

**PART D.  
PRECAUTIONARY PROCEDURES**

**RH-1300.     Surveys.**

- a.     As used in these Regulations, "survey" means an evaluation of actual or potential radiation hazards incident to the production, use, release, disposal and/or presence of sources of radiation under a specific set of conditions. When appropriate, such evaluation includes, but is not limited to, tests, a physical survey of the location of materials and equipment, and measurements of levels of radiation or concentrations of radioactive material present.
  
- b.     Each licensee or registrant shall make or cause to be made, surveys that:
  - 1.     May be necessary for the licensee or registrant to comply with the Regulations in this Part; and
  
  - 2.     Are reasonable under the circumstances to evaluate:
    - A.     The magnitude and extent of radiation levels,
  
    - B.     Concentrations or quantities of radioactive material, and
  
    - C.     The potential radiological hazards.
  
- c.     The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring are calibrated periodically for the radiation measured.)

**RH-1301.     Personnel Monitoring.**

- a.     All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees or registrants to comply with RH-1302.a, with other applicable provisions of these Regulations, or with conditions specified in a license must be processed and evaluated by a dosimetry processor:
  - 1.     Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology [formerly called National Bureau of Standards], and

Revisions effective July 1, 2002

RH-1301. (Cont'd)

2. Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

RH-1302. Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

Each licensee or registrant shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits this Part. As a minimum: of

- a. Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:
  1. Adults likely to receive, in one (1) year from sources external to the body, a dose in excess of ten (10) percent of the limits in RH-1200.a;
  2. Minors and declared pregnant women likely to receive, in one (1) year from sources external to the body, a dose in excess of ten (10) percent of any of the applicable limits in RH-1206 or RH-1207; and
  3. Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv) and

**NOTE:** All of the occupational doses in RH-1200 continues to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.

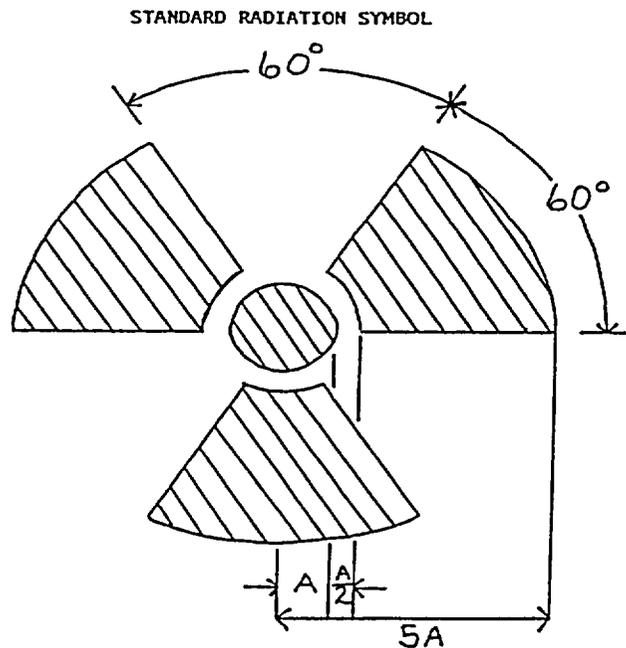
4. Individuals entering a high or very high radiation area.
- b. Each licensee or registrant shall monitor (See RH-1203) the occupational intake of radioactive material by and assess the committed effective dose equivalent to:
  1. Adults likely to receive, in one (1) year, an intake in excess of 10 percent of the applicable ALI(s) in Table 1, Columns 1 and 2, of Appendix G to RH-1000 through RH-2110; and
  2. Minors and declared pregnant women likely to receive, in one (1) year, a committed effective dose equivalent in excess of 0.05 rem (0.5 mSv).

Revisions effective July 1, 2002

RH-1303. Caution Signs, Labels and Signals.

a. Symbol.

1. Except as otherwise authorized by the Department, symbols prescribed by this Section shall use the conventional radiation caution colors (magenta, or purple, or black, on yellow background).
2. The symbol prescribed by this Section is the conventional three-bladed design. The cross-hatched area shall be magenta, or purple, or black and the background yellow.
3. Notwithstanding the requirements of RH-1303.a. of this Section, licensees or registrants are authorized to label sources, source holders, or device components containing sources of licensed materials that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.
4. In addition to the contents of signs and labels prescribed in this Section, a licensee or registrant may provide on or near such signs and labels any additional information which may be appropriate in aiding individuals to minimize exposure to radiation.





5. The licensee or registrant shall establish the controls required by RH-1303.c.2 and RH-1303.c.4 of this Section in a way that does not prevent individuals from leaving a high radiation area.
  6. Control is not required for each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the Department of Transportation provided that:
    - A. The packages do not remain in the area longer than three (3) days, and
    - B. The dose rate at one (1) meter from the external surface of any package does not exceed 0.01 rem (0.1 mSv) per hour.
  7. Control of entrance or access to rooms or other areas in hospitals is not required solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who will take the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the limits established in this Part and to operate within the ALARA provisions of the licensee's radiation protection program.
- d.
1. Very high radiation areas. In addition to the requirements in RH-1311, the licensee or registrant shall institute additional 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 500 rads (5 grays) or more in one (1) hour at one (1) meter from a radiation source or any surface through which the radiation penetrates.
  2. Posting of very high radiation areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words:  

**GRAVE DANGER, VERY HIGH RADIATION AREA**
- e.
- Very high radiation areas - irradiators.
1. Each area in which there may exist radiation levels in excess of 500 rads (5 grays) in one (1) hour at one (1) meter from a sealed radioactive source<sup>2f</sup> that is used to irradiate materials must meet the following requirements.

- A. Each entrance or access point must be equipped with entry control devices which:
  - i. Function automatically to prevent any individual from inadvertently entering the area when very high radiation levels exist;
  - ii. Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the sealed source, to be reduced below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (1 mSv) in one (1) hour; and
  - iii. Prevent operation of the source if the source would produce radiation levels in the area that could result in a deep-dose equivalent to an individual in excess of 0.1 rem (1 mSv) in one (1) hour.
- B. Additional control devices must be provided so that upon failure of the entry control devices to function as required by RH-1303.e.1.A. of this Section:
  - i. The radiation level within the area, from the sealed source, is reduced below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (1 mSv) in one (1) hour; and
  - ii. Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.
- C. The licensee shall provide control devices so that, upon failure or removal of physical radiation barriers other than the source's shielded storage container:

- i. The radiation level from the source is reduced below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (1 mSv) in one (1) hour; and
  - ii. Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee 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 barrier.
- D. When the shield for the stored source is a liquid, the licensee shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.
- E. 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 C and D of this Paragraph.
- F. Each area must be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source can be put into operation and in sufficient time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source from being put into operation.
- G. Each area must be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source.
- H. Each area must be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source, the radiation level from the source in the area is below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (1 mSv) in one (1) hour.

- I. The entry control devices required in RH-1303.e.1.A. must have been tested for proper functioning (See RH-1500 for recordkeeping requirements).
    - i. Testing must be conducted prior to initial operation with the source of radiation on any day (unless operations were continued uninterrupted from the previous day);
    - ii. Testing must be conducted prior to resumption of operation of the source of radiation after any unintended interruption; and
    - iii. The licensee shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.
  - J. The licensee may not conduct operations, other than those necessary to place the source in safe condition or to effect repairs on controls, unless control devices are functioning properly.
  - K. 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, must be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for processed materials must be equipped to detect and signal the presence of any loose radiation sources that are carried toward such an exit and to automatically prevent loose radiation sources from being carried out of the area.
2. Persons holding licenses or applicants for licenses for radiation sources that are within the purview of Part D of this Section and that will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of Part D of this Section, such as those for the automatic control of radiation levels, may apply to the Director, Division of Radiation Control and Emergency Management, for approval of the use of alternative safety measures. Any alternative safety measures must provide a degree of personnel protection at least equivalent to those specified in Part D of this Section.



4. Use of other controls.

- A. When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:
- i. Control of access;
  - ii. Limitation of exposure times;
  - iii. Use of respiratory protection equipment; or
  - iv. Other controls.
- B. If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

5. Use of individual respiratory protection equipment.

- A. If the licensee assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material.
- i. 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 (NIOSH) except as otherwise noted in this Part.
  - ii. If the licensee wishes to use equipment that has not been tested or certified by NIOSH, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of this equipment, except as provided in this Part. The application must include evidence that the material and performance characteristics of the equipment are capable of providing the proposed anticipated conditions of use. This must be demonstrated either by licensee testing

- iii. The licensee shall implement and maintain a respiratory protection program that includes:
  - (a). Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;
  - (b). Surveys and bioassays, as necessary, to evaluate actual intakes;
  - (c). Testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use;
  - (d). Written procedures regarding:
    - (i) Monitoring, including air sampling and bioassays;
    - (ii) Supervision and training of respirator users;
    - (iii) Fit testing;
    - (iv) Respirator selection;
    - (v) Breathing air quality;
    - (vi) Inventory and control;
    - (vii) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;
    - (viii) Recordkeeping; and
    - (ix) Limitations on periods of respirator use and relief from respirator use;

- (e). Determination by a physician prior to initial fitting of respirators, and at least every twelve (12) months thereafter or periodically at a frequency determined by a physician, that the individual user is medically fit to use the respiratory
  - (f). Fit testing, with fit factor greater than or equal to ( $\geq$ ) 10 times the APF for negative pressure devices, and a fit factor greater than or equal to ( $\geq$ ) 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed one (1) year. Fit testing must be performed with the facepiece operating in the negative pressure mode.
- iv. 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.
- v. The licensee shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

- vi. Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.
  
- vii. Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997 and included in the regulations of the Occupational Safety and Health Administration (29 CFR 1910.134(i)(1)(ii)(A) through (E)). Grade D quality air criteria include:
  - (1) Oxygen content (v/v) of 19.5-23.5%;
  - (2) Hydrocarbon (condensed) content of five (5) milligrams per cubic meter of air or less;
  - (3) Carbon monoxide (CO) content of ten (10) ppm or less;
  - (4) Carbon dioxide content of 1,000 ppm or less; and
  - (5) Lack of noticeable odor.

viii. The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face-facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

ix. In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

B. The licensee shall notify, in writing, the Director of the Division of Radiation Control and Emergency Management at least thirty (30) days before the date that respiratory protection equipment is first used under the provisions of RH-1303.f.5.A.

6. Further restrictions on the use of respiratory protection equipment.

The Department may impose restrictions in addition to those in RH-1303.f.4 and RH-1303.f.5 and Appendix E to RH-1000 through RH-2110 to:

A. Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with; and

B. Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.





RH-1303. (Cont'd)

- j. All devices and equipment capable of producing radiation when operated shall be appropriately labeled so as to caution individuals that such devices or equipment produce radiation when operated.
- k. Each radiation machine, except radiographic and fluoroscopic x-ray machines used solely in the healing arts, which is capable of producing, in any area accessible to individuals, a dose rate in excess of 10 millirems per hour shall be provided with a warning signal or light. Such a signal or light shall be so connected as to be activated automatically when the machine is "on" in order to provide adequate warning against entering the area.

RH-1304. Exceptions From Posting Requirements. Notwithstanding the provisions of RH-1303:

- 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 twelve (12) inches (30) centimeters from the surface of the source container or housing does not exceed five (5) millirems (0.05 mSv) per hour.
- b. Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs provided that the patient could be released from licensee control pursuant to RH-1214.
- c. Caution signs are not required to be posted in areas or rooms containing radioactive materials for periods of less than eight (8) hours provided that:
  - 1. The materials are constantly attended during such periods by an individual who shall take the precautions necessary to prevent the exposure of any individual to radiation or radioactive materials in excess of the limits established in this Part; and
  - 2. Such area or room is subject to the licensee's control.
- d. A room or other area is not required to be posted with caution sign and control is not required for each a entrance or access point to a room or other area which is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with regulations of the Department of Transportation.

Revisions effective July 1, 2002

RH-1305. Instruction of Personnel; Posting of Notice to Employees.

Instructions required for individuals working in or frequenting any portion of a restricted area are specified in Part N of this Section.

RH-1306. Storage of Sources of Radiation.

- a. The licensee or registrant shall secure sources of radiation from unauthorized removal or access.
- b. Sources of radiation shall not be stored in residential areas.

RH-1307. Procedures for Picking Up, Receiving and Opening Packages.

- a. As used in these Regulations, Special Form means any of the following physical forms of licensed material:
  1. The material is in solid form having no dimension less than 0.5 millimeter or at least one dimension greater than five (5) millimeters; does not melt, sublime or ignite in air at a temperature of 1,000<sup>o</sup>F. (538<sup>o</sup>C), will not shatter or crumble if subjected to the percussion test described in Appendix B of this Part; and is not dissolved or converted into dispersible form to the extent of more than 0.005 percent by weight by immersion for one week in water at 68<sup>o</sup>F. (20<sup>o</sup>C) or in air at 86<sup>o</sup>F. (30<sup>o</sup>C); or
  2. The material is securely contained in a capsule having no dimension less than 0.5 millimeter or at least one dimension greater than five (5) millimeters, which will retain its contents if subjected to the tests prescribed in Appendix B of this Part; and which is constructed of materials which do not melt, sublime or ignite in air at 1,475<sup>o</sup>F (802<sup>o</sup>C), and do not dissolve or convert into dispersible form to the extent of more than 0.005 percent by weight by immersion for one week in water at 68<sup>o</sup>F (20<sup>o</sup>C) or in air at 86<sup>o</sup>F (30<sup>o</sup>C).
- b. Procedures for picking up, receiving and opening packages. Each licensee who expects to receive a package containing quantities of radioactive material in excess of a "Type A" quantity specified in or determined by procedures described in Appendix C of this Section, shall make arrangements:
  1. To receive the package when the carrier offers it for delivery; or
  2. To receive notification of the arrival of the package at the carrier's terminal and to pick up the package when the carrier offers it for delivery.

RH-1307. (Cont'd)

- c. Each licensee shall:
1. Monitor the external surfaces of a labeled\* package for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as described in RH-3100.
  2. Monitor the external surfaces of a labeled\* package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity as defined RH-3100 and RH-2700; and
  3. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.
- d. The licensee shall perform the monitoring required by RH-1307.c of this Section as soon as practical after receipt of the package, but not later than three (3) 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 (3) hours from the beginning of the next working day if it is received after working hours.
- e. The licensee shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram or facsimile, the Department, if packages, other than those transported by exclusive use vehicle, are found to have:
1. Removable radioactive contamination in excess of 0.001 microcurie per 100 square centimeters on the external surfaces of the package; or
  2. Radiation levels at the external surface of the package in excess of 200 mRem/hr or at one (1) meter from the external surface of the package in excess of 10 mRem/hr.
- f. Each licensee or registrant shall establish and maintain procedures for safely opening packages in which radioactive material is received and shall assure that such procedures are followed and that due consideration is given to special instructions for the type of package being opened.

\* Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 and 172.436-440.

RH-1307. (Cont'd)

- g. Licensees transferring special form sources in licensee-owned or licensee-operated vehicles to and from a work site are exempt from the contamination monitoring requirements of RH-1307.c of this Section, but are not exempt from the survey requirement in RH-1307.c of this Section for measuring radiation levels that is required to ensure that the source is still properly lodged in its shield.

RH-1308. Control of Material Not in Storage.

The licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

RH-1309.

RH-1399. Reserved.

**PART E.  
WASTE DISPOSAL**

RH-1400     General Requirements.     A licensee shall dispose of licensed material only:

- a.     By transfer to an authorized recipient as provided in Section 2 of these Regulations; or
- b.     By decay in storage; or
- c.     By release in effluents within the limits in RH-1210; or
- d.     As authorized under RH-1402, RH-1403, RH-1404, or RH-1405.
- e.     A person must be specifically licensed to receive waste containing licensed material from other persons for:
  - 1.     Treatment prior to disposal;
  - 2.     Treatment or disposal by incineration; or
  - 3.     Decay in storage.

RH-1401     Method for Obtaining Approval of Proposed Disposal Procedures.

A licensee or applicant for a license may apply to the Department for approval of proposed procedures, not otherwise authorized in the Regulations in this Section, to dispose of licensed material generated in the licensee's activities. Each application shall include:

- a.     A description of the waste containing licensed material to be disposed of, including the physical and chemical properties important to risk evaluation, and the proposed manner and conditions of waste disposal;
- b.     An analysis and evaluation of pertinent information on the nature of the environment;
- c.     The nature and location of other potentially affected licensed and unlicensed facilities; and
- d.     Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in this Part.

RH-1402

Disposal by Release Into Sanitary Sewerage.

- a. A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:
  1. The material is readily soluble (or is readily dispersible biological material) in water;
  2. The quantity of licensed or other 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 does not exceed the concentration listed in Table 3 of Appendix G to RH-1000 through RH-2101; and
  3. If more than one radionuclide is released, the following conditions must also be satisfied:
    - i. The licensee shall determine the fraction of the limit in Table 3 of Appendix G to RH-1000 through RH-2101 represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table 3 of Appendix G to RH-1000 through RH-2101; and
    - ii. The sum of the fractions for each radionuclide required by Paragraph a.3.i. of this Section does not exceed unity; and
  4. The total quantity of licensed and other radioactive material that the licensee releases into the sanitary sewerage system in a year does not exceed five (5) curies (185 GBq) of Hydrogen-3, one (1) curie (37 GBq) of Carbon-14, and one (1) curie (37 GBq) of all other radioactive materials combined.
- b. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material is not subject to the limitations contained in Paragraph a of this Section.

RH-1403.

Disposal by Burial in Soil.

No licensee shall dispose of radioactive material by burial in soil unless specific approval has been granted by the Department.

RH-1404. Treatment or Disposal by Incineration.

A licensee may treat or dispose of licensed material by incineration only in the amounts and forms specified in RH-1405 or as specifically approved by the Department pursuant to RH-1401.

RH-1405. Disposal of Specific Wastes.

- a. Any licensee may dispose of the following licensed material without regard to its radioactivity:
  1. 0.05 microcuries (1.85 kBq) or less of Hydrogen-3, Carbon-14 or Iodine-125 per gram of medium, used for liquid scintillation counting; and
  2. 0.05 microcuries (1.85 kBq) or less of Hydrogen-3 Carbon-14 or Iodine-125 per gram of animal tissue, averaged over the weight of the entire animal.
- b. A licensee may not dispose of tissue under RH-1405.b of this Section in a manner that would permit its use either as food for humans or as animal feed.
- c. The licensee shall maintain records in accordance with RH-1500.h.
- d. Nothing in this Section, however, relieves the licensee of maintaining records showing the receipt, transfer and disposal of such byproduct material as specified in RH-600; and
- e. Nothing in this Section relieves the licensee from complying with other applicable federal, state and local regulation governing any other toxic or hazardous property of these materials.

RH-1406. Transfer for Disposal and Manifests.

*(Appendix F and Appendix G to 10 CFR Part 20 referenced in this Part are available from the Department.)*

- a. The requirements of this Section and Appendix F and Appendix G to 10 CFR Part 20 are designed to:
  - i. Control transfers of low-level radioactive waste (LLW) by any waste generator, waste collector, or waste processor licensee, as defined in this Part, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility as defined in Section 2 of these Regulations;
  - ii. Establish a manifest tracking system; and

RH-1406. (Cont'd)

- iii. Supplement existing requirements concerning transfers and recordkeeping for those wastes.
- b. Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G to 10 CFR Part 20.
- c. Each shipment manifest must include a certification by the waste generator as specified in Section II.
- d. Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix G to 10 CFR Part 20.

RH-1407. Compliance with Environmental and Health Protection Regulations.

Nothing in this Subpart 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 under this Part E.

RH-1408.

RH-1499.

Reserved.

Revisions effective July 1, 2002

**PART F.**  
**RECORDS, REPORTS, NOTIFICATIONS, AND TESTS**

RH-1500.

a. General provisions.

1. Each licensee or registrant shall use the units: curie, rad, rem, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this Part.
2. In the records required by this Part, the licensee may record quantities in International System of Units (SI) units in parentheses following each of the units specified in RH-1500.a.1. of this section. However, all quantities must be recorded as stated in RH-1500.a.1. of this section.
3. Notwithstanding the requirements of RH-1500.a.1 of this Section, when recording information on shipment manifests, as required in RH-1406.b, information must be recorded in the International System of Units (SI) or; in SI and units as specified in RH-1500.a.1 of this Section.
4. The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this Part (e.g., total effective dose equivalent, shallow-dose equivalent, eye dose equivalent, deep-dose equivalent, committed effective dose equivalent).

b. Records of radiation protection programs.

1. Each licensee or registrant shall maintain records of the radiation protection program, including:
  - A. The provisions of the program; and
  - B. Audits and other reviews of program content and implementation.
2. The licensee or registrant shall retain the records required by RH-1500.b.1.A of this Section until the Department terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by RH-1500.b.1.B of this Section for three (3) years after the record is made.

RH-1500. (Cont'd)

c. Records of surveys.

1. Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by RH-1300 and RH-1307. The licensee or registrant shall retain these records for three (3) years after the record is made.
2. The licensee or registrant shall retain each of the following records until the Department terminates each pertinent license or registration requiring the record:
  - A. Records of the results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents;
  - B. Records of the 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 pursuant to RH-1303.f.5.A.iii; and
  - D. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

d. Determination of prior occupational dose.

1. For each individual who may enter the licensee's or registrant's restricted or controlled area and is likely to receive, in a year, an occupational dose requiring monitoring pursuant to RH-1302, the licensee shall:
  - A. Determine the occupational radiation dose received during the current year; and
  - B. Attempt to obtain the records of lifetime cumulative occupational radiation dose.
2. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:
  - A. The internal and external doses from all previous planned special exposures; and

- B. All doses in excess of the limits (including doses received during accidents and emergencies) received during the lifetime of the individual.
3. In complying with the requirements of RH-1500.d.1 of this Section, a licensee or registrant may:
- A. Accept, as a record of the occupational dose that the individual received during the current year, a written 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 may have received during the current year;
  - B. Accept, as the record of lifetime cumulative radiation dose, an up-to-date Department Form Z, or equivalent, signed by the individual and counter-signed by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee); and
  - C. Obtain reports of the individual's dose equivalent(s) from the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee or registrant) by telephone, telegram, electronic media, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.
4. The licensee or registrant shall record the exposure history, as required by RH-1500.d.1 of this Section, on Department Form Z, or other clear and legible record, of all the information required on that form.<sup>6/</sup> The form or record must show each period in which the individual received occupational exposure to radiation or radioactive material and must 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 in preparing Department Form Z. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on Department Form Z indicating the periods of time for which data are not available.

5. 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 RH-1200.f for the current year, that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 mSv) 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. That the individual is not available for planned special exposures.
6. The licensee or registrant shall retain the records on Department Form Z or equivalent until the Department terminates each pertinent license requiring this record. The licensee or registrant shall retain records used in preparing Department Form Z for three (3) years after the record is made.

e. Records of planned special exposures.

1. For each use of the provisions of RH-1205 for planned special exposures, the licensee shall maintain records that describe:
  - A. The exceptional circumstances requiring the use of a planned special exposure;
  - B. The name of the management official who authorized the planned special exposure and a copy of the signed authorization;
  - C. What actions were necessary;
  - D. Why the actions were necessary;
  - E. How doses were maintained ALARA; and
  - F. What individual and collective doses were expected to result, and the doses actually received in the planned special exposure.
2. The licensee shall retain the records until the Department terminates each pertinent license requiring these records.

RH-1500. (Cont'd)

f. Records of individual monitoring results.

1. Recordkeeping requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to RH-1302, and records of doses received during planned special exposures, accidents, and emergency conditions. These records<sup>II</sup> must include, when applicable:
  - A. The deep-dose equivalent to the whole body, eye dose equivalent, shallow-dose equivalent to the skin, and shallow-dose equivalent to the extremities;
  - B. The estimated intake of radionuclides (See RH-1201);
  - C. The committed effective dose equivalent assigned to the intake or body burden of radionuclides;
  - D. The specific information used to calculate the committed effective dose equivalent pursuant to RH-1203.c;
  - E. The total effective dose equivalent when required by RH-1202; and
  - F. The total of the deep-dose equivalent and the committed dose to the organ receiving the highest total dose.
2. Recordkeeping frequency. The licensee or registrant shall make entries of the records specified in RH-1500.f.1 of this Section at least annually.
3. Recordkeeping format. The licensee or registrant shall maintain the records specified in RH-1500.f.1 of this Section on Department Form Y, in accordance with the instructions for Department Form Y, or in clear and legible records containing all the information required by that form.
4. Privacy protection. The records required under this Section should be protected from public disclosure because of their personal privacy nature.

RH-1500. (Cont'd)

5. The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy shall also be kept on file, but may be maintained separately from the dose records.
  6. The licensee or registrant shall retain each required form or record until the Department terminates each pertinent license or registration requiring the record.
- g. Records of dose to individual members of the public.
1. Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public (See RH-1208).
  2. The licensee or registrant shall retain the records required by RH-1500.g.1 of this Section until the Department terminates each pertinent license or registration requiring the record.
- h. Records of waste disposal.
1. Each licensee or registrant shall maintain records of the disposal of licensed materials made under RH-1401, RH-1402, RH-1403, RH-1404, RH-1405, and disposal by burial in soil, including burials authorized before January 28, 1981.<sup>g</sup>
  2. The licensee or registrant shall retain the records required by RH-1500.h.1 of this Section until the Department terminates each pertinent license requiring the record.
- i. Records of testing entry control devices for very high radiation areas.
1. Each licensee or registrant shall maintain records of tests made under RH-1303.e.1.i on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.
  2. The licensee or registrant shall retain the records required by RH-1500.i.1 of this Section for three years after the record is made.

RH-1500. (Cont'd)

- j. Form of records. Each record required by this Part must be legible throughout the specified retention period. The record may 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. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

RH-1501. Reports of Theft or Loss of Sources of Radiation.

Each licensee or registrant shall report promptly by telephone and confirm promptly by letter to the Division of Radiation Control and Emergency Management, Arkansas Department of Health, 4815 West Markham, Mail Slot 30, Little Rock, Arkansas 72205-3867, the theft or loss as soon as such theft or loss becomes known to the licensee or registrant of:

- a. Any radiation machine; or
- b. Any quantity of radioactive material in excess of a quantity generally licensed under RH-900, Schedule A or RH-901, Schedule B, in Section 2 of these Regulations.
- c. Telephone reports.
  - 1. Each licensee shall report by telephone as follows:
    - A. Immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix G to RH-1000 through RH-2110 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas; or
    - B. Within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than ten (10) times the quantity specified in Appendix G to RH-1000 through RH-2110 that is still missing at this time.

RH-1501. (Cont'd)

2. Reports must be made as follows:

All licensees or registrants shall make reports to the Department at 1-800-633-1735.

d. Written reports.

1. Each licensee required to make a report under RH-1501 of this Section shall, within thirty (30) days after making the telephone report, make a written report setting forth the following information:

- A. A description of the licensed material involved, including kind, quantity, and chemical and physical form;
- B. A description of the circumstances under which the loss or theft occurred;
- C. A statement of disposition, or probable disposition, of the licensed material involved;
- D. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;
- E. Actions that have been taken, or will be taken, to recover the material; and
- F. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

2. Reports must be made as follows:

- A. All licensees or registrants shall make reports to the Director of the Division of Radiation Control and Emergency Management, Arkansas Department of Health, 4815 West Markham, Mail Slot 30, Little Rock, Arkansas 72205-3867.
- B. Subsequent to filing the written report, the licensee or registrant shall also report any additional substantive information on the loss or theft within thirty (30) days after the licensee or registrant learns of such information.
- C. The licensee or registrant shall prepare any report filed with the Department pursuant to this Section so that names of individuals who may have received exposure to radiation are stated in a separate and detachable part of the report.

