

RH-6010. (Cont'd)

- c. No person shall transfer land for unrestricted use where the concentration of radium-226 or radium-228 in soil averaged over any 100 square meters exceeds the background level by more than:
 1. 5 pCi/g, averaged over the first 15 cm of soil below the surface; and
 2. 15 pCi/g, averaged over 15 cm thick layers of soil more than 15 cm below the surface.
- d. Equipment contaminated with NORM is exempt from the requirements of these ~~Regulations~~ Rules if the maximum radiation exposure level does not exceed 50 microroentgen per hour including background at any accessible point, and radioactive contamination levels do not exceed levels set forth in Appendix A of this Section.
- e. The decontamination of equipment, facilities and land, as described in RH-6020.b. shall only be performed by persons specifically licensed by the Department or another Licensing State to conduct such work.
- f.
 1. The transfer of NORM not exempt from these ~~Regulations~~ Rules from one general licensee to another general licensee may be authorized by the Department if:
 - A. The equipment and facilities containing NORM are to be used by the recipient for the same purpose or at the same site;
 - B. The transfer of control or ownership of land containing NORM includes an annotation of the deed records to indicate the presence and quantity of NORM; or
 - C. The materials being transferred are ores or raw materials for processing or refinement.
 2. Transfers made under RH-6010.f.1. do not relieve the general licensee who makes the transfer from the responsibilities of assessing the extent of NORM contamination or material present, evaluating the hazards of the NORM, informing the general licensee receiving the NORM of these assessments and evaluations, and maintaining records required by these ~~Regulations~~ Rules.

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g. **Storage of NORM and NORM waste from remediation.**

1. A general licensee is authorized to store NORM waste generated during remediation in a container for ninety (90) days from the date of generation. After such time, the NORM waste must be transferred to an authorized facility for the purposes of treatment, storage, or disposal unless otherwise exempted in writing by the Department.
2. To store NORM waste in an approved container for up to one (1) year from generation, a general licensee must first submit a written NORM waste management plan to the Department and receive authorization from the Department. The general licensee may store NORM waste in an approved container up to one (1) year [365 days] from generation under the written NORM waste management plan while waiting for Department determination unless otherwise exempted in writing by the Department.

RH-6011. **Protection of Workers During Operations.** Each person subject to the general license in RH-6010. or a specific license shall conduct operations in compliance with the standards for radiation protection set out in Section 2 and 3, except for releases of radioactivity in effluents, which shall be regulated by RH-6012. and disposal, which shall be governed by RH-6013.

RH-6012. **Protection of the General Population from Releases of Radioactivity.** Each person subject to the general license in RH-6010. or a specific license shall conduct operations such that concentrations of radioactive material which are released to the general environment in groundwater, surface water, air, soil, plants, and animals do not result in an annual dose above the limits specified in RH-1208. and RH-1209. Doses due to radon-220, radon-222, and their respective decay products, are excluded from these limits.

RH-6013. **Disposal and Transfer of Waste for Disposal.**

- a. Each person subject to the general license in RH-6010. or a specific license shall manage and dispose of wastes containing NORM:
 1. In accordance with the applicable requirements of the U.S. Environmental Protection Agency for disposal of such wastes;

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2. By transfer of the wastes for disposal to a land disposal facility licensed by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or
 3. In accordance with alternate methods authorized by the Department upon application or upon the Department's initiative.
- b. Records of disposal, including manifests, shall be maintained pursuant to the provisions of Part E of Section 3, ~~Part E of these Regulations~~.
 - c. Transfers of waste containing NORM for disposal shall be made to a person specifically authorized to receive such waste.

RH-6014. **Containers.**

- a. NORM and NORM waste shall be kept in a container that is in good and safe condition.
- b. The licensee shall use a container made of, or lined with, materials that will not react with, or be incompatible with, the NORM waste to be stored so that the ability of the container to contain the waste is not impaired or compromised.
- c. A container holding NORM waste shall always be closed and sealed during storage, except when it is necessary to add or remove waste.
- d. A container holding NORM waste shall not be opened, handled, or stored in a manner that may rupture the container or cause it to leak.
- e. At least quarterly, the licensee shall inspect areas where containers of NORM waste are stored, looking for leaking or deteriorating containers or containment systems. Records of these inspections shall be made.
- f. All containers of NORM waste shall be stacked in such a manner that each container identification label can be read from the access aisle or area.
- g. Each container of NORM shall be labeled with the following information prior to storage:
 1. Name and address of generator.
 2. Type of material (i.e., sludge, scale, dirt, scrap metal, et cetera).

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3. Date stored.
 4. Microroentgen per hour exposure readings on contact and at one (1) meter. (These exposure readings shall be updated if NORM waste is added to the container.)
 5. Labeled as Radioactive Material.
- h. Records of inspections shall be maintained by the licensee for inspection by the Department for five (5) years.

RH-6015. **Tanks Containing NORM.** The licensee shall develop a schedule and procedure for assessing the condition of each tank containing NORM waste. The schedule and procedure must be adequate to detect cracks, leaks, corrosion and erosion that may lead to cracks, leaks, or wall thinning to less than the required thickness to maintain vessel integrity. Procedures for emptying a tank to allow entry, procedures for personnel protection, and inspection of the interior must be established when necessary to detect corrosion of the tank sides and bottom. The frequency of these inspections will be determined based on the type of NORM material being stored and the tank construction material and the type of erosion/corrosion that may exist.

RH-6016. **Transportation of NORM.** Transportation of NORM contaminated equipment and/or waste shall be subject to the applicable parts of Section 4 of these Regulations and the requirements listed below.

- a. Each shipment of NORM waste and NORM contaminated equipment to a facility specifically licensed for treatment, decontamination, storage, or disposal shall be accompanied by a manifest.
- b. The manifest form must consist of, at a minimum, the number of copies that will provide the licensee, each transporter, and the operator of the designated facility with one (1) copy each for their records with at least one (1) copy signed by all parties involved returned to the generator/shipper for their records.

c. **General requirements.**

1. A licensee who transports, or offers for transportation, NORM waste and/or NORM contaminated equipment to a facility specifically licensed for treatment, decontamination, storage, or disposal must prepare and sign sufficient copies of a manifest before transporting the NORM off-site.
2. A licensee must designate on the manifest one facility which is permitted to handle the NORM described on the manifest.
3. If the transporter is unable to deliver the NORM to the designated facility, the licensee must either designate another facility or instruct the transporter to return the NORM.
4. Licensees must provide a statement concerning the nature of the material and general guidelines for an emergency situation involving this waste to accompany the manifest on shipments and loads.
5. If the NORM is to be transported out-of-state, the licensee will be responsible for receiving the completed signed manifest from the out-of-state treatment, decontamination, storage, or disposal facility.
6. Before initiating the shipment, licensees shall obtain written confirmation of the acceptability of the NORM; NORM contaminated equipment, or NORM waste from the operation of the specifically licensed commercial facility. The confirmation must be maintained with the licensee's manifest records.
7. The licensee receiving the shipment is required to report to the Department and to the licensee initiating the shipment any discrepancies between the NORM actually received by the designated facility and the NORM described on the manifest, or any other irregularities, within fifteen (15) days.

If the designated facility or receiving licensee is located outside the State of Arkansas, the generating or originating licensee must report the irregularities to the Department.

d. **Required information.**

1. The manifest must contain all of the following information prior to leaving the licensee's site:
 - A. The licensee's (generator's) name, mailing address, and telephone number;
 - B. The name, address, and telephone number of each transporter;
 - C. The name, address, telephone number, and NORM specific license number of the designated facility, if applicable;
 - D. The description of the waste(s) [e.g., scale, soil, sludge, et cetera]; and
 - E. The total quantity of all NORM by units of weight in tons or pounds, and the type and number of containers as loaded into or onto the transport vehicle. If the weight is unknown, the volume and estimated weight should be provided.
2. The following certification must appear on the manifest, and must read, and be signed and dated by the licensee as follows:

"I hereby declare that the contents of this consignment are fully and accurately described above by proper shipping name and are classified, packed, marked and labeled, and are in all respects in proper condition for transport according to applicable international and national government regulations."

e. **Use of the manifest.**

1. The licensee must:
 - A. Sign and date the manifest certification by hand when the initial transporter accepts the shipment;
 - B. Obtain a handwritten signature of the initial transporter and date of the acceptance of the manifest; and
 - C. Retain one copy.

2. The licensee must give the transporter the remaining copies of the manifest.
3. The licensee must receive the fully signed copy of the manifest from the designated facility within 45 days from the delivery to the initial transporter. In the event the licensee does not receive the signed manifest, the licensee shall:
 - A. Notify the Department within seven (7) days;
 - B. Conduct an investigation into the reasons why the manifest was not received; and
 - C. Report the results of the investigation to the Department.

f. **Transporters.**

1. A transporter may not accept NORM for transportation unless the NORM is accompanied by sufficient copies of a manifest properly prepared, with each copy signed and dated by the licensee and each previous transporter in accordance with these ~~Regulations~~ Rules.
 2. Before transporting the NORM, the transporter must sign and date each copy of the manifest acknowledging acceptance of the NORM from the licensee or previous transporter and return a signed copy to the licensee or previous transporter.
 3. A transporter who delivers NORM to a designated facility or another transporter must obtain the signature and date of the accepting party and retain one copy of the manifest for their records.
- g. The designated facility should fill out their portion of the manifest, retain a copy for their files, and send all remaining copies to the licensee no later than fifteen (15) days after delivery of the NORM waste or contaminated equipment.

RH-6017. **Radiation Survey and Counting Instrumentation.**

- a. Survey instrumentation used at NORM sites shall consist of, but not be limited to, a minimum of the following:
 1. Instrumentation to determine rates pursuant to this Section shall be capable of measuring 1 microrentgen per hour through at least 500 microrentgen per hour; and
 2. Instrumentation utilized to determine potential contamination, whether wipe tests or airborne, pursuant to this Section shall be able to measure gross alpha (radium-226) and gross beta (radium-228) quantitatively.
- b. Each radiation/contamination survey meter shall be calibrated:
 1. At intervals not to exceed one (1) year, any time the instrument is found to respond inconsistently to a known source or shows any indication of physical damage, and after each instrument servicing;
 2. At energies and radiation levels appropriate for use; and
 3. So that accuracy within plus or minus twenty percent ($\pm 20\%$) of the true radiation level can be demonstrated on each scale.

RH-6018. **Site Surveys and Training.**

This section describes the requirements for confirmatory site release surveys, and the training required before an individual may use survey instruments to release a NORM site or previously NORM contaminated equipment.

- a. **Surveys.**
 1. Upon completion of land remediation operations or equipment decontamination, a confirmatory survey shall be performed to verify that NORM regulated in this Section is not present, and therefore, the land or equipment in question is exempt from the requirements of this Section pursuant to RH-6005.
 2. Any survey submitted to the Department or kept by the specific licensee for review by the Department must include the qualifications of the individual performing the survey. Individuals performing and documenting surveys shall demonstrate understanding of the subjects outlined in RH-6018.b.

b. The following outline describes the subjects that individuals must demonstrate competence in prior to being approved as a NORM surveyor.

1. Fundamentals of Radiation Safety.
 - A. Characteristics of radiation.
 - B. Units of radiation dose and quantity of radioactivity.
 - C. Levels of radiation from sources of radiation.
 - D. Methods of minimizing radiation dose:
 - i. Working time.
 - ii. Working distance.
 - iii. Shielding.
 - iv. Respiratory precautions.
 - v. Use of anti-contamination clothing.
2. Radiation Detection Instrumentation to be Used.
 - A. Use of radiation survey instruments:
 - i. Operation
 - ii. Calibration
 - iii. Limitations
 - B. Survey techniques.
 - C. Use of personnel-monitoring equipment.
3. The Requirements of Pertinent State Regulations.

RH-6019. **Worker Protection Plans.**

A Worker Protection Plan must be submitted to the Department which includes, but may not be limited to, the following items:

- a. **Posting procedures.** How an area will be posted to alert the general public of NORM contamination or NORM storage areas.
- b. **Dosimetry procedures/program.** Including how determination of potential internal dose associated with NORM will be calculated (i.e., bioassay, whole body counting; et cetera).
- c. **Contamination control procedures.** Including:
 1. Personnel exit procedures from a NORM contaminated area (i.e., frisking, et cetera).
 2. Protective clothing requirements depending on the work to be performed.
 3. Instrumentation to be used by the licensee to perform surveys and counting procedures, including manufacturer, model number, type of survey meter or counting instrument, probe type, and ranges of detection as well as calibration certificates.
 4. **Surveying and Counting Procedures** - This section should include the proper procedure for personnel and equipment exit surveys, as well as procedures for land surveys, airborne contamination surveys (air sampling), and counting procedures. This section should also include the licensee's action levels and limits, if more conservative than the Department's outlined in Section 3 or Section 7 of these Regulations.
 5. **Operational Procedures** - This section should encompass any operations that might involve the spread of NORM contamination or the potential for internal dose to the worker and how each operation should be handled.

6. **Respiratory Protection Program** - For operations that have a potential to produce NORM contaminated dusts (i.e., cutting, grinding, sandblasting, welding, drilling, polishing, or handling dry soil) or when loose contamination is suspected, the following additional items should be addressed in the Worker Protection Plan:

The use of a respirator appropriate for radioactive particulates shall be worn or engineering controls should be utilized to prevent the potential airborne contaminants.
 7. **ALARA Procedures** - An explanation of how the licensee will attempt to maintain worker's exposure As Low As Reasonably Achievable with regard to engineering controls and the use of time, distance, and shielding.
- d. **Training Program.** Including but not limited to the following requirements:
1. **NORM Worker** – eight (8) Classroom Hours.
 - A. Fundamentals of Radiation Safety.
 - i. Characteristics of radiation.
 - ii. Units of radiation dose and definitions of radioactivity, including different sources of radioactivity (including NORM).
 - iii. Levels of radiation from different sources of radiation.
 - iv. Methods of minimizing radiation exposure dose.
 - (a). Working time
 - (b). Working distance
 - (c). Shielding
 - (d). Respiratory precautions
 - (e). Use of anti-contamination clothing
 - v. Use and types of personnel-monitoring equipment.

- vi. Personnel exit contamination surveys, including meter operation and surveying techniques.
 - vii. Personnel general decontamination procedures.
 - viii. Biological effects of ionizing radiation (including effects on the embryo or fetus).
 - ix. Risks associated with working with NORM.
 - x. Requirements of pertinent State regulations concerning worker's rights and responsibilities.
2. **Radiation Safety Officer** - 40 classroom hours plus six (6) months on-the-job training.
- A. Fundamentals of Radiation Safety.
 - i. Characteristics of radiation.
 - ii. Units of radiation dose and definitions of radioactivity, including different sources of radioactivity (including NORM).
 - iii. Levels of radiation from different sources of radiation.
 - iv. Methods of minimizing radiation exposure dose.
 - (a). Working time
 - (b). Working distance
 - (c). Shielding
 - (d). Respiratory precautions
 - (e). Use of anti-contamination clothing
 - v. Use and types of personnel-monitoring equipment.
 - vi. Biological effects of ionizing radiation (including the effects on embryo or fetus).

- vii. Risks associated with working with NORM.
 - viii. Requirements of pertinent State regulations concerning worker's rights and responsibilities.
- B. Radiation Detection Instrumentation.
- i. Use of survey instruments.
 - (a). Operation
 - (b). Calibration requirements
 - (c). Limitations
 - ii. Survey techniques.
 - (a). Personnel contamination surveys
 - (b). Equipment surveys
 - (c). Land surveys
 - (d). Documentation and record retention requirements
- C. Use of counting instrumentation for wipes and air sample filter papers.
- D. Personnel decontamination techniques.
- E. Air sampling techniques and equipment.
- F. Shipping requirements for NORM and NORM-contaminated equipment.
- G. Pertinent State regulations.
- H. Six (6) months on-the-job training with a State-qualified third party Radiation Safety Officer or Health Physicist documented.
3. **NORM Field Supervisor** - Forty (40) hours classroom and six (6) months on-the-job training.

- A. Fundamentals of Radiation Safety.
 - i. Characteristics of radiation.
 - ii. Units of radiation dose and definitions of radioactivity, including different sources of radioactivity (including NORM).
 - iii. Levels of radiation from different sources of radiation.
 - iv. Methods of minimizing radiation exposure dose.
 - (a). Working time
 - (b). Working distance
 - (c). Shielding
 - (d). Respiratory precautions
 - (e). Use of anti-contamination clothing
 - v. Use and types of personnel-monitoring equipment.
 - vi. Biological effects of ionizing radiation including meter operation and surveying techniques.
 - vii. Risks associated with working with NORM.
 - viii. Requirements of pertinent State regulations concerning worker's rights and responsibilities.
- B. Radiation Detection Instrumentation.
 - i. Use of survey instruments.
 - (a). Operation
 - (b). Calibration requirements
 - (c). Limitations

- ii. Survey techniques.
 - (a). Personnel contamination surveys
 - (b). Equipment surveys
 - (c). Land surveys
 - (d). Documentation and record retention requirements
- C. Use of counting instrumentation for wipes and air sample filter papers.
- D. Personnel decontamination techniques.
- E. Air sampling techniques and equipment.
- F. Shipping requirements for NORM and NORM-contaminated equipment.
- G. Pertinent State regulations.
- H. Six (6) months on-the-job training with a State-qualified Radiation Safety Officer or Health Physicist documented.

RH-6020. **Specific Licenses.**

- a. Unless otherwise exempted under the provisions of RH-6005, or licensed under the provisions of Section 2 of the Regulations, the manufacturing and distribution of any material or product containing NORM shall be specifically licensed pursuant to the requirements of this Section or pursuant to equivalent regulations of another Licensing State.
- b. Persons conducting the following activities involving equipment or facilities contaminated with NORM in excess of the levels set forth in Appendix A of this Section or land contaminated in excess of the limits set forth in RH-6010. shall be specifically licensed pursuant to the requirements of this Section:
 - 1. Decontamination of equipment, facilities, and land; or
 - 2. Disposal of the resulting waste.

RH-6021. Filing Application for Specific Licenses.

- a. Applications for specific licenses shall be filed in a manner and on a form prescribed by the Department.
- b. The Department may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Department to determine whether the application should be granted or denied or whether a license should be modified or revoked.
- c. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on the licensee's behalf.
- d. An application for a license may include a request for a license authorizing one or more activities.
- e. In an application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Department provided such references are clear and specific.
- f. Applications and documents submitted to the Department may be made available for public inspection except that the Department may withhold any document or part thereof from public inspection if disclosure of its contents is not required in the public interest and would adversely affect the interest of a person concerned.

RH-6022. Requirements for the Issuance of Specific Licenses.

- a. A license application will be approved if the Department determines that:
 1. The applicant is qualified by reason of training and experience to use the NORM in question for the purpose requested in accordance with these rules in such a manner as to minimize danger to public health and safety or property;
 2. The applicant's proposed equipment, facilities, and procedures are adequate to minimize the danger to public health and safety or property;
 3. The issuance of the license will not be inimical to the health and safety of the public;
 4. The applicant satisfies any applicable special requirements in this Section; and

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5. The applicant has met the financial surety requirements of RH-6033.
- b. An application for a specific license to decontaminate equipment and/or facilities contaminated with NORM in excess of the levels set forth in RH-6005.a., RH-6010.c., or Appendix A of this Section, as applicable, and to dispose of the resulting waste will be approved if:
1. The applicant satisfies the general requirements specified in RH-6022.a.; and
 2. The applicant has adequately addressed the following items in the application:
 - A. Procedures and equipment for protection of workers;
 - B. An evaluation of the radiation levels and concentrations of contamination expected during normal operations;
 - C. Operating and emergency procedures, including procedures for waste reduction and quality assurance of items released for unrestricted use; and
 - D. Method of disposing of the NORM removed from contaminated equipment, facilities, and/or land.
- c. An application for a specific license to manufacture and/or initially transfer products or materials containing NORM to persons exempted from these ~~Regulations~~ Rules pursuant to RH-6005.b. will be approved if:
1. The applicant satisfies the general requirements specified in RH-6022.a.;
 2. The NORM is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, human being; and

3. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the NORM material or product to demonstrate that the material or product will meet the safety criteria set forth in RH-6023. The information shall include:
 - A. A description of the material or product and its intended use or uses;
 - B. The type, quantity, and concentration of NORM in each material or product;
 - C. The chemical and physical form of the NORM in the material or product, and changes in chemical and physical form that may occur during the useful life of the material or product;
 - D. An analysis of the solubility in water and body fluids of the NORM in the material or product;
 - E. The details of manufacture and design of the material or product relating to containment and shielding of the NORM and other safety features under normal and severe conditions of handling, storage, use, reuse, and disposal of the material or product;
 - F. The degree of access of human beings to the material or product during normal handling, use, and disposal;
 - G. The total quantity of NORM expected to be distributed annually in the material or product;
 - H. The expected useful life of the material or product;
 - I. The proposed method of labeling or marking each unit of the material or product with identification of the manufacturer and/or initial transferor of the product and the radionuclide(s) and quantity of NORM in the material or product;

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- J. The procedures for prototype testing of the material or product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, reuse, and disposal;
 - K. The results of the prototype testing of the material or product, including any change in the form of the NORM contained in it, the extent to which the NORM may be released to the environment, any change in radiation levels, and any other changes in safety features;
 - L. The estimated external radiation doses and dose commitments relevant to the safety criteria in RH-6023. and the basis for such estimates;
 - M. A determination that the probabilities with respect to doses referred to in RH-6023. meet the safety criteria;
 - N. The quality control procedures to be followed in the production of production lots of the material or product, and the quality control standards the material or product will be required to meet; and
 - O. Any additional information, including experimental studies and tests, required by the Department to facilitate a determination of the radiation safety of the material or product.
- d. Notwithstanding the provisions of RH-6023.b., the Department may deny an application for a specific license if the end uses of the product are frivolous or cannot be reasonably foreseen.

RH-6023. **Safety Criteria.**

An applicant for a license under RH-6022.c. shall demonstrate that the product is designed and will be manufactured so that:

- a. In normal use and disposal, it is unlikely that the external radiation dose in anyone year, or the dose commitment resulting from the intake of NORM, excluding the radon and radon decay products, in any one (1) year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or NORM from the material or product, will exceed the doses in Column I of RH-6024.
- b. In normal handling and storage of the quantities of the material or product likely to accumulate in one location during marketing, distribution, installation, and servicing of the material or product, it is unlikely that the external radiation dose in anyone year, or the dose commitment resulting from the intake of NORM, excluding radon, in any one (1) year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or NORM from the material or product, will exceed the doses in Column II of RH-6024.
- c. In normal use, disposal, handling, and storage, it is unlikely that the radon released from the material or product will result in an increase in the average radon concentration in air of more than 0.4 picocuries per liter.
- d. It is unlikely that a significant reduction will occur in the effectiveness of the containment, shielding, or other safety features of the material or product (from wear and abuse in normal handling and use of the material or product during its useful life).

RH-6024. **Table of Organ Doses.**

Part of Body	Column I* Dose in Rem	Column II* Dose in Rem
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.005	0.5
Hands and forearms; feet and ankles; localized area of skin averaged over areas no larger than 1 square centimeter	0.075	7.5
Other organs	0.015	1.5

*** Dose limit is the dose above background from the product**

RH-6025. **Issuance of Specific Licenses.**

- a. Upon determination that an application meets the requirements of the Act and rules of the Department, the Department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.
- b. The Department may incorporate in any license at the time of issuance, or thereafter by amendment, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of NORM subject to this Section as it deems appropriate or necessary in order to:
 1. Minimize danger to public health and safety or property;
 2. Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and
 3. Prevent loss or theft of NORM subject to this Section.

RH-6026. **Conditions of Specific Licenses Issued Under RH-6022.**

a. **General terms and conditions.**

1. Each specific license issued pursuant to this Section shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, ~~regulations~~, and orders of the Department.
2. No specific license issued or granted under this Section and no right to possess or utilize NORM granted by any license issued pursuant to this Section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Department shall, after securing full information, find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.
3. Each person specifically licensed by the Department pursuant to this Section shall confine use and possession of the NORM licensed to the locations and purposes authorized in the specific license.
4. Each person specifically licensed by the Department pursuant to this Section is subject to the general license provisions of RH-6011., RH-6012., and RH-6013.

5. **Notification of bankruptcy.**

- A. Each licensee shall notify the Department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapters of Title 11 (Bankruptcy) of the United States Code (11 U.S.C.) by or against:
 - i. A licensee;
 - ii. An entity [as that term is defined in 11 U.S.C. 101 (15)] controlling a licensee or listing the license or licensee as property of the estate; or
 - iii. An affiliate [as that term is defined in 11 U.S.C. 101(2)] of the licensee.

- B. This notification must indicate:
 - i. The bankruptcy court in which the petition for bankruptcy was filed; and
 - ii. The date of the filing of the petition.

6. Notification of commencement of activities.

Each licensee shall notify the Department, in writing, at least five (5) days prior to commencing decontamination or remediation activities at a customer's site. If, for a specific case, the five (5) day period would pose an undue hardship on the licensee, the licensee may, upon application to the Department, obtain permission to proceed sooner. The notification shall specify the following:

- A. Type of operation;
- B. Mode of decontamination (if more than one mode is authorized on the license);
- C. Address and physical location of the decontamination or remediation activity;
- D. Dates when the activities will be conducted; and
- E. Name of the person supervising the operations at the site.

7. Notification of completion of activities.

Each licensee shall notify the Department, in writing, within thirty (30) days following completion of NORM decontamination or remediation work. The notification shall specify the following:

- A. Customer name, mailing address, and telephone number;
- B. Quantity of contaminated material generated as a result of the decontamination or remediation process;
- C. Disposition of contaminated material;
- D. Type of container used for storage of the contaminated material; and

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- E. Location and description of where contaminated material is stored. (If a street address is not available, a map must be provided.)

b. **Quality control, labeling, and reports of transfer.**

Each person licensed under RH-6022.c. shall:

1. Carry out adequate control procedures in the manufacture of the material or product to assure that each production lot meets the quality control standards approved by the Department;
2. Label or mark each unit so that the manufacturer, processor, producer, or initial transferor of the material or product and the NORM in the material or product can be identified; and
3. Maintain records identifying, by name and address, each person to whom NORM is transferred for use under RH-6005.b. or the equivalent regulations of another Licensing State, and stating the kinds, quantities, and uses of NORM transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Department. Each report shall cover the year ending December 31, and shall be filed within thirty (30) days thereafter. If no transfers of NORM have been made pursuant to RH-6022.c. during the reporting period, the report shall so indicate.

RH-6027. **Expiration and Termination of Licenses.**

- a. Except as provided in RH-6027.d.3. and RH-6028.b., each specific license shall expire at the end of the specified day in the month and year stated therein.
- b. Each licensee shall notify the Department in writing and request termination of the license when the licensee decides to terminate all activities involving NORM authorized under the license. This notification and request for termination of the license must include the reports and information specified in RH-6027.d.1.D. The licensee is subject to the provisions of RH-6027.d. and e. as applicable.

RH-6027. (Cont'd)

- c. No less than thirty (30) days before the expiration date specified in a specific license, the licensee shall either:
 1. Submit an application for license renewal under RH-6028.; or
 2. Notify the Department in writing, under RH-6027.b. if the licensee decides to discontinue all activities involving NORM.
- d.
 1. If a licensee does not submit an application for license renewal under RH-6028., the licensee shall on or before the expiration date specified in the license:
 - A. Terminate use of NORM;
 - B. Remove NORM contamination to the extent practicable;
 - C. Properly dispose of NORM; and
 - D. Submit a report of disposal of NORM and radiation survey(s) to confirm the absence of NORM or to establish the levels of residual NORM contamination. The licensee shall, as appropriate:
 - i. Report levels of radiation in units of microrads per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces and report levels of radioactivity in units of disintegrations per minute (or microcuries) per 100 square centimeters removable and fixed on surfaces, microcuries per milliliter in water, and picocuries per gram in contaminated solids such as soils or concrete: and
 - ii. Specify the instrument(s) used and certify that each instrument is properly calibrated and tested.
 2. If no radioactivity attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable NORM contamination was found. If the Department determines that the information submitted under RH-6027.d.1.D. and d.2. and is adequate and surveys confirm the findings. The Department will notify the licensee in writing that the license is terminated.

RH-6027.d. (Cont'd)

3. If detectable levels of residual NORM attributable to activities conducted under the license are found, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual NORM until the Department notifies the licensee in writing that the license is terminated. During this time, the licensee is subject to the provisions of RH-6027.e. In addition to the information submitted under RH-6027.d.1.D., the licensee shall submit a plan, if appropriate, for decontaminating the location(s) and disposing of the residual NORM.
- e. Each licensee who possesses residual NORM under RH-6027.d.3., following the expiration date specified in the license, shall:
 1. Be limited to actions involving NORM related to preparing the location(s) for release for unrestricted use; and
 2. Continue to control entry to restricted areas until the location(s) are suitable for release for unrestricted use and the Department notifies the licensee in writing that the license is terminated.

RH-6028. Renewal of Licenses.

- a. Applications for renewal of specific licenses shall be filed in accordance with RH-6021.
- b. In any case in which a licensee, not less than thirty (30) days prior to expiration of an existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the Department.

RH-6029. Amendment of Licenses at Request of Licensee.

Applications for amendment of a license shall be filed in accordance with RH-6021. and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

RH-6030. Department Action on Applications to Renew and Amend.

In considering an application by a licensee to renew or amend the license, the Department will apply the criteria set for in RH-6022.

RH-6031. **Modification and Revocation of Licenses.**

- a. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of rules, ~~regulations~~, and orders issued by the Department.
- b. Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by such application or statements of fact or any report, record, or inspection or other means which would warrant the Department to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rules, ~~regulation~~, or order of the Department.
- c. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefore, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

RH-6032. **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 Naturally Occurring 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-6033. **Financial Assurance and Recordkeeping for Decommissioning.**

Each specific licensee shall be subject to the financial assurance and recordkeeping for decommissioning under RH-409.h. ~~of these Regulations.~~

RH-6034.- RH-6039. Reserved.

PART E.
RECIPROCITY

RH-6040. Reciprocal Recognition of Licenses.

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

- a. The licensing document does not limit the activity authorized by such document to specific installations or locations;
- b. The out-of-state licensee notifies the Department in writing at least five (5) days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the five (5) day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Department, obtain permission to proceed sooner;
- c. The out-of-state licensee complies with all applicable ~~regulations~~ rules of the Department and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable ~~regulations~~ rules of the Department;
- d. The out-of-state licensee supplies such other information as the Department may request; and
- e. The out-of-state licensee shall not transfer or dispose of NORM possessed or used under the general license provided in RH-6040.a. except by transfer to a person:
 1. Specifically licensed by the Department or by another Licensing State to receive such NORM; or
 2. Exempt from the requirements for a license for such NORM under RH-6005.

RH-6041.- RH-6999. Reserved.

APPENDIX A TO SECTION 7
ACCEPTABLE SURFACE CONTAMINATION^a LEVELS FOR NORM

	Average^{b,c,f}	Maximum^{b,d,f}	Removable^{b,c,e,f}
Alpha	5,000 dpm/100 cm ²	15,000 dpm/100 cm ²	1,000 dpm/100 cm ²
Beta-gamma	5,000 dpm /100 cm ²	15,000 dpm/100 cm ²	1,000 dpm /100 cm ²

- ^a Where surface contamination by both alpha and beta-gamma emitting nuclides exists, the limits established for alpha and beta-gamma emitting nuclides should apply independently.
- ^b As used in this table, dpm (disintegrations per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.
- ^c Measurements of average contamination level should not be averaged over more than one square meter. For objects of less surface area, the average should be derived for each object.
- ^d The maximum contamination level applies to an area of not more than 100 cm².
- ^e The amount of removable radioactive material per 100 cm² of surface area should be determined by wiping that area with dry filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of surface area A (where A is less than 100 sq. cm) is determined, the entire surface should be wiped and the contamination level multiplied by 100/A to convert to a “per 100 sq. cm” basis.
- ^f The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 mrad/hr (2 μGy/hr) at one (1) cm and 1.0 mR/hr (10 μGy/hr) at 1 cm, respectively, measured through not more than seven (7) milligrams per square centimeter of total absorber.

SECTION 8.
LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

PART A.
GENERAL

RH-7000. Reserved.

RH-7001. **Purpose and Scope.**

- a. This Section contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This Section also contains radiation safety requirements for operating irradiators. The requirements of this Section are in addition to and not in substitution for other requirements of these ~~Regulations~~ Rules. Nothing in this Section relieves the licensee from complying with other applicable Federal, State and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.
- b. The ~~Regulations~~ rules in this Section apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at one (1) meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this Section.
- c. The ~~Regulations~~ rules in this Section do not apply to self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of material for nondestructive testing purposes), gauging, or open-field (agricultural) irradiation.

RH-7002. **Definitions.**

Act - Act 8 of Second Extraordinary Session of 1961, as amended.

Annually - Either:

1. At intervals not to exceed one (1) year, or
2. Once per year, at about the same time each year (plus or minus one [1] month).

Commencement of construction - Any action defined as “construction” or any other activity at the site of a facility subject to the ~~regulations~~ rules in this Section that has a reasonable nexus to radiological health and safety.

Construction - The installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the ~~regulations~~ rules in this Section that are related to radiological safety or security. The term “construction” does not include:

1. Changes for temporary use of the land for public recreational purposes;
2. Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;
3. Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;
4. Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this part;
5. Excavation;
6. Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;
7. Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);

8. Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or
9. Taking any other action that has no reasonable nexus to radiological health and safety.

Doubly encapsulated sealed source - A sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

Irradiator - A facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (550 rads) per hour exist at one (1) meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

Irradiator operator - An individual who has successfully completed the training and testing described in RH-7051. and is authorized by the terms of the license to operate the irradiator without a supervisor present.

Panoramic dry-source-storage irradiator - An irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

Panoramic irradiator - An irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

Panoramic wet-source-storage irradiator - An irradiator in which the irradiations are done in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

Pool irradiator - Any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

Product conveyor system - A system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

Radiation room - A shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

RH-7002. (Cont'd)

Radiation safety officer - An individual with responsibility for the overall radiation safety program at the facility.

Sealed source - Any radioactive material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the radioactive material.

Seismic area - Any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than ten percent (10%), as designated by the U.S. Geological Survey.

Underwater irradiator - An irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

RH-7003. **Communications.**

Except where otherwise specified, all communications concerning these ~~Regulations~~ Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-7004. Reserved.

RH-7005. **Interpretations.**

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the ~~regulations~~ rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-7006.- RH-7010. Reserved.

**PART B.
LICENSES**

RH-7011. Application for a Specific License.

A person, as defined in RH-1100., shall file an application for a specific license authorizing the use of sealed sources in an irradiator in accordance with RH-403. and RH-404.

RH-7012. Reserved.

RH-7013. Specific Licenses for Irradiators.

The Department will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

- a. The applicant shall satisfy the general requirements specified in RH-404.a.-d. of these Regulations and the requirements contained in this Section.
- b. The application must describe the training provided to irradiator operators including:
 1. Classroom training;
 2. On-the-job or simulator training;
 3. Safety reviews;
 4. Means employed by the applicant to test each operator's understanding of the Department's ~~Regulations~~ rules and licensing requirements and the irradiator operating and emergency procedures; and
 5. Minimum training and experience of personnel who may provide training.
- c. The application must include an outline of the written operating and emergency procedures listed in RH-7053. that describes the radiation safety aspects of the procedure.

RH-7013. (Cont'd)

- d. The application must describe the organizational structure for managing the irradiator, specifically the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.
- e. The application must include a description of the access control systems required by RH-7023., the radiation monitors required by RH-7029., the method of detecting leaking sources required by RH-7059. including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.
- f. If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the Department. The description must include the:
 - 1. Instruments to be used;
 - 2. Methods of performing the analysis; and
 - 3. Pertinent experience of the individual who analyzes the samples.
- g. If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading must be done by an organization specifically authorized by the Department, U.S. Nuclear Regulatory Commission, or an Agreement State to load or unload irradiator sources.
- h. The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by RH-7061.

RH-7014. Reserved.

RH-7015. **Commencement of Construction.**

The applicant may not begin construction of a new irradiator prior to the submission to the Department of both an application for a license for the irradiator and the fee required. As used in this section, the term “construction” includes the construction of any portion of the permanent irradiator structure on the site but does not include: engineering and design work, purchase of a site, site surveys or soil testing, site preparations, site excavation, construction of warehouse or auxiliary structures, and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and having no bearing on the issuance of a license with respect to the requirements of the Act, and rules, ~~regulations~~, and orders issued under the Act.

RH-7016. Reserved.

RH-7017. **Specific Exemptions.**

- a. The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the ~~regulations~~ rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.
- b. Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this Section. The Department will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

RH-7018. Reserved.

RH-7019. **Request for Written Statements.**

- a. After the filing of the original application, the Department may request further information necessary to enable the Department to determine whether the application should be granted or denied.

RH-7019. (Cont'd)

- b. Each license 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 to enable the Department to determine whether the license should be modified, suspended, or revoked.

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PART C.
DESIGN AND PERFORMANCE REQUIREMENTS FOR IRRADIATORS

RH-7020. Reserved.

RH-7021. **Performance Criteria for Sealed Sources.**

- a. **Requirements.** Sealed sources installed after January 1, 1997:
1. Must have a certificate of registration issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or by an Agreement State pursuant to provisions comparable to 10 CFR 32.210;
 2. Must be doubly encapsulated;
 3. Must use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;
 4. Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and
 5. In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in paragraphs b. through g. of this section.
- b. **Temperature.** The test source must be held at -40°C for twenty (20) minutes, 600°C for one (1) hour, and then be subjected to a thermal shock test with a temperature drop from 600°C to 20°C within fifteen (15) seconds.
- c. **Pressure.** The test source must be twice subjected for least five (5) minutes to an external pressure (absolute) of at two (2) million newtons per square meter.
- d. **Impact.** A 2-kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of one (1) meter onto the test source.

RH-7021. (Cont'd)

- e. **Vibration.** The test source must be subjected three (3) times for ten (10) minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of five (5) times the acceleration of gravity. In addition, each test source must be vibrated for thirty (30) minutes at each resonant frequency found.
- f. **Puncture.** A 50-gram weight and pin, 0.30-centimeter pin diameter, must be dropped from a height of one (1) meter onto the test source.
- g. **Bend.** If the length of the source is more than fifteen (15) times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2,000 newtons at its center equidistant from two (2) support cylinders, the distance between which is ten (10) times the minimum cross-sectional dimension of the source.

RH-7022. Reserved.

RH-7023. **Access Control.**

- a. Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The doors and barriers must not prevent any individual in the radiation room from leaving.
- b. In addition, each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert at least one other individual who is onsite of the entry. That individual shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

RH-7023. (Cont'd)

- c. A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels, must activate the alarm described in RH-7023.b. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.
- d. Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.
- e. Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.
- f. Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.
- g. Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must be posted as required by RH-1303.b. Radiation postings for panoramic irradiators must comply with the posting requirements of RH-1303.b., except that signs may be removed, covered, or otherwise made inoperative when the sources are fully shielded.
- h. If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

RH-7023. (Cont'd)

- i. Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to keys to the personnel access barrier. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual (not necessarily onsite) who is prepared to respond or summon assistance.

RH-7024. Reserved.

RH-7025. **Shielding.**

- a. The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 millisievert (2 millirems) per hour at any location thirty (30) centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than twenty (20) centimeters. Areas where the radiation dose rate exceeds 0.02 millisievert (2 millirems) per hour must be locked, roped off, or posted.
- b. The radiation dose at thirty (30) centimeters over the edge of the pool of a pool irradiator may not exceed 0.02 millisievert (2 millirems) per hour when the sources are in fully shielded position.
- c. The radiation dose rate at one (1) meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 0.02 millisievert (2 millirems) per hour and at five (5) centimeters from the shield must not exceed 0.02 millisievert (20 millirems) per hour.

RH-7026. Reserved.

RH-7027. **Fire Protection.**

- a. The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must automatically become fully shielded if a fire is detected.

RH-7027. (Cont'd)

- b. The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

RH-7028. Reserved.

RH-7029. **Radiation Monitors.**

- a. Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.
- b. Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

RH-7030. Reserved.

RH-7031. **Control of Source Movement.**

- a. The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.

RH-7031. (Cont'd)

- b. The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.
- c. The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.
- d. Each control for a panoramic irradiator must be clearly marked as to its function.

RH-7032. Reserved.

RH-7033. **Irradiator Pools.**

- a. For licenses initially issued after January 1, 1997, irradiator pools must either:
 - 1. Have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or
 - 2. Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination.

In either case, the licensee shall have a method to safely store the sources during repairs of the pool.
- b. For licenses initially issued after January 1, 1997, irradiator pools must have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have siphons breakers to prevent the siphoning of pool water.
- c. A means must be provided to replenish water losses from the pool.
- d. A visible indicator must be provided in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.

RH-7033. (Cont'd)

- e. Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of twenty (20) microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.
- f. A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.
- g. If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not exceed 0.02 millisievert (2 millirems) per hour.

RH-7034. Reserved.

RH-7035. **Source Rack Protection.**

If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

RH-7036. Reserved.

RH-7037. **Power Failure.**

- a. If electrical power at a panoramic irradiator is lost for longer than 10 (ten) seconds, the sources must automatically return to the shielded position.
- b. The lock on the door of the radiation room of a panoramic irradiator may not be deactivated by power failure.
- c. During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

RH-7038. Reserved.

RH-7039. **Design Requirements.**

Irradiators whose construction begins after January 1, 1997, must meet the design requirements of this section.

- a. **Shielding.** For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of RH-7025. If the irradiator will use more than 2×10^{17} becquerels (5 million curies) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.
- b. **Foundations.** For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.
- c. **Pool integrity.** For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of RH-7033.b., and that metal components are metallurgically compatible with other components in the pool.
- d. **Water handling system.** For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of RH-7033.e. The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.
- e. **Radiation monitors.** For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by RH-7029.a. The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under RH-7059.b., the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

RH-7039. (Cont'd)

- f. **Source rack.** For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.
- g. **Access control.** For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of RH-7023.
- h. **Fire protection.** For panoramic irradiators, the licensee shall verify that the number, location, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.
- i. **Source return.** For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than ten (10) seconds.
- j. **Seismic.** For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as American Concrete Institute Standard ACI 318-89, “**Building Code Requirements for Reinforced Concrete,**” Chapter 21, “**Special Provisions for Seismic Design,**” or local building codes, if current.
- k. **Wiring.** For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

RH-7040. Reserved.

RH-7041. **Construction Monitoring and Acceptance Testing.**

These requirements must be met for irradiators whose construction begins after January 1, 1997. The requirements must be met prior to loading sources.

- a. **Shielding.** For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.
- b. **Foundations.** For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.
- c. **Pool integrity.** For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of RH-7033.b.
- d. **Water handling system.** For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.
- e. **Radiation monitors.** For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by RH-7029.a. For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet RH-7059.b. For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by RH-7029.b.
- f. **Source rack.** For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in RH-7035. are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.
- g. **Access control.** For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

RH-7041. (Cont'd)

- h. **Fire protection.** For panoramic irradiators, the licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee shall test the operability of the fire extinguishing system.
- i. **Source return.** For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without offsite power.
- j. **Computer systems.** For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if offsite power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.
- k. **Wiring.** For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

RH-7042.- RH-7050. Reserved.

PART D.
RADIATION SAFETY REQUIREMENTS FOR THE
OPERATION OF IRRADIATORS

RH-7051. **Training.**

- a. Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in:
 1. The fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination, units of radiation dose, Department dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator);
 2. The requirements of Section 3 of these Regulations that are relevant to the irradiator;
 3. The operation of the irradiator;
 4. Those operating and emergency procedures listed in RH-7053. that the individual is responsible for performing; and
 5. Case histories of accidents or problems involving irradiators.
- b. Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.
- c. Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

RH-7051. (Cont'd)

- d. The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:
1. Changes in operating and emergency procedures since the last review, if any;
 2. Changes in ~~regulations~~ rules and license conditions since the last review, if any;
 3. Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;
 4. Relevant results of inspections of operator safety performance;
 5. Relevant results of the facility's inspection and maintenance checks; and
 6. A drill to practice an emergency or abnormal event procedure.
- e. The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that Regulations rules, license conditions, and operating and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.
- f. Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in RH-7053. that they are expected to perform or comply with, and their proper response to alarms required in this Section. Tests may be oral.
- g. Individuals who must be prepared to respond to alarms required by RH-7023.b., RH-7023.i., RH-7027.a., RH-7029.a., RH-7029.b., and RH-7059.b. shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.

RH-7052. Reserved.

RH-7053. **Operating and Emergency Procedures.**

- a. The licensee shall have and follow written operating procedures for:
 1. Operation of the irradiator, including entering and leaving the radiation room;
 2. Use of personnel dosimeters;
 3. Surveying the shielding of panoramic irradiators;
 4. Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;
 5. Leak testing of sources;
 6. Inspection and maintenance checks required by RH-7061;
 7. Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and
 8. Inspection of movable shielding required by RH-7023.h., if applicable.
- b. The licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:
 1. Sources stuck in the unshielded position;
 2. Personnel overexposures;
 3. A radiation alarm from the product exit portal monitor or pool monitor;
 4. Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;
 5. A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;
 6. A prolonged loss of electrical power;
 7. A fire alarm or explosion in the radiation room;

8. An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarm area;

RH-7053.b. (Cont'd)

9. Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and

10. The jamming of automatic conveyor systems.

c. The licensee may revise operating and emergency procedures without Department approval only if all of the following conditions are met:

1. The revisions do not reduce the safety of the facility;
2. The revisions are consistent with the outline or summary of procedures submitted with the license application;
3. The revisions have been reviewed and approved by the radiation safety officer; and
4. The users or operators are instructed and tested on the revised procedures before they are put into use.

RH-7054. Reserved.

RH-7055. **Personnel Monitoring.**

- a. Irradiator operators shall wear a personnel dosimeter ~~that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor~~ while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter ~~processor~~ must be ~~accredited for~~ capable of detecting high-energy photons in the normal and accident dose ranges (See RH-1301.a.). Each personnel dosimeter must be assigned to and worn by only one (1) individual. Film badges must be ~~processed~~ replaced at least monthly, and all other personnel dosimeters must be ~~processed~~ replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.
- b. Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements

of this paragraph, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within plus or minus thirty percent ($\pm 30\%$) of the true radiation dose.

RH-7056. Reserved.

RH-7057. **Radiation Surveys.**

- a. A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed three (3) years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.
- b. If the radiation levels specified in RH-7025. are exceeded, the facility must be modified to comply with the requirements in RH-7025.
- c. Portable radiation survey meters must be calibrated at least annually to an accuracy of plus or minus twenty percent ($\pm 20\%$) for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.
- d. Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in Table II-Column 2 or Table III of Appendix G entitled "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage" in Section 3.
- e. Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than 0.05 millirem (0.5 microsievert) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of 0.05 millirem (0.5 microsievert) per hour.

RH-7058. Reserved.

RH-7059. **Detection of Leaking Sources.**

a. Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed six (6) months using a leak test kit or method approved by the Department, U.S. Nuclear Regulatory Commission, or an Agreement State. 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. The test must be capable of detecting the presence of 200 becquerels (0.005 microcurie) of radioactive material and must be performed by a person approved by the Department, U.S. Nuclear Regulatory Commission, or an Agreement State to perform the test.

b. For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that a leak test has been done within six (6) months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours.

If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

RH-7059. (Cont'd)

- c. If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by a Department, U.S. Nuclear Regulatory Commission, or Agreement State licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by a Department, U.S. Nuclear Regulatory Commission, or Agreement State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table II-Column 2 of Appendix G to Section 3. (See RH-601. for reporting requirements.)

RH-7060. Reserved.

RH-7061. **Inspection and Maintenance.**

- a. The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:
 1. Operability of each aspect of the access control system required by RH-7023.
 2. Functioning of the source position indicator required by RH-7031.b.
 3. Operability of the radiation monitor for radioactive contamination in pool water required by RH-7059.b. using a radiation check source, if applicable.

RH-7061.a. (Cont'd)

4. Operability of the over-pool radiation monitor at underwater irradiators as required by RH-7029.b.
 5. Operability of the product exit monitor required by RH-7029.a.
 6. Operability of the emergency source return control required by RH-7031.c.
 7. Leak-tightness of systems through which pool water circulates (visual inspection).
 8. Operability of the heat and smoke detectors and extinguisher system required by RH-7027. (but without turning extinguishers on).
 9. Operability of the means of pool water replenishment required by RH-7033.c.
 10. Operability of the indicators of high and low pool water levels required by RH-7033.d.
 11. Operability of the intrusion alarm required by RH-7023.i., if applicable.
 12. Functioning and wear of the system, mechanisms, and cables used to raise and lower sources.
 13. Condition of the barrier to prevent products from hitting the sources or source mechanism as required by RH-7035.
 14. Amount of water added to the pool to determine if the pool is leaking.
 15. Electrical wiring on required safety systems for radiation damage.
 16. Pool water conductivity measurements and analysis as required by RH-7063.b.
- b. Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

RH-7062. Reserved.

RH-7063. **Pool Water Purity.**

- a. Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below twenty (20) microsiemens per centimeter under norm circumstances. If pool water conductivity rises above twenty (20) microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.
- b. The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below twenty (20) microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

RH-7064. Reserved.

RH-7065. **Attendance During Operation.**

- a. Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present onsite:
 1. Whenever the irradiator is operated using an automatic product conveyor system; and
 2. Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.
- b. At a panoramic irradiator at which static irradiations (no movement of the product) are occurring, a person who has received the training on how to respond to alarms described in RH-7051.g. must be onsite.
- c. At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in RH-7051.f. and RH-7051.g. Static irradiations may be performed without a person present at the facility.

RH-7066. Reserved.

RH-7067. **Entering and Leaving the Radiation Room.**

- a. Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.
- b. Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:
 1. Visually inspect the entire radiation room to verify that no one else is in it; and
 2. Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.
- c. During a power failure, the area around the pool of an under-water irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by RH-7029.b. is operating with backup power.

RH-7068. Reserved.

RH-7069. **Irradiation of Explosive or Flammable Materials.**

- a. Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Department. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.
- b. Irradiation of more than small quantities of flammable material (flash point below 140° F) is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the Department. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed

sources or safety systems and without radiation overexposures of personnel.

RH-7070.- RH-7079. Reserved.

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PART E.
RECORDS AND REPORTS

RH-7080. Reserved.

RH-7081. **Records and Retention Periods.**

The licensee shall maintain the following records at the irradiator for the periods specified.

- a. A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the Department terminates the license for documents not superseded.
- b. The report must include a telephone report within twenty-four (24) hours as described in RH-601.c.1. and a written report within thirty (30) days as described in RH-601.c.2.
- c. Records of the annual evaluations of the safety performance or irradiator operators required by RH-7051.e. for three (3) years after the evaluation.
- d. A copy of the current operating and emergency procedures required by RH-7053. until superseded or the Department terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by RH-7053.c.3. retained for three (3) years from the date of the change.
- e. Evaluations of personnel dosimeters required by RH-7055. until the Department terminates the license
- f. Records of radiation surveys required by RH-7057. for three (3) years from the date of the survey.
- g. Records of radiation survey meter calibrations required by RH-7057. and pool water conductivity meter calibrations required by RH-7063.b. until three (3) years from the date of calibration.
- h. Records of the results of leak tests required by RH-7059.a. and the results of contamination checks required by RH-7059.b. for three (3) years from the date of each test.

RH-7081. (Cont'd)

- i. Records of inspection and maintenance checks required by RH-7061. for three (3) years.
- j. Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for three (3) years after repairs are completed.
- k. Records of the receipt, transfer, and disposal, of all licensed sealed sources as required by Part F and RH-600. of Section 2-of these Regulations.
- l. Records on the design checks required by RH-7039. and the construction control checks as required by RH-7041. until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.
- m. Records related to decommissioning of the irradiator as required by RH-409.h.

RH-7082. Reserved.

RH-7083. **Reports.**

- a. In addition to the reporting requirements in other Sections of these Rules, the licensee shall report the following events if not reported under other Sections of the Department rules:
 - 1. Source stuck in an unshielded position.
 - 2. Any fire or explosion in a radiation room.
 - 3. Damage to the source racks.
 - 4. Failure of the cable or drive mechanism used to move the source racks.
 - 5. Inoperability of the access control system.
 - 6. Detection of radiation source by the product exit monitor.
 - 7. Detection of radioactive contamination attributable to licensed radioactive material.

RH-7083.a. (Cont'd)

8. Structural damage to the pool liner or walls.
 9. Abnormal water loss or leakage from the source storage pool.
 10. Pool water conductivity exceeding 100 microsiemens per centimeter.
- b. The report must include a telephone report within 24 (twenty-four) hours as described in RH-601.c.1. and a written report within thirty (30) days as described in RH-601.c.2.

RH-7084.- RH-7090. Reserved.

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**PART F.
ENFORCEMENT**

RH-7091. Violations.

a. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any ~~regulation~~ rule or order issued thereunder. Any person who willfully violates any provision of the Act or any ~~regulation~~ rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

b. **Impounding.**

Sources of radiation shall be subject to impounding pursuant to Section 5 of these ~~Regulations~~ Rules.

RH-7092.- RH-7999. Reserved.

**SECTION 9.
USE OF RADIONUCLIDES IN THE HEALING ARTS**

**PART A.
GENERAL**

RH-8000. Purpose and Scope.

This Section establishes additional requirements and provisions for the specific use of radionuclides in the healing arts. These requirements and provisions provide for the protection of public health and safety. The requirements and provisions of this Section are in addition to, and not in substitution for, others in these ~~Regulations~~ Rules. The requirements and provisions of these ~~Regulations~~ Rules apply to applicants and licensees subject to this Section unless specifically exempted.

RH-8001. Implementation.

- a. Deleted.
- b. When a requirement in Section 9 differs from the requirement in an existing license condition, the requirement in this Section shall govern.
- c. Any existing license condition that is not affected by a requirement in Section 9 remains in effect until there is a license amendment or license renewal.
- d. If a license condition exempted a licensee from a provision of Section 9 on October 1, 2006, it will continue to exempt a licensee from the corresponding provision in Section 9.
- e. Licensees shall continue to comply with any license condition that requires it to implement procedures required by RH-8633., RH-8643., RH-8644., and RH-8645. until there is a license amendment or renewal that modifies the license condition.

RH-8002. Maintenance of Records.

Each record required by Section 9 must be legible throughout the retention period specified by each Department ~~regulation~~ rule. The record may be the original, a reproduced copy, or a microform provided that the copy or microform is authenticated by authorized personnel and 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 of reproducing 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 shall maintain adequate safeguards against tampering with and loss of records.

RH-8003. U.S. Food and Drug Administration, Federal, and State Requirements.

Nothing in this Section relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs or devices.

RH-8004. Provisions for Research Involving Human Subjects.

A licensee may conduct research involving human subjects using radioactive material provided:

- a. That the research is conducted, funded, supported, or regulated by a Federal Agency, which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its Department license before conducting such research. Both types of licensees shall, at a minimum, obtain prior informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects;
- b. The research involving human subjects authorized in RH-8004.a. shall be conducted using radioactive material authorized for medical use in the license; and
- c. Nothing in RH-8004. relieves licensees from complying with the other requirements in Section 9.

RH-8005. License Required.

- a. A person shall only manufacture, produce, prepare, acquire, receive, possess, use, or transfer radioactive material for medical use in accordance with a specific license issued by the Department, the Nuclear Regulatory Commission, or an Agreement State, or as allowed in RH-8005.b. or RH-8005.c.
- b. An individual may receive, possess, use, or transfer radioactive material in accordance with the ~~regulations~~ rules in Section 9 under the supervision of an authorized user as provided in RH-8306., unless prohibited by license condition.
- c. An individual may prepare unsealed radioactive material for medical use in accordance with the ~~regulations~~ rules in Section 9 under the supervision of an authorized nuclear pharmacist or authorized user as provided in RH-8306., unless prohibited by license condition.

RH-8006. Communications.

Except where otherwise specified, all communications concerning these ~~Regulations~~ Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-8007. Interpretations.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the ~~regulations~~ rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-8008.- RH-8009. Reserved.

RH-8010. Application for License, Amendment, or Renewal.

- a. An application must be signed by the applicant's or licensee's management.

RH-8010. (Cont'd)

- b. An application for a license or renewal of a license for medical use of radioactive material as described in RH-8500., RH-8530., RH-8550., RH-8600., RH-8620., RH-8630., or RH-8670. must be made by:
1. Filing an original ~~and one (1) copy~~ of the “Application for Radioactive Material License” and all appropriate information required by the form;
 2. Submitting procedures required by sections RH-8308., RH-8400., RH-8633., RH-8643., RH-8644., and RH-8645., as applicable; and
 3. Submitting the applicable fee if the application is for a new license. A renewal license application does not require a fee to be paid.
- c. A request for a license amendment must be made by:
1. Submitting an original in letter format;
 2. Submitting procedures required by sections RH-8308., RH-8400., RH-8633., RH-8643., RH-8644., and RH-8645., as applicable; and
 3. Submitting ~~any~~ the applicable fee.
- d. In addition to the requirements in ~~RH-8010.b. and RH-8010.c.~~ paragraphs b. and c. of this section, an application for a license, renewal of a license, or amendment of a license for medical use of radioactive material as described in RH-8670. must also include ~~information regarding any radiation safety aspects of the medical use of the material that is not addressed in Parts A – D of Section 9, as well as any specific information on:~~
1. Any additional aspects of the medical use of the material that are applicable to radiation safety that are not addressed in, or differ from, Parts A through D, M, and N of this Section;
 2. Identification of and commitment to follow the applicable radiation safety program requirements in Parts E through I of this Section that are appropriate for the specific RH-8670. medical use; and
 3. Any additional specific information on:
 - † A. Radiation safety precautions and instructions;

- 2 B. Training and experience of proposed users;
 - 3 C. Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and
 - 4 D. Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.
- e. The applicant or licensee shall also provide any other information requested by the Department in its review of the application.
 - f. An applicant that satisfies the requirements specified in RH-406.b. may apply for a Type A specific license of broad scope.

RH-8011. **License Amendments.**

A licensee shall apply for and must receive a license amendment:

- a. Before it receives, prepares or uses radioactive material for a type of use that is permitted under Section 9, but that is not authorized on the licensee's current license issued pursuant to Section 9;
- b. Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, ~~or~~ authorized medical physicist, or ophthