensee or registrant shall not permit any individual to act as a radiographer until the ~~such~~ individual:
   1. No change.
      a. No change.

i No change.
ii. No change.
iii. Significance of radiation dose, radiation protection standards, and biological effects of radiation;
~~(1) Radiation protection standards~~
~~(2) Biological effects of radiation~~
iv. No change.
v. Methods of controlling radiation dose by minimizing working time, maximizing working distance, and use of shielding;
~~(1) Working time~~
~~(2) Working distance~~
~~(3) Shielding~~

b. No change.
i. Use of radiation survey instruments, including their operation, calibration, and limitations;
~~(1) Operation~~
~~(2) Calibration~~
~~(3) Limitations~~
ii. No change.
iii. Use of personnel monitoring equipment, including film badges, thermoluminescent dosimeters, alarm rate meters, and direct reading dosimeters;
~~(1) Film badges~~
~~(2) Thermoluminescent dosimeters~~
~~(3) Alarming and direct reading dosimeters~~

c. No change.
i. No change.
ii. No change.
iii. No change.
iv. No change.

d. No change.
e. No change.
f. No change.

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

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

**C.** A licensee or registrant shall not permit an individual to act as an industrial radiographer until the individual is certified by passing the certification examination provided by the Conference of Radiation Control Program Directors (CRCPD), or any other radiographer certification examination the Agency deems equivalent. The licensee or registrant shall provide the Agency with proof of a candidate's passing score on the certification examination if the licensee or registrant is requesting that the candidate be added as an authorized user, and the proof of a passing score shall be maintained at the job site where a radiographer is performing field radiography. An uncertified individual may act as a radiographer until October 1, 2001. After October 1, 2001, an individual is no longer authorized to use radioactive material unless the individual is certified under this subsection.

**D.~~C.~~** Each licensee or registrant shall retain records of training and testing which demonstrate that the requirements of this rule are met for each radiographer and radiographer's assistant.

**E.~~D.~~** Each licensee or registrant shall conduct an internal audit program to ensure that the rules of this Chapter, the conditions of the license, and the ~~licensee's~~ operating and emergency procedures are followed by each radiographer and radiographer's assistant. The audit program shall include:
1. No change.
2. No change.
3. No change.

**R12-1-522. Operating and Emergency Procedures ~~emergency procedures~~**

A ~~the~~ licensee's or registrant's operating and emergency procedures shall include, at minimum, the following instructions ~~for at least the following~~:

1. Methods used to maintain individual radiation exposure below the limits in Article 4, "Standards for Protection Against Radiation" when handling and using sources of radiation ~~The handling and use of sources of radiation to be~~

~~employed to be employed such that no individual is likely to be exposed to radiation doses in excess of the limits established in Article 4, "Standards for Protection Against Radiation";~~

2. No change.
3. No change.
4. Methods and occasions for locking and securing radiographic exposure devices ~~sources of radiation~~ and storage containers;
5. No change.
6. Transportation to field locations, including packing of sources of radiation and storage containers in the vehicles, posting and placarding of vehicles, and control of sources of radiation during transportation;
7. No change.
8. The procedure for notifying the Agency ~~proper persons~~ in the event of an accident;
9. No change.
10. No change.

**R12-1-523. Personnel Monitoring Control**

**A.** A ~~The~~ licensee or registrant shall not permit any individual to act as a radiographer or as a radiographer's assistant unless, at all times during radiographic operations, each individual wears on the trunk of the body a direct-reading pocket dosimeter, ~~either~~ a film badge or a thermoluminescent dosimeter (TLD), and an alarm ~~alarming~~ rate meter at all times during radiographic operations. For permanent radiographic installations where other appropriate alarm ~~alarming~~ warning devices are in routine use, the wearing of an alarm ~~alarming~~ rate meter is not required.

**B.** No change.

1. Pocket dosimeters shall:
   a. Meet the criteria in American National Standards Publication N13.5-1972, "Performance Specifications For Direct Reading and Indirect Reading Pocket Dosimeters for X- and Gamma Radiation," 1972 Edition, published December 9, 1971, by the American National Standards Institute, incorporated by reference and on file with the Agency and the Office of the Secretary of State. This incorporation by reference contains no future editions or amendments. The incorporated material may be purchased from the American National Standards Institute, Inc. 1430 Broadway, New York, New York, 10018.
   b. Have a range of 0 to 2 millisieverts (200 mRem).

~~1. Pocket dosimeters shall meet the criteria in American National Standards Publication N13.5-1972, "Performance Specifications For Direct Reading and Indirect Reading Pocket Dosimeters for X- and Gamma Radiation," 1972 Edition, published December 9, 1971, by the American National Standards Institute, incorporated by reference and on file with the Agency and the Office of the Secretary of State; and shall have a range of 0 to 51.6 microcoulomb/kg (200 milliroentgen). This incorporation by reference contains no future editions or amendments.~~

2. No change.
3. At ~~As~~ a minimum, pocket dosimeters shall be recharged and initial use readings recorded:
   a. No change.
   b. Before beginning radiographic operations on any subsequent calendar day (if the source of radiation has not been checked back into an authorized storage location ~~site~~).
4. If ~~Whenever~~ radiographic operations are concluded for the day, final use readings on pocket dosimeters shall be recorded and the accumulated occupational doses for that day determined and recorded.
5. If an individual's pocket dosimeter is discharged beyond its range (for example, goes "off scale"), industrial radiography operations by that individual shall be discontinued until the individual's film badge or TLD has been processed. The individual shall not return to work with sources of radiation until a determination of the individual's radiation exposure ~~to the individual~~ has been made.
6. Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed one year. Acceptable dosimeters shall read within plus or minus 20% ~~30%~~ of the true radiation exposure. Records of pocket dosimeter response shall be maintained for three ~~2~~ years after the record is made. ~~by the licensee or registrant for Agency inspection~~.
7. Records of pocket dosimeter readings of personnel exposure shall be maintained for two years after the record is made ~~by the licensee or registrant for Agency inspection~~. If the dosimeter readings were used to determine external radiation dose (for example, no film badge or TLD exposure records exist), the records shall be maintained according to R12-1-419 ~~until the Agency authorizes disposal~~.

**C.** No change.

1. No change.
2. No change.
3. If a film badge or TLD is ~~A~~ lost or damaged, ~~film badge, or TLD, shall result in~~ the worker affected shall cease ~~discontinuing~~ work immediately until a replacement film badge or TLD is provided and the exposure is calculated for the time period from issuance to loss or damage.
4. No change.

**D.** Alarm ~~Alarming~~ rate meters:
1. Each alarm ~~alarming~~ rate meter shall be tested ~~have a function test~~ to ensure that the audible alarm functions ~~is functioning~~ properly before ~~prior to~~ use at the start of each work shift.
2. Each alarm ~~alarming~~ rate meter shall be set to give an alarm at a preset dose rate of 5 millisieverts ~~129 microcoulomb/kg~~/hr (500 mRem ~~milliroentgen~~/ hr).
3. Each alarm ~~alarming~~ rate meter shall require special means to change the preset alarm function.
4. Each alarm ~~alarming~~ rate meter shall be calibrated at periods ~~intervals~~ not to exceed one year for correct response to radiation. Acceptable rate meters shall give an alarm within plus or minus 20% of the true radiation dose rate.
5. Records of alarm ~~alarming~~ rate meter calibration shall be maintained for two years for Agency inspection from the date the record is made. ~~by the licensee or registrant for Agency inspection.~~

**R12-1-524. Supervision of Radiographer's Assistants ~~radiographers' assistants~~**
If ~~Whenever~~ a radiographer's assistant uses radiographic exposure devices, associated equipment, or sealed sources ~~or related source handling tools~~, or conducts radiation surveys required by R12-1-533 to determine that the sealed source has returned to the shielded position after an exposure, the radiographer's assistant shall be under the personal supervision of a radiographer.

**R12-1-531. Security**
During each radiographic operation, the radiographer or radiographer's assistant shall maintain continuous ~~a~~ direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area ~~areas~~, as defined in Article 1, unless ~~except~~:
1. The ~~Where the~~ high radiation area is equipped with a control device or an alarm system as prescribed ~~described~~ in R12-1- 420(A), or
2. The ~~Where the~~ high radiation area is locked to protect against unauthorized or accidental entry.

**R12-1-533. Radiation Surveys ~~surveys~~ and Survey Records ~~survey records~~**
**A.** A licensee or registrant shall provide and use at ~~At~~ least one calibrated and operable radiation survey instrument, as described in R12-1-504, ~~shall be available and used~~ at each site where radiographic exposures are made and at each storage area when an exposure device, storage container, or sealed source is placed in storage.
**B.** A radiographer or radiographer's assistant shall conduct a survey with a radiation survey instrument ~~shall be made~~ after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall include the guide tube.
**C.** A radiographer or radiographer's assistant shall conduct a ~~physical~~ radiation survey ~~shall be made~~ to determine the exposure levels from a sealed source if the sealed source has been ~~that the sealed source has been~~ returned to its shielded position and the ~~at any time a~~ radiographic exposure device ~~is~~ placed in a storage area. The entire circumference of the radiographic exposure device shall be surveyed.
**D.** Records of all ~~physical~~ radiation surveys performed with a survey meter, as required in this Article, shall be retained for three years after completion of the survey, except that records of a survey to determine an individual's dose shall be retained for the period of time specified in R12-1-418(D)(2) ~~permanently~~.

**R12-1-534. Records Required at Temporary Job Sites ~~required at temporary job sites~~**
Each licensee or registrant conducting industrial radiography at a temporary job site shall maintain ~~have~~ the following records ~~available~~ at that site:
1. A copy of the ~~Copy of~~ appropriate license or registration certificate;
2. No change.
3. No change.
4. Survey records required under ~~pursuant to~~ R12-1-533 for the period of operation at the site;
5. Daily dosimeter records for the period of operation at the site; ~~and~~
6. The latest instrument calibration and leak test record for specific devices in use at the site, or instead of the instrument calibration record, a legible label detailing the calibration results affixed to the instrument by the licensed person performing the calibration; and ~~,~~
7. A radiographer certification card, or other proof of certification, for each radiographer working at the temporary job site.

**R12-1-541. Enclosed Radiography Using X-ray Machines**
**A.** No change.
1. The registrant shall make, or cause to be made, an evaluation of each certified and certifiable cabinet x-ray system, at intervals not to exceed 12 months, to determine conformance with the standards for certified and certifiable cabinet x-ray systems defined in Article 1. Records of the ~~such~~ evaluations shall be retained for three years from the date of their creation; and
2. Physical radiation surveys shall be performed with a survey instrument appropriate for the energy range and levels of radiation to be assessed and calibrated within the preceding 12 months.

**B.** The registrant shall ensure that cabinet ~~Cabinet~~ x-ray systems not exempted in subsection (A) ~~above shall~~ comply with the recordkeeping requirements of this Article and the following special requirements:

1. Radiation levels measured at 5 centimeters (2 inches) ~~two inches (five centimeters)~~ from any accessible exterior surface of the enclosure shall not exceed 50 microsievert (0.5 milliroentgen) in one hour for any combination of technical factors (i.e., mA, kVp);
2. Access to the interior of the enclosure shall be possible only through interlocked doors or panels that ~~which~~ allow production of radiation only when all interlocked ~~such~~ doors or panels are securely closed. Opening any point of access shall result in immediate termination of radiation production, and subsequent reactivation of the x-ray tube shall only be possible at the control panel;
3. Visible warning signals that ~~which~~ are activated only during production of radiation shall be provided at the control panel and at each point of access to the interior of the enclosure;
4. The registrant shall make, or cause to be made, evaluations of each x-ray system to determine conformance with this Article, before placing the x-ray ~~prior to such~~ system ~~systems~~ into use and thereafter at intervals not to exceed three months. Records of the ~~such~~ evaluations shall be retained for two years, and
5. Physical radiation surveys to satisfy the requirements of subsection (B)(4) shall be performed only with instrumentation meeting the requirements of R12-1-504.

**C.** The registrant shall ensure that shielded room x-ray systems ~~shall~~ comply with the recordkeeping requirements of this Article and the following special requirements;

1. No change.
2. Access to the interior of a shielded x-ray room shall only be possible through doors or panels which are interlocked. Radiation production shall be possible only ~~so interlocked that radiation production is only possible~~ when all interlocked ~~such~~ doors and panels are securely closed. Opening of any interlocked access points shall result in immediate termination of radiation production, and subsequent reactivation of the x-ray tube shall only be possible at the control panel;
3. Each access point shall be provided with two interlocks, each on a separate circuit so that failure of one 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 before ~~prior to~~ placing the system into use and thereafter at intervals not to exceed three months to determine compliance ~~conformation~~ with this Article. Records of the ~~such~~ evaluations shall be retained for two years.
6. Radiation ~~Physical radiation~~ surveys performed to determine exposure shall be performed ~~only~~ with instrumentation that meets ~~meeting~~ the requirements of R12-1-504;
7. Electrical interlocks and warning devices shall be inspected for proper operation at the beginning of each period of use, and records ~~results~~ of the ~~these~~ inspections shall be prepared ~~documented~~ and retained for two years;
8. The registrant shall not permit any individual to operate an x-ray machine for shielded room radiography unless that individual has received a copy of, and instruction in, the operating procedures and has demonstrated competence in the safe use of the ~~such~~ equipment;
9. No change.
10. No change.
11. No change.
    a. No change.
    b. No change.
12. No change.

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

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

~~**A.** Equipment~~

~~1. Leakage radiation~~

~~a. X-ray leakage radiation from the source housing assembly shall not exceed 0.1% of the maximum dose equivalent rate of the unattenuated useful beam.~~

~~b. Neutron leakage radiation from the source housing assembly shall not exceed 0.5% of the maximum dose equivalent rate of the unattenuated useful beam.~~

~~c. 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.

2. Beam limiting devices. Adjustable or interchangeable beam limiting devices shall be provided and shall transmit no more than 2% of the useful beam for the portion of the useful beam which is to be attenuated by the beam limiting device. The neutron component of the useful beam shall not be included in this requirement. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters (15.5 square inches) at the normal treatment distance.

3. Filters. The following requirements shall apply to systems which utilize a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters:
   a. Irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;
   b. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
   c. An indication of the wedge filter orientation with respect to the treatment field shall be provided at the control panel, by direct observation or by electronic means, when wedge filters are used;
   d. A display shall be provided at the treatment control panel showing the filter or filters in use;
   e. Each filter which is removable from the system shall be clearly identified as to that filter's material of construction, thickness, and the wedge angle for wedge filters; and
   f. An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.

4. Beam monitor. Equipment installed after the effective date of this Section shall be provided with at least one radiation detector in the radiation head. This detector shall be incorporated into a primary system in such a manner that all of the following criteria are met:
   a. Each primary system shall have a detector which is a transmission detector and a full beam detector and which is placed on the patient side of any fixed added filters other than a wedge filter;
   b. The detectors shall be removable only with tools and shall be interlocked to prevent incorrect positioning;
   c. Each detector shall be capable of independently monitoring and controlling the useful beam;
   d. Each detector shall form part of a dose-monitoring system from which the absorbed dose can be calculated at a reference point in the treatment volume;
   e. Each dose monitoring system shall have a legible display at the treatment control panel that:
      i. Maintains a reading until intentionally reset to 0;
      ii. Has only 1 scale and no scale multiplying factors in replacement equipment; and
      iii. Utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined under all nominal conditions of use or foreseeable failures;
   f. In the event of power failure, the dose monitoring information required in subsection (A)(4) displayed at the control panel at the time of failure shall be retrievable in at least 1 system; and
   g. Selection and display of dose monitor units
      i. Irradiation shall not be possible until a selection of dose monitor units has been made at the treatment control panel.
      ii. Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.
      iii. Each secondary system shall terminate irradiation when 102% of the preselected number of dose monitor units has been detected by the system.
      iv. 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. 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. Timer. A timer shall be provided and shall meet all of the following requirements:
   a. The timer shall have a display at the treatment control panel, and shall have a preset time selector and elapsed time indicator.
   b. The timer shall be a cumulative timer which switches on and off with the radiation and retains its reading after irradiation is interrupted or terminated. It shall be necessary to zero and subsequently reset the elapsed time indicator and the preset time selector after irradiation is terminated before further irradiation is possible.
   c. The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems fail to do so.

6. Treatment beam mode selection. In equipment capable of both x-ray and electron therapy:
   a. Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.

b. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
c. An interlock system shall be provided to prevent irradiation with x-rays when electron applicators are fitted and irradiation with electrons when accessories specific for x-ray therapy are fitted.
d. The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

7. Treatment beam energy selection. Equipment capable of generating radiation beams of different energies shall meet all of the following requirements:
a. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;
b. An interlock system shall be provided to insure that the equipment can emit only the energy of radiation which has been selected;
c. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel; and
d. The energy selected shall be displayed at the treatment control panel before and during irradiation.

8. Selection of stationary or moving beam therapy. Equipment capable of both stationary and moving beam therapy modes shall meet all of the following requirements:
a. Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel;
b. An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected;
c. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel;
d. An interlock system shall be provided to terminate irradiation if the movement stops during moving beam therapy;
e. Moving beam therapy shall be so controlled that the required relationship between the number of dose monitor units and movement is obtained; and
f. The mode of operation shall be displayed at the treatment control panel.

9. Focal spot location and beam orientation. The registrant shall determine, or obtain from the manufacturer, the location in reference to an accessible point on the radiation head of all of the following:
a. The x-ray target or the virtual source of x-rays;
b. The electron window or the scattering foil; and
c. All possible orientations of the useful beam.

10. System checking facilities. Capabilities shall be provided for checking of all safety interlock systems.

**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. Except for entrance doors or beam interceptors, all the required barriers shall be fixed barriers;
b. The treatment control panel shall be located outside the treatment room;
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.
d. Provision shall be made for two-way oral communication between the patient and the operator at the treatment control panel;
e. Each point of entry into the treatment room shall be provided with warning lights which will indicate when the useful beam is "on" in a readily observable position outside of the room; and
f. Interlocks shall be provided and shall result in all entrance doors being closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall be possible to restore the machine to operation only by closing the door and reinitiating exposure by manual action at the control panel.

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.

3. Calibrations.
a. Calibration of the therapy system, including radiation output calibration, shall be performed prior to placing new installations into operation for the purpose of irradiation of patients. Subsequent calibrations shall be made at intervals not to exceed 6 months, and after any change which may cause the calibration of the therapy system to change.
b. Calibration of the radiation output of the therapy beam shall be performed with an instrument which has been calibrated directly traceable to a national standard within the preceding 24 months.

~~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), and a copy of the calibration report shall be maintained by the registrant for inspection by the Agency~~

~~d. Calibration of the therapy beam shall include, but not necessarily be limited to, all of the following determinations:~~

~~i. Verification that the equipment is operating within the design specifications concerning the light localizer, the side light and back pointer alignment with the isocenter, when applicable, variation in the axis of rotation for the table, gantry and jaw system, and beam flatness and symmetry at specific depths;~~

~~ii. The exposure rate or dose rate in air and at various depths of water for the range of field sizes used for each effective energy, and for each treatment distance used for radiation therapy;~~

~~iii. The congruence between the radiation field and the field defined by the localizing device;~~

~~iv. The uniformity of the radiation field and its dependency upon the direction of the useful beam; and~~

~~v. The calibration determinations above shall be provided in sufficient detail, to allow the absorbed dose to tissue in the useful beam to be calculated to within +/-5%.~~

~~e. Records of calibrations shall be maintained for 2 years following the date the calibration was performed.~~

~~f. A copy of the current calibration report shall be available in the therapy facility 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.** Spot checks.~~

~~1. The spot check procedures shall be in writing and shall have been developed by a person trained and experienced in performing calibrations.~~

~~2. The measurements taken during spot checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the system or the radiation dose delivered to a patient during a therapy procedure.~~

~~3. The written spot check procedure shall indicate the frequency at which tests or measurements are to be performed, riot to exceed monthly.~~

~~4. The spot check procedure shall note conditions which shall require, recalibration of the therapy system prior to further human irradiation.~~

~~5. Records of spot checks shall be maintained available for inspection by the Agency for 2 years following the spot check measurements.~~

~~**D.** Operating procedures~~

~~1. Only the patient shall be in the treatment room during irradiation.~~

~~2. If a patient must be held in position during treatment only, mechanical supporting or restraining devices shall be used for this purpose.~~

~~3. The therapy system shall not be used for human irradiation unless the requirements of R12-1- 611(B)(2) and (3) are met.~~

**A.** Definitions:

1. "CT" means computerized tomography.
2. "CT conditions of operation" means all selectable parameters governing the operation of a CT including, but not limited to, nominal tomographic section thickness, and technique factors.
3. "CTDI" means computed tomography dose index, the integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic thickness and the number of tomogram produced in a single scan.
4. "CTN" means CT number, the number used to represent the x-ray attenuation associated with each elemental area of the CT image.
5. "Dose profile" means the dose as a function of position along a line.
6. "Elemental area" means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted.
7. "Multiple tomogram system" means a CT system that obtains x-ray transmissions data simultaneously during a single scan to produce more than one tomogram.
8. "Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-section volume over which x-ray transmission data are collected.
9. "Reference plane" means a plane that is displaced from and parallel to the tomographic plane.
10. "Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram.

**B.** Facility: A registrant shall ensure that a CT facility has:

1. An operable two-way communication system between the patient and the operator in each CT room.
2. A viewing system that will allow the operator to continuously view the patient from the control panel during each examination. If the viewing system malfunctions the CT shall not be used until the viewing system is repaired.

**C.** Equipment. A registrant shall ensure that:

1. There is a means to terminate x-ray exposure automatically in the event of equipment failure by:
   a. De-energizing the x-ray source; or
   b. Shuttering the x-ray beam.
2. The equipment shall provide the operator the ability to terminate the x-ray exposure at any time during the examination, provided the scan or series of scans is greater than 1/2 second duration.
   a. If an operator terminates an x-ray exposure, the operator shall reset the CT conditions of operation before the initiation of another scan.
   b. A visible signal shall indicate when an x-ray exposure has been terminated because of equipment failure.
3. A means is provided to permit visual determination of the tomographic plane for a single tomogram system, or the location of a reference plane offset from a single tomograph or multiple tomogram system.
   a. If a light source is used to satisfy this requirement, it shall provide illumination of the tomographic plane or reference plane under ambient light conditions.
   b. The difference between the actual plane location and the indicated location of a tomographic plane or reference plane shall not exceed 5 millimeters.
   c. The deviation of indicated scan increment versus actual increment shall not exceed plus or minus one millimeter with any mass from 0 to 100 kilograms resting on the patient support device.
4. The control panel and gantry provides a visual indication, if x-rays are produced.
5. Emergency buttons and switches are marked by function.
6. Parameters of CT operation used during a patient examination are visible to the operator upon initiation of the scan. If an operational parameter is not adjustable by the operator, this subsection may be met by indicating on the control panel the parameter is not adjustable by the operator.
7. Radiation exposure does not exceed 100 mR in one hour at one meter in any direction from the tube port of an operating CT.
8. The angular position or positions where the maximum surface CTDI occurs is identified to allow for reproducible positioning of a CT dosimetry phantom, except in those cases where the x-ray tubes are designed to move, in which case, the maximum dose and associated tube position shall be evaluated according to manufacturer recommendations.

**D.** Operating Procedures. A registrant shall ensure that:

1. Operating procedures are available at the control panel, or by electronic means, regarding the operation of a CT and evaluation of a CT's operation.
2. The operating procedures contain the following information:
   a. A copy of the latest evaluation of the CT's operation, to include output for each CT procedure, performed by a qualified expert;
   b. Instructions on the use of the CT performance phantom by the qualified expert, a schedule of quality control tests with the results of the most recent quality control test, and the allowable variations for the indicated parameters;
   c. The distance in millimeters between the tomographic plane and the reference plane if a reference plane is used; and
   d. A current technique chart containing the CT's operating parameters, if applicable, and a procedure for determining whether a CT has been performed according to instructions of a physician.
3. If the evaluation of the CT's operation or quality control test identifies a parameter exceeding the tolerance established by a qualified expert, the use of a CT for patient examination is limited to those uses established in written instructions from the qualified expert.

**E.** Quality control tests. A registrant shall have a written quality control test procedure, developed by a qualified expert, and ensure that the quality control test procedure:

1. Incorporates the use of a CT performance phantom that indicates:
   a. Contrast scale;
   b. Nominal tomographic section thickness;
   c. Resolution capability of the system for low and high contrast objects; and
   d. The mean CTN for water or other reference materials;
2. Is included in the evaluation of the CT's operation and that the interval and system conditions are specified by the registrant's qualified expert.
3. Includes obtaining quality control test images with the CT performance phantom using the same processing mode and CT conditions of operation that are used to perform the evaluation of the CT's operation.
4. Requires that images obtained under subsection (E)(3) be retained until a new evaluation of the CT's operation is performed.

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

**F.** Evaluation of a CT's operation. A registrant shall ensure that:

1. The evaluation of a CT's operation is performed by, or under the direct supervision of, a qualified expert who is physically present at the facility during the evaluation of the CT's operation.
2. The evaluation of a CT's operation:
   a. Is performed before initial patient use and annually (within two months of the annual due date) and after any change or replacement of components that could, in the opinion of the qualified expert, cause a change in radiation output; and
   b. Shall measure the CTDI in a dosimetry phantom along the two axes specified in subsection (F)(4)(b).
3. The evaluation of a CT's x-ray system is performed with a calibrated dosimetry system that:
   a. Has been calibrated using a method that is traceable to the National Institute of Standards and Technology (NIST), and
   b. Has been calibrated within the preceding two years.
4. CT dosimetry phantoms used in determining radiation output meet the requirements specified by the CT manufacturer or a qualified expert who is responsible for maintaining proper operation and:
   a. Are constructed in a way that the parameters used to image the most commonly imaged parts of the human body are evaluated; and
   b. At a minimum, provide means for placement of a dosimeter along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom.
5. Any effects on the measured dose due to the removal of phantom material to accommodate the dosimeter are accounted for in the reported data or included in the statement of maximum deviation for the measured values.

## ARTICLE 7. USE OF RADIONUCLIDES IN THE HEALING ARTS

**R12-1-702. Definitions**

"Authorized user" No change.
"Brachytherapy" No change.
"High dose rate afterloading brachytherapy" No change.
"Medical institution" No change.
"Medical use" No change.
"Misadministration" means:
No change.
No change.
No change.
No change.
No change.
No change.
The administration of a diagnostic dose of a radiopharmaceutical involving:
The wrong patient, or
The wrong radiopharmaceutical, or
The wrong route of administration; and ~~or~~
A dose to an individual that exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ; or
No change.
"Radiopharmaceutical" No change.
"Remote afterloading brachytherapy device" No change.
"Stereotactic radiosurgery" No change.
"Teletherapy" No change.
"Written directive" No change.

**R12-1-720. Decay in Storage**

Radioactive waste held for decay in storage shall be handled according to R12-1-438(C).

## ARTICLE 9. ~~RADIATION SAFETY REQUIREMENTS FOR~~ PARTICLE ACCELERATORS

**R12-1-904. Special Registration Requirements for Medical Use of Particle Accelerators**

**A.** No change.
**B.** No change.
**C.** No change.
1. No change.
   a. No change.
   b. No change.

c. No change.
d. No change.
2. No change.
a. No change.
i. No change.
ii. No change.
iii. No change.
iv. No change.
b. No change.
i. No change.
ii. No change.
iii. No change.
iv. No change.
v. No change.
c. No change.
i. No change.
ii. No change.
iii. No change.
iv. No change.

**D.** No change.

**E.** No change.

**F.** No change.

~~**G.** The Agency shall inspect a particle accelerator before it is used to treat a human.~~

**R12-1-905. ~~Repealed~~ Medical Particle Accelerator Equipment, Facility and Shielding, and Spot Checks**

**A.** Equipment

1. Leakage radiation
   a. X-ray leakage radiation from the source housing assembly shall not exceed 0.1% of the maximum dose equivalent rate of the unattenuated useful beam.
   b. Neutron leakage radiation from the source housing assembly shall not exceed 0.5% of the maximum dose equivalent rate of the unattenuated useful beam.
   c. Leakage radiation measurements made at any point one 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 one 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 that show leakage radiation measurements for the life of the operation.
2. Beam limiting devices (not to include blocks or wedges). Adjustable or interchangeable beam limiting devices shall be provided and shall transmit no more than 2% of the useful beam for the portion of the useful beam that is to be attenuated by the beam limiting device. The neutron component of the useful beam shall not be included in this requirement. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters (15.5 square inches) at the normal treatment distance.
3. Filters. The following requirements apply to systems that use a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters:
   a. Irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;
   b. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
   c. An indication of the wedge filter orientation with respect to the treatment field shall be provided at the control panel, by direct observation, or by electronic means, when wedge filters are used;
   d. A display shall be provided at the treatment control panel showing the filter or filters in use;
   e. Each filter that is removable from the system shall be clearly identified as to that filter's material of construction, thickness, and the nominal wedge angle for wedge filters, or a record tracing these factors for each filter shall be maintained at the system console, and
   f. An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.
4. Beam monitor. Equipment installed after the effective date of this Section shall be provided with at least one radiation detector in the radiation head. This detector shall be incorporated into a primary system so that all of the following criteria are met:
   a. Each primary system shall have a detector that is a transmission detector and a full beam detector and that is placed on the patient side of any fixed added filters other than a wedge filter;

b. The detectors shall be removable only with tools and shall be interlocked to prevent incorrect positioning;
c. Each detector shall be capable of independently monitoring and controlling the useful beam;
d. Each detector shall form part of a dose-monitoring system from which the absorbed dose can be calculated at a reference point in the treatment volume;
e. Each dose monitoring system shall have a legible display at the treatment control panel that:
i. Maintains a reading until intentionally reset to 0;
ii. Has only one scale and no scale multiplying factors in replacement equipment; and
iii. Utilizes a design such that increasing dose is displayed by increasing numbers and is designed so that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined under all nominal conditions of use or foreseeable failures;
f. In the event of power failure, the dose monitoring information required in subsection (A)(4) displayed at the control panel at the time of failure shall be retrievable in at least one system; and
g. Selection and display of dose monitor units
i. Irradiation shall not be possible until a selection of dose monitor units has been made at the treatment control panel.
ii. Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.
iii. Each secondary system shall terminate irradiation when 110% of the preselected number of dose monitor units has been detected by the system.
iv. 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. 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. Beam monitoring system. All accelerator systems shall be provided with a beam monitoring system in the radiation head capable of monitoring and terminating irradiation.
a. Each beam monitoring system shall have a display at the treatment control panel that registers the accumulated monitor units.
b. The beam monitoring system shall terminate irradiation if the preselected number of monitor units has been detected by the system.
c. For units with a secondary beam monitoring system, the primary beam monitoring system shall terminate irradiation if the preselected number of monitor units has been detected. The secondary beam monitoring system shall terminate irradiation if the primary system fails.
d. In the event of a power failure, the display information required in subsection (A)(5)(a) shall be retained in at least one system following the power failure.
e. An interlock device shall prevent irradiation if any beam monitoring system is inoperable.
f. For purposes of this rule:
i. "Beam monitoring system" means a system of devices that will monitor the useful beam during irradiation and will terminate irradiation if a preselected number of monitor units is accumulated.
ii. "Monitor unit" means a unit response from the beam monitoring system from which the absorbed dose can be calculated.

6. Treatment beam mode selection. In equipment capable of both x-ray and electron therapy:
a. Irradiation shall not be possible until a selection of radiation type is made at the treatment control panel;
b. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations indicated at the treatment control panel;
c. An interlock system shall be provided to prevent irradiation with x-rays when electron applicators are fitted and irradiation with electrons when accessories specific for x-ray therapy are fitted; and
d. The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

7. Treatment beam energy selection. Equipment capable of generating radiation beams of different energies shall meet all of the following requirements:
a. Irradiation shall not be possible until a selection of energy is made at the treatment control panel;
b. An interlock system shall be provided to ensure that the equipment can emit only the energy of radiation that is selected;
c. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations indicate at the treatment control panel; and
d. The energy selected shall be displayed at the treatment control panel before and during irradiation.

8. Selection of stationary or moving beam therapy. Equipment capable of both stationary and moving beam therapy modes shall meet all of the following requirements:

a. Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy is made at the treatment control panel;
b. An interlock system shall be provided to ensure that the equipment can operate only in the mode that is selected;
c. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations indicated at the treatment control panel;
d. An interlock system shall be provided to terminate irradiation if the movement stops during moving beam therapy;
e. Moving beam therapy shall be so controlled that the required relationship between the number of dose monitor units and movement is obtained; and
f. The mode of operation shall be displayed at the treatment control panel.

9. Focal spot location and beam orientation. The registrant shall determine, or obtain from the manufacturer, the location in reference to an accessible point on the radiation head of all of the following:
a. The x-ray target or the virtual source of x-rays,
b. The electron window or the scattering foil, and
c. All possible orientations of the useful beam.

10. System checking facilities. Capabilities shall be provided for checking of all safety interlock systems.

**B.** Facility and shielding requirements.

1. In addition to protective barriers sufficient to ensure compliance with R12-1-907, all of the following design requirements apply:
a. Except for entrance doors or beam interceptors, all the required barriers shall be fixed barriers;
b. The treatment control panel shall be located outside the treatment room;
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;
d. Provision shall be made for two-way oral communication between the patient and the operator at the treatment control panel;
e. Each point of entry into the treatment room shall be provided with warning lights that will indicate when the useful beam is "on" in a readily observable position outside of the room; and
f. Interlocks shall be provided and shall result in all entrance doors being closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall be possible to restore the machine to operation only by closing the door and reinitiating exposure by manual action at the control panel.

2. A qualified expert trained and experienced in the principles of radiation protection shall perform a radiation protection survey on all installations before 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.

3. Calibrations.
a. Calibration of the therapy system, including radiation output calibration, shall be performed before placing new installations into operation for the purpose of irradiation of patients. Subsequent calibrations shall be made at intervals not to exceed 12 months, and after any change that may cause the calibration of the therapy system to change.
b. Calibration of the radiation output of the therapy beam shall be performed with an instrument that has been calibrated using a method that is traceable to the National Institute of Standards and Technology (NIST), within the preceding two years.
c. Calibration of a particle accelerator shall be performed by, or under the supervision of a person who meets the qualification requirements specified in R12-1-716(G), and a copy of the calibration report shall be maintained by the registrant for inspection by the Agency
d. Calibration of the therapy beam shall include, but not necessarily be limited to, all of the following determinations:
i. Verification that the equipment is operating within the design specifications concerning the light localizer, the side light and back pointer alignment with the isocenter, when applicable, variation in the axis of rotation for the table, gantry and jaw system, and beam flatness and symmetry at specific depths;
ii. The exposure rate or dose rate in air or at various depths of water for the range of field sizes used for each effective energy, and for each treatment distance used for radiation therapy;
iii. The congruence between the radiation field and the field defined by the localizing device;
iv. The uniformity of the radiation field and its dependency upon the direction of the useful beam; and
v. The calibration determinations above shall be provided in sufficient detail, to allow the absorbed dose to tissue in the useful beam to be calculated to within +/-5%.
e. Records of calibrations shall be maintained for two years following the date the calibration was performed.

f. A copy of the current calibration report shall be available in the therapy facility 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.** Spot checks.
1. The spot check procedures shall be in writing and shall have been developed by a person trained and experienced in performing calibrations.
2. The measurements taken during spot checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the system or the radiation dose delivered to a patient during a therapy procedure.
3. The written spot check procedure shall indicate the frequency at which tests or measurements are to be performed, not to exceed monthly.
4. The spot check procedure shall note conditions that require recalibration of the therapy system before further human irradiation.
5. Records of spot checks shall be maintained available for inspection by the Agency for two years following the spot check measurements.

**D.** Operating procedures
1. Only the patient shall be in the treatment room during irradiation.
2. If a patient must be held in position during treatment only, mechanical supporting or restraining devices shall be used for this purpose.

**R12-1-911. Radiation Surveys ~~Survey Requirements~~**

**A.** No change.
**B.** No change.
**C.** The registrant shall retain the following records:
1. Records of the ~~any~~ radiation protection surveys ~~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~~ the surveys required in subsection (B)(3) and (B)(4) shall be maintained for three years following the measurement. ~~until the registration is terminated~~.

**R12-1-912. ~~Ventilation systems~~ Repealed**

~~**A.** A registrant or licensee shall provide the means to ensure that personnel entering any area where airborne radioactivity may be produced will not be exposed to airborne radioactive material in excess of those limits specified in Article 4, Appendix B, Table II of this Chapter.~~

~~**B.** A registrant or licensee shall not vent, release, or otherwise discharge airborne radioactive material to an uncontrolled area which exceed the limits specified in Article 4, Appendix B, Table II of this Chapter, except as authorized pursuant to R12-1-435. For purposes of this Section, concentrations may be averaged over a period not greater than 1 year. Every reasonable effort should be made to maintain releases of radioactive material to uncontrolled areas as far below the limits in Appendix B, Table II of this Chapter, as practicable.~~

**R12-1-913. Misadministration**

**A.** For purposes of this rule "misadministration" means:
1. A therapeutic radiation dose from a machine:
   a. Delivered to the wrong patient;
   b. Delivered using the wrong mode of treatment;
   c. Delivered to the wrong treatment site; or
   d. Delivered in one week to the correct patient, using the correct mode, to the correct therapy site, but greater than 130% of the prescribed weekly dose; or
2. A therapeutic radiation dose from a machine with errors in the calibration, time of exposure, or treatment geometry that result in a calculated total treatment dose differing from the final, prescribed total treatment dose by more than 20%, except for treatments given in 1 to 3 fractions, in which case a difference of more than 10% constitutes a misadministration.

**B.** Reports of therapy misadministration
1. Within 24 hours after a misadministration, a registrant shall notify the Agency by telephone. The registrant shall also notify the referring physician of the affected patient and the patient or a responsible relative or guardian, unless the referring physician personally informs the registrant either that he or she will inform the patient, or that in his or her medical judgment, telling the patient or the patient's responsible relative or guardian would be harmful to one or the

other, respectively. If the referring physician or the patient's responsible relative or guardian cannot be reached within 24 hours, the registrant shall notify them as soon as practicable. The registrant shall not delay medical care for the patient because of notification problems.

2. Within 15 days following the verbal notification to the Agency, the registrant shall report, in writing, to the Agency and individuals notified under subsection (B)(1). The written report shall include the registrant's name, the referring physician's name, a brief description of the event, the effect on the patient, the action taken to prevent recurrence, whether the registrant informed the patient or the patient's responsible relative or guardian, and if not, why not. The report shall not include the patient's name or other information that could lead to identification of the patient.
3. Records of misadministration shall be maintained according to R12-1-708(C).

**R12-1-914. Initial Inspections of Particle Accelerators Used in the Practice of Medicine**

The Agency shall inspect a particle accelerator, used in the practice of medicine, before its initial use to treat human disease.

## ARTICLE 12. ADMINISTRATIVE PROVISIONS

**R12-1-1209. Notice of Violation**

**A.** No change.

**B.** ~~The notice shall specify the severity level and circumstances of the alleged violation, and the particular statute, rule or license condition violated. The notice shall also specify the category of the registration or license.~~The notice shall specify:

1. The severity level and circumstances of the alleged violation;
2. The particular statute, rule, or license condition violated; and
3. The division of the registration or license.

**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 waived authorized in R12-1-1216(C).~~The notice shall specify a civil penalty if one is proposed by the Agency.