RH-1502.

Notification of Incidents.

a. Immediate notification. Each licensee or registrant shall immediately notify the Division of Radiation Control and Emergency Management, Arkansas Department of Health, 4815 West Markham, Mail Slot 30, Little Rock, Arkansas 72205-3867, by telephone and confirming letter of any incident involving any source of radiation possessed by the licensee or registrant and which may have caused or threatens to cause:

1. An individual to receive:
  - A. A total effective dose equivalent of 25 rems (0.25 Sv) or more; or
  - B. A lens dose equivalent of 75 rems (0.75 Sv) or more; or
  - C. A shallow-dose equivalent to the skin or extremities of 250 rads (2.5 Gy) or more; or
2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for twenty-four (24) hours, the individual could have received an intake five (5) times the occupational annual limit on intake (The provisions of this Paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.).

b. Twenty-four hour notification. Each licensee or registrant shall within twenty-four (24) hours notify the Division of Radiation Control and Emergency Management, Arkansas Department of Health, 4815 West Markham, Mail Slot 30, Little Rock, Arkansas 72205-3867, by telephone and confirming letter of any incident involving any source of radiation possessed by the licensee or registrant and which may have caused or threatens to cause:

1. An individual to receive, in a period of twenty-four (24) hours:
  - A. A total effective dose equivalent exceeding five (5) rems(0.05 Sv); or
  - B. A lens dose equivalent exceeding fifteen (15) rems (0.15 Sv); or
  - C. A shallow-dose equivalent to the skin or extremities exceeding fifty (50) rems (0.5 Sv); or

RH-1502. (Cont'd)

2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for twenty-four (24) hours, the individual could have received an intake in excess of one occupational annual limit on intake (The provisions of this Paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).
- c. The licensee or registrant shall prepare any report filed with the Department pursuant to this Section so that names of individuals who have received exposure to radiation or radioactive material are stated in a separate and detachable part of the report.
- d. The provisions of this Section do not include doses that result from planned special exposures, that are within the limits for planned special exposures, and that are reported under RH-1504.
- e. Immediate report. Each licensee or registrant shall notify the Department as soon as possible but not later than four (4) hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, et cetera).
- f. Twenty-four hour report. Each licensee or registrant shall notify the Department within twenty-four (24) hours after the discovery of any of the following events involving licensed material:
  1. An unplanned contamination event that:
    - A. Requires access to the contamination area, by workers or the public, to be restricted for more than twenty-four (24) hours by imposing additional radiological controls or by prohibiting entry into the area;
    - B. Involves a quantity of material greater than five (5) times the lowest annual limit on intake specified in Appendix G to RH-1000 through RH-2110 for the material; and
    - C. Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than twenty-four (24) hours to decay prior to decontamination.

RH-1502. (Cont'd)

2. An event in which equipment is disabled or fails to function as designed when:
    - A. The equipment is required by regulation or licensee condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;
    - B. The equipment is required to be available and operable when it is disabled or fails to function; and
    - C. No redundant equipment is available and operable to perform the required safety function.
  3. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.
  4. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:
    - A. The quantity of material involved is greater than five (5) times the lowest annual limit on intake specified in Appendix G of RH-1000 through RH-2110 of these Regulations for the material; and
    - B. The damage affects the integrity of the licensed material or its container.
- g. Preparation and submission of reports. Reports made by licensees or registrants in response to the requirements of this Section must be made as follows:
1. Licensees or registrants shall make reports required by RH-1502.a and RH-1502.b by telephone to the Department at 1-800-633-1735. To the extent that the information is available at the time of notification, the information provided in these reports must include:
    - A. The caller's name and call back telephone number;
    - B. A description of the event, including date and time;
    - C. The exact location of the event;

RH-1502. (Cont'd)

- D. The isotopes, quantities, and chemical and physical form of the licensed material involved; and
  - E. Any personnel radiation exposure data available.
2. Written report. Each licensee or registrant who makes a report required by RH-1502.a and RH-1502.b of this Section shall submit a written follow-up report within 30 (thirty) days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the Division of Radiation Control and Emergency Management; Arkansas Department of Health; 4815 West Markham Street, Mail Slot # 30; Little Rock, Arkansas 72205-3867. The reports must include the following:
- A. A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;
  - B. The exact location of the event;
  - C. The isotopes, quantities and chemical and physical form of the licensed material involved;
  - D. Date and time of the event;
  - E. Corrective actions taken or planned and the results of any evaluations or assessments; and
  - F. The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

RH-1503. Tests. Each licensee and registrant shall perform upon instructions from the Department or shall permit the Agency to perform, such reasonable tests as the Department deems appropriate or necessary including, but not limited to, tests of:

- a. Sources of radiation;
- b. Facilities wherein sources of radiation are used or stored;
- c. Radiation detection and monitoring instruments; and

RH-1502. (Cont'd)

- d. Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

RH-1504. Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Limits.

- a. Reportable events. In addition to the notification required by RH-1502, each licensee or registrant shall submit a written report within thirty (30) days after learning of any of the following occurrences:
  - 1. Any incident for which notification is required by RH-1502; or
  - 2. Doses in excess of any of the following:
    - A. The occupational dose limits for adults in RH-1200; or
    - B. The occupational dose limits for a minor in RH-1206; or
    - C. The limits for an embryo/fetus of a declared pregnant woman in RH-1207; or
    - D. The limits for an individual member of the public in RH-1208; or
    - E. Any applicable limit in the license; or
    - F. The ALARA constraints for air emissions established under RH-1004.d.
  - 3. Levels of radiation or concentrations of radioactive material in:
    - A. A restricted area in excess of any applicable limit in the license; or
    - B. An unrestricted area in excess of ten (10) times any applicable limit set forth in this Part or in the license (whether or not involving exposure of any individual in excess of the limits in RH-1208); or
  - 4. For licensees subject to the provisions of EPA's generally applicable environmental radiation standards levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

Revisions effective July 1, 2002

RH-1504. (Cont'd)

b. Contents of reports.

1. Each report required by RH-1504.a of this Section must describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:
  - A. Estimates of each individual's dose;
  - B. The levels of radiation and concentrations of radioactive material involved;
  - C. The cause of the elevated exposures, dose rates, or concentrations; and
  - D. Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions.
2. Each report filed pursuant to RH-1504.a of this Section must include for each occupationally overexposed<sup>9f</sup> individual: the name, Social Security account number, and date of birth. The report must be prepared so that this information is stated in a separate and detachable part of the report.
3. The licensee or registrant shall prepare any report filed with the Department pursuant to this Section so that names of individuals who may have received exposure to radiation are stated in a separate and detachable part of the report.

RH-1505. Notifications and Reports to Individuals.

- a. Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in Part N of this Section.
- b. Reports to individuals of exceeding dose limits. When a licensee or registrant is required, pursuant to the provisions of RH-1504, RH-1505.b, or RH-1509, to report to the Department any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, licensee or registrant shall also provide a copy of the report submitted to the Department to the individual. The report must be transmitted at a time no later than the transmittal to the Department.

Revisions effective July 1, 2002

RH-1506. Vacating Premises.

Each specific licensee shall, no less than thirty (30) days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of the activities, notify the Department in writing of intent to vacate. When deemed necessary by the Department, the licensee shall decontaminate the premises in such a manner as the Department may specify.

RH-1507. Records and Reports of Misadministrations.

a. For a misadministration:

1. The licensee or registrant shall notify the Department by telephone no later than the next calendar day after the discovery of the misadministration.
2. The licensee or registrant shall submit a written report to the Department within fifteen (15) days after the discovery of the misadministration. The written report must include the licensee's or registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual who received the misadministration; what improvements are needed to prevent recurrence; actions take to prevent recurrence; whether the licensee or registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not; and, if there was notification, what information was provided. The report must not include the individual's name or any other information that could lead to identification of the individual. To meet the requirements of this section, the notification of the individual receiving the misadministration may be made instead to that individual's responsible relative or guardian when appropriate.
3. The licensee or registrant shall notify the referring physician and also notify the individual receiving the misadministration no later than twenty-four (24) hours after its discovery, unless the referring physician personally informs the licensee or registrant either that he/she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee or registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the individual receiving the misadministration cannot be reached within twenty-four (24) hours, the licensee or registrant shall notify the individual as soon as possible thereafter. The licensee or registrant may not delay any appropriate medical care

Revisions effective July 1, 2002

RH-1507. (Cont'd)

for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

4. If the individual was notified, the licensee or registrant shall also furnish, within fifteen (15) days after discovery of the misadministration, a written report to the individual by sending either:

- A. A copy of the report that was submitted to the Department; or
- B. A brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the Department can be obtained from the licensee or registrant.

b. Each licensee or registrant shall retain a record of each misadministration for five (5) years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual who received the misadministration, and the individual's referring physician, if applicable), the individual's social security number or other identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the individual, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

c. Aside from the notification requirement, nothing in this Section affects any rights or duties of licensees or registrants and physicians in relation to each other, to individuals receiving misadministrations, or that individual's responsible relatives or guardians.

RH-1508. Deleted.

RH-1509. Reports of Individual Monitoring.

a. This Section applies to each person licensed by the Department to:

- 1. Possess or use radioactive material for purposes of radiography pursuant to Part I of these Regulations; or
- 2. Possess or use at any time, for processing or manufacturing for distribution pursuant to Section 2 of these Regulations, radioactive material in quantities exceeding any one of the following quantities.

Revisions effective July 1, 2002

TABLE RH-1509.a.2.

Radionuclide	Quantity of Radionuclide <sup>a</sup> in Curies
Cesium-137	1
Cobalt-60	1
Gold-198	100
Iodine-131	1
Iridium-192	10
Krypton-85	1,000
Promethium-147	10
Technetium-99m	1,000

<sup>a</sup> The Department may require as a license condition, or by rule, Regulation, or order pursuant to RH-2002, reports from licensees who are licensed to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

- b. Each licensee in a category listed in RH-1509.a shall complete an annual report of the results of individual monitoring carried out by the licensee for each individual for whom monitoring was required by RH-1302 during that year. The licensee may include additional data for individuals for whom monitoring was provided but not required. The licensee shall use Department Form Y or electronic media containing all the information required by Department Form Y.
- c. The licensee shall complete the report required by RH-1509.b, covering the preceding year, on or before May 31 of each year. The licensee shall retain the report and submit it if requested to the Director, Division of Radiation Control and Emergency Management, Arkansas Department of Health, 4815 West Markham, Mail Slot 30, Little Rock, Arkansas 72205-3867.

RH-1510.

Quality Management Program

a. Each applicant or licensee under this Part, as applicable, shall establish and maintain a written quality management program to provide high confidence that radioactive material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific objectives:

1. That, prior to administration, a written directive<sup>10/</sup> is prepared for:
  - A. Any teletherapy radiation dose;
  - B. Any gamma stereotactic radiosurgery radiation dose;
  - C. Any brachytherapy radiation dose;
  - D. Any administration of quantities greater than 30 microcuries of either Sodium Iodine I-125 or I-131;
  - E. Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131; and
  - F. Any medical particle accelerators dose.
2. That, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;
3. That final plans of treatment and related calculations for brachytherapy, teletherapy, particle accelerator therapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;
4. That each administration is in accordance with the written directive; and
5. That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

b. The licensee shall:

1. Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:

RH-1510. (Cont'd)

- A. A representative sample of patient and human research subject administrations;
  - B. All recordable events; and
  - C. All misadministrations to verify compliance with all aspects of the quality management program. These reviews shall be conducted at intervals no greater than 12 (twelve) months;
2. Evaluate each of these reviews to determine the effectiveness of the quality management program, and if required, make modifications to meet the objectives of RH-1510.a; and
  3. Retain records of each review, including the evaluations and findings of the review, in an auditable form for three (3) years.
- c. The licensee shall evaluate and respond, within 30 days after discovery of the recordable event by:
1. Assembling the relevant facts including the cause;
  2. Identifying what, if any, corrective action is required to prevent recurrence; and
  3. Retaining a record, in an auditable form, for three (3) years, of the relevant facts and what corrective action, if any, was taken.
- d. The licensee shall retain:
1. Each written directive; and
  2. A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in RH-1510.a.1 above, in an auditable form, for three (3) years after the date of administration.
- e. The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The licensee shall furnish the modification to the Department within 30 days after the modification has been made.
- f. 1. Each applicant for a new license, as applicable, shall submit to the Department in accordance with RH-1510 a quality management program as part of the application for a license and implement the program upon issuance of the license by the Department.

RH-1510. (Cont'd)

2. Each existing licensee as applicable, shall submit to the Department, in accordance with RH-1510, by January 1, 1994 a written certification that the quality management program has been implemented along with a copy of the program.

RH-1511. Deliberate Misconduct

- a. Any licensee, registrant, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee or registrant, certificate of registration holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor, of any licensee, registrant or certificate of registration holder or applicant for a license, registration, or certificate of registration, who knowingly provides to any licensee, registrant, applicant, certificate holder, contractor or subcontractor, any components, equipment, materials or other goods or services that relate to a licensee's, registrant's, certificate holder's or applicant's activities subject to this Part may not:
  1. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, registrant, certificate of registration holder, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license, issued by the Department; or
  2. Deliberately submit to the Department, a licensee, registrant, certificate of registration holder, an applicant, or a licensee's or registrant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Department.
- b. A person who violates RH-1511.a.1 or 2 of this Section may be subject to enforcement action in accordance with the procedures in RH-2110.
- c. For purposes of RH-1511.a.1, deliberate misconduct by a person means an intentional act or omission that the person knows:
  1. Would cause a licensee, registrant, certificate of registration holder, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Department; or
  2. Constitutes a violation of a requirement, procedure, instruction, contract, purchase order or policy of a licensee, registrant, certificate of registration holder, applicant, contractor, or subcontractor.

Revisions effective July 1, 2002

RH-1512

"Records Required at Temporary Jobsites"

- a. Each licensee or registrant conducting activities as defined in RH-1100.df. shall have the following records available at the temporary jobsite for inspection by the Department:
1. Current copy of appropriate license issued by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State.
  2. A copy of these regulations.
  3. Operating and Emergency Procedures.
  4. The latest instrument calibration, if applicable.
  5. Survey records required pursuant to RH-1803.c. for the period of operation at the jobsite, if applicable.
  6. The latest leak test record for the device(s) in use at the jobsite.
  7. Daily pocket dosimeter record for the period of operation at the jobsite, if applicable.

RH-1513.-  
RH-1599.

Reserved

**PART G.**  
**SPECIAL REQUIREMENTS FOR THE USE OF**  
**X-RAYS IN THE HEALING ARTS**

RH-1600.     Scope.

This Part establishes requirements, for which a registrant (or licensee) is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provisions of this Part are in addition to and not in substitution for, other applicable provisions of these Regulations.

RH-1601.     Definitions as Used in these Regulations. Additional definitions used only in a certain Part will be found in that Part.

- a.     Accessible surface - The external surface of the enclosure or housing provided by the manufacturer.
- b.     Added filtration - Any filtration which is in addition to the inherent filtration
- c.     Aluminum equivalent - The thickness of type 1100 aluminum alloy<sup>11/</sup>affording the same attenuation, under specified conditions, as the material in question.
- d.     Assembler - Any person engaged in the business of assembling, replacing or installing one or more components into an x-ray system or subsystem.
- e.     Attenuation block - A block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy<sup>11/</sup> or other materials having equivalent attenuation.
- f.     Automatic exposure control - A device which automatically controls one or more technique factors in order to obtain at a pre-selected location(s) a required quantity of radiation (See also "Phototimer").
- g.     Barrier - See "Protective barrier".
- h.     Beam axis - A line from the source through the centers of the x-ray fields.
- i.     Beam-limiting device - A device which provides a means to restrict the dimensions of the x-ray field.
- j.     Beam monitoring system - A system designed to detect and measure the radiation present in the useful beam.

RH-1601. (Cont'd)

- k. Calibration - The determination of (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument or (2) the strength of a source of radiation relative to a standard.
- l. Cephalometric device - A device intended for the radiographic visualization and measurement of the dimensions of the human head.
- m. Certified components - Components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.
- n. Certified system - Any x-ray system which has one or more certified component(s).
- o. Changeable filters - Any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical or physical process.
- p. Coefficient of variation or "C" - The ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{X}} = \frac{1}{\bar{X}} \left[ \sum_{i=1}^n \frac{(X_i - \bar{X})^2}{n - 1} \right]^{1/2}$$

where:

s = Estimated standard deviation of the population.

X = Mean value of observations in sample.

X<sub>i</sub> = i<sup>th</sup> observation in sample.

n = Number of observations in sample.

- q. Contact therapy system - An x-ray system used for therapy with the x-ray tube port placed in contact with or within 5 centimeters of the surface being treated.
- r. Control panel - That part of the x-ray control upon which are mounted the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors.
- s. Cooling curve - The graphical relationship between heat units stored and cooling time.

RH-1601. (Cont'd)

- t. Dead-man switch - A switch constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.
- u. Detector - See "Radiation detector".
- v. Diagnostic source assembly - The tube housing assembly with a beam-limiting device attached.
- w. Diagnostic x-ray system - An x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.
- x. Direct scattered radiation - The scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").
- y. Entrance exposure - The roentgens per unit time at the point where the center of the useful beam enters the patient.
- z. Equipment - See "X-ray equipment".
- aa. Exposure - The quotient of  $dQ$  by  $dm$  where  $dQ$  is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass  $dm$  are completely stopped in air. (The special unit of exposure is the roentgen [R]).
- ab. Field emission equipment - Equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.
- ac. Filter - Material placed in the useful beam to absorb preferentially selected radiations.
- ad. Fluoroscopic imaging assembly - A subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any and structural material providing linkage between the image receptor and diagnostic source assembly.
- ae. Focal spot - The area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.
- af. Full beam detector - A radiation detector of such size that the total cross section of the maximum size useful beam is intercepted.
- ag. General purpose radiographic x-ray system - Any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

RH-1601. (Cont'd)

- ah. Gonad shield - A protective barrier for the testes or ovaries.
- ai. Half-value layer - The thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.
- aj. Healing arts screening - The testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.
- ak. Heat unit - A unit of energy equal to the product of the peak kilovoltage, milliamperes and seconds, i.e., kVp x mA x second.
- al. HVL - See "Half-value layer".
- am. Image intensifier - A device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.
- an. Image receptor - Any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.
- ao. Image receptor support - For mammographic systems, that part of the system designed to support the image receptor in a horizontal plane during a mammographic examination.
- ap. Inherent filtration - The filtration of the useful beam provided by the permanently installed components of the tube housing assembly.
- aq. Interlock - A device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.
- ar. Irradiation - The exposure of matter to ionizing radiation.
- as. Kilovolts peak - See "Peak tube potential".
- at. kV - Kilovolts.
- au. kVp - See "Peak tube potential".
- av. kWs - Kilowatt second. It is equivalent to  $10^3$  kV.mA.sec, i.e.,

$$(A)kW_s = (X)kV \times (Y)mA \times (Z)sec \times \frac{kW_s}{10^3 kV \times mA \times s} = \frac{XYZ kW_s}{10^3}$$

RH-1601. (Cont'd)

- aw. Lead equivalent - The thickness of lead affording the same attenuation, under specified conditions, as the material in question.
- ax. Leakage radiation - Radiation emanating from the diagnostic or therapeutic source assembly except for:
1. the useful beam, and
  2. radiation produced when the exposure switch or timer is not activated.
- ay. Leakage technique factors - The technique factors associated with the tube housing assembly which are used in measuring leakage radiation. They are defined as follows:
1. For capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliamperere seconds or the minimum obtainable from the unit, whichever is larger.
  2. For field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.
  3. For all other equipment, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.
- az. Light field - That area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.
- ba. Line-voltage regulation - The difference between the no-load and the load line potentials expressed as a percentage of the load line potential. It is calculated using the following equation:
- Percent line-voltage regulation -  $100(V_n - V_l)/V_l$
- where
- $V_n$  = No-load line potential and  
 $V_l$  = Load line potential.
- bb. mA - Milliampere.
- bc. mAs - Milliampere second.

RH-1601. (Cont'd)

- bd. Maximum line current - The root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.
- be. Mobile equipment - See "X-ray equipment".
- bf. Patient - An individual subjected to healing arts examination, diagnosis or treatment.
- bg. Peak tube potential - The maximum value of the potential difference across the x-ray tube during an exposure.
- bh. Phantom - A volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.
- bi. Phototimer - A method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (See "Automatic exposure control").
- bj. PID - See "Position indicating device".
- bk. Position indicating device - A device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.
- bl. Primary dose monitoring system - A system which will monitor the useful beam during irradiation and which will terminate irradiation when pre-selected number of dose monitor units have been acquired.
- bm. Primary protective barrier - See "Protective barrier".
- bn. Protective apron - An apron made of radiation attenuating materials used to reduce radiation exposure.
- bo. Protective barrier - A barrier of radiation attenuating material(s) used to reduce radiation exposure. The types of protective barriers are as follows:
  - 1. Primary protective barrier - The material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.
  - 2. Secondary protective barrier - A barrier sufficient to attenuate the stray radiation to the required degree.
- bp. Protective glove - A glove made of radiation attenuating materials used to reduce radiation exposure.

RH-1601. (Cont'd)

- bq. Qualified expert - An individual who has demonstrated to the satisfaction of the Department that such individual possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques and to advise regarding radiation protection needs.
- br. Radiation detector - A device which in the presence of radiation provides by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.
- bs. Radiation therapy simulation system - A radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.
- bt. Radiograph - An image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.
- bu. Radiograph imaging system - Any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.
- bv. Rating - The operating limits as specified by the component manufacturer.
- bw. Recording - Producing a permanent form of an image resulting from x-ray photons (e.g., film, video tape).
- bx. Response time - The time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state mid scale reading.
- by. Scattered radiation - Radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").
- bz. Secondary dose monitoring system - A system which will terminate irradiation in the event of failure of the primary system.
- ca. Secondary protective barrier - See "Protective barrier".
- cb. Shutter - A device attached to the tube housing assembly which can totally intercept the useful beam and which as a lead equivalency not less than that of the tube housing assembly.
- cc. SID - See "Source-image receptor distance".
- cd. Source - The focal spot of the x-ray tube.

RH-1601. (Cont'd)

- ce. Source-image receptor distance - The distance from the source to the center of the input surface of the image receptor.
- cf. Spot check - A procedure which is performed to assure that a previous calibration continues to be valid.
- cg. Spot film - A radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.
- ch. Spot-film device - A device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.
- ci. SSD - The distance between the source and the skin of the patient.
- cj. Stationary equipment - See "X-ray equipment".
- ck. Stray radiation - The sum of leakage and scattered radiation.
- cl. Technique factors - The conditions of operation. They are specified as follows:
  - 1. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs.
  - 2. For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses.
  - 3. For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs.
- cm. Termination of irradiation - The stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.
- cn. Traceable to a national standard - A quantity or a measurement that has been compared to a NIST\* (National Institute of Standards and Technology) standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

\*formerly NBS (National Bureau of Standards)

RH-1601. (Cont'd)

- co. Therapeutic-type housing -
  1. For x-ray therapy equipment not capable of operating at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that the leakage radiation averaged over any 100 cm<sup>2</sup> area at a distance of one meter from the source does not exceed one roentgen in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential.
  2. For x-ray therapy equipment capable of operation at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that leakage radiation averaged over any 100 cm<sup>2</sup> area at a distance of one meter from the source does not exceed 0.1 percent of the useful beam dose rate at one meter from the source for any of its operating conditions.
- cp. Therapeutic x-ray and/or electron system - A system designed for irradiation of any part of the human body for the purpose of treatment or alleviation of symptoms of disease.
- cq. Tube - An x-ray tube, unless otherwise specified.
- cr. Tube housing assembly - The tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.
- cs. Tube rating chart - The set of curves which specify the rated limits of operation of the tube in terms of the technique factors.
- ct. Useful beam - The radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.
- cu. Variable-aperture beam-limiting device - A beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a give SID.
- cv. Visible area - That portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.
- cw. Wedge filter - An added filter effecting continuous progressive attenuation on all or part of the useful beam.
- cx. X-ray control - A device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers and similar devices, which control the technique factors of an x-ray exposure.

RH-1601. (Cont'd)

- cy. X-ray equipment - An x-ray system, subsystem or component thereof. Types of x-ray equipment are as follows:
  - 1. Mobile x-ray equipment: X-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.
  - 2. Portable x-ray equipment: X-ray equipment designed to be hand-carried.
  - 3. Stationary x-ray equipment: X-ray equipment which is installed in a fixed location.
- cz. X-ray field - The area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.
- da. X-ray high-voltage generator - A device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices and other appropriate elements.
- db. X-ray system - An assemblage of components for the controlled production of x-rays. It includes an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.
- dc. X-ray subsystem - Any combination of two or more components of an x-ray system.
- dd. X-ray tube - Any electron tube which is designed to be used primarily for the production of x-rays.

RH-1602. General Requirements.

- a. Administrative Controls. Registrant. The registrant shall be responsible for directing the operation of the x-ray systems which have been registered with the Department. The registrant or the registrant's agent shall assure that the requirements of RH-1602.a are met in the operation of the x-ray system(s).
  - 1. An x-ray system which does not meet the provisions of these Regulations shall not be operated for diagnostic or therapeutic purposes.

RH-1602. (Cont'd)

2. Individuals who will be operating the x-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment.
3. A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel which specifies, for all examinations performed with that system, the following information:
  - A. Patient's anatomical size versus technique factors to be utilized;
  - B. Type and size of the film or film-screen combination to be used;
  - C. Type and focal distance of the grid to be used, if any;
  - D. Source to image receptor distance to be used; and
  - E. Type and location of placement of gonad shielding to be used.
  - F. For mammography, indication of kVp/target/filter combination.
4. Written safety procedures and rules shall be provided to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these rules.
5. Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:
  - A. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.
  - B. Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

RH-1602. (Cont'd)

- C. Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.
- 6. New gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.
- 7. Individuals shall not be exposed to the useful beam except for healing arts purposes and such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:
  - A. Exposure of an individual for training, demonstration or other non-healing-arts purposes; and
  - B. Exposure of an individual for the purpose of healing arts screening except as authorized by RH-1602.a.11.
- 8. When a patient or film must be provided with auxiliary support during a radiation exposure:
  - A. Mechanical holding devices shall be used when the technique permits.
  - B. If a human holder must be utilized:
    - i. Written safety procedures, as required by RH-1602.a.4 shall indicate the requirements for selecting a holder and the procedure the holder shall follow;
    - ii. The human holder shall be protected as required by RH-1602.a.5;
    - iii. No individual shall be used routinely to hold film or patients;
    - iv. Such holding shall be permitted only in very unusual and rare situations;

- v. In those cases where the patient must hold the film, except during intra-oral examinations, any portion of the body, other than the area of clinical interest, struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material; and
  - vi. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with x-ray operations and who are otherwise not shielded.
9. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. This is interpreted to include but not limited to:
- A. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.
  - B. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.
  - C. Portable or mobile equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary radiographic installation.
  - D. X-ray systems subject to RH-1604 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.
    - i. X-ray systems shall not be utilized in procedures where the source to patient distance is less than 30 centimeters, except for veterinary systems.
    - ii. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:
      - (a) Be positioned properly, i.e., tube side facing the right direction, and grid centered to the central ray;

- (b). If of the focused type, be of the proper focal distance for the SIDs being used.
- 10. All individuals who are associated with the operation of an x-ray system are subject to the requirements of RH-1200.
  - A. When protective clothing or devices are worn on portions of the body and a monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:
    - i. When an apron is worn, the monitoring device shall be worn at the collar outside of the apron.
    - ii. The dose to the whole body based on the maximum dose attributed to the most critical organ shall be recorded in the reports required by Part F of these Regulations. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.
  - B. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.
- 11. Health arts screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Department. When requesting such approval, that person shall submit the information as deemed necessary by the Department. If any information submitted to the Department becomes invalid or outdated, the Department will be notified in writing within thirty (30) days.
- 12. Information and maintenance record and associated information. The registrant shall maintain the following information for each x-ray system for inspection by the Department:
  - A. Maximum rating of technique factors;
  - B. Model and serial numbers of all certifiable components;
  - C. Aluminum equivalent filtration of the useful beam, including any routine variation;

- D. Tube rating charts and cooling curves;
- E. Records of surveys, calibrations, maintenance and modifications performed on the X-ray system(s) after July 1, 1983 with the names of persons who performed such services;
- F. A scale drawing of the room in which a stationary x-ray system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:
  - i. The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or
  - ii. The type and thickness of materials or lead equivalency, of each protective barrier; and
- G. A copy of all correspondence with the Department regarding that x-ray system.

13. X-ray log. Each facility shall maintain an x-ray log containing the patient I.D., the type of examinations and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

b. General Requirements for All Diagnostic X-Ray Systems. In addition to other requirements of this Part, all diagnostic x-ray systems shall meet the following requirements:

1. Warning label. The control panel containing the main power switch shall bear the warning statement or its equivalent, legible and accessible to view:

**"WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."**

2. Battery charge indicator. On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

3. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one (1) meter in any direction from the source shall not exceed 100 milliroentgens in one (1) hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
4. Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens in one (1) hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
5. Beam quality.
  - A. Half-value layer.
    - i. The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I

Design Operating Range (Kilovolts peak)	Measured Potential (Kilovolts peak)	Half-value Layer (Millimeters of aluminum)
----- Below 50 -----	30	0.3
	40	0.4
	49	0.5
----- 50 to 70 -----	50	1.2
	60	1.3
	70	1.5
----- Above 70 -----	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

- ii. The requirements of RH-1602.b.5.A.i will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table II.

TABLE II

Filtration Required vs. Operating Voltage	
Operating Voltage (kVp)	Total Filtration (inherent plus added) (millimeters aluminum equivalent)
Below 50	0.5 millimeters
50 to 70	1.5 millimeters
Above 70	2.5 millimeters

RH-1602. (Cont'd)

- iii. Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.
- iv. For capacitor energy storage equipment, compliance with the requirements of RH-1602.b.5 shall be determined with the maximum quantity of charge per exposure.
- v. The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.

B. Filtration controls. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by RH-1602.b.5.A.i or ii is in the useful beam for the given kVp which has been selected.

- 6. Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.
- 7. Mechanical support of tube head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

c. Other Requirements

- 1. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

2. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density for 1 to 2 when processed shall not suffer an increase in density greater than 0.1 (0.05 mammography) when exposed in the darkroom for two (2) minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.
3. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.
4. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.
5. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.
6. Outdated x-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.
7. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.
  - A. The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated. The requirement may be permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.
  - B. The requirement may be permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

RH-1602. (Cont'd)

8. Maintaining Compliance. Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-Ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.
9. Locks. All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.

RH-1603. Fluoroscopic X-Ray Systems. All fluoroscopic x-ray systems shall meet the following requirements:

- a. Limitation of Useful Beam.
  1. Primary barrier.
    - A. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.
    - B. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.
  2. X-ray field.
    - A. The x-ray field produced by non-image intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size for both fluoroscopic procedures and spot filming procedures. In addition:
      - i. Means shall be provided for stepless adjustment of the field size;
      - ii. The minimum field size at the greatest SID shall be equal to or less than five (5) centimeters by five centimeters; and
      - iii. For equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

Revisions effective July 1, 2002

Compliance with RH-1603.a.2.A shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

- B. For image-intensified fluoroscopic equipment, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent of the SID. The sum of the excess length and the excess width shall be no greater than four percent of the SID. This requirement applies to field size for both fluoroscopic and spot filming procedures. In addition:
- i. Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979 and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;
  - ii. The minimum field size at the greatest SID shall be equal to or less than five centimeters by five centimeters;
  - iii. All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of five (5) by five centimeters or less;
  - iv. For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; and

- v. Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular x-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.
- C. Spot-film devices which are certified components shall meet the following additional requirements:
- i. Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;
  - ii. It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to or less than, five (5) centimeters by five centimeters;
  - iii. The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two (2) percent of the SID; and

RH-1603. (Cont'd)

- iv. For spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance with RH-1603.a.2.A and B shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.
  
- b. Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.
  
- c. Exposure Rate Limits.
  - 1. Entrance exposure rate allowable limits.
    - A. The exposure measured at the point where the center of the useful beam enters the patient shall not exceed 10 roentgens per minute, except during recording of fluoroscopic images or when provided with optional high level control.
  
    - B. When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient unless the high level control is activated.
      - i. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator.
  
      - ii. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

RH-1603. (Cont'd)

- C. In addition to the other requirements of RH-1603, certified equipment which does not incorporate an automatic exposure control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of beam enters the patient except during recording of fluoroscopic images or when provided with an optional high level control.
- D. Compliance with the requirements of RH-1603.c shall be determined as follows:
  - i. Movable grids and compression devices shall be removed from the useful beam during the measurement.
  - ii. If the source is below the table, exposure rate shall be measured or referenced to a point one (1) centimeter above the tabletop or cradle.
  - iii. If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
  - iv. In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.
  - v. For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.

2. Barrier transmission radiation rate limits.
  - A. For non-image intensified fluoroscopes, the exposure rate due to transmission through the viewing screen shall not exceed 50 milliroentgens per hour;
  - B. For image intensified fluoroscopes, the exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with the radiation from the image intensifier shall not exceed 2 milliroentgens per hour at 18 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.
  - C. For certified image intensified fluoroscopic systems, the exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with the radiation from the image intensifier, shall not exceed 2 milliroentgens per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.
  - D. Measuring compliance of barrier transmission.
    - i. For non-image intensified fluoroscopes, the exposure rate shall be determined with the screen positioned 35 centimeters from the panel or tabletop with no attenuation block in the beam.
    - ii. For image intensified fluoroscopes:
      - (a). The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

- (b). If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.
  - (c). If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.
  - (d). Movable grids and compression devices shall be removed from the useful beam during the measurement.
  - (e). The attenuation block shall be positioned in the useful beam ten (10) centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.
- d. Indication of Potential and Current. During fluoroscopy and cinefluorography, the kV and the mA shall be continuously indicated.
- 1. Periodic measurement of entrance exposure rate shall be performed by a qualified expert for both typical and maximum values as follows:
    - A. Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate.
    - B. Results of these measurements shall be available where any fluoroscopist may have ready access to such results while using the fluoroscope. The measurement results shall be stated in coulombs per kilogram or mR/hr and included the technique factors used in measurements and the date the measurements were performed shall be included in the results.

- C. Conditions of periodic measurement of typical entrance exposure rate are as follows:
  - i. The measurement shall be made under the conditions that satisfy the requirement;
  - ii. The kVp, MA, and /or other selectable parameters shall be adjusted to those settings typical of clinical use on 23 cm thick abdominal patient;
  - iii. The x-ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliamperage and/or kilovoltage to satisfy the conditions.
  
- D Conditions of periodic measurement of maximum entrance exposure rate are as follows:
  - i. The measurements shall be made under the conditions that satisfy the requirements.;
  - ii. The kVp, mA and/or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate;
  - iii. The x-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum entrance exposure rate of the system.
  
- e. Source-Skin Distance. The source to skin distance shall not be less than:
  - 1. 38 centimeters on stationary fluoroscopes installed after July 1, 1974;
  - 2. 30.5 centimeters on stationary fluoroscopes which are in operation prior to July 1, 1975;
  - 3. 30.5 centimeters on all mobile fluoroscopes; and
  - 4. 20 centimeters for image intensified fluoroscopes used for specific surgical application. The users' operating manual must provide precautionary measures to be adhered to during the use of this device.

RH-1603. (Cont'd)

f. Fluoroscopic Timer.

1. Means shall be provided to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.
2. At the completion of any preset cumulative on-time either:
  - A. The fluoroscopic tube output will be terminated; or
  - B. A signal audible to the fluoroscopist indicate the completion of any preset shall cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

g. Mobile Fluoroscopes. In addition to the other requirements of RH-1603, mobile fluoroscopes shall provide intensified imaging.

h. Control of Scattered Radiation.

1. Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to un-attenuated scattered radiation which originates from under the table.

The attenuation required shall be not less than 0.25 millimeter lead equivalent.
2. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the un-attenuated scattered radiation emanating from above the tabletop unless that individual;
  - A. Is at least 120 centimeters from the center of the useful beam, or
  - B. The radiation has passed through not less than 0.25 millimeter lead equivalent material (e.g., drapes, Bucky-slot cover, sliding or folding panel or self-supporting curtains) in addition to any lead equivalency provided by the protective apron referred to in RH-1602.a.5.

RH-1603. (Cont'd)

3. Exceptions to RH-1603.h.2 may be made in some special procedures where a sterile field will not permit the use of the normal protective barriers. Where the use of pre-fitted sterilized covers for the barriers is practical, the Department shall not permit such exception.
- i. Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of RH-1603.a, c.2 and f provided that:
  - A. Such systems are designed and used in such manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and
  - B. Such systems as do not meet the requirements of RH-1603.f are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.
- j. Override. If a means exists to override any of the automatic x-ray field size adjustments, that means:
  1. Shall be designed for use only in the event of system failure;
  2. Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and
  3. Shall be clearly and durably labeled.

RH-1604. Radiographic Systems Other than Fluoroscopic, Dental Intraoral or Veterinarian Systems.

- a. Beam Limitation and Alignment. The useful beam shall be limited to the area of clinical interest.
  1. The size of the x-ray beam projected by fixed aperture cones and collimators shall not exceed the dimensions of the image receptor by more than two (2) inches for a source to image receptor distance of seventy-two (72) inches or one (1) inch for a source to film distance of forty (40) inches or less.
  2. For systems with variable aperture beam limiting devices, means shall be provided for visually defining the perimeter of the x-ray field.

RH-1604. (Cont'd)

- A. The beam-limiting device for stationary general purpose x-ray systems shall numerically indicate the field size in the plane of the image receptor to which it is adjusted.
  - B. Indication of field size dimensions and SID's shall be specified in inches and/or centimeters and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two (2) percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.
  - C. The total misalignment of the edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.
3. For stationary general purpose x-ray systems, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor and to align the center of the image receptor to within two percent of the source to image receptor distance.
4. The Department may grant an exemption on non-certified x-ray systems to RH-1604.a.2.B provided the registrant makes a written application for such exemption and in that application:
- A. demonstrates it is impractical to comply with RH-1604.a.2.B; and
  - B. the purpose of RH-1604.a.2.B will be met by other methods.

5. Systems designed for or provided with special attachments for mammography. Radiographic systems designed only for mammography and general purpose radiographic systems, when special attachments for mammography are in service, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than two (2%) percent of the SID. This requirement can be met with a system which performs as prescribed in RH-1604.f.8. When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in RH-1604.f.8.c.i and ii shall be the maximum SID for which the beam-limiting device or aperture is designed. In addition, each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

b. Radiation Exposure Control Devices.

1. Technique indicators.

- A. The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated.
- B. The requirement of RH-1604.b.1.A may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

2. Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

3. X-ray control.

- A. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:
  - i. Exposure of one-half second or less, or
  - ii. During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.
  
- B. Each x-ray control shall be located in such a way as to meet the following requirements:
  - i. For stationary x-ray systems:
    - (a). The operator's station at the control shall be behind a protective barrier. The exposure switch shall be of the dead-man type and shall be so arranged that it cannot be conveniently operated outside a shielded area. Exposure switches for "spot film" devices used in conjunction with fluoroscopes are exempted from this shielding requirement.
    - (b). A window of lead-equivalent glass equal to that required by the adjacent barrier or a mirror system, shall be provided and it shall be large enough and so placed that the operator can see the patient during the exposure without having to leave the protected area.
  - ii. For mobile and portable x-ray systems:
    - (a). The exposure switch shall be of the dead-man type and shall be so arranged that the operator can stand at least six (6) feet from the patient and well away from the useful beam.

- (b). Used for greater than one (1) week in the same location, i.e., a room or suite, shall meet the requirements of RH-1604.b.3.B.i.(a).
      - (c). Used for greater than one hour and less than one (1) week at the same location, i.e., a room or suite, shall meet the requirement of RH-1604.b.3.B.ii.(b) or be provided with a 6.5 feet [11.98 m] high protective barrier which is placed at least six (6) feet [1.83 m] from the tube housing assembly and at least six (6) feet [1.83 m] from the patient; or
    - iii. For all x-ray systems, the x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.
- 4. Automatic exposure controls. When an automatic exposure control is provided:
  - A. Indication shall be made on the control panel when this mode of operation is selected;
  - B. If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two (2) pulses;
  - C. The minimum exposure time for all equipment other than that specified in RH-1604.b.4.B shall be equal to or less than one-sixtieth second or a time interval required to deliver 5 mAs, whichever is greater;
  - D. Either the product of peak x-ray tube potential, current and exposure time shall be limited to not more than 60 kW per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except when the x-ray tube potential is less than 50 kVp in which case the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

E. A visible signal shall indicate when an exposure has been terminated at the limits required by RH-1604.b.3.D and manual resetting shall be required before further automatically timed exposures can be made.

5. Timer reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to five (5) times the maximum exposure period ( $T_{max}$ ) minus the minimum exposure period ( $T_{min}$ ) when four timer tests are performed:  $T \geq 5(T_{max} - T_{min})$ .

c. Source-to-Skin Distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to not less than 30 centimeters.

d. Exposure Reproducibility. The exposure reproducibility shall meet the following requirements:

The coefficient of variation shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four (4) exposures are made at identical technique factors, that the value of the average exposure (E) is greater than or equal to five times the maximum exposure ( $E_{max}$ ) minus the minimum exposure ( $E_{min}$ ):

$$\text{i.e., } E \geq 5(E_{max} - E_{min}).$$

e. Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

f. Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

1. Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

2. Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliamperere-seconds product, i.e., mR/mAs, obtained at any two (2) consecutive tube current settings shall not differ by more than 0.10 times their sum,

$$\text{i.e., } \left| \overline{X}_1 - \overline{X}_2 \right| \leq 0.10(\overline{X}_1 + \overline{X}_2),$$

where  $X_1$  and  $X_2$  are the average mR/mAs values obtained at each of two (2) consecutive tube current settings.

3. Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.
4. Beam limitation for stationary and mobile general purpose x-ray systems.
- A. There shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters.
- B. Means shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two (2%) percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.
- C. When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 foot-candles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on or after May 27, 1980, are exempt from this requirement.

- D. The edge of the light field at 100 centimeters or at the maximum SID, whichever is - less, shall have a contrast ratio, corrected for ambient lighting, of not less than four (4) in the case of beam-limiting devices designed for use on stationary equipment and a contrast ratio of not less than three (3) in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as  $I_1/I_2$  where  $I_1$  is the illumination three millimeters from the edge of the light field toward the center of the field; and  $I_2$  is the illumination three millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of one millimeter in diameter.
- 5. Beam limitation for portable x-ray systems. Beam limitation for portable x-ray systems shall meet the beam limitation requirements of RH-1604.a and RH-1604.f.4.
  - 6. Field limitation and alignment on stationary general purpose x-ray systems.
    - A. Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within two (2%) percent of the SID and to indicate the SID to within two (2%) percent.
    - B. The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted; and
    - C. Indication of field size dimensions and SID's shall be specified in inches and/or centimeters and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.
    - D. The following requirements shall apply to stationary general purpose x-ray systems which contain a tube housing assembly, an x-ray control and for those systems so equipped, a table, all of which are certified components:

- i. Means shall be provided for positive beam limitation which will, at the SID for which the device is designed, either cause automatic adjustment of the x-ray field in the plane of the image receptor to the image receptor size within five (5) seconds after insertion of the image receptor or, if adjustment is accomplished automatically in a time interval greater than five (5) seconds or is manual, will prevent production of x-rays until such adjustment is completed. For the SID at which the device is not intended to operate, the device shall prevent the production of x-rays.
- ii. The x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, shall be such that neither the length nor the width of the x-ray field differs from that of the image receptor by greater than three percent of the SID and that the sum of the length and width differences without regard to sign (+/-) be no greater than four (4%) percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.
- iii. The radiographic system shall be capable of operation, at the discretion of the operator, such that the field size at the image receptor can be adjusted to a size smaller than the image receptor. The minimum field size at a distance of 100 centimeters shall be equal to or less than five (5) centimeters by five (5) centimeters. Return to positive beam limitation as specified in RH-1604.f.6.D.i and ii shall occur upon a change in image receptor.

- iv. Positive beam limitation may be bypassed when radiography is conducted which does not use the cassette holder or when either the beam axis or table angulation is not within ten ( $10^0$ ) degrees of the horizontal or vertical during any part of the exposure or during stereoscopic radiography. If the bypass mode is provided, return to positive beam limitation shall be automatic.
  - v. A capability may be provided for overriding positive beam limitation in the event of system failure or to perform special procedures which cannot be performed in the positive mode. If so provided, a key shall be required to override the positive mode. It shall be impossible to remove the key while the positive mode is overridden.
- 7. X-ray systems designed for one image receptor size.  
Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor and to align the center of the x-ray field with the center of the image receptor to within two percent of the SID or shall be provided with means to both size and align the x-ray field at the plane of the image receptor such that the x-ray field does not extend beyond any edge of the image receptor.
- 8. Special purpose x-ray systems.
  - A. Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.
  - B. Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent of the SID.
  - C. RH-1604.f.8.A and B may be met with a system that meets the requirements for a general purpose x-ray system as specified in RH-1604.a or, when alignment means are also provided, may be met with either:

RH-1604. (Cont'd)

- i. An assortment of removable, fixed aperture, beam-limiting devices sufficient to meet the requirement for combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or
  - ii. A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture in position for use is in position for use.
9. Timers. Termination of exposures shall cause automatic resetting of the timer to its initial setting or to "zero."

RH-1605. Reserved.

RH-1606. Intraoral Dental Radiographic Systems. In addition to the provisions of RH-1602, the requirements of RH-1606 apply to x-ray equipment and associated facilities used for dental radiography. Requirements for extra-oral dental radiographic systems are covered in RH-1604.

a. Equipment.

1. Diaphragms, cones or position indicating devices shall be used for collimating the useful beam and shall provide the same degree of protection as the housing. The diameter of the useful beam at the end of the position indicating device shall not be more than three (3) inches.
2. A cone, spacer frame or position indicating device shall provide a source-to-skin distance of not less than seven (7) inches with equipment above 50 kVp or four (4) inches with equipment operating at 50 kVp or below.
3. The exposure control switch shall be of the dead-man type.

4. Each installation shall be provided with a protective barrier for the operator or shall be so arranged that the operator can stand at least six (6) feet from the patient and well away from the useful beam.
5. The tube head shall remain stationary when placed in exposure position.
6. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half second or less.
7. Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.
8. Exposure reproducibility. The exposure reproducibility shall meet the following requirements:

The coefficient of variation shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four (4) exposures are made at identical technique factors, the value of the average exposure ( $E$ ) is greater than or equal to five (5) times the maximum exposure ( $E_{\max}$ ) minus the minimum exposure ( $E_{\min}$ ):

$$\text{i.e., } E \geq 5(E_{\max} - E_{\min})$$

9. The x-ray control shall provide a signal audible to the operator to indicate that the exposure has terminated.
  10. In addition to the requirements of RH-1602.c.5, all intraoral dental radiographic systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent filtration permanently installed in the useful beam.
- b. Additional Requirements Applicable to Certified Systems Only.
- Only diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

1. Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.
2. Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, for any fixed x-ray tube potential within the range of forty (40%) percent to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliamperereconds product, i.e., mR/mAs, obtained at any two (2) consecutive tube current settings shall not differ by more than 0.10 times their sum, i.e.,

$$\left| \bar{X}_1 - \bar{X}_2 \right| \leq 0.10(\bar{X}_1 + \bar{X}_2),$$

where  $X_1$  and  $X_2$  are the average mR/mAs values obtained at each of two consecutive tube current settings.

3. Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.
4. Timers. Termination of exposure shall cause automatic resetting of the timer to its initial - setting or to "zero."
5. Field limitation. Radiographic systems designed for use with an intra-oral image receptor shall be provided with means to limit the x-ray beam such that:
  - A. If the minimum SSD is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters.
  - B. If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters.
  - C. An open ended, shielded PID shall be used. The shielding shall be equivalent to the requirements of RH-1602.b.4.

RH-1606. (Cont'd)

6. Source-to-skin distance. X-ray systems designed for use with an intra-oral image receptor shall be provided with means to limit source-to-skin distance, i.e., SSD, to not less than:
  - A. 18 centimeters if operable above 50 kVp; or
  - B. 10 centimeters if not operable above 50 kVp.

c. Operating Procedures.

1. Neither the dentist nor his/her assistant shall be permitted to hold patients or films during exposure; neither shall any individual be regularly used for this service.
2. During each exposure, the operator shall stand at least six (6) feet from the patient or behind a protective barrier.
3. Only the patient shall be in the useful beam.
4. Neither the tube housing nor the position indicating device shall be hand-held during exposure.
5. Intraoral fluoroscopic mirrors shall not be used in dental examinations.
6. The x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of RH-1606.b.5.
7. Dental fluoroscopy without image intensification shall not be used.
8. Structural shielding. Dental rooms containing x-ray machines shall be provided with such primary barriers and/or secondary barriers as are necessary to assure compliance with RH-1200.

**NOTE: In many cases structural materials of ordinary walls suffice as a protective barrier without addition of special shielding material.**

RH-1607. Therapeutic X-Ray Systems of Less Than One MeV.

a. Equipment Requirements.

1. Leakage radiation. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified at the distance specified for the classification of the x-ray system.
  - A. Contact therapy systems. Leakage radiation shall not exceed 100 milliroentgens per hour at 5 centimeters from the surface of the tube housing assembly.
  - B. 0-150 kVp systems. Systems which are manufactured or installed prior to the July 1, 1983 date shall have a leakage radiation which does not exceed one (1) roentgen in one hour at one (1) meter from the source.
  - C. 0-150 kVp systems. Systems which are manufactured on or after July 1, 1983 shall have a leakage radiation which does not exceed 100 milliroentgens in one (1) hour at one (1) meter from the source.
  - D. 151 to 999 kVp systems. The leakage radiation shall not exceed one (1) roentgen in one hour at one (1) meter from the source except systems that operate in excess of 500 kVp may have a leakage radiation at one (1) meter from the source equivalent to the exposure within one hour of the useful beam at one (1) meter from the source multiplied by a factor of 0.001.
2. Permanent beam limiting devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or higher degree of protection as required by the tube housing assembly.
3. Removable and adjustable beam limiting devices.
  - A. Removable beam limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than one (1) percent of the original x-ray beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

RH-1607. (Cont'd)

- B. Adjustable beam limiting devices installed after July 1, 1983 shall meet the requirements of RH-1607.a.3.A.
  - C. Adjustable beam limiting devices installed before July 1, 1983 shall, for the portion of the x-ray beam to be blocked by these devices, transmit not more than five (5) percent of the original x-ray beam at the maximum kilovoltage and maximum treatment filter.
4. Filter system. The filter system shall be so designed that:
- A. Filters cannot be accidentally displaced from the useful beam at any possible tube orientation;
  - B. Each filter is marked as to its material of construction and its thickness or wedge angle for wedge filters; and
  - C. It shall be possible for the operator to determine the presence or absence of each filter and the orientation of each wedge filter in the useful beam when the operator is at the control panel, either by display at the control panel or by direct observation.
  - D. The radiation at five (5) centimeters from the filter insertion slot opening does not exceed 30 roentgens per hour under any operating conditions.
5. Tube immobilization. The tube housing assembly shall be capable of being immobilized during stationary treatments.
6. Focal spot marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within five (5) millimeters and such marking shall be readily accessible for use during calibration procedures.
7. Beam block. Contact therapy tube housing assemblies shall have a removable shield of at least 0.5 millimeter lead equivalence at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.

8. Beam monitor system. Systems of greater than 150 kVp manufactured after July 1, 1983 shall be provided with a beam monitor system which:
  - A. Shall include a transmission detector which is a full beam detector and which is placed on the patient side of any fixed added filters other than a wedge filter;
  - B. Shall have the detector interlocked to prevent incorrect positioning in the useful beam;
  - C. Shall not allow irradiation until a pre-selected value of exposure (i.e. roentgens, rads/unit time, etc.) has been made at the treatment control panel;
  - D. Shall independently terminate irradiation when the pre-selected exposure has been reached;
  - E. Shall be so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined;
  - F. Shall have a display at the control panel from which the dose at the reference point in the treatment volume can be calculated;
  - G. Shall have a control panel display which maintains the reading until intentionally reset to zero; and
  - H. Shall have a control panel display which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.
9. Timer.
  - A. A timer shall be provided which has a display at the treatment control panel. The timer shall be graduated in minutes and fraction of minutes. The timer shall have a pre-set timer selector and an elapsed time indicator.

RH-1607. (Cont'd)

- B. The timer shall be a cumulative timer which activates with the radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to cycle the pre-set time selector through zero time.
  - C. The timer shall terminate irradiation when pre-selected time has elapsed if any dose monitoring system present has not previously terminated irradiation.
  - D. The timer shall permit accurate pre-setting and determination of exposure times as short as one (1) second.
  - E. The timer shall not permit an exposure if set at zero.
  - F. The timer shall comply with the provisions of RH-1607.a.13 where applicable.
  - G. The timer shall not activate until the shutter is opened when patient irradiation is controlled by a shutter mechanism.
10. Control panel functions. The control panel, in addition to the displays required in other provision of RH-1607, shall have:
- A. An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;
  - B. An indication of whether x-rays are being produced;
  - C. Means for indicating kV and x-ray tube current;
  - D. The means for terminating an exposure at any time;
  - E. A locking device which will prevent unauthorized use of the x-ray system; and
  - F. For x-ray equipment manufactured after July 1, 1983, a positive display of specific filter(s) in the beam.

11. Multiple tubes. When a control panel may energize more than one x-ray tube:
    - A. It shall be possible to activate only one x-ray tube during any time interval;
    - B. There shall be an indication at the control panel identifying which x-ray tube is energized; and
    - C. There shall be an indication at the tube housing assembly when that tube is energized.
  12. Source-to-patient distance. There shall be means of determining the source-to-patient distance to within one (1) centimeter.
  13. Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five (5) seconds, the entire useful beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition,
    - A. After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel; and
    - B. An indication of shutter position shall appear at the control panel.
  14. Low filtration x-ray tubes. Each x-ray system equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.
- b. Facility Design Requirements for Systems Capable of Operating Above 50 kVp. In addition to shielding adequate to meet requirements of Section 2 and Section 3, the treatment room shall meet the following design requirements:
1. Warning lights. Treatment rooms to which access is possible through more than one entrance shall be provided with warning lights, in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "on".
  2. Voice communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel; however, where excessive noise levels make aural communication impractical, other methods of communication shall be used.

3. Viewing systems. Windows, mirrors or closed-circuit television or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel. When the primary viewing system is by electronic means (e.g., television), an alternate viewing system shall be available for use in the event of electronic failure.
  
4. Additional requirements for x-ray systems capable of operation above 150 kVp.
  - A. All protective barriers shall be fixed except for entrance doors or beam interceptors.
  
  - B. The control panel shall be outside the treatment room;
  
  - C. All doors of the treatment room shall be electrically connected to the control panel such that x-ray production cannot occur unless all doors are closed;
  
  - D. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.
  
  - E. When any door is opened while the x-ray tube is activated, the exposure at a distance of one (1) meter from the source shall be reduced to less than 100 milliroentgens per hour within one (1) second.
  
  - F. After the radiation output of the x-ray tube has been affected by the opening of any door referred to in RH-1607.b.4.C, it shall be possible to restore the x-ray system to full operation only upon:
    - i. closing the door; and subsequently,
  
    - ii. reinitiating the exposure at the control panel.

c. Surveys, Calibrations, Spot Checks and Operating Procedures.

1. Surveys.

- A. All new facilities and existing facilities not previously surveyed, shall have a survey made by or under the direction of, a qualified expert. Such surveys shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
- B. The registrant shall obtain a written report of the survey from the qualified expert and a copy of the report shall be transmitted by the registrant to the Department within thirty (30) days of receipt of the report.
- C. The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable regulations and shall cite all items of noncompliance.

2. Calibrations.

- A. The calibration of an x-ray system shall be performed at intervals not to exceed one (1) year and after any change or replacement of components which could cause a change in the radiation output
- B. The calibration of the radiation output of the x-ray system shall be performed by or under the direction of a qualified expert who is physically present at the facility during such calibration.
- C. Calibration of the radiation output of an x-ray system shall be performed with a calibrated instrument. The calibration of such instrument shall be directly traceable to a national standard. The instrument shall have been calibrated within the preceding two (2) years.
- D. The calibrations made pursuant to RH-1607.c.2 shall be such that the dose at a reference point in soft tissue can be calculated to within five (5) percent.
- E. The calibration of the x-ray system shall include, but not be limited to, the following determinations:

RH-1607. (Cont'd)

- i. Verification that the x-ray system is operating in compliance with the design specifications;
    - ii. The exposure rates for each combination of field size technique factors, filter and treatment distance used;
    - iii. The degree of congruence between the radiation field and the field indicated by the localizing device if such device is present; and
    - iv. An evaluation of the uniformity of the radiation field symmetry for the field sizes used and any dependence upon tube housing assembly orientation.
  - F. Records of calibration performed pursuant to RH-1607.c.2 shall be maintained by the registrant for five (5) years after completion of the calibration.
  - G. A copy of the most recent x-ray system calibration shall be available for use by the operator at the control panel.
3. Spot checks. Spot checks shall be performed on x-ray systems capable of operation at greater than 150 kVp. Such spot checks shall meet the following requirements:
  - A. The spot check procedures shall be in writing and shall have been developed by a qualified expert. A copy shall be submitted to the Department prior to its implementation.
  - B. If a qualified expert does not perform the spot-check measurement, the results of the spot-check measurements shall be reviewed by a qualified expert within fifteen (15) days.
  - C. The measurements taken during the spot checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the x-ray system.

- D. The spot check procedure shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration specified in RH-1607.c.2.
  - E. The cause for a parameter exceeding a tolerance set by the qualified expert shall be investigated and corrected before the system is used for patient irradiation.
  - F. The procedure shall also note conditions which shall require that the system be recalibrated in accordance with RH-1607.c.2.
  - G. Records of spot check measurements performed pursuant to RH-1607.c.3 shall be maintained by the registrant for two (2) years following such measurement.
  - H. Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of RH-1607.c.2 or which has been inter-compared with a system meeting those requirements within the previous year.
4. Operation procedures.
- A. Therapeutic x-ray systems shall not be left unattended unless the system is secured pursuant to RH-1607.a.10.E.
  - B. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.
  - C. The tube housing assembly shall not be held by an individual during exposures unless the system is designed to require such holding and the peak tube potential of the system does not exceed 50 kVp. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 mm lead equivalency at 100 kVp.
  - D. No individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of RH-1200. No individual other than the patient shall be in the treatment room during exposures when the kVp exceeds 150.

RH-1607. (Cont'd)

- E. The x-ray system shall not be used in the administration of radiation therapy unless the requirements of RH-1607.c.2 and RH-1507.c.3.D have been met.

RH-1608. X-Ray and Electron Therapy Systems with Energies of One MeV and Above. Section 6 shall apply to medical facilities using therapy systems with energies one MeV and above.

- a. Definitions. In addition to the definitions provided in RH-1601, the following definitions shall be applicable to RH-1608.
  - 1. Applicator - A structure which indicates the extent of the treatment field at a given distance from the virtual source and which may or may not incorporate the beam limiting device.
  - 2. Beam scattering filter - A filter used in order to scatter a beam of electrons.
  - 3. Central axis of the beam - A line passing through the virtual source and the center of the plane figure formed by the edge of the final beam limiting device.
  - 4. Depth dose - The absorbed dose at a specified depth in a phantom.
  - 5. Dose monitoring system - A system of devices for the detection and display of quantities of radiation.
  - 6. Dose monitor unit - A unit from which the absorbed dose can be calculated.
  - 7. Existing equipment - Therapy systems subject to RH-1608 which were manufactured before the effective date of these Regulations.
  - 8. Field flattening filter - A filter used to homogenize the dose rate over the area of a useful beam of x-rays.
  - 9. Field size - The dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the fifty (50%) percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.

RH-1608. (Cont'd)

10. Gantry - The part of the system supporting and allowing possible movements of the radiation head.
11. Interruption of irradiation - The stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.
12. Isocenter - A fixed point in space located at the intersection of the rotation axes of the principal movements of the therapy system.
13. Moving beam therapy - Radiation therapy with relative displacement of the useful beam and the patient during irradiation. This includes arc therapy, skip therapy and rotational therapy.
14. New equipment - Systems subject to RH-1608 which were manufactured after the effective date of these Regulations.
15. Normal treatment distance:
  - i. For electron irradiation, this distance is the virtual source to surface distance along the central axis of the useful beam as specified by the manufacturer for the applicator.
  - ii. For x-ray irradiation this distance is the virtual source to isocenter distance along the central axis of the useful beam. For non-isocentric equipment this distance shall be that specified by the manufacturer.
16. Patient - An individual subjected to examination and treatment.
17. Phantom - A volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.
18. Primary dose monitoring system - A system which will monitor the quantity of radiation produced during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been acquired.
19. Radiation treatment prescription - The absorbed dose which is intended to be delivered to the treatment volume.
20. Radiation head - The structure from which the useful beam emerges.

21. Redundant dose monitoring combination - A combination of two dose monitoring systems in which both systems are arranged to terminate irradiation in accordance with a pre-selected number of dose monitor units.
22. Secondary dose monitoring system - A system which will terminate irradiation in the event of failure of the primary system.
23. Shadow tray - A device attached to the radiation head to support auxiliary beam limiting material.
24. Spot check - A procedure which is performed to assure that a previous calibration continues to be valid.
25. Stationary beam therapy - Radiation therapy without relative displacement of the useful beam and the patient during irradiation.
26. Target - The part of a radiation head which intercepts a beam of accelerated particles with subsequent emission of other radiation.
27. Termination of irradiation - The stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.
28. Treatment field - The area of the patient's skin which is to be irradiated.
29. Virtual source - A point from which radiation appears to originate.

b. Requirements for Equipment.

1. Leakage radiation inside patient area.
  - A. New equipment shall meet the following requirements:
    - i. For all operating conditions, the dose in rads (grays) due to leakage radiation, including x-rays, electrons and neutrons, at any point in a circular plane of two (2) meters radius centered on a perpendicular to the central axis of the beam at the normal treatment distance and outside the maximum useful beam,

shall not exceed 0.1 percent of the maximum dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface.

Measurements excluding those for neutrons shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to but not exceeding 200 square centimeters.

- ii. For each system the licensee shall determine or obtain from the manufacturer, the leakage radiation existing at the positions specified in RH-1608.b.1.A.i for specified operating conditions. Records on leakage radiation shall be maintained at the installation for inspection by the Department.
- B. Existing equipment shall meet the following requirements:
- i. The leakage radiation, excluding neutrons, at any point in the area specified by RH-1608.b.1.A.i where such area intercepts the central axis of the beam one (1) meter from the virtual source, shall not exceed 0.1 percent of the maximum dose in rads of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in RH-1608.b.1.A.i.
  - ii. For each system, the licensee shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in RH-1608.b.1.B.i for specified operating conditions. Records on radiation leakage shall be maintained at the installation for inspection by the Department.

2. Leakage radiation outside the patient area.
  - A. The dose equivalent in rem due to leakage radiation, except in the area specified in RH-1608.b.1.A.i, when measured at any point one (1) meter from the path of the charged particle, before the charged particle strikes the target or window, shall not exceed 0.1 percent for x-ray leakage nor 0.5 percent for neutron leakage of the maximum dose equivalent in rem of the un-attenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in RH-1608.b.1.A.i.
  - B. The licensee shall determine or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in RH-1608.b.2.A for specified operating conditions. Measurements, excluding neutrons, shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified. Neutron measurements shall be averaged over an area up to but not exceeding 200 square centimeters.
3. Beam limiting devices. Adjustable or interchangeable beam limiting devices shall be provided and such devices shall transmit no more than two (2) percent 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 at the normal treatment distance.
4. Filters.
  - A. If the absorbed dose rate information required by RH-1608.b.16 related exclusively to operation with a field flattening or beam scattering filter in place, such filter shall be removable only by the use of tools.
  - B. In systems which utilize a system of wedge filters, interchangeable field flattening or interchangeable beam scattering filters:
    - i. Irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;

- ii. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
- iii. 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;
- iv. A display shall be provided at the treatment control panel showing the filter(s) in use;
- v. Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.
- vi. 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.

5. Beam quality. The licensee shall determine or obtain from the manufacturer, data sufficient to assure that the following beam quality requirements are met:

- A. The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam ten (10) centimeters greater than the practical range of the electrons shall not exceed the values stated in Table III. Linear interpolation shall be used for values not stated.

TABLE III

Maximum Energy of Electron Beam in MeV	X-ray Absorbed Dose as a Fraction of Maximum Absorbed Dose
1	0.03
15	0.05
35	0.10
50	0.20

- B. Compliance with RH-1608.b.5.A shall be determined using:
- i. A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;
  - ii. The largest field size available which does not exceed 15 centimeters by 15 centimeters; and
  - iii. A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least five (5) centimeters and whose depth is sufficient to perform the required measurement.
- C. The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during x-ray irradiation, shall not exceed the limits stated in Table IV. Linear interpolation shall be used for values not stated.

TABLE IV

Maximum Photon Energy in MeV	Absorbed Dose at the Surface as a Fraction of the Maximum Absorbed Dose
1	0.80
2	0.70
5	0.60
15	0.50
35	0.40
50	0.20

- D. Compliance with RH-1608.b.5.C shall be determined by:
- i. Measurements made within a phantom using an instrument which will allow extrapolation to the surface absorbed dose;
  - ii. Use of a phantom whose size and placement meet the requirements of RH-1608.b.5.B;

- iii. Removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam flattening filters; and
  - iv. The largest field size available which does not exceed 15 centimeters by 15 centimeters.
- E. The licensee shall determine or obtain from the manufacturer the maximum percentage absorbed dose in the useful beam due to neutrons, excluding stray neutron radiation, for specified operating conditions.
6. Beam monitors. All therapy systems shall be provided with radiation detectors in the radiation head.
- A. New equipment shall be provided with at least two radiation detectors. The detectors shall be incorporated into two monitoring systems arranged either as a primary/primary combination or as a primary/secondary combination.
  - B. Existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated into a primary system.
  - C. The detectors and system into which the detector is incorporated shall meet the following requirements:
    - i. 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.
    - ii. The detectors shall be removable only with tools and shall be interlocked to prevent incorrect positioning.
    - iii. Each detector shall be capable of independently monitoring and controlling the useful beam.
    - iv. Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

- v. For new equipment the design of the dose monitoring systems of RH-1608.b.6.C.iv shall assure that the malfunctioning of one system shall not affect the correct functioning of the second system. In addition:
  - (a). The failure of any element which may be common to both systems shall terminate the useful beam.
  - (b). The failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation.
- vi. Each dose monitoring system shall have a legible display at the treatment control panel. Each display shall:
  - (a). Maintain a reading until intentionally reset to zero;
  - (b). Have only one scale and no scale multiplying factors in new equipment; and
  - (c). Utilize a design such that increasing dose is displayed by increasing numbers and shall also be so designed that, in the event of an over-dosage of radiation, the absorbed dose may be accurately determined under all normal conditions of use or foreseeable failures.
- vii. In the event of power failure, the dose monitoring information required in RH-1608.b.6.C.vi displayed at the control panel at the time of failure shall be retrievable in at least one system for a twenty (20) minute period of time.

7. Beam symmetry.

- A. In new equipment inherently capable of producing useful beams with asymmetry exceeding five (5) percent, at least four (4) different parts of the radiation beam shall be monitored before the beam passes through the beam limiting device and facilities shall be provided so that if the difference in dose rate between any two of these different parts exceeds five (5) percent an indication of this condition is made at the control panel and so that if the difference in dose rates between any two (2) of these different parts exceeds twenty (20%) percent the irradiation is terminated.
- B. Beam symmetry requirements of RH-1608.a.7. A shall be met if the user can demonstrate to the satisfaction of the Department that adequate fail-safe protection against the beam asymmetry is incorporated into the inherent design of the accelerator.
- C. On existing equipment where the Department has determined that beam symmetry is inadequate, the use of an automatic beam asymmetry warning system may be required.

8. Selection and display of dose monitor units.

- A. Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.
- B. After useful beam termination, it shall be necessary to manually reset the pre-selected dose monitor units before treatment can be reinitiated.
- C. The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.
- D. After termination of irradiation, it shall be necessary to reset the dosimeter display to zero before subsequent treatment can be initiated.

9. Termination of irradiation by the dose monitoring system.

- A. Each of the required monitoring systems shall be capable of independently terminating irradiation. Provisions shall be made to test the correct operation of each system.

- B. Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.
  - C. If original design of the equipment included a second dose monitoring system, that system shall be capable of terminating irradiation when not more than 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.
  - D. For new equipment a second dose monitoring system shall be present. That system shall be capable of terminating irradiation when not more than ten (10%) percent or 25 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitor system.
  - E. For new equipment an indicator on the control panel shall show which dose monitoring system has terminated irradiation.
10. Interruption switches. It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption the equipment shall go to termination condition.
11. Termination switches. It shall be possible to terminate irradiation and equipment movements or go from an interruption condition to termination condition, at any time from the operator's position at the treatment control panel.
12. Timer.
- A. A timer shall be provided which has a display at the treatment control panel. The timer shall be graduated in minutes and decimals of minutes. The timer shall have a pre-set 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 pre-set time selector after irradiation is terminated before irradiation shall again be possible.
  - C. The timer shall terminate irradiation with a pre-selected time has elapsed if the dose monitoring systems fail to do so.
13. Selection of radiation type. Equipment capable of both X-ray therapy and electron therapy shall meet the following requirements:
- 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 insure that the equipment can emit only the radiation type 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 prevent irradiation with x-rays when electron applicators are fitted and irradiation with electrons when accessories specific for x-ray therapy are fitted.
  - E. The radiation type selected shall be displayed at the treatment control panel before and during irradiation.
14. Selection of energy. Equipment capable of generating radiation beams of different energies shall meet 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.
  - D. The energy selected shall be displayed at the treatment control panel before and during irradiation.
  - E. For new equipment, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the x-ray target or electron window deviates by more than + 20% or + 3 MeV, whichever is smaller, from the selected nominal energy.
15. Selection of stationary beam therapy or moving beam therapy. Equipment capable of both stationary beam therapy and moving beam therapy shall meet 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. The mode of operation shall be displayed at the treatment control panel.
  - F. For new equipment, an interlock system shall be provided to terminate irradiation if:
    - i. Movement of the gantry occurs during stationary beam therapy; or
    - ii. Movement of the gantry stops during moving beam therapy unless such stoppage is a preplanned function.

- G. Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.
    - i. For new equipment, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of arc differs by more than twenty (20%) percent from the selected value.
    - ii. For new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than five (5) percent from the value calculated from the absorbed dose per unit angle relationship.
  - H. Where the dose monitor system terminates the irradiation in arc therapy, the termination of irradiation shall be as required by RH-1608.b.9.
16. Absorbed dose rate. For new equipment, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated.<sup>12f</sup> In addition:
- A. The quotient of the number of dose monitor units by time shall be displayed at the treatment control panel.
  - B. If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer's anticipated dose rate for any machine parameters utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation will be terminated shall be a record maintained by the licensee.
17. Location of focal spot and beam orientation. The licensee shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:
- A. The x-ray target or the virtual source of x-rays.
  - B. The electron window or the scattering foil.

C. All possible orientations of the useful beam.

18. System checking facilities. Capabilities shall be provided so that all radiation safety interlocks can be checked. When pre-selection of any of the operating conditions requires action in the treatment room and/or at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.
19. Shadow trays shall be designed such that the skin entrance dose due to electrons produced within the shadow tray are minimized.

c. Facility and Shielding Requirements. In addition to Section 3, the following design requirements shall apply:

1. Except for entrance doors or beam interceptors, all the required barriers shall be fixed barriers.
2. The treatment control panel shall be located outside the treatment room.
3. Windows, mirrors, close-circuit television, or other equivalent viewing systems shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. When the viewing system is by electronic means (e.g., television), an alternate viewing system shall be provided for use in the event of failure of the primary system.
4. Provision shall be made for two-way aural communication between the patient and the operator at the treatment control panel. However, where excessive noise levels makes aural communications impractical, other methods of communications shall be used.
5. Treatment rooms to which access is possible through more than one entrance shall be provided with warning lights, which will indicate when the useful beam is "on" in a readily observable position near the outside of all access doors.
6. Interlocks shall be provided such that all entrance doors shall be 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.

7.
  - A. A licensee shall install in each treatment room a permanent radiation monitor capable of continuously monitoring beam status.
  - B. Each radiation monitor must be capable of providing visible notice of a therapy unit malfunction that results in failure to terminate the useful beam. The visible indicator of high radiation levels must be observable by an individual entering the treatment room.
  - C. Each radiation monitor must be equipped with an emergency power supply separate from the power supply to the therapy unit. This emergency power supply may be a battery system.
  - D. Each radiation monitor must be checked for proper operation each day before the therapy unit is used for treatment of patients.
  - E. A licensee shall maintain a record of the check required by Paragraph D of this Section for two (2) years. The record must include the date of the check, notation that the monitor indicates when the useful beam is "off" and "on" and the initials of the individual who performed the check.
  - F. If a radiation monitor is inoperable for any reason, the licensee shall require any individual entering the treatment room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the unit that may result in failure to terminate the useful beam. The instrument or dosimeter must be checked for proper operation at the beginning of each day of use.
  - G. A licensee shall promptly repair or replace the radiation monitor if it is inoperable.
- d. Surveys, Calibrations, Spot Checks, and Operating Procedures.
  1. Survey.
    - A. All new facilities and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified expert. Such surveys shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

- B. The licensee shall obtain a written report of the survey from the qualified expert and a copy of the report shall be transmitted by the licensee to the Department within thirty (30) days of receipt of the report.
- C. The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable regulations and shall cite the Section violated.

2. Calibrations.

- A. The full calibration of systems subject to RH-1608 shall be performed in accordance with an established calibration protocol<sup>13/</sup> before the system is first used for irradiation of a patient and thereafter at time intervals which do not exceed twenty (12) months and after any change which might significantly alter the calibration, spatial distribution or other characteristics of the therapy beam.
- B. The full calibration shall be performed under the direct supervision of a qualified expert.
- C. Calibration of the dose equivalent of the therapy beam shall be performed with a dosimeter system.
  - i. Having a calibration factor for Cobalt-60 gamma rays traceable to a national standard;
  - ii. Which has been calibrated within the previous two years and after any servicing that may have affected its calibration;
  - iii. Which has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system; and
  - iv. Which has had constancy checks performed on the system as specified by a radiological physicist.
- D. Calibrations made pursuant to RH-1608.d.2 shall be such that the dose at a reference point in soft tissue can be calculated with  $\pm 5$  percent.

- E. The calibration of the therapy beam shall include but not be limited to the following determinations:
- i. Verification that the equipment is operating in compliance with 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 specified depths.
  - ii. The absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam.
  - iii. The congruence between the radiation field and the field indicated by the localizing device.
  - iv. The uniformity of the radiation field and its dependency upon the direction of the useful beam.
  - v. The calibration determinations above shall be provided in sufficient detail such that the absorbed dose to tissue in the useful beam may be calculated to within  $\pm 5$  percent.
  - vi. Verification of depth-dose data and isodose curves applicable to the specific machine continue to be valid or are updated to existing machine conditions.
  - vii. Verification of the applicability of transmission factors of all accessories such as wedges, shadow trays, compensators; and their effects on electron buildup.
- F. Records of the calibration performed pursuant to RH-1608.d.2.A shall be maintained by the licensee for five (5) years after completion of the calibration.

- G. A copy of the latest calibration performed pursuant to RH-1608.d.2.A shall be available for use by the operator at the treatment control panel.
3. **Spot checks.** Spot checks shall be performed on systems subject to RH-1608 during full calibrations and thereafter at intervals not to exceed one (1) month.

**NOTE: Spot checks shall include absorbed dose measurements at a minimum of two (2) depths in a phantom at intervals not to exceed one (1) month. Such spot checks shall meet the following requirements:**

- A. The spot check procedures shall be in writing and shall have been developed by a qualified expert. A copy of the procedure shall be submitted to the Department prior to its implementation.
- B. 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 delivered to a patient during a therapy procedure.
- C. If a qualified expert does not perform the spot-check measurements, these measurements shall be reviewed by a qualified expert within fifteen (15) days.
- D. The spot check procedures shall specify the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the full calibration.
- E. For systems in which beam quality can vary significantly, spot checks shall include quality checks.
- F. Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot check measurement.
- G. Where a system has built-in devices which provide a self-check of any parameter during irradiation, the spot check procedures shall require that the parameter be independently verified at specific time intervals.

RH-1608. (Cont'd)

- H. The reasons for spot checks which are erratic or inconsistent with calibration data shall be promptly investigated and corrected before the system is used for patient irradiation.
  - I. Whenever a spot check indicates a significant change, as specified in the qualified expert's spot check procedures, in the operating characteristics of a system, the system shall be recalibrated as required in RH-1608.d.2.
  - J. Records of spot-check measurements performed pursuant to RH-1608.d.3 shall be maintained by the licensee for a period of two (2) years.
  - K. Where a spot check involves a radiation measurement, such measurement shall be obtained using an instrument satisfying the requirements of RH-1608.d.2.C or which has been inter-compared with an instrument meeting those requirements within the previous year.
4. Operating procedures.
- A. No individual other than the patient shall be in the treatment room during treatment of a patient.
  - B. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.
  - C. The system shall not be used in the administration radiation therapy unless RH-1608.d.1, 2 and 3 have been met.

Veterinary Medicine Radiographic Installations.a. Equipment.

1. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one (1) meter in any direction from the source shall not exceed 100 milliroentgens in one hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
2. Beam limitation. All provisions of RH-1604.a (1-3) apply.
3. A device shall be provided to terminate the exposure after a pre-set time or exposure.
4. A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length so that the operator can stand out of the useful beam and at least six (6) feet from the animal during all x-ray exposures.

b. Operating procedures.

1. The operator shall stand well away from the tube housing and the animal during radiographic exposures. The operator shall not stand in the useful beam. If film must be held, it shall be held by individuals not occupationally exposed to radiation. Hand-held fluoroscopic screens shall not be used. The tube housing shall not be held by the operator. No individuals other than the operator shall be in the x-ray room while exposures are being made unless such person's assistance is required.
2. In any application in which the operator is not located behind a protective barrier, clothing consisting of a protective apron having a lead equivalent of not less than 0.5 millimeter shall be worn by the operator and any other individuals in the room during exposures.
3. No individual shall be regularly employed to hold or support animals during radiation exposures. Operation personnel shall not perform this service except in cases in which no other method is available. If the animal must be held by an individual, the individuals shall be protected with appropriate shielding devices, such as protective gloves and apron, with a lead equivalent of not less than 0.5 millimeter and they shall be so positioned that no part of the body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

Mammography Systemsa. Definitions

1. Accreditation body or body means an entity that has been approved by FDA accredit mammography facilities.
2. Action limits or action levels means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action must be taken by the facility. Action limits or levels are also sometimes called control limits or levels.
3. Air kerma means kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For x-rays with energies less than 300 kiloelectronvolts (keV), 1 Gy = 100 rad. In air, 1 Gy of absorbed dose is delivered by 114 roentgens (R) of exposure.
4. Breast implant means a prosthetic device implanted in the breast.
5. Calendar quarter means any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31.
6. Category I means medical educational activities that have been designed as Category I by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society, or an equivalent organization.
7. Certificate means the certificate described in 21 CFR Part 900 the Quality Mammography Standards; Final Rule section 900.11(a).
8. Certification means the process of approval of a facility by FDA to provide mammography services.
9. Clinical image means a mammogram.
10. Consumer means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).
11. Continuing education unit or continuing education credit means one contact hour of training of training.

12. Contact hour means an hour of training received through direct instruction.
13. Diagnostic Mammography - A problem solving radiographic procedure of higher intensity than screening mammography provided to women who are suspected to have breast pathology. Patients are usually referred for analyses of palpable abnormalities or for further evaluation of mammographically detected abnormalities. All images are immediately reviewed by the physicians interpreting the study, and additional views are obtained as needed. Physical examinations of the breast by the interpreting physician to correlate the radiologic findings is often performed as part of the study.
14. Direct instruction means Face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or the administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).
15. Direct Supervision of Interpreting Physicians means that: During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records.
16. Direct Supervision of Radiologic Technologists means that: during the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.
17. Established operating level means the value of a particular quality assurance parameter that has been established as an acceptable normal level by the facility's quality assurance program.
18. Facility means a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: Operation of equipment to produce a mammogram, processing of the mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for the interpretation. This term does not include a facility of the Department of Veterans Affairs.

RH-1610. (Cont'd)

19. FDA means the Food and Drug Administration.
20. First allowable time means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body. The "first allowable time" may vary with the certifying body.
21. Interim regulations means the regulations entitled "Requirements for Accrediting Bodies of Mammography Facilities" (58 FR 67558-67565), published by FDA on December 21, 1993, and amended on September 30, 1994 (59 FR 49808-49813). These regulations established the standards that had to be met by mammography facilities in order to lawfully operate between October 1, 1994, and April 28, 1999.
22. Interpreting physician means a licensed physician who interprets mammograms and who meets the requirements set forth in 21 CFR Part 900 the Quality Mammography Standards; Final rule section 900.12(a)(1).
23. Kerma means the sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.
24. Laterality means the designation of either the right or left breast.
25. Lead interpreting physician means the interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements of 21 CFR Parts 16 and 900 the Quality Mammography Standards; Final Rule section 900.12(d) through (f). The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.
26. Mammogram means a radiographic image produced through mammography.
27. Mammographic Modality means a technology, within the scope of 42 U.S.C. 263b, for radiography of the breast. Examples are screen-film mammography and digital mammography.

Revisions effective July 1, 2002

28. Mammography means radiography of the breast but for the purposes of this part, does not include: radiography of the breast performed during invasive interventions for localization or biopsy procedures; or radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA's investigational device exemption regulations.
29. Mammography equipment evaluation means an onsite assessment of mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards in 21 CFR Part 900 the Quality Mammography Standards; Final Rule section 900.12(b) and (e).
30. Mammography medical outcomes audit means a systematic collection of mammography results and the comparison of those results with outcomes data.
31. Mammography unit or units means an assemblage of components for the production of x-rays for use during mammography, including, at a minimum: An x-ray generator, and x-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.
32. Mean optical density means the average of the optical densities measured using phantom thickness of 2, 4, and 6 centimeters with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.
33. Medical physicist means a person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications for a medical physicist set forth in 21 CFR Part 900 the Quality Mammography Standards; Final Rule section 900.12(a)(3).
34. MQSA means the Mammography Quality Standards Act.
35. Multi-reading means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram.

RH-1610. (Cont'd)

36. Patient means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.
37. Phantom means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.
38. Phantom image means a radiographic image of a phantom.
39. Physical science means physics, chemistry, radiation science (including medical physics and health physics), and engineering.
40. Positive mammogram means a mammogram that has an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy."
41. Provisional certificate means the provisional certificate described in section 900.11(b)(2).
42. Qualified instructor means an individual whose training and experience adequately prepares him or her to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of section 900.12(a) would be considered qualified instructors in their respective areas of mammography. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the regulations of this part include, but are not limited to, instructors in a post-high school training institution and manufacturer's representatives.
43. Quality control technologist means an individual meeting the requirements of section 900.12(a)(2) who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.
44. Radiographic equipment means x-ray equipment used for the production of static x-ray images.
45. Radiologic technologist means an individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations and who meets the requirements set forth in section 900.12(a)(2).

Revisions effective July 1, 2002

RH-1610. (Cont'd)

46. Review physician means a physician who, by meeting the requirements set out in Section 900.4(c)(5), is qualified to review clinical images on behalf of the accreditation body.
47. Screening Mammography - Radiographic procedure provided to a woman, who has no signs or symptoms of breast cancer, for the purpose of early detection of breast cancer. The procedure entails two views of each breast and includes a physician's interpretation of the results of the procedure.
48. Serious adverse event means an adverse event that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.
49. Serious compliant means a report of a serious adverse event.
50. Standard breast means a 4.2 centimeter (cm) thick compressed breast consisting of fifty (50%) percent glandular and fifty (50%) percent adipose tissue.
51. Survey means an onsite physics consultation and evaluation of a facility quality assurance program performed by a medical physicist.
52. Time cycle means the film development time.
53. Traceable to a national standard means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every two (2) years and the results of the proficiency test conducted within twenty-four (24) months of calibration show agreement within +/- 3 percent of the national standard in the mammography energy range.

b. Accreditation

1. All facilities performing screening or diagnostic mammography shall be accredited every three (3) years by the Arkansas Department of Health or the American College of Radiology. Such accreditation shall in accordance with Food and Drug Administration (FDA) Mammography Quality Standards 21 CFR Parts 16 and 900 the Quality Mammography Standards; Final Rule.

Revisions effective July 1, 2002

2. No mammography shall be performed in an unaccredited facility after January 1, 1990. The owners of any unaccredited facility where in mammography is performed after January 1, 1990 shall be subject to a civil penalty imposed by the Arkansas Department of Health in an amount not to exceed one hundred dollars (\$100) for each day the facility operates without accreditation by the Department.

c. Quality Standards.

1. Personnel. The following requirements apply to personnel involved in any aspect of mammography, including production, processing, and interpretation of mammograms and related quality assurance activities.
  - A. Interpreting Physicians. Interpreting Physicians shall meet the minimum requirements of 21 CFR Part 900.12(a)(1) of the Food and Drug Administration's Quality Mammography Standards; Final Rule.
  - B. Radiological Technologist.
    - i. Radiological Technologists shall meet the minimum requirements of 21 CFR Part 900.12.(a)(2) of the Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule.
    - ii. Licensed by the State of Arkansas as a Registered Radiologic Technologist.
  - C. Mammography Imaging Medical Physicist.
    - i. Mammography Imaging Medical Physicists shall meet the minimum requirements of 21 CFR Part 900.12.(a)(3) of the Quality Mammography Standards; Final Rule.
    - ii. All Mammography Imaging Medical Physicists must be registered with the State as a vendor as required by RH-34.
2. Medical Physicist's Survey Requirements.
  - A. Medical Physicist's Surveys must be performed at least annually.
  - B. A Mammography Medical Physicist who meets the qualification requirements of RH-1610.c.1.C must sign all physicist survey reports.

- C. Mammography Medical Physicists who sign a facility survey report must have been present in that facility during the survey.
  - D. Medical Physicist's Surveys must meet the requirements of the Food and Drug Administration (FDA) 21 CFR Part 900.12(e)(9).
3. Obtaining and preserving records. All reasonable efforts must be made to obtain any of the beneficiary's previous mammogram records, including original images and films, copies of written reports prepared by interpreting physicians, and other relevant information pertinent to previous mammograms that might be available from others, for comparison with current mammogram records. All reporting and record keeping must meet the requirements of the Food and Drug Administration (FDA) 21 CFR Part 900.12(c).
4. Equipment. The equipment used to perform mammography should be specifically designed for mammography and must meet the following standards:
- A. Food and Drug Administration (FDA) Standards Quality Mammography Standards; Final Rule: 21 CFR Part 900.12(b).
  - B. Food and Drug Administration (FDA) Standards. Certified must meet the FDA; performance standards for diagnostic x-ray systems and their major components at 21 CFR 1020.30 and FDA's standards for radiographic equipment at 21 CFR 1020.31.
  - C. Focal spot size. The measured focal spot size of the x-ray tube should not exceed 0.7 mm.
  - D. Control panel indicators. The equipment must have a control panel that includes a device (usually a milliammeter) or means for an audible signal to give positive indication of the production of x-rays whenever the x-ray tube is energized. The control panel must include appropriate indicators (labeled control settings of meters that show the physical factors such as kilovoltage potential [kVp], milliamperere seconds [mAs], exposure time, or whether timing is automatic) used for exposure.

RH-1610. (Cont'd)

- E. All mammography units must be registered with the State of Arkansas as required by RH-21.
  - F. Mammography equipment evaluations. All variable parameters of the equipment must be evaluated and adjusted as needed to comply with the Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule 21 CFR Part 900.12(e)(10). This includes but is not limited to the following:
    - i. When the equipment is installed;
    - ii. After any major changes or replacement of parts;
    - iii. When quality assurance tests indicate that calibration or other maintenance is needed;
    - iv. When equipment is disassembled and reassembled.
- 5 Safety standards. Mammograms must be conducted using equipment and operating procedures free of unnecessary hazards and providing minimum radiation exposure to patients, personnel, and other persons in the immediate environment.
- A. Safety precautions. Proper safety precautions must be maintained. This includes adequate shielding for patients, personnel, and facilities. The equipment must be operable only from a shielded position.
  - B. Exposure badges. Personnel operating the equipment must be monitored in accordance with RH-1301 and RH-1302.
  - C. Equipment inspection. Periodic inspection of equipment and shielding must be made by a staff or consultant medical physicist or by a physicist approved by an appropriate State or local government agency as meeting the qualification requirements of RH-1610. Identified hazards must be promptly corrected.
  - D. Protection against electrical hazards. All equipment must be shockproof and grounded.

Revisions effective July 1, 2002

6. Quality assurance. Each facility must establish and maintain a quality assurance program that meets the requirements of 21 CFR Part 900.12(d) of the Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule.
  - A. Responsibilities for the Lead Interpreting Physician. The Lead interpreting physician has the following responsibility:
    - i. Ensuring that the facility's quality assurance program meets all the requirements of 21 CFR Part 900.12(d) Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule.
  - B. Responsibilities for the Mammography Medical Physicist. The person furnishing medical physics support has the overall responsibility for establishing and conducting the ongoing equipment quality assurance program. That individual's specific duties must include:
    - i. The duties outlined in 21 CFR Part 900.12 (d)(iii) of the Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule.
    - ii. Conducting or training others to conduct equipment performance monitoring functions;
    - iii. Analyzing the monitoring results to determine if there are any problems requiring correction; and
    - iv. Carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventive maintenance.
    - v. Conduct an annual survey of the facility's equipment quality assurance program as required by the Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule 21 CFR Part 900.12(e)(10).

- vi. Submit a written report describing the results of the survey as required by the Food and Drug Administration Quality Mammography Standards; Final Rule 21 CFR Part 900.12(e)(9)(iii).
- C. Responsibilities of the Quality Control Technologist. The quality control technologist must perform the tasks within the quality assurance program that are not assigned to the Lead Interpreting Physician or the Medical Physicist.
- D. Quality Assurance. The facility must ensure the quality of mammography by maintaining a quality assurance program that meets the requirements of the Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule 21 CFR Part 900.12(e) and verifying that the action limits described in Part 900.12(e) have been met. These tests and their frequencies are as follows:
- i. Daily: processor Performance tests, which includes assessment of base plus fog density, mid-density, and density difference.
  - ii. Weekly: image quality evaluation test using a FDA approved phantom.
  - iii. Quarterly: fixer retention in film test, repeat film analysis.
  - iv. Semi-annually: dark room fog evaluation, screen film contact test and compression device evaluation.
  - v. Annual testing: automatic exposure control performance, kilovoltage peak (kVp) accuracy and reproducibility, focal spot condition, breast entrance air kerma and AEC reproducibility, dosimetry, x-ray field/light field/image receptor/compression paddle alignment, uniformity of screen speed, radiation output, system artifacts, and decompression.

- vi. Mobile Units. The facility shall verify that mammography units used to produce mammograms at more than one location meet the requirements in paragraphs (e)(1) through (e)(6) of this section. In addition, at each examination location, before any examinations are conducted, the facility shall verify satisfactory performance of such units using a test method that establishes the adequacy of the image quality produced by the unit.
- vii. Quality control tests - other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in the Food and Drug Administration (FDA) 21 CFR Part 900.12 (e)(5)(vi).
- viii. The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and view box cleanliness and shall document that all cleaning procedures are performed at the frequencies specified in the protocols.
- ix. Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall comply with the requirements of the Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule 21 CFR Part 900.12(e)(13).

- E. Evaluation of monitoring results. Quality Assurance test results must be evaluated in a timely manner by the individual that is responsible for performing the test to ensure compliance with the Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule 21 CFR Part 900.12(e)(8). The responsible individuals are limited to the Lead Interpreting Physician, the Medical Physicist and the Quality Control Technologist.
  - F. Medical Outcomes Audit. Each facility must establish and maintain a medical outcomes audit program to follow-up positive mammographic assessments and to correlate pathology results to the interpreting physician's findings. This program must comply with the Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule 21 CFR Part 900.12(f).
  - G. Procedures and Techniques for Mammography of patients with breast implants. Each facility must have procedures, which specify techniques, and procedures for imaging patients with breast implants. These procedures must comply with the Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule 21 CFR Part 900.12(g).
  - H. Consumer Complaint Mechanism. Each facility must have a consumer complaint mechanism. This mechanism must comply with the Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule 21 CFR Part 900.12(h).
7. Standards For Diagnostic Mammography. Facilities who wish to be accredited for diagnostic mammography shall, in addition to meeting all of the requirements for mammography also:
- A. Have the interpreting physician as defined in RH-1610.c.1.A. present during all diagnostic mammography for direct supervision of the exam and film interpretation.
  - B. Have mammography systems with cone down compression and magnification capabilities, to enhance film interpretation.

RH-1610. (Cont'd)

- d. Applications and Fees. Applications for accreditation or renewal shall be made on forms supplied by the Department. Evidence of compliance with all of the requirements for performing screening and/or diagnostic mammography and the accreditation fee must be included with the application.
  
- e. Additional Review and Patient Notification
  - 1. When quality assurance tests indicate that calibration is needed, and the Department believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by the Department, for review by the accreditation body. This additional mammography review will help the Department to determine whether the facility is in compliance with RH-1610 and, if not, whether there is a need to notify affected patients, their physicians or the public that the reliability, clarity and accuracy of interpretation of mammograms has been compromised.
  
  - 2. If the Department determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or their designees, their physicians or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a timeframe and in a manner specified and approved by the Department.
  
- f. Retention of Personnel Records. Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records must be available for review by the MQSA inspectors. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed and FDA has determined that the facility is in compliance with MQSA personnel requirements.

RH-1610. (Cont'd)

- g. Quality Assurance Record Keeping. All quality assurance record keeping shall meet the requirements of the Food and Drug Administration (FDA) Quality Mammography Standards; Final Rule 21 CFR Part 900.12(d)(2): The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, and protection employee qualifications to meet assigned quality assurance tasks, are properly maintained and updated.

The quality control records shall be kept for each test specified in paragraphs (e) and (f) of this section until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

- h. Clinical Image Quality. Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.

RH-1611. Bone Densitometry

- a. Bone densitometry systems shall be:
  1. Certified by the U.S. Department of Health and Human Services
  2. Registered in accordance with these regulations; and
  3. Maintained and operated in accordance with the manufacturer's specifications.
- b. Operators of bone densitometry systems shall be:
  1. Licensed, certified, or permitted as a radiologic technologist by the Department; or
  2. Licensed as a practitioner of the healing arts; or
  3. Permitted or approved by the Department as a bone densitometry operator.
- c. During the operation of any bone densitometry system:
  1. The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during the examination.
  2. The operator shall advise the patient the bone densitometry examination is a type of x-ray procedure.
- d. The registrant shall keep maintenance records for bone densitometry systems as prescribed. These records shall be maintained for inspection by the Department recordkeeping timelines as appropriate.
- e. Bone densitometry on human patients shall be conducted only:
  1. Under a prescription of a licensed practitioner of the healing arts; or
  2. Under a screening program approved by the Department.
- f. Any person proposing to conduct a bone densitometry screening program shall submit the information outlined in Schedule A of this Part with the exception of g, h, i, j, k, and m, and include the name and address of the individual who will interpret the screening results.

## Schedule A

### INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the Agency approve a healing arts screening program shall submit the following information and evaluation:

- a. Name and address of the applicant and, where applicable, the names and addresses of agents within this State;
- b. Diseases or conditions for which the x-ray examinations are to be used in diagnoses;
- c. A detailed description of the x-ray examinations proposed in the screening program;
- d. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information;
- e. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations;
- f. An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these regulations. The evaluation shall include a measurement of patient exposures from the x-ray examinations to be performed;
- g. A description of the diagnostic x-ray quality control program;
- h. A copy of the technique chart for the x-ray examination procedures to be used;
- i. The qualifications of each individual who will be operating the x-ray system(s);
- j. The qualifications of the individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified;
- k. The name and address of the individual who will interpret the radiograph(s);

Schedule A (Cont'd)

**INFORMATION TO BE SUBMITTED BY PERSONS  
PROPOSING TO CONDUCT HEALING ARTS SCREENING**

- l. A description of the procedures to be used in advising the individual screening procedure and any further medical needs indicated;
- m. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations;
- n. An indication of the frequency of screening and the duration of the entire screening program.

RH-1612.-  
RH-1699. Reserved.

Revisions effective July 1, 2002

**PART H.**  
**SPECIAL REQUIREMENTS FOR THE USE OF SEALED  
RADIOACTIVE SOURCES IN THE HEALING ARTS**

- RH-1700. a. General Provisions. The provisions of this Part apply to all licensees who use sealed sources in medicine and veterinary medicine and are in addition to, and not in substitution for, other applicable provisions of these Regulations set out in Sections 1 and 2.
- b. Definitions. As used in this Part, the following definitions apply:
- Brachytherapy - A method of radiation therapy in which an encapsulated source or group of sources is utilized to deliver beta or gamma radiation at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.
- Teletherapy - Therapeutic irradiation in which the source of radiation is at a distance from the body.
- RH-1701. Interstitial, Intracavitary and Superficial Applications.
- a. Accountability, Storage and Transit.
1. Except as otherwise specifically authorized by the Department, each licensee shall provide accountability of sealed sources and shall keep a permanent record of the issue and return of all sealed sources.
  2. When not in use, sealed sources and applicators containing sealed sources shall be kept in a protective enclosure of such material and wall thickness as may be necessary to assure compliance with the provisions of RH-1200 and RH-1203.
  3. Each licensee shall conduct a physical inventory at intervals not to exceed six (6) months to account for all sources and devices received and possessed. Records of the inventories shall be maintained for inspection by the Department and shall include the quantities and kinds of radioactive material, location of sources and devices and the date of the inventory.
  4. Each licensee shall follow the radiation safety and handling instructions approved by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State, and furnished by the manufacturer on the label attached to the source, device or permanent container thereof, or in the leaflet or brochure which accompanies the source or device, and maintain such instruction in a legible and conveniently available form.

5. Sealed sources shall not be opened by the licensee unless specifically authorized by a license issued by the Department, the U.S. NRC, or an Agreement State.

b. Testing Sealed Sources for Leakage and Contamination.

1. All sealed sources, containing more than 100 microcuries of radioactive material with a half-life greater than thirty (30) days, or 10 micro-curies of Radium-226, shall be tested for leakage and/or contamination at intervals not to exceed six (6) months or at such other intervals as are approved by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State and described by the manufacturer on the label attached to the source, device or permanent container thereof or in the leaflet or brochure which accompanies the source or device. Each source or device shall be so tested prior to its first use unless the supplier furnishes a certificate that the source or device has been so tested within six (6) months prior to the transfer.
2. Leak tests shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the source or from the surfaces of the device in which the source is permanently or semi-permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Department.
3. Any leak test conducted pursuant to RH-1701.b.1 which reveals the presence of 0.005 microcurie or more of removable contamination shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the source from use and cause it to be decontaminated and repaired or to be disposed of in accordance with Department Regulations. A report shall be filed within five (5) days of the test with the Department describing the equipment involved, the tests results and the corrective action taken.

c. Radiation Surveys.

1. The maximum radiation level at a distance of one (1) meter from the patient in whom brachytherapy sources have been inserted shall be determined by measurement or calculation. This radiation level shall be documented and maintained for inspection by the Department.

RH-1701. (Cont'd)

2. The radiation levels in the patient's room and the surrounding area shall be determined, recorded and maintained for inspection by the Department.
3. The licensee shall assure that patients treated with temporary brachytherapy implants remain hospitalized until a source count and radiation survey of the patient confirm that all implants have been removed.

d. Signs and Records.

1. In addition to the requirements outlined in RH-1303, the bed, cubicle or room of the hospital brachytherapy patient shall be marked with a sign indicating the presence of brachytherapy sources. This sign shall incorporate the radiation symbol and specify the radionuclide, the activity, date and the individual(s) to contact for radiation safety instructions. The sign is not required provided the exception in RH-1304 is met.
2. The following information shall be documented and maintained for review by the Department:
  - A. The radionuclide administered, number of sources, activity in millicuries and time and date of administration;
  - B. The exposure rate at one (1) meter, the time the determination was made and by whom;
  - C. The radiation symbol; and
  - D. The precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted under Part C.

RH-1702. Teletherapy.

a. Equipment.

1. The housing shall be so constructed that at one meter from the source, the maximum exposure rate does not exceed 10 milliroentgens per hour when the beam control mechanism is in the "off" position. The average exposure rate measured at a representative number of points about the housing, each one meter from the source, shall not exceed 2 milliroentgens per hour.

RH-1702. (Cont'd)

2. For teletherapy equipment installed after the effective date of these Regulations, the leakage radiation measured at one meter from the source when the beam control mechanism is in the "on" position shall not exceed the larger of one (1) roentgen per hour or 0.1 percent of the useful beam exposure rate.
3. Adjustable or removable beam-defining diaphragms, shall allow transmission of not more than five percent of the useful beam.
4. The beam control mechanism shall be of a positive design capable of acting in any position of the housing. In addition to an automatic closing device, the mechanism shall be designed so that it can be manually returned to the "off" position with a minimum risk of exposure.
5. The closing device shall be so designed as to return automatically to the "off" position in the event of any breakdown or interruption of the activating force and shall stay in the "off" position until activated from the control panel.
6. When any door to the treatment room is opened, the beam control mechanism shall automatically and rapidly restore the unit to the "off" position and cause it to remain there until the unit is reactivated from the control panel.
7. The equipment shall be provided with a locking device to prevent unauthorized use.
8. There shall be at the housing and at the control panel a warning device that plainly indicates whether the beam is "on" or "off".
9. The control panel shall be provided with a timer that automatically terminates the exposure after a pre-set time.
10. Provision shall be made to permit continuous audible and visual observation of patients during irradiation.

b. Shielding.

1. Primary protective barriers, as defined in RH-1601.bo.1, shall be provided for any area that the useful beam may strike when using the largest possible diaphragm opening. Such barriers should extend at least one foot beyond the useful beam for any possible orientation.

RH-1702. (Cont'd)

2. Secondary protective barriers, as defined in RH-1601.bo.2, shall be provided for all occupied areas exposed to leakage and scattered radiation.
- c. Testing for Leakage and Contamination. Teletherapy sources shall be tested for leakage and contamination in accordance with the procedures described in RH-1701.b except that the leak tests shall be capable of detecting 0.05 microcuries of removable contamination and a source shall be considered to be leaking if the test reveals the presence of 0.05 microcuries or more of removable contamination. Tests of leakage may be made by wiping accessible surfaces of the housing port or collimator while the source is in the "off" position and measuring these wipes for transferred contamination.
- d. Operation. No individual shall be in the treatment room during irradiation unless that individual is the patient. Mechanical restraining or supporting devices shall be used for positioning the patient, if necessary.
- e. Requirement to Perform Full Calibration Measurements of Teletherapy Units.
  1. Any licensee authorized under RH-405.d to use teletherapy units for treating humans shall cause full calibration measurements to be performed on each teletherapy unit:
    - A. Prior to the first use of the unit for treating humans;
    - B. Prior to treating humans:
      - i. Whenever spot-check measurements indicate that the output value differs by more than five (5) percent from the value obtained at the last full calibration corrected mathematically for physical decay;
      - ii. Following replacement of the radiation source or following reinstallation of the teletherapy unit in a new location;
      - iii. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly.

RH-1702. (Cont'd)

- C. At intervals not exceeding one year.
- 2. Full calibration measurements required by RH-1702.e.1 of this Section shall include determination of:
  - A. The exposure rate or dose rate to an accuracy with plus three (+3%) percent for the range of field sizes and for the range of distances (or for the axis distance) used in radiation therapy;
  - B. The congruence between the radiation field and the field indicated by the light beam localizing device;
  - C. The uniformity of the radiation field and its dependence upon the orientation of the useful beam;
  - D. Timer accuracy; and
  - E. The accuracy of all distance measuring devices used for treating humans.
- 3. Full calibration measurements shall be made in accordance with the procedures approved by the Department.
- 4. The exposure rate or dose rate values determined in RH-1702.e.2.A shall be corrected mathematically for physical decay for intervals not exceeding one month.
- 5. Full calibration measurements required by RH-1702.e of this Section and physical decay corrections required by RH-1702.e.4 shall be performed by an expert qualified by training and experience in accordance with RH-1702.h.
- f. Requirement to Perform Periodic Spot-Check Measurements of Teletherapy Units.
  - 1. Any licensee authorized under RH-405.d to use teletherapy units for treating humans shall cause spot-check measurements to be performed on each teletherapy unit at intervals not exceeding one month.
  - 2. Spot-check measurements required by RH-1702.f.1 shall include determination of:
    - A. Timer accuracy;
    - B. The congruence between the radiation field and the field indicated by the light beam localizing device;

Revisions effective July 1, 2002

RH-1702. (Cont'd)

- C. The accuracy of all distance measuring devices used for treating humans;
  - D. The exposure rate, dose rate or a quantity related in a known manner to these rates for one typical set of operating conditions; and
  - E. The difference between the measurement made in RH-1702.f.2.D and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).
3. Spot-check measurements required by RH-1702.f.1 shall be performed in accordance with procedures established by an expert qualified by training and experience in accordance with RH-1702.h. (A qualified expert need not actually perform the spot-check measurements.) If a qualified expert does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a qualified expert within fifteen (15) days.
- g. Requirement to Calibrate Instruments Used for Full Calibration and Spot-Check Measurements.
- 1. Full calibration required by RH-1702.e shall be performed using a dosimetry system that satisfies one of the two following conditions:
    - A. The system must have been calibrated by the National Institute of Standards and Technology [formerly called National Bureau of Standards] or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two (2) years and after any servicing that may have affected system calibration; or

- B. The system must have been calibrated by the National Institute of Standards and Technology [formerly called National Bureau of Standards] or by a calibration laboratory accredited by the AAPM within the previous four (4) years; 18 to 30 months after that calibration, the system must have been inter-compared at an inter-comparison meeting with another dosimetry system that was calibrated within the past twenty-four (24) months by the National Institute of Standards and Technology or by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the inter-comparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than two (2) percent. The licensee may not use the inter-comparison result to change the calibration factor. When inter-comparing dosimetry systems to be used for calibrating Cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a Cobalt-60 source. When inter-comparing dosimetry systems to be used for calibrating Cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a Cesium-137 source.
- 2. Spot-check measurements required by RH-1702.f shall be performed using a dosimetry system that has been calibrated in accordance with RH-1702.g.1. Alternatively, a dosimetry system used solely for spot-check measurements may be calibrated by direct inter-comparison with a system that has been calibrated in accordance with RH-1702.g.1. This alternative calibration method shall have been performed within the previous one (1) year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.
- h. Qualified Expert.
  - 1. The licensee shall determine if a person is an expert qualified by training and experience to calibrate a teletherapy unit and establish procedures for (and review the results of) spot-check measurements.

RH-1702. (Cont'd)

2. Licensees that have their teletherapy units calibrated by individuals that do not meet these criteria for minimum training and experience may request a license amendment excepting them from RH-1702.h.1. The request should include the name of the proposed expert, a description of the individual's training and experience including information similar to that specified in RH-1100.ca., reports of at least one calibration and spot-check program based on measurements personally made by the proposed expert within the last 10 years and written endorsement of the technical qualifications of the proposed expert from the personal knowledge by a physicist certified by the American Board of Radiology in one of the specialties listed in RH-1100.ca.

i. Records. The licensee shall maintain, for inspection by the Department, records of the measurements, tests, corrective actions and instrument calibrations made under the provisions of RH-1702.e through g and records of the licensee's evaluation of the qualified expert's training and experience made under RH-1702.h.

1. Records of:

- A. Full calibration measurements under RH-1702.e; and
- B. Calibration of the instruments used to make these measurements under RH-1702.g, shall be preserved for five (5) years after completion of the full calibration.

2. Records of:

- A. Spot-check measurements and corrective action under RH-1702 and;
- B. Calibration of instruments used to make spot-check measurements under RH-1702.g shall be preserved for two (2) years after completion of the spot-check measurements and corrective actions.

3. Records of the licensee's evaluation of the qualified expert's training and experience under RH-1702.h shall be preserved for five (5) years after the qualified expert's last performance of a full calibration on the licensee's teletherapy unit.

RH-1702. (Cont'd)

j.

Radiation Monitoring Device.

1. A licensee shall install in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.
2. Each radiation monitor must be capable of providing visible notice of teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels must be observable by an individual entering the teletherapy room.
3. Each radiation monitor must be equipped with an emergency power supply separate from the power supply to the teletherapy unit. This emergency power supply may be a battery system.
4. Each radiation monitor must be checked for proper operation each day before the teletherapy unit is used for treatment of patients.
5. A licensee shall maintain a record of the check required by RH-1702.j.4 of this Section for two (2) years. The record must include the date of the check, notation that the monitor indicates when the source is and is not exposed and the initials of the individual who performed the check.
6. If a radiation monitor is inoperable for any reason, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter must be checked for proper operation at the beginning of each day of use.
7. A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

k.

Five-Year Inspection.

1. A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five (5) years, whichever comes first, to assure proper functioning of the source exposure mechanism.
2. This inspection and servicing shall only be performed by persons specifically licensed to do so by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State.

RH-1703.-  
RH-1799.

Reserved.

**PART I.**  
**RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL  
RADIOGRAPHIC OPERATIONS.**

RH-1800.      General Provisions.

- a.      Purpose. The Regulations in this Part establish radiation safety requirements for persons utilizing sources of radiation for industrial radiography. The requirements of this Part are in addition to and not in substitution for other applicable requirements of these Regulations.
  
- b.      Scope. The Regulations in this Part apply to all licensees or registrants who use sources of radiation for industrial radiography. Except for the Regulations in this Part clearly applicable only to sealed radioactive sources, both radiation machines and sealed radioactive sources are covered by this Part. The provisions of this Part are not applicable to systems designed exclusively for microscopic examination of material, e.g., x-ray diffraction, spectroscopic and electron microscope equipment or to systems for intentional exposure of humans to x-rays.
  
- c.      Definitions. As used in these Regulations. Additional definitions used only in a certain part will be found in that part.
  - 1.      Access panel - Any barrier or panel which is designed to be removed or opened for maintenance or service purposes, requires tools to open and permits access to the interior of the cabinet.
  
  - 2.      ALARA (acronym for "as low as is reasonably achievable") - Making every reasonable effort to maintain exposures to radiation as far below the dose limits specified in Section 3, Part C. **PERMISSIBLE DOSES, LEVELS, AND CONCENTRATIONS** as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvement in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy, licensed materials, and x-ray equipment in the public interest.
  
  - 3.      Annual refresher safety training - A review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, new or revised regulations, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions.

Revisions effective July 1, 2002

RH-1800. (Cont'd)

4. Aperture - Any opening in the outside surface of the cabinet, other than a port, which remains open during generation of x-radiation.
5. Associated equipment - Equipment that is used in conjunction with a radiographic exposures device to make radiographic exposures that drives, guides, or comes in contact with the source, (e.g., guide tube, control tube, control (drive) cable, removable source stop, "J" tube and collimator when it is used as an exposure head.
6. Becquerel (Bq) - One disintegration per second.
7. Cabinet radiography - Industrial radiography conducted in an enclosed cabinet which is so shielded that every location on the exterior meets conditions for an unrestricted area as specified in RH-1208.
8. Cabinet x-ray system - An x-ray system with the x-ray tube installed in an enclosure (hereinafter termed "cabinet") which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation and exclude personnel from its interior during generation of x-radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad and bus terminals and in similar facilities. An x-ray tube used within a shielded part of a building or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.
9. Certified cabinet system - X-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.
10. Certifying Entity - An independent certifying organization meeting the requirements in Appendix "IRC" or an Agreement State meeting the requirements in Appendix "IRC", Parts II and III of this Part.
11. Collimator - A device used to limit the size and direction of radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

RH-1800. (Cont'd)

12. Control (drive) cable - The cable that is connected to the source assembly and used to drive the source to and from the exposure location.
13. Control drive mechanism - A device that enables the source assembly to be moved to and from the exposure device.
14. Control tube - A protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.
15. Door - Any barrier which is designed to be movable or opened for routine operations purposes, does not generally require tools to open and permits access to the interior of the cabinet. For the purposes of RH-1803.g.1.A of this Section, inflexible hardware rigidly affixed to the door shall be considered part of the door.
16. Enclosed radiography - Industrial radiography conducted in an enclosed cabinet or room and includes cabinet radiography, cabinet x-ray systems and shielded room radiography.
17. Exposure head - A device that locates the gamma radiography sealed source in the selected working position. (An exposure head is also known as a source stop).
18. External surface - The outside surface of the cabinet x-ray system, including the high-voltage generator, doors, access panels, latches, control knobs and other permanently mounted hardware and including the plane across any aperture or port.
19. Field station - A facility where licensed material or registered x-ray equipment may be stored or used and from which equipment is dispatched.
20. Floor - The underside external surface of the cabinet.
21. Gray - The SI unit of absorbed dose. A gray is equal to an absorbed dose of one (1) Joule/kilogram. It is also equal to 100 rads.
22. Ground fault - An accidental electrical grounding of an electrical conductor.

Revisions effective July 1, 2002

RH-1800. (Cont'd)

23. **Guide tube (Projection sheath)** - A flexible or rigid tube (i.e., "J" tube) for guiding the source assembly and the attached control cable from the exposure device and to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.
24. **Hands-on experience** - Experience in all of those areas considered to be directly involved in the radiography process.
25. **Independent Certifying Organization** - An independent organization that meets all the criteria of Appendix "IRC".
26. **Industrial radiography (radiography)** An examination of the structure of materials by non-destructive methods, utilizing ionizing radiation to make radiographic images.
27. **Lay-barge radiography** - Industrial radiography performed on any water vessel used for laying pipe.
28. **Offshore platform radiography** – Industrial radiography performed from a platform over a body of water.
29. **Permanent radiographic installation** An enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed.
30. **Personal supervision** - Supervision such that the supervisor is physically present at the radiography site and in such proximity that contact can be maintained and immediate assistance given as required.
31. **Port** - Any opening in the outside surface of the cabinet which is designed to remain open, during generation of x-rays, for the purpose of conveying material to be irradiated into and out of the cabinet or for partial insertion for irradiation of an object whose dimensions do not permit complete insertion into the cabinet.
32. **Practical Examination** - A demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.
33. **Primary beam** - The x-radiation emitted directly from the target and passing through the window of the x-ray tube.

Revisions effective July 1, 2002

RH-1800. (Cont'd)

34. Radiation Safety Officer for industrial radiography - An individual with the responsibility for the overall radiation safety program on behalf of the licensee or registrant and who meets the requirements of RH-1802.d.
35. Radiographer - Any individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of these regulations and the conditions of registration or of a license.
36. Radiographer's assistant - Any individual who, under the direct supervision of a radiographer, uses radiographic exposure devices, sealed sources or related handling tools, or radiation survey instrumentation in industrial radiography.
37. Radiographer certification - Written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.
38. Radiographer instructor - Any radiographer who has been listed on a specific license from the Department and meeting the requirements of RH-1803.f.5.
39. Radiographic exposure device - Any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.
40. Radiographic operations - All activities associated with the presence of radioactive sources in a radiographic exposure device or x-ray equipment during use of the device or transport (except when being transported by a common or contract transport), to include surveys to confirm the adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.
41. Radiography - The examination of the structure of materials by nondestructive methods, utilizing sealed sources of radioactive materials.

Revisions effective July 1, 2002

RH-1800. (Cont'd)

42. Safety interlock - A device which is intended to prevent the generation of x-radiation when access by any part of the human body to the interior of the cabinet x-ray system through a door or access panel is possible.
43. Sealed source - Any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.
44. Shielded room radiography - Industrial radiography conducted in an enclosed room, the interior of which is not occupied during radiographic operations, which is so shielded that every location on the exterior meets condition for an unrestricted area as specified in RH-1208.
45. Shielded position - The location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.
46. Sievert - The SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1Sv = 100 rems).
47. Source Assembly - An assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may also include a stop ball used to secure the source in the shielded position.
48. Source changer - A device designed and used for replacement of sealed sources in radiographic exposure devices, including those also used for transporting and storage of sealed sources.
49. S-tube - A tube through which the radioactive source travels when inside a radiographic exposure device.
50. Storage area - Any location, facility, or vehicle which is used to store, to transport, or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.
51. Storage container - A container in which sealed sources are secured and stored.

- 52. Temporary job site - A location where radiographic operations are conducted and where licensed material may be stored other than the location(s) of use authorized on the license or registration.
  - 53. Transport container - A package that is designed to provide radiation safety and security when sealed sources are transported and meets all applicable requirements of the U.S. Department of Transportation.
  - 54. Underwater radiography - Industrial radiography performed when the radiographic exposure device and/or related equipment are beneath the surface of the water.
  - 55. X-ray system - An assemblage of components for the controlled generation of x-rays.
  - 56. X-ray tube - Any electron tube which is designed for the conversion of electrical energy into x-ray energy.
- d. Recordkeeping Requirements.
- 1. Records of the specific license for industrial radiography.

Each licensee shall maintain a copy of its license, license conditions, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Department or until the Department terminates the license.
  - 2. Records of receipt and transfer of sealed sources.
    - A. Each licensee shall maintain records showing the receipts and transfers of sealed sources and devices using depleted uranium (DU) for shielding and retain each record for three (3) years after it is made.
    - B. These records must include the date, the name of the individual making the record, radionuclide, number of curies (becquerels) or mass (for depleted uranium (DU)) and manufacturer, model, and serial number of each sealed source and/or device, as appropriate.

3. Records of radiation survey instruments

Each licensee or registrant shall maintain records of the calibrations of its radiation survey instruments that are required in RH-1801.e.and retain each record for three (3) years after it is made.

4. Records of leak testing of sealed sources and devices containing depleted uranium (DU).

Each licensee shall maintain records of leak test results for sealed sources and for devices containing depleted uranium (DU). The results must be stated in units of microcuries (becquerels). The licensee shall retain each record for three (3) years after it is made or until the source in storage is removed.

5. Records of quarterly inventory.

A. Each licensee shall maintain records of the quarterly inventory of sealed sources and of devices containing depleted uranium (DU) as required by RH-1801.g.and retain each record for three (3) years after it is made.

B. The record must include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of curies (becquerels) or mass (for DU) in each device, location of sealed source and/or devices, and manufacturer, model, and serial number of each sealed source and/or device, as appropriate.

6. Utilization Logs

A. Each licensee or registrant shall maintain utilization logs showing for each sealed source or x-ray unit the following information:

i. A description, including the make, model, and serial number of the radiographic exposure device or transport or storage container in which the sealed source or x-ray tube is located;

ii. The identity and signature of the radiographer to whom assigned; and

- iii. The plant or site where used and dates of use, including the dates removed and returned to storage.
  - B. The licensee or registrant shall retain the logs required by RH-1800.d.6.i. for three (3) years after the log is made.
- 7. Records of inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments.
  - A. Each licensee or registrant shall maintain records specified in RH-1801.i. of equipment problems found in daily checks and quarterly inspections of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments; and retain each record for three (3) years after it is made.
  - B. The record must include the date of the check or inspection, name of the inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was done.
- 8. Records of alarm system and entrance control checks at permanent radiographic installation.

Each licensee or registrant shall maintain records of alarm system and entrance control device tests required under RH-1801.j. and retain each record for three (3) years after it is made.
- 9. Records of training and certification.

Each licensee or registrant shall maintain the following records (of training and certification) for three (3) years after the record is made:

  - A. Records of training of each radiographer and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, and names of individuals conducting and receiving the oral and practical examinations; and

- B. Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and the names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any non-compliances observed by the Radiation Safety Officer (RSO).

10. Copies of Operating and Emergency Procedures.

Each licensee or registrant shall maintain a copy of current operating and emergency procedures until the Department terminates the license or registration. Superseded material must be retained for three (3) years after the change is made.

11. Records of Personnel Monitoring.

Each licensee or registrant shall maintain the following sure records specified in RH-1802.c.:

- A. Direct reading dosimeter readings and yearly operability checks required by RH-1802.c.2. and 3. for three (3) years after the record is made.
- B. Records of alarm ratemeter calibrations for three (3) years after the record is made.
- C. Reports received from the film badge, TLD, or Optically Stimulated Luminescent Dosimeter processor until the Department terminates the license or registration.
- D. Records or estimates of exposures as a result of: off-scale personal direct reading dosimeters, or lost or damaged film badges, TLDs, or Optically Stimulated Luminescent Dosimeters, until the Department terminates the license or registration.

12. Records of Radiation Surveys.

Each licensee or registrant shall maintain a record of each exposure device survey conducted before the device is placed in storage as specified in RH-1803.c.3. if that survey is the last one performed in the workday. Each record must be maintained for three (3) years after it is made.

13. Form of Records.

Each record required by RH-1800.d. must be legible throughout the specified retention period. The record may 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 reproducing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

14. Location of documents and records.

- i. Each licensee or registrant shall maintain copies of records required by RH-1800.d. and other applicable regulations at the location specified in the licensee's license application.
- ii. Each licensee or registrant shall also maintain copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite:
  - A. The license or certificate of registration authorizing the use of licensed material or x-ray equipment;
  - B. A current copy of the Arkansas Rules and Regulations for Control of Sources of Ionizing Radiation
  - C. Utilization records for each radiographic exposure device dispatched from that location as required by RH-1800.d.6.

RH-1800. (Cont'd)

- D. Records of equipment problems identified in daily checks of equipment as required by RH-1800.d.7.
- E. Records of alarm system and entrance control checks as required by RH-1801.j.
- F. Records of direct reading dosimeters such as pocket dosimeter and/or electronic personal dosimeters readings as required by RH-1800.d.11.
- G. Operating and emergency procedures as required by RH-1802.b.
- H. Evidence of the latest calibration of the radiation survey instruments in use at the site as required by RH-1801.e.
- I. Evidence of the latest calibration of alarm ratemeters and operability checks of pocket dosimeters and/or electronic personal dosimeters as required by RH-1800.d.11.
- J. Latest survey records as required by RH-1803.c.
- K. The shipping papers for the transportation of radioactive materials as required by the U.S. Department of Transportation Regulations 49 CFR Parts 170 through 187; and
- L. When operating under reciprocity pursuant to RH-750, a copy of the Agreement State or Nuclear Regulatory Commission license authorizing the use of licensed materials.

Revisions effective July 1, 2002

Equipment Control.

- a. Performance requirements for radiography equipment. Equipment used in industrial radiographic operations must meet the following minimum criteria:

1. Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standards Institute N432-1980, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography", (published as NBS Handbook 136, issued January 1981). This publication has been approved for incorporation by the Director, Division of Radiation Control and Emergency Management. This publication may be purchased from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018 Telephone (212) 642-4900.

A copy of the document is available for inspection in the Division of Radiation Control and Emergency Management, Arkansas Department of Health, 5800 West 10<sup>th</sup> Street, Suite 100, Little Rock, Arkansas 72204.

Engineering analysis may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the Department may find this an acceptable alternative to actual testing of the component pursuant to the reference standard.

2. In addition to the requirements specified in RH-1801.a.1., the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources.

- A. The licensee shall ensure that each radiographic exposure device has attached to it by the user a durable, legible, clearly visible label bearing the:

- 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 (or product code) and serial number of the sealed source;
- iv. Manufacturer's identity of the sealed source; and
- v. Licensee's name, address, and telephone number.

RH-1801. (Cont'd)

- B. Radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of Section 4, Transportation of Radioactive Materials.
  - C. Modification of radiographic exposure devices, source changers, source assemblies, and associated equipment is prohibited, unless the design of any replacement component, including the 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 RH-1801.a.1. and 2., the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operation or to source changers.
- A. The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.
  - B. The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system 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 must be equipped with safety plugs or covers which 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 must have attached to it or engraved on it, a durable, legible, visible label with the words

**"DANGER - RADIOACTIVE".**

The label must not interfere with the safe operation of the exposure device or associated equipment.

Revisions effective July 1, 2002

- E. The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use and be able to withstand a kinking resistance test that closely approximates the kinking forces likely to be encountered during use.
  - F. Guide tubes 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 of the end of the guide tube must be attached to the outermost end of the guide tube during radiographic operations.
  - H. The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432- 1980.
  - I. Source changers must provide a system for 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.
4. All radiographic exposure devices and associated equipment in use after January 10, 1996 must comply with the requirements of this Section.
5. Notwithstanding RH-1801.a, RH-1801.d, and RH-1801.e, equipment used in industrial radiographic operations need not comply with Section 8.9.2(c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism
- b. Limits on external radiation levels from storage containers and source changers.

The maximum exposure rate limit for storage containers and source changers are 200 millirem (2 millisieverts) per hour at any external surface, and ten (10) millirem (0.1 millisieverts) per hour at one (1) meter from any exterior surface with the sealed source in the shielded position.

c. Locking of radiographic exposure devices, storage containers, and source changers.

1. Each radiographic exposure device must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device and/or its container must be kept locked (and if a keyed-lock, with the key removed at all times) when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as in RH-1803.a. In addition, during radiographic operations the sealed source assembly must be secured in the shielded position each time the source is returned to that position.
2. Each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be kept locked (and if a keyed-lock, with the key removed at all times) when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

d. Storage precautions.

1. Locked radiographic exposure devices, storage containers and radiation machines shall be physically secured to prevent tampering or removal by unauthorized personnel.
2. Radiographic exposure devices, source changers, or transport containers that contain radioactive material may not be stored in residential locations. This rule does not apply to storage of radioactive material in a vehicle in transit for use at temporary job sites, if the licensee complies with RH-1801.d.3 and if the vehicle does not constitute a permanent storage location as described in RH-1801.d.4.
3. If a vehicle is to be used for storage of radioactive material, a vehicle survey shall be performed after securing radioactive material in the vehicle and before transport to ensure that radiation levels do not exceed the limits specified in RH-1208 at the exterior surface of the vehicle.

RH-1801. (Cont'd)

4. A storage or use location is permanent if radioactive material is stored or used at the location for more than 90 days and any one or more of the following applies to the location:
  - A. Telephone service is established by the licensee;
  - B. Industrial radiographic services are advertised for or from the location;
  - C. Industrial radiographic operations are conducted at other sites due to arrangements made from the location.

e. Radiation survey instruments.

1. The licensee or registrant shall keep sufficient calibrated and operable radiation survey instruments at each location where radioactive material or industrial radiographic x-ray equipment is present to make the radiation surveys as required by this Part and RH-1300.
2. Instrumentation required by this Part shall have a range such that 2 milliroentgens per hour through 1 roentgen per hour can be measured and other ranges as necessary to determine conformance with other requirements of this Part must be capable of measuring a range from two (2) millirems (0.02 millisieverts) per hour through one (1) rem (0.01 millisieverts) per hour.
3. The licensee or registrant shall have each radiation survey instrument required in RH-1801.e.1. calibrated:
  - A. At intervals not to exceed three (3) months and after each instrument servicing, except for battery changes;
  - B. For linear scale instruments, at two (2) points located approximately one-third and two-thirds of full-scale; for logarithmic scale instruments, at midrange of each decade and at two (2) points on at least one decade, and for digital instruments at three (3) points between 2 and 1000 millirems (0.02 and 10 millisieverts) per hour; and
  - C. So that an accuracy within plus or minus twenty (20) percent of the calibration source can be demonstrated at each point checked.

4. The licensee shall maintain records of these calibrations in accordance with RH-1800.d.3.
5. Each radiation survey instrument shall be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is operating properly.

f. Leak testing, and replacement of sealed sources.

1. The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source must be performed only by persons specifically authorized to do so by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State.
2. The opening, repair, or modification of any sealed source must be performed only by persons specifically authorized to do so by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State.
3. Testing and recordkeeping requirements.
  - A. Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed six (6) months. The leak testing of the source must be performed using a method approved by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample and must be performed by a person specifically authorized by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform the analysis.
  - B. The licensee shall maintain records of the leak tests in accordance with RH-1800.d.4.

- C. Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within six (6) months before the transfer, it may not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the interval of storage exceeds six (6) months.
- 4. Any test conducted pursuant to the requirements of RH-1801.f.2 and 3 which reveals the presence of 0.005 microcurie (185 Bq) or more of removable radioactive material must be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or disposed of in accordance with Regulations of the Department. A report must be filed with the Department within five (5) days of any test with results that exceed the threshold in RH-1801.f., describing the equipment involved, the test results, and the corrective action taken.
- 5. Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed twelve (12) months. The analysis must be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample and must be performed by a person specifically authorized by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform the analysis. Should such testing reveal the presence of 0.005 microcurie (185 Bq) or more of removable DU contamination, the exposure device must be removed from use until an evaluation of the wear on the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while in storage and not in use. Before using or transferring such a device however, the device must be tested for DU contamination if the interval of storage exceeds twelve (12) months. A record of the DU leak-test must be made in accordance with RH-1800.d.
- g. Quarterly inventory.
  - 1. Each licensee shall conduct a quarterly physical inventory to account for all sealed sources and devices containing depleted uranium (DU) received and possessed under this license.

- 2 The licensee shall maintain records of the quarterly inventory in accordance with RH-1800.d.5.
- h. Utilization logs. Each licensee or registrant shall maintain current logs, which shall be kept available for inspection by the Department, showing for each source of radiation the following information:
1. A unique identification (e.g., serial number) of each radiation machine, each radiographic exposure device in which a sealed source is located, and each sealed source;
  2. The identity of the radiographer to whom assigned;
  3. Locations where used and dates of use; and
  4. The date(s) each source of radiation is removed from storage and returned to storage.
- i. Inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments.
1. The licensee or registrant shall perform visual and operability checks on survey meters, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and shutters on x-ray units before use on each day the equipment is used to ensure that the equipment is in good working condition, that the sources are adequately shielded, and that required labeling is present. Survey instrument operability must be performed using check sources or other appropriate means. If equipment problems are found, the equipment must be removed from service until repaired.
  2. Each licensee or registrant shall have written procedures for:
    - A. Inspection and routine maintenance of radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed three (3) months or before the first use thereafter to ensure the proper functioning of components important to safety. Replacement components shall meet design specifications. If equipment problems are found, the equipment must be removed from service until repaired.

- B. Inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive materials. The inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.
  - C. Records of equipment problems and of any maintenance performed under RH-1801.i.1. and i.2. must be made in accordance with RH-1800.d.7.
- j. Permanent radiographic installations.
- 1. Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either:
    - A. An entrance control of the type described in RH-1303.c.2 through 4 that reduces the radiation level upon entry into the area, or
    - B. Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal must be activated by radiation whenever the source is exposed. The audible signal must be actuated when an attempt is made to enter the installation while the source is exposed.
  - 2. The alarm system must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry (designated in RH-1801.j.A. (1)) must be tested monthly. If an entrance control device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within seven (7) calendar days. The facility may continue to be used during this seven (7) day period, provided the licensee or registrant implements the continuous surveillance requirements or RH-1803.a. and uses an alarming ratemeter, Test records for entrance controls and audible and visual alarm must be maintained in accordance with RH-1800.d.8.

k. Notifications

1. In addition to the reporting requirements specified in RH-1502 and under other Sections, each licensee or registrant shall provide a written report to the Director, Division of Radiation Control and Emergency Management, Arkansas Department of Health, 4815 West Markham Street, Mail Slot #30, Little Rock, Arkansas 72205-3867 within thirty (30) days of the occurrence of any of the following incidents involving radiographic equipment:
  - A. Unintentional disconnection of the source assembly from the control cable.
  - B. Inability to retract the source assembly to its fully shielded position and secure it in this position.
  - C. Failure of any component (critical to safe operation of the device) to properly perform its intended function.
2. The licensee or registrant shall include the following information in each report submitted under RH-1801.a and in each report of overexposure submitted under RH-1504 which involves failure of safety components of radiography equipment:
  - A. A description of the equipment problem.
  - B. Cause of each incident, if known.
  - C. Name of the manufacturer and model number of equipment involved in the incident.
  - D. Place, time, and date of the incident.
  - E. Actions taken to establish normal operations.
  - F. Corrective actions taken or planned to prevent recurrence.
  - G. Qualifications of personnel involved in the incident.
3. Any licensee or registrant conducting radiographic operations or storing radioactive material at any location not listed on the license or registration for a period in excess of 180 days in a calendar year, shall notify the Department prior to exceeding the 180 days.

RH-1801. (Cont'd)

I. Labeling, storage, and transportation.

1. The licensee may not use a source changer or a container to store licensed material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol in conventional colors, i.e., magenta, purple or black on a yellow background having a minimum diameter of 25 mm, and the wording

**"CAUTION \*  
RADIOACTIVE MATERIAL  
NOTIFY CIVIL AUTHORITIES  
(or "NAME OF COMPANY")  
\* \_\_\_\_\_ or "DANGER"**

2. The licensee may not transport licensed material unless the material is packaged, and the package is labeled, marked and accompanied with appropriate shipping papers in accordance with regulations set out in SECTION 4. TRANSPORTATION OF RADIOACTIVE MATERIALS.
3. Locked radiographic exposure devices and storage containers must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store licensed material in a manner which will minimize danger from explosion or fire.
4. The licensee shall lock and physically secure the transport package containing licensed material in the transport vehicle to prevent accidental loss, tampering, or unauthorized removal of the licensed material from the vehicle.

RH-1802. Personnel Radiation Safety Requirements for Radiographers and Radiographer's Assistants.

- a. Conducting industrial radiographic operations.
  - 1. Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of RH-1802.b.3. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one (1) qualified individual is present.
  - 2. All radiographic operations conducted at locations of use authorized on the license or on the x-ray registration must be conducted in a permanent radiographic installation, unless specifically authorized by the Department.
  - 3. A licensee or registrant may conduct lay-barge or underwater radiography only if the procedures have been approved by the Department, by an Agreement State, or by the Nuclear Regulatory Commission.
- b. Training.
  - 1. The licensee or registrant may not permit any individual to act as a radiographer until the individual:
    - A. Has received training in RH-1804 in addition to a minimum of two (2) months of on-the-job training, and is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in Appendix IRC.

2. In addition, the licensee or registrant may not permit any individual to act as a radiographer until the individual:
  - A. Has received copies of and instructions in the requirements described in this Part; RH-1511; in the applicable sections of Section 3. **“STANDARDS FOR PROTECTION AGAINST RADIATION”** including its Part N: **“NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS: INSPECTIONS”** and in applicable Department of Transportation (DOT) as referenced in the Nuclear Regulatory Commission’s (NRC) 10 CFR Part 71, in the Department license(s) under which the radiographer will perform industrial radiography, the licensee’s or registrant’s operating and emergency procedures;
  - B. Has demonstrated understanding of the licensee’s license and the licensee’s or registrant’s operating and emergency procedures by successful completion of a written or oral examination covering this material.
  - C. Has received training in the use of the licensee’s or registrant’s radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments.
  - D. Has demonstrated understanding of the use of radiographic exposure devices, sources, survey instruments and associated equipment described above in RH-1802.b.2.A. and RH-1802.b.2.C. by the successful completion of a practical examination covering this material.
3. The licensee or registrant may not permit any individual to act as a radiographer’s assistant until the individual:

RH-1802. (Cont'd)

- A. Has received copies of and instructions in the requirements described in this Part; RH-1511; in the applicable sections of Section 3. **"STANDARDS FOR PROTECTION AGAINST RADIATION" including its Part N: "NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS: INSPECTIONS"** and in applicable Department of Transportation (DOT) as referenced in the Nuclear Regulatory Commission's (NRC) 10 CFR Part 71, in the Department license(s) under which the radiographer will perform industrial radiography, the licensee's or registrant's operating and emergency procedures;
  - B. Has developed competence in the use, under the personal supervision of the radiographer, radiographic exposure devices, sealed sources, associated equipment, and radiation survey instruments that the assistant will use; and
  - C. Has demonstrated understanding of the instructions provided above in RH-1802.b.3.A. by the successful completion of a written test on the subjects covered and has demonstrated competence in the use of hardware described in RH-1802.b.3.B. by the successful completion of a practical examination on the use of such hardware.
- 4. The licensee or registrant shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed twelve (12) months.
  - 5. Except as provided in RH-1802.b.5.d., the RSO or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Department's regulations, license requirements, and the applicant's operating emergency procedures are followed. The inspection program must:
    - A. Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed six (6) months; and

Revisions effective July 1, 2002

RH-1802. (Cont'd)

- B. Provide that, if a radiographer or radiographer's assistant has not participated in an industrial radiographic operation for more than six (6) months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of RH1802.b.2.C. and the radiographer's assistant must re-demonstrate knowledge of the training requirements of RH-1802.b.3.B by a practical examination before these individuals can next participate in a radiographic operation.
  - C. The Department may consider alternatives in those situations where the individual serves as both radiographer and RSO.
  - D. In those operations where a single individual serves as both radiographer and RSO, and performs all radiography operations, an inspection program is not required.
- 6. The licensee or registrant shall maintain records of the above training to include certification documents, written and practical examinations, refresher safety training and inspections of job performance in accordance with RH-1800.d.9.
  - 7. The licensee or registrant shall include the subjects detailed in RH-1804.
  - 8. Records of radiographer certification maintained in accordance with RH-1800.d.9. provide appropriate affirmation of certification requirements specified in RH-1802.b.1.A.
- c. Radiographer Certificate Card Confiscation. The Department may confiscate a radiographer's certification card should there be serious health and safety violations relating to the Regulations, license conditions, and/or licensee Operating and Emergency Procedures. The radiographer will be restricted from conducting radiographic operations within the State of Arkansas.
- 1. Following the confiscation of the radiographer's certification card, the conduct of any radiographic operations by this radiographer within the State of Arkansas shall be deemed deliberate misconduct as detailed in RH-1511.
  - 2. The Department shall notify the licensee's management and the Certifying Entity of the certification card confiscation and the restrictions placed on the radiographer.

Revisions effective July 1, 2002

3. The Department shall return the Certification Card when the radiographer has been satisfactorily retrained and/or recertified by a Certifying Entity.

d. Radiation Safety Officer for Industrial Radiography. The Radiation Safety Officer (RSO) shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's or registrant's program.

1. The minimum qualifications, training, and experience of Radiation Safety Officers (RSO) for industrial radiography are as follows:

- A. Completion of the training and testing requirements of RH 1802.b.3.A.;
- B. 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and
- C. Formal training in the establishment and maintenance of a radiation protection program.

2. The Department will consider alternatives when the RSO has appropriate training and/or experience in the field of ionizing radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

3. The specific duties and authorities of the RSO include, but are not limited to:

- A. Establishing and overseeing all operating, emergency, and ALARA procedures as required by Section 3 "STANDARDS FOR PROTECTION AGAINST RADIATION", and reviewing them regularly to ensure that the procedures in use conform to current Section 3 procedures, conform to other Department regulations, and to the license conditions.
- B. Overseeing and approving all phases of the training program for radiographic personnel, ensuring that appropriate and effective radiation protection practices are taught;
- C. Ensuring that required radiation surveys and leak tests are performed and documented in accordance with the regulations, including any corrective measures when levels of radiation exceed established limits;

- D. Ensuring that personnel monitoring devices are calibrated and used properly by personnel, that records are kept of the monitoring results, and that timely notifications are made as required by RH-1504; and
  - E. Ensuring that operations are conducted safely and to assume control for instituting corrective actions including stopping of operations when necessary.
- e. Operating and emergency procedures.
- 1. The licensee's or registrant's operating and emergency procedures must include as a minimum, instructions in the following:
    - A. Appropriate handling and use of licensed sealed sources, radiographic exposure devices, and x-ray equipment (if used) so that no person is likely to be exposed to radiation doses in excess of the limits established in Part C of these Regulations;
    - B. Methods and occasions for conducting radiation surveys;
    - C. Methods for controlling access to radiographic areas;
    - D. Methods and occasions for locking and securing radiographic exposure devices, transport and storage containers and sealed sources;
    - E. Personnel monitoring and the use of personnel monitoring equipment;
    - F. Transporting sealed sources to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when needed, and control of the sealed sources during transportation.
    - G. The inspection, maintenance, and operability checks of radiographic exposure devices, survey instruments, transport containers, and storage containers;
    - H. Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarm ratemeter alarms unexpectedly.

- I. The procedure for notifying proper persons in the event of an accident;
  - J. Minimizing exposure of persons in the event of an accident;
  - K. Source recovery procedure if licensee will perform source recovery;
  - L. Maintenance of records.
2. The licensee or registrant shall maintain copies of current operating and emergency procedures in accordance with RH-1800.d.10.and RH-1800.d.14.
- f. Personnel monitoring.
- 1. A licensee or registrant may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a combination of a direct reading pocket dosimeter, an operable alarm ratemeter, and either a film badge, a thermoluminescent dosimeter (TLD), or an Optically Stimulated Luminescent Dosimeter. At permanent radiography installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required.
    - A. Pocket dosimeters shall have a range from zero to 200 millirems (2 millisieverts) and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.
    - B. Each film badge, thermoluminescent dosimeter (TLD), and/or Optically Stimulated Luminescent Dosimeter must be assigned to and worn by only one (1) individual.
    - C. Film badges, thermoluminescent dosimeters (TLD), and Optically Stimulated Luminescent Dosimeter must be replaced at periods not to exceed one (1) month.
    - D. After replacement each film badge, thermoluminescent dosimeter (TLD), or Optically Stimulated Luminescent Dosimeter must be processed as soon as possible.

RH-1802. (Cont'd)

2. Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with RH-1800.d.11.
3. Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed twelve (12) months for correct response to radiation, and records must be maintained in accordance with RH-1800.d.11. Acceptable dosimeters shall be read within plus or minus twenty (20) percent of the true radiation exposure
4. If an individual's pocket dosimeter is found to be off-scale, or if his or her electronic personal dosimeter reads greater than 200 millirems (2 millisieverts), and the possibility of radiation exposure can not be ruled out as the cause, the individual's film badge, TLD, or Optically Stimulated Luminescent Dosimeter must be sent for processing within twenty-four (24) hours. In addition, the individual may not resume work associated with licensed material or other sources of radiation until a determination of the individual's radiation exposure has been made. This determination must be made by the RSO or the RSO's designee. The results of this determination must be included in the records maintained in accordance with RH-1800.d.11.
5. Reports received from the film badge thermoluminescent dosimeter, or Optically Stimulated Luminescent Dosimeter disposal must be retained in accordance with RH-1800.d.11.
6. If a film badge, TLD, or Optically Stimulated Luminescent Dosimeter is lost or damaged, the worker shall cease 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 of the film badge, TLD, or Optically Stimulated Luminescent Dosimeter. The results of the calculated exposure and the time period for which the film badge, TLD, or Optically Stimulated Luminescent Dosimeter was lost or damaged must be included in the records maintained in accordance with RH-1800.d.11.
7. Each alarm ratemeter shall:
  - A. Be checked to ensure that the alarm functions properly (sounds) before using at the start of each shift:

Revisions effective July 1, 2002

RH-1802. (Cont'd)

- B. Be set to give an alarm signal at a preset dose rate of 500 mrem/hr (5 mSv/hr); with an accuracy rate of plus or minus twenty ( $\pm 20\%$ ) percent of the true radiation dose rate;
- C. Require special means to change the preset alarm function; and
- D. Be calibrated at periods not to exceed twelve (12) months for correct response to radiation. The licensee or registrant shall maintain records of alarm ratemeter calibrations in accordance with RH-1800.d.11.

RH-1803. Precautionary Procedures in Radiographic Operations.

- a. Surveillance. During each radiographic operation the radiographer or the other individual present as required in RH-1802.a. shall maintain continuous direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in Section 3, Part D, RH-1303.c., except at permanent radiographic installations where all entryways are locked and the requirements of RH-1801.j. are met.
- b. Posting. All areas in which industrial radiography is being performed must be conspicuously posted as required by RH-1303.b. Exceptions listed in RH-1304.c. do not apply to industrial radiographic operations.
- c. Radiation surveys. The licensee or registrant shall:
  - 1. Conduct surveys with a calibrated and operable radiation survey instrument that meets the requirements of RH-1801.e.
  - 2. Using a survey instrument meeting the requirement of RH-1803.c.1. above, conduct a survey of the radiographic exposure device and the guide tube after each exposure when approaching the device or the guide tube. The survey must determine that the sealed source has been returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment.

RH-1803. (Cont'd)

3. Conduct a survey of the radiographic exposure device with a calibrated radiation survey instrument any time the source is exchanged and whenever a radiographic exposure device is placed in a storage area (as defined in RH-1800.c.), to ensure that the sealed source is in its shielded position.
  4. Maintain records in accordance with RH-1800.d.12.
- d. Supervision of radiographer's assistants. Whenever a radiographer's assistant uses radiographic exposure devices, associated equipment or sealed sources or conducts radiation surveys required by RH-1803.c.2 to determine that the sealed source has returned to the shielded position after an exposure, the assistant shall be under the personal supervision of a radiographer. The personal supervision shall include:
1. The radiographer's physical presence at the site where the sealed sources are being used,
  2. The availability of the radiographer to give immediate assistance if required, and
  3. The radiographer's direct observation of the assistant's performance of the operations referred to in this Section.
- e. Records required at temporary job sites. Each licensee or registrant conducting industrial radiography at temporary site shall have the following records available at that site for inspection by the Department:
1. Current copy of appropriate license, certificate of registration or an equivalent document.
  2. Operating and emergency procedures.
  3. Applicable regulations.
  4. Survey records required pursuant to RH-1803.c for the period of operation at the site.
  5. Daily pocket dosimeter records for the period of operation at the site.
  6. The latest instrument calibration and leak test record for specific devices in use at the site.

RH-1803. (Cont'd)

- f. Specific requirements for radiographic personnel performing industrial radiography.
1. At a job site, the following shall be supplied by the licensee or registrant:
    - A. At least one operable, calibrated survey instrument;
    - B. A current whole body personnel monitor (TLD or film badge) for each individual;
    - C. An operable, calibrated pocket dosimeter with a range of zero to 200 milliroentgens for each worker; and
    - D. An operable, calibrated alarming ratemeter set to give an alarm signal at a preset dose rate of 500 mR/hr; and
    - E. The appropriate barrier ropes and signs.
  2. Industrial radiographic operations shall not be performed if any of the items in RH-1803.f.1 are not available at the job site or are inoperable.
  3. No individual other than a radiographer or a radiographer's assistant who is under the personal supervision of a radiographer instructor shall manipulate controls or operate equipment used in industrial radiographic operations.
  4. During an inspection by the Department, the Department inspector may terminate an operation if any of the items in RH-1803.f.1 are not available and operable or if the required number of radiographic personnel are not present. Operations shall not be resumed until such conditions are met.
  5. No individual shall act as a radiographer instructor unless such individual:
    - A. Has met the requirements of RH-1802.b.1;
    - B. Has one year of documented experience as an radiographer; and
    - C. Has been named as a radiographer instructor on the license or registration certificate issued by the Department.

g. Special Requirements and Exemptions for Enclosed Radiography.

1. Cabinet X-ray Systems.

A. Emission limit.

- i. Radiation emitted from the cabinet x-ray system shall not exceed an exposure of 0.5 milliroentgen in one hour at any point five (5) centimeters outside the external surface.
- ii. Compliance with the exposure limit in RH-1803.g.1.A.i of this Section shall be determined by measurements averaged over a cross sectional area of 10 (ten) square centimeters with no linear dimension greater than five (5) centimeters, with the cabinet x-ray system operated at those combinations of x-ray tube potential, current, beam orientation and conditions of scatter radiation which produce the maximum x-ray exposure at the external surface and with the door(s) and access panel(s) fully closed as well as fixed at any other position(s) which will allow the generation of x-radiation.

B. Floors. A cabinet x-ray system shall have a permanent floor. Any support surface to which a cabinet x-ray system is permanently affixed may be deemed the floor of the system.

C. Ports and apertures.

- i. The insertion of any part of the human body through any port into the primary beam shall not be possible.
- ii. The insertion of any part of the human body through any aperture shall not be possible.

- D. Safety interlocks.
- i. Each door of a cabinet x-ray system shall have a minimum of two safety interlocks. One, but not both of the required interlocks shall be such that door opening results in physical disconnection of the energy supply circuit to the high-voltage generator and such disconnection shall not be dependent upon any moving part other than the door.
  - ii. Each access panel shall have at least one safety interlock.
  - iii. Following interruption of x-ray generation by the functioning of any safety interlock, use a control provided in accordance with RH-1803.g.1.F shall be necessary for resumption of x-ray generation.
  - iv. Failure of any single component of the cabinet x-ray system shall not cause failure of more than one required safety interlock.
- E. Ground fault. A ground fault shall not result in the generation of x-rays.
- F. Controls and indicators for all cabinet x-ray systems. For all systems to which this Section is applicable there shall be provided:
- i. A key-actuated control to insure that x-ray generation is not possible with the key removed.
  - ii. A control or controls to initiate and terminate the generation of x-rays other than by functioning of a safety interlock or the main power control.
  - iii. Two independent means which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second, in which case the indicators shall be activated for one-half second and which are discernible from any point at which initiation of x-ray generation is possible.

Failure of a single component of the cabinet x-ray system shall not cause failure of both indicators to perform their intended function. One, but not both of the indicators required by this subdivision may be a milliammeter labeled to indicate x-ray tube current. All other indicators shall legibly labeled "X-RAY ON".

- iv. Additional means other than milliammeters which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second, as need to ensure that at least one indicator is visible from each door, access panel and port and is legibly labeled "X-RAY ON".

G. Additional controls and indicators for cabinet x-ray systems designed to admit humans. For cabinet x-ray systems designed to admit humans there shall also be provided:

- i. Comply with all applicable requirements of this Part and RH-1208 of these Regulations. If such a system is a certified cabinet x-ray system, it shall comply with all applicable requirements of this Part and 21 CFR 1020.40.
- ii. Be evaluated at intervals not to exceed one (1) year to assure compliance with the applicable requirements as specified in RH-1803.g.1.A. Records of these evaluations shall be maintained for inspection by the Department for a period of five (5) years after the evaluation.
- iii. A control within the cabinet for preventing and terminating x-ray generation, which cannot be reset, overridden or bypassed from the outside of the cabinet.
- iv. No means by which x-ray generation can be initiated from within the cabinet.

- v. Audible and visible warning signals within the cabinet which are actuated for at least ten (10) seconds immediately prior to the first initiation of x-ray generation after closing any door designed to admit humans. Failure of any single component of the cabinet x-ray system shall not cause failure of both the audible and visible warning signals.
- vi. A visible warning signal within the cabinet which remains actuated when and only when x-rays are being generated, unless the x-ray generation period is less than one-half-second in which case the indicators shall be activated for one-half second.
- vii. Signs indicating the meaning of the warning signals provided pursuant to RH-1803.g.1.G.v and iv and containing instructions for the use of the control provided pursuant to RH-1803.g.1.G.iii. These signs shall be legible, accessible to view and illuminated when the main power control is in the "on" position.

H. Warning labels.

- i. There shall be permanently affixed or inscribed on the cabinet x-ray system at the location of any controls which can be used to initiate x-ray generation, a clearly legible and visible label bearing the statement:

**CAUTION:  
X-RAYS PRODUCED WHEN  
ENERGIZED**

- ii. There shall be permanently affixed or inscribed of the cabinet x-ray system at the location of any controls which can be used to initiate x-ray generation, a clearly legible and visible bearing the statement:

**CAUTION: DO NOT INSERT ANY  
PART OF THE BODY  
WHEN SYSTEM IS  
ENERGIZED--  
X-RAY HAZARD**

- I. Instructions.
  - i. Manufacturers of cabinet x-ray systems shall provide for purchasers and to others upon request at a cost not to exceed the cost of preparation and distribution, manuals and instructions which shall include at least the following technical and safety information: Potential, current and duty cycle ratings of the x-ray generation equipment; adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the system; and a schedule of maintenance necessary to keep the system in compliance with this Section.
  - ii. Manufacturers of cabinet x-ray systems which are intended to be assembled or installed by the purchaser, shall provide instructions for assembly, installation, adjustment and testing of the cabinet x-ray system adequate to assure the system is in compliance with applicable provisions of this Section when assembled, installed, adjusted and tested as directed.
  
- J. Additional requirements for x-ray baggage inspection systems. X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad and bus terminals and at similar facilities, shall be provided with means, pursuant to RH-1803.g.1.J.i and ii, to insure operator presence at the control area in a position which permits surveillance of the ports and doors during generation of x-radiation.
  - i. During an exposure or preset succession of exposures of one-half second or greater duration, the means provided shall enable the operator to terminate the exposure or preset succession of exposures at any time.
  - ii. During an exposure or preset succession of exposures of less than one-half second or greater duration, the means provided may allow completion of the exposure in progress but shall enable the operator to prevent additional exposures.

2. Cabinet Radiography. Cabinet radiography units are exempt from other requirements of this Part; however,
    - A. No licensee or registrant shall permit any individual to operate a cabinet radiography unit until such individual has received a copy of, and instruction in, and demonstrated an understanding of operating procedures for the unit, and has demonstrated competence in its use.
    - B. A cabinet radiography unit shall not be operated until a physical radiation survey of the unit and areas adjacent to the unit has been performed. The licensee or registrant shall perform survey with a properly calibrated instrument as described in RH-1803.c. to determine conformance with RH-1200.
    - C. The registrant shall perform an evaluation, at intervals not to exceed one (1) year, to determine conformance with Part C of these Regulations. If such a system is a certified cabinet x-ray system, it shall be evaluated at intervals not to exceed one (1) year to determine conformance with 21 CFR 1020.40. Records of these evaluations shall be maintained for inspection by the Department for a period of five (5) years after the evaluation.
    - D. The operating personnel must be provided with either a film badge or a thermoluminescent dosimeter and reports of the results must be maintained for inspection by the Department.
    - E. Tests for proper operation of high radiation control devices or alarm systems must be conducted and recorded in accordance with RH-1801.i.
  3. Shielded room radiography. Shielded room radiography shall comply with all applicable requirements of this Part.
  4. Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the Department pursuant to RH-55 of these Regulations.
- h. Prohibitions. - Industrial radiography performed with a sealed source which is not fastened to or contained in a radiographic exposure device (fish pole technique) is prohibited unless specifically authorized in a license issued by the Department.

RH-1804. Subjects to be Covered During the Instruction of Radiographers.

- a. Fundamentals of radiation safety including;
  - 1. Characteristics of gamma and/or x-ray radiation; |
  - 2. Units of radiation dose and quantity of radioactivity |
  - 3. Hazards of exposure to radiation; |
  - 4. Levels of radiation from sources of radiation.
  - 5. Methods of controlling radiation dose.
    - A. Time. |
    - B. Distance. |
    - C. Shielding
- b. Radiation detection instruments including:
  - 1. Use of radiation survey instruments.
    - A. Operation.
    - B. Calibration.
    - C. Limitations.
  - 2. Survey techniques.
  - 3. Use of personnel monitoring equipment.
    - A. Film badges.
    - B. Thermoluminescent dosimeters (TLDs).
    - C. Optically Stimulated Luminescent dosimeters. |
    - D. Pocket dosimeters.
    - E. Alarm ratemeters.
- c. Equipment to be used including:
  - 1. Operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtailed). |
  - 2. Storage, control, and disposal of licensed material. |

Revisions effective July 1, 2002

RH-1804. (Cont'd)

3. Inspection and maintenance of equipment.
  4. Operation and control of x-ray equipment if applicable.
  5. Collimators.
- d. The requirements of pertinent State regulations.
  - e. The licensee's or registrant's written operating and emergency procedures.
  - f. Case histories of accidents in radiography.

RH-1805.-  
RH-1899. Reserved.

**APPENDIX IRC**  
**RADIOGRAPHIC CERTIFICATION**

- I. Requirements for an Independent Certifying Organization.  
An independent certifying organization shall:
1. Be an organization such as a society or association, whose members participate in, or have an interest in, the fields of industrial radiography;
  2. Make its membership available to the general public nationwide that is not restricted because of race, color, religion, sex, age, national origin or disability;
  3. Have a certification program open to nonmembers, as well as members;
  4. Be an incorporated, nationally recognized organization, that is involved in setting national standards of practice within its fields of expertise;
  5. Have an adequate staff, a viable system for financing its operations, and a policy-and-decision-making review board;
  6. Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;
  7. Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;
  8. Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;
  9. Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program;
  10. Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;

Revisions effective July 1, 2002

## APPENDIX IRC

### RADIOGRAPHIC CERTIFICATION (Cont'd)

11. Have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the individuals proctoring each examination are not employed by the same company or corporation (or a wholly-owned subsidiary of such company or corporation) as any of the examinees;
  12. Exchange information about certified individuals with the Department and other independent certifying organizations and/or the Nuclear Regulatory Commission and/or Agreement States and allow periodic review of its certification program and related records; and
  13. Provide a description to the Department of its procedures for choosing examination sites and for providing an appropriate examination environment.
- II. Requirements for Certification Programs. All certification programs must:
1. Require applicants for certification to:
    - A. Receive training in the topics set forth in RH-1804 or equivalent to NRC and/or Agreement State Regulations, and
    - B. Satisfactorily complete a written examination covering these topics;
  2. Require applicants for certification to provide documentation that demonstrates that the applicant has:
    - A. Received training in the topics set forth in RH-1804 or equivalent NRC and/or Agreement State regulations;
    - B. Satisfactorily completed a minimum period of on-the-job training; and
    - C. Has received verification by an Agreement State or NRC licensee that the applicant has demonstrated the capability of independently working as a radiographer;

Revisions effective July 1, 2002

Appendix IRC. (Cont'd)

3. Include procedures to ensure that all examination questions are protected from disclosure;
  4. Include procedures for denying an application, revoking, suspending, and reinstating a certificate;
  5. Provide a certificate period of not less than three (3) years nor more than five (5) years;
  6. Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training.
  7. Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.
- III. Requirements for Written Examinations. All examinations must be:
1. Designed to test an individual's knowledge and understanding of the topics listed in RH-1804 or equivalent Agreement State and/or NRC requirements;
  2. Written in a multiple-choice format;
  3. Have test items drawn from a question bank containing psychometrically valid questions based on the material in RH-1804.

**PART J.**  
**RADIATION SAFETY REQUIREMENTS FOR WIRELINE  
SERVICE OPERATIONS AND SUBSURFACE  
TRACER STUDIES.**

RH-1900.

General Provisions.

- a. Scope. The Regulations in this Part apply to all licensees who use sources of radiation for Wireline service operations including mineral logging, radioactive markers or subsurface tracer studies.
- b. Purpose. The Regulations in this Part establish radiation safety requirements for persons utilizing sources of radiation for wireline service operations including mineral logging, radioactive markers and subsurface tracer studies. The requirements of this Part are in addition to and not in substitution for other applicable requirements of these Regulations.
- c. Definitions. As used in this Part, the following definitions apply. Additional definitions used only in a certain Part will be found in that Part.
  1. Energy Compensation Sources (ECS). A small sealed source, with an activity not exceeding 100 microcurie (3.7 MBq), used within a logging tool, or other tool components, to provide a reference standard to maintain the tool's calibration when in use.
  2. Field station - A facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary job sites.
  3. Fresh water aquifer - A geologic formation that is capable of yielding fresh water to a well or spring.
  4. Injection tool - A device used for controlled subsurface injection or radioactive tracer material.
  5. Irretrievable well logging source - Any sealed source containing radioactive material that is pulled off or not connected to the wireline that suspend the source in the well and for which all reasonable effort at recovery has been expended.
  6. Logging assistant - Any individual who, under the personal supervision of a logging supervisor, handles sealed sources, tracers, or radiation producing machines that are not in logging tools or shipping containers or who performs surveys required by RH-1967.

Revisions effective July 1, 2002

RH-1900. (Cont'd)

7. Logging supervisor - Any individual who uses radioactive material or radiation producing machines, or provides personal supervision in the use of radioactive material or radiation producing machines at a temporary jobsite and who is responsible to the licensee for assuring compliance with the requirements of the Department's Regulations and the conditions of the license.
8. Logging tool - Any device used subsurface to perform well-logging.
9. Mineral logging - Any logging performed for the purpose of mineral exploration other than oil or gas.
10. Particle accelerator - Any machine capable of accelerating electrons, protons, deuterons or their charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one (1) MeV.
11. Personal supervision - Guidance and instruction by the logging supervisor who is physically present at the job site and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required.
12. Radioactive marker - Radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.
13. Safety review - A periodic review provided by the licensee for its employees on radiation safety aspects of well logging. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, accidents or errors that have been observed, and opportunities for employees to ask safety questions.
14. Sealed source - Any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.
15. Source holder - A housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.

Revisions effective July 1, 2002

RH-1900. (Cont'd)

16. Subsurface tracer study - the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.
17. Surface casing for protecting fresh water aquifers - a pipe or tube used as a lining in a well to isolate fresh water aquifers from the well.
18. Temporary jobsite - A location to which radioactive materials have been dispatched to perform wireline service operations and subsurface tracer studies are performed.
19. Tritium Neutron Generator Target Source - A tritium source used within a neutron generator tube to produce neutrons for use in well-logging applications.
20. Uranium sinker bar - A weight containing depleted Uranium used to pull a logging tool toward the bottom of a well.
21. Well-bore - A drilled hole in which wireline service operations and subsurface tracer studies are performed.
22. Well-logging - the lowering and raising of measuring devices or tools which may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well and/or adjacent formations.
23. Wireline - A cable containing one or more electrical conductor which is used to lower and raise logging tools in the well-bore.
24. Wireline service operation - Any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.

RH-1901-  
RH-1910. Reserved.

RH-1911 Application for a Specific License. A person, as defined in RH-1100b.c. of these Regulations, shall file an application for a specific license authorizing the use of radioactive material in well logging in accordance with RH-403 and RH-404.

RH-1912. Reserved.

Revisions effective July 1, 2002

RH-1913.

Specific Licenses for Well Logging. The Department will approve an application for a specific license for the use of radioactive material in well logging if the applicant meets the following requirements.

- a. The application shall satisfy the general requirements specified in RH-404 of these Regulations, and any special requirements contained in this Part.
- b. The applicant shall develop a program for training logging supervisors and logging assistants and submit to the Department a description of this program which specifies the:
  1. Initial training;
  2. On-the-job training;
  3. Annual safety reviews provided by the licensee;
  4. Means the applicant will use to demonstrate the logging supervisor's knowledge and understanding of and ability to comply with the Department's Regulations and licensing requirements and the applicant's operating and emergency procedures; and
  5. Means the applicant will use to demonstrate the logging assistant's knowledge and understanding of and ability to comply with the applicant's operating and emergency procedures.
- c. The applicant shall submit to the Department written operating and emergency procedures as described in RH-1963 or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures.
- d. The applicant shall establish and submit to the Department its program for annual inspections of the job performance of each logging supervisor to ensure that the Department's regulations, license requirements, and the applicant's operating and emergency procedures are followed. Inspection records must be retained for three (3) years after each annual internal inspection.
- e. The applicant shall submit a description of its overall organizational structure as it applies to the radiation safety responsibilities in well logging, including specified delegations of authority and responsibility.
- f. If an applicant wants to perform leak testing of sealed sources, the applicant shall identify the manufacturers and model numbers of the leak test kits to be used. If an applicant want to analyze its own wipe samples, the applicant shall establish procedures to be followed and submit a description of these procedures to the Department. The description must include the:

RH-1913. (Cont'd)

1. Instruments to be used;
2. Methods of performing the analysis; and
3. Pertinent experience of the person who will analyze the wipe samples.

RH-1914. Reserved.

RH-1915. Agreement with Well Owner or Operator.

- a. A licensee may perform well logging with a sealed source only after the licensee has a written agreement with the employing well owner or operator. This written agreement must identify who will meet the following requirements:
  1. If a sealed source becomes lodge in the well, a reasonable effort will be made to recover it.
  2. A person may not attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture.
  3. The radiation monitoring required in RH-1969.a will be performed.
  4. If the environment, any equipment, or personnel are contaminated with radioactive material, they must be decontaminated before release from the site or release for unrestricted use. And;
  5. If the sealed source is classified as irretrievable after reasonable efforts at recovery have been expended, the following requirements must be implemented within thirty (30) days:
    - i. Each irretrievable well logging source must be immobilized and sealed in place with a cement plug;
    - ii. A means to prevent inadvertent intrusion on the source unless the source are not accessible to any subsequent drilling operations; and

Revisions effective July 1, 2002

RH-1915. (Cont'd)

- iii. A permanent identification plaque, constructed of long-lasting material such as stainless steel, brass, bronze, or monel, must be mounted at the surface of the well, unless the mounting of the plaque is not practical. The size of the plaque must be at least seven (7) inches (17cm) square and 1/8-inch (3 mm) thick. The plaque<sup>14/</sup> must contain:
  - A. The word "CAUTION";
  - B. The radiation symbol (the color requirement in RH-1303.a.1 need not be met);
  - C. The date the source was abandoned;
  - D. The name of the well owner or operator, as appropriate;
  - E. The well name and well identification numbers(s) or other designation;
  - F. An identification of the sealed source(s) by radionuclide and quantity;
  - G. The depth of the source and depth to the top of the plug; and
  - H. An appropriate warning, such as "DO NOT RE-ENTER THIS WELL".<sup>15/</sup>
- b. The licensee shall retain a copy of the written agreement for three (3) years after.
- c. A licensee may apply, pursuant to RH-1991, for Department approval, on a case-by-case basis, of proposed procedures to abandon an irretrievable well logging source in a manner not otherwise authorized in RH-1915.a.5 of this Section.
- d. A written agreement between the licensee and the well owner or operator is not required if the licensee and the well owner or operator are part of the same corporate structure or otherwise similarly affiliated. However, the licensee shall still otherwise meet the requirements of RH-1915.a.1 through RH-1915.a.5.

RH-1916. Reserved.

Revisions effective July 1, 2002

RH-1917. Request for Written Statements. Each licensee is issued with the condition that the licensee will, at any time before expiration of the license, upon the Department's request, submit written statements, signed under oath or affirmation, to enable the Department to determine whether or not the license should be modified, suspended, or revoked.

RH-1918.  
RH-1930. Reserved.

RH-1931. Labels, Security, and Transportation Precautions.

a. Labels.

1. The licensee may not use a source, source holder, or logging tool that contains radioactive material unless the smallest component that is transported as a separate piece of equipment with the radioactive material inside bears a durable, legible, and clearly visible marking or label. The marking or label must contain the radiation symbol specified in RH-1303.a.1 and 2, without the conventional color requirements, and the wording

**"DANGER (or CAUTION)  
RADIOACTIVE MATERIAL."**

2. The licensee may not use a container to store radioactive material unless the container has securely visible label. The label must contain the radiation symbol specified in RH-1303.a and the wording

**"CAUTION (or DANGER), RADIOACTIVE MATERIAL,  
NOTIFY CIVIL AUTHORITIES OR  
\_\_\_\_\_ IF FOUND.  
(Name of Company)"**

3. The licensee may not transport radioactive material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with Section 4 of these Regulations.

b. Security Precautions During Storage and Transportation.

1. The licensee shall store each source containing radioactive material in a storage container or transportation package. The container or package must be locked and physically secured to prevent tampering or removal of radioactive material from storage by unauthorized personnel, the licensee will minimize the danger from explosion or fire.

Revisions effective July 1, 2002

RH-1931. (Cont'd)

2. The licensee shall lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the radioactive material from the vehicle.

RH-1932. Reserved.

RH-1933. Radiation Detection Instruments.

- a. The licensee shall keep a calibrated and operable radiation survey instrument capable of detecting beta and gamma radiation at each field station and temporary jobsite to make the radiation surveys required by this Part and by other Parts of Section 3. To satisfy this requirement, the radiation survey instrument must be capable of measuring 0.1 mrem (0.001 mSv) per hour through at least 50 mrem (0.5 mSv) per hour.
- b. The licensee shall have available additional calibrated and operable radiation detection instruments sensitive enough to detect the low radiation and contamination levels that could be encountered if a sealed source ruptured. The licensee may own the instruments or may have a procedure to obtain them quickly from a second party.
- c. The licensee shall have each radiation survey instrument required under RH-1933.a of this Section calibrated:
  1. At intervals not to exceed six (6) months and after instrument servicing;
  2. For linear scale instruments, at two (2) points located approximately 1/3 and 2/3 of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two (2) points of at least one decade; and for digital instruments, at appropriate points; and
  3. So that an accuracy within plus or minus 20 percent ( $\pm 20\%$ ) of the calibration standard can be demonstrated on each scale.
- d. The licensee shall retain calibration records for a period of three (3) years after the date of calibration for inspection by the Department.

RH-1934. Reserved.

Leak Testing of Sealed Sources.

- a. Testing and recordkeeping requirements. Each licensee who uses a sealed source shall have the source leak tested for leakage periodically. The licensee shall keep a record of leak test results in units of microcuries and retain the record for inspection by the Department for three (3) years after the leak test is performed.
- b. Method of testing. The wipe of a sealed source must be performed using a leak test kit or method approved by the Department, The U.S. Nuclear Regulatory Commission, or an Agreement State. The wipe sample must be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample and must be performed by a person approved by the Department, U.S. Nuclear Regulatory Commission, or an Agreement State to perform the analysis.
- c. Test frequency.
  1. Each sealed source (except an Energy Compensation Source (ECS)) must be tested at intervals not to exceed six (6) months. In the absence of a certificate from a transferor that a test has been made within the six (6) months before the transfer, the sealed source may not be used until tested.
  2. Each ECS that is not exempt from testing in accordance with RH-1935.c. must be tested at intervals not to exceed three (3) years. In the absence of a certificate from a transferor that a test has been made within the three (3) years before the transfer, the ECS may not be used until tested.
- d. Removal of leaking source from service.
  1. If the test conducted pursuant to RH-1935.a and RH-1935.b reveals the presence of 0.005 microcurie (185 Bq) or more of removable radioactive material, the licensee shall remove the sealed source from service immediately and have it decontaminated, repaired, or disposed of by a Department, U.S. Nuclear Regulatory Commission, or an Agreement State licensee that is authorized to perform these functions. The licensee shall check the equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of by a Department, U.S. Nuclear Regulatory Commission, or an Agreement State licensee that is authorized to perform these functions.

RH-1935. (Cont'd)

2. The licensee shall submit a report to the Department within five (5) days of receiving the test results. The report must describe the equipment involved in the leak, the test results, any contamination which resulted from the leaking source, and the corrective actions taken up to the time the report is made.

e. Exemptions from testing requirements. The following sealed sources are exempt from the periodic leak requirements set out in RH-1935.a through RH-1935.d:

1. Hydrogen-3 (tritium) sources;
2. Sources containing licensed material with a half-life of thirty (30) days or less;
3. Sealed sources containing licensed material in gaseous form;
4. Sources of beta- or gamma-emitting radioactive material with an activity of 100 microcuries (3.7 MBq) or less.
5. Sources of alpha- or neutron-emitting radioactive material with an activity of ten (10) microcuries (370,000 Bq) or less.

RH-1936. Reserved.

RH-1937. Physical Inventory. Each licensee shall conduct a quarterly physical inventory to account for all radioactive material received and possessed under the license. The licensee shall date the inventory for inspection by the Department. The inventory must indicate the quantity and type of radioactive material, the location of the radioactive material, the date of the inventory, and the name of the individual conducting the inventory.

RH-1938. Reserved.

RH-1939.

Records of Material Use.

- a. Each licensee shall maintain records for each use of radioactive material showing:
  - 1. The make, model number, and a serial number or a description of each sealed source used;
  - 2. In the case of unsealed radioactive material used for subsurface tracer studies, the radionuclide and quantity of activity used in a particular well and the disposition of any unused tracer material;
  - 3. The identity of the logging supervisor who is responsible for the licensed material and the identity of logging assistants present; and
  - 4. The location and date of use of the radioactive material.
- b. The licensee shall make the records required by RH-1939.a of this Section available for inspection by the Department. The licensee shall retain the records for three (3) years from the date of the recorded event

RH-1940.

Reserved.

RH-1941.

Design and Performance Criteria for Sealed Sources.

- a. A licensee may not use a sealed source in well-logging applications if:
  - 1. The sealed source is doubly encapsulated;
  - 2. The sealed source licensed material whose chemical and physical forms are as insoluble and nondispersible as practical; and
- b. For a sealed source manufactured on or before July 14, 1989, a licensee may use the sealed source, for use in well-logging applications if it meets the requirements of USASI N5.10-1968, "Classification of Sealed Radioactive Sources," or the requirements in RH-1941.c. or d.
- c. For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in well-logging applications if it meets the oil-well logging requirements of ANSI/HPS N43.6-1997, "Sealed Radioactive Sources-Classification."

Revisions effective July 1, 2002

RH-1941. (Cont'd)

- d. For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in well-logging applications, if:
  - 1. The sealed source's prototype has been tested and found to maintain its integrity after each of the following tests:
    - A. Temperature. The test source must be held at -40° C for 20 minutes, 600° C for 1 hour, and then be subject to a thermal shock test with a temperature drop from 600° C to 20° C within 15 seconds.
    - B. Impact test. A 5 kg steel hammer, 2.5 cm in diameter, must be dropped from a height of 1 meter onto the test source.
    - C. Vibration test. The test source must be subject to a vibration from 25 Hz to 500 Hz at 5 gram amplitude for 30 minutes.
    - D. Puncture test. A 1 gram hammer and pin, 0.3 cm pin diameter, must be dropped from a height of 1 meter onto the test source.
    - E. Pressure test. The test source must be subject to an external pressure 24,600 pounds per square inch absolute ( $1.695 \times 10^7$  pascals).
- e. The requirements of RH-1941.a., b., c., and d. do not apply to sealed sources that contain radioactive material in gaseous form.
- f. The requirements in RH-1941.a., b., c., and d. do not apply to energy compensation sources (ECS). ECSs must be registered with the Department under RH-403.i., the Nuclear Regulatory Commission or with an Agreement State.

RH-1942. Reserved.

RH-1943.

Inspection, Maintenance, and Opening of a Source or Source Holder.

- a. Each licensee shall visually check source holders, logging tools, and source handling tools for defects before each use to ensure that the equipment is in good working condition and that required labeling is present. If defects are found, the equipment must be removed from service until repaired, and a record must be made listing: the date of the check, name of inspector, equipment involved, defects found, and repairs made. These records must be retained for three (3) years after the defect is found.
- b. Each licensee shall have a program for semiannual visual inspection and routine maintenance of source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and Uranium sinker bars to ensure that the required labeling is legible and that no physical damage is visible. If defects are found, the equipment must be removed from service until repaired, and a record must be made listing: date, equipment involved, inspection and maintenance operations performed, any defects found, and any actions taken to correct the defects. These records must be retained for three (3) years after the defect is found.
- c. Removal of a sealed source from a source holder or logging tool, and maintenance on sealed sources or holders in which sealed sources are contained may not be performed by the licensee unless a written procedure developed pursuant to RH-1963 has been approved either by the Department, U.S. Nuclear regulatory commission, or by an Agreement State pursuant to RH-1913.c.
- d. If a sealed source is stuck in the source holder, the licensee may not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the licensee is specifically approved by the Department, U.S. Nuclear Regulatory Commission, or by an Agreement State to perform this operation.
- e. The opening, repair, or modification of any sealed source must be performed by persons specifically approved to do so by the department, U.S. Nuclear Regulatory Commission, or by an Agreement State.

RH-1944.

Reserved.

- RH-1945.      Subsurface Trace Studies.
- a.      The licensee shall require all personnel handling radioactive tracer material to use protective gloves and, if required by the license, other protective clothing and equipment. The licensee shall take precautions to avoid ingestion or inhalation of radioactive tracer material and to avoid contamination of field stations and temporary jobsites.
  - b.      A licensee may not knowingly inject radioactive material into fresh water aquifers unless specifically authorized to do so by the Department.
- RH-1946.      Reserved.
- RH-1947.      Radioactive Markers.      The licensee may use radioactive markers in wells only if the individual markers contain quantities of radioactive material not exceeding the quantities specified in RH-901, Schedule B. The use of markers is subject to the requirements of RH-1937.
- RH-1948.      Reserved.
- RH-1949.      Uranium Sinker Bars.      The licensee may use a Uranium sinker bar in a well logging applications after July 14, 1988, only if it is legibly impressed with the words
- "CAUTION - RADIOACTIVE - DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES OR \_\_\_\_\_ (or Company Name) IF FOUND"      (fill in Company Name).**
- RH-1950.      Reserved.
- RH-1951.      Use of a Sealed Source in a Well Without a Surface Casing.      The licensee may use a sealed source in a well without a surface casing for protecting fresh water aquifers only if the licensee follows a procedure for reducing the probability of the source becoming lodged in the well. The procedure must be approved by the Department pursuant to RH-1913.
- RH-1952.      Reserved.

- RH-1953. Energy Compensation Source. The licensee may use an energy compensation source (ECS) which is contained within a logging tool, or other tool components, only if the ECS contains quantities of licensed material not exceeding 100 microcuries (3.7 MBq).
- a. For well logging applications with a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of RH-1935, RH-1937, and RH-1939.
  - b. For well logging applications without a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of RH-1915, RH-1935, RH-1937, RH-1939, RH-1951, and RH-1977.
- RH-1954. Reserved.
- RH-1955. Tritium Neutron Generator Target Source.
- a. Use of a tritium neutron generator target source, containing quantities not exceeding thirty (30) curies (1,110 MBq) and in a well with a surface casing to protect fresh water aquifers, is subject to the requirements of this part except for RH-1915, RH-1941, and RH-1977.
  - b. Use of a tritium neutron generator target source, containing quantities exceeding thirty (30) curies (1,110 MBq) or in a well without a surface casing to protect fresh water aquifers, is subject to the requirements of this part except for RH-1941.
- RH-1956-  
RH-1960. Reserved.
- RH-1961. Training.
- a. The licensee may not permit an individual to act as a logging supervisor until that person:
    1. Has completed training in the subjects outlined in RH-1961.e of this Section;
    2. Has received copies of, and instruction in:
      - A. The applicable Parts of Section 3 of these Regulations;
      - B. The license under which the logging supervisor will perform well logging; and

Revisions effective July 1, 2002

RH-1961. (Cont'd)

- C. The licensee's operating and emergency procedures required by RH-1963.
- 3. Has completed on-the-job training and demonstrated competence in the use of radioactive materials, remote handling tools, and radiation survey instruments by a field evaluation; and
- 4. Has demonstrated understanding of the requirements in RH-1961.a.1 and RH-1961.a.2 by successfully completing a written test.
- b. The licensee may not permit an individual to act as a logging assistant until that person:
  - 1. Has received instruction in applicable Parts of Section 3 of these Regulations;
  - 2. Has received copies of, and instruction in, the licensee's operating and emergency procedures required by RH-1963;
  - 3. Has demonstrated understanding of the material in RH-1961.b.1 and RH-1961.b.2 of this Section by successfully completing a written or oral test; and
  - 4. Has received instruction in the use of radioactive materials, remote handling tools, and radiation survey instruments, as appropriate for the logging assistant's intended job responsibilities.
- c. The licensee shall provide safety reviews for logging supervisors and logging assistants at least once during each calendar year.
- d. The licensee shall maintain a record on each logging supervisor's and logging assistant's training and annual safety review. The training records must include copies of written tests and dates of oral tests given after July 14, 1987. The training records must be retained until three (3) year following the termination of employment. Records of annual safety reviews must list the topics discussed and be retained for three (3) years.
- e. The licensee shall include the following subjects in the training required in RH-1961.a.1 of this Section.
  - 1. Fundamentals of radiation safety, including:
    - A. Characteristics of radiation;
    - B. Units of radiation dose and quantity of radioactivity;

Revisions effective July 1, 2002

RH-1961. (Cont'd)

- C. Hazards of exposure to radiation;
  - D. Levels of radiation from licensed material;
  - E. Methods of controlling radiation dose (time, distance, and shielding); and
  - F. Radiation safety practices, including prevention of contamination, and methods of decontamination.
2. Radiation detection instruments, including:
- A. Use, operation, calibration, and limitations of radiation survey instruments;
  - B. Survey techniques; and
  - C. Use of personnel monitoring equipment.
3. Equipment to be used, including:
- A. Operation of equipment, including source handling equipment and remote handling tools;
  - B. Storage, control, and disposal of radioactive material;
  - C. Maintenance of equipment.
4. The requirements of pertinent Department regulations; and
5. Case histories of accidents in well-logging.

RH-1962. Reserved.

RH-1963. Operating and Emergency Procedures. Each licensee shall develop and follow written operating and emergency procedures that cover:

- a. The handling and use of radioactive materials including the use of sealed sources in wells without surface casing for protecting fresh water aquifers, if appropriate;
- b. The use of remote handling tools for handling sealed sources and radioactive tracer material except low-activity calibration sources;

RH-1963. (Cont'd)

- c. Methods and occasions for conducting radiation surveys, including surveys for detecting contamination, as required by RH-1967.c through RH-1967.e;
- d. Minimizing personnel exposure including exposures from inhalation and ingestion of radioactive materials;
- e. Methods and occasions for locking and securing stored radioactive materials;
- f. Personnel monitoring and the use of personnel monitoring equipment;
- g. Transportation of radioactive material to field stations or temporary jobsites, packaging of radioactive materials for transport in vehicles; placarding of vehicles when needed, and physically securing radioactive materials in transport vehicles during transportation to prevent accidental loss, tampering, or unauthorized removal;
- h. Picking up, receiving, and opening packages containing radioactive materials, in accordance with RH-1307;
- i. For the use of tracers, decontamination of the environment, equipment, and personnel;
- j. Maintenance of records generated by logging personnel at temporary jobsites;
- k. The inspection and maintenance of sealed sources, source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and Uranium sinker bars as required by RH-1943;
- l. Actions to be taken if a sealed source is lodged in a well;
- m. Notifying proper persons in the event of an accident; and
- n. Actions to be taken if a sealed source is ruptured including actions to prevent the spread of contamination and minimize inhalation and ingestion of radioactive materials and actions to obtain suitable radiation survey instruments as required by RH-1933.b.

RH-1964. Reserved.

RH-1965. Personnel Monitoring.

- a. The licensee may not permit an individual to act as a logging supervisor or logging assistant unless that person wears, at all times during the handling of licensed radioactive materials, either a film badge or a thermoluminescent dosimeter (TLD). Each film badge or TLD must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and TLD replaced at least quarterly. After replacement, each film badge or TLD must be promptly processed.
- b. The licensee shall provide bioassay services to individuals using radioactive materials in subsurface tracer studies if required by the license.
- c. The licensee shall retain records of film badge, TLD, and bioassay results for inspection until the Department authorized disposition of the records.

RH-1966. Reserved.

RH-1967. Radiation Surveys.

- a. The licensee shall make radiation surveys, including but not limited to the surveys required under RH-1967.b through RH-1967.e of this Section, of each area where radioactive materials are used and stored.
- b. Before transporting radioactive materials, the licensee shall make a radiation survey of the position occupied by each individual in the vehicle and of the exterior of each vehicle used to transport the radioactive materials.
- c. If the sealed source assembly is removed by the logging tool before departure from the temporary jobsite, the licensee shall confirm that the logging tool is free of contamination by energizing the logging tool detector or by using a survey meter.
- d. If the licensee has reason to believe that, as a result of any operation involving a sealed source, the encapsulation of the sealed source could be damaged by the operation, the licensee shall conduct a radiation survey, including a contamination survey, during and after the operation.
- e. The licensee shall make a radiation survey at the temporary jobsite before and after each subsurface tracer study to confirm the absence of contamination.

RH-1967. (Cont'd)

- f. The results of surveys required under RH-1967.a through RH-1967.e of this Section must be recorded and must include the date of the survey, the name of the individual making the survey, the identification of the survey, instrument used, and the location of the survey. The licensee shall retain records of surveys for inspection by the Department for three (3) years after they are made.

RH-1968. Reserved.

RH-1969. Radioactive Contamination Control.

- a. If the licensee detects evidence that a sealed source has ruptured or radioactive materials have caused contamination, the licensee shall initiate immediately the emergency procedures required by RH-1963.
- b. If contamination results from the use of radioactive material in well logging, the licensee shall decontaminate all work areas, equipment, and unrestricted areas.
- c. During efforts to recover a sealed source lodged in the well, the licensee shall continuously monitor, with an appropriate radiation detection instrument or a logging tool with a radiation detector, the circulating fluids from the well, if any, to check for contamination resulting from damage to the sealed source.

RH-1970. Reserved.

RH-1971. Security.

- a. A logging supervisor must be physically present at a temporary jobsite whenever radioactive materials are being handled or are not stored and locked in a vehicle or storage place. The logging supervisor may leave the jobsite in order to obtain assistance if a source becomes lodged in a well.
- b. During well logging, except when radiation sources are below ground or in shipping or storage containers, the logging supervisor or other individual designated by the logging supervisor shall maintain direct surveillance of the operation to prevent unauthorized entry into a restricted area, as defined in RH-1100.

RH-1972. Reserved.

RH-1973. Documents and Records Required at Field Stations. Each licensee shall maintain the following documents and records at the field station:

- a. A copy of these Regulations;
- b. The license authorizing the use of radioactive material;
- c. Operating and emergency procedures required by RH-1963;
- d. The record of radiation survey instrument calibrations required by RH-1933;
- e. The record of leak test results required by RH-1935;
- f. Physical inventory records required by RH-1937;
- g. Utilization records required by RH-1939;
- h. Records of inspection and maintenance required by RH-1943;
- i. Training records required by RH-1961.d; and
- j. Survey records required by RH-1967.

RH-1974. Reserved.

RH-1975. Documents and Records Required at Temporary Jobsites. Each licensee conducting operations at a temporary jobsite shall maintain the following documents and records at the temporary jobsite until the well-logging operation is completed:

- a. Operating and emergency procedures required by RH-1963;
- b. Evidence of latest calibration of the radiation survey instruments in use at the site required by RH-1933;
- c. Latest survey records required by RH-1967.b, RH-1967.c, and RH-1967.e.
- d. The shipping papers for the transportation of radioactive materials required by Section 4 of these Regulations;
- e. When operating under reciprocity pursuant to Section 2, Part H of these Regulations, a copy of the U.S. Nuclear Regulatory Commission license or Agreement State license authorizing use of radioactive materials.

RH-1976. Reserved.

RH-1977. Notification of Incidents and Lost Sources; Abandonment Procedures for Irretrievable Sources.

- a. The licensee shall immediately notify the Department by telephone and subsequently, within thirty (30) days, by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. The letter must designate the well or other location, describe the magnitude and extent of the escape of radioactive materials, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.
- b. The licensee shall notify the Department of the theft or loss of radioactive materials, radiation overexposures, excessive levels and concentrations of radiation, and certain other accidents as required by RH-1501, RH-1502, and RH-1504 of these Regulations.
- c. If a sealed source becomes lodged in a well, and when it becomes apparent that efforts to recover the sealed source will not be successful, the licensee shall:
  1. Notify the Department by telephone of the circumstances that resulted in the inability to retrieve the source and
    - A. Obtain the Department's approval to implement abandonment procedures; or
    - B. That the licensee implemented abandonment before receiving the Department's approval because the licensee believed there was an immediate threat to public health and safety; and
  2. Advise the well owner or operator, as appropriate, of the abandonment procedures under RH-1915.a or RH-1915.c; and
  3. Either ensure that abandonment procedures are implemented within thirty (30) days after the sealed source has been classified as irretrievable or request an extension of time if unable to complete the abandonment procedures.

Revisions effective July 1, 2002

RH-1977. (Cont'd)

- d. The licensee shall, within thirty (30) days after a sealed source has been classified as irretrievable, make a report in writing to the Department. The licensee shall send a copy of the report to each appropriate State or Federal agency that issued permits or otherwise approved the drilling operation. The report shall contain the following information:
1. Date of occurrence;
  2. A description of the irretrievable well-logging source involved including the radionuclide and its quantity, chemical, and physical form;
  3. Surface location and identification of the well;
  4. Results of effort to immobilize and seal the source in place;
  5. A brief description of the attempted recovery effort;
  6. Depth of the source;
  7. Depth of the top of the cement plug;
  8. Depth of the well;
  9. The immediate threat to public health and safety justification for implementing abandonment if prior Department approval was not obtained in accordance with RH-1977.c.1.ii.;
  10. Any other information, such as a warning statement, contained on the permanent identification plaque; and
  11. State and Federal agencies receiving a copy of this report.

RH-1978.

RH-1990.

Reserved.

Revisions effective July 1, 2002

RH-1991. Applications for Exemptions. The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the Regulations in this Part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Example of Plaque for Identifying Wells Containing Sealed Sources Containing Radioactive Material Abandoned Downhole

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[COMPANY NAME]

[WELL IDENTIFICATION]



ONE 2 CURIE CS-137 RADIOACTIVE SOURCE ABANDONED  
3-3-75 AT 8400 FT PLUG BACK DEPTH 8200 FT  
DO NOT RE-ENTER THIS WELL BEFORE CONTACTING  
ARKANSAS DEPARTMENT OF HEALTH

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The size of the plaque should be convenient for use on active or inactive wells, e.g., a 7-inch square. Letter size of the word "CAUTION" should be approximately twice the letter size of the rest of the information, e.g., 1/2-inch and 1/4-inch letter size, respectively.

RH-1992. Subjects to be Included in Training Courses for Logging Supervisors.

- a. Fundamentals of radiation safety.
  - 1. Characteristics of radiation.
  - 2. Units of radiation dose (rem) and quantity of radioactivity (curie).
  - 3. Significance of radiation dose.
    - A. Radiation protection standards.
    - B. Biological effects of radiation dose.
  - 4. Levels of radiation from sources of radiation.
  - 5. Methods of minimizing radiation dose.
    - A. Working time.
    - B. Working distances.
    - C. Shielding.
- b. Radiation detection instrumentation to be used.
  - 1. Use of radiation survey instruments.
    - A. Operation.
    - B. Calibration.
    - C. Limitations.
  - 2. Survey techniques.
  - 3. Use of personnel monitoring equipment.
- c. Equipment to be used.
  - 1. Handling equipment.
  - 2. Sources of radiation.
  - 3. Storage and control of equipment.
  - 4. Operation and control of equipment.
- d. The requirements of pertinent federal and state regulations.

RH-1992. (Continued)

- e. The licensee's written operating and emergency procedures.
- f. The licensee's record keeping procedures.

RH-1993.

RH-1999. Reserved.

## PART K. EXEMPTIONS AND ADDITIONAL REQUIREMENTS

RH-2000. Applications for Exemptions. The Department may, upon application therefore or upon its own initiative, grant such exemptions or exceptions from the requirements of these Regulations as it determines are authorized by law and will not result in undue hazard to public health and safety or to property.

RH-2001. Orders. The Department may, by order, impose upon any licensee or registrant such requirements, issued in furtherance of these Regulations, as it deems appropriate or necessary to protect health or minimize danger to life or property.

RH-2002.-

RH-2009. Reserved.

## PART L. ENFORCEMENT

RH-2110. Violations.

- a. Any person who violates any of the provisions of the Act or rules, regulations or orders in effect pursuant thereto of the Department shall, upon conviction thereof, be punished by a fine of not less than one hundred dollars (\$100.00) nor more than two thousand dollars (\$2,000.00) or by imprisonment for not more than six (6) months or be both so fined and imprisoned.
- b. Impounding. Sources of radiation shall be subject to impounding pursuant to Section 5 of these Regulations.

RH-2111.-

RH-2199. Reserved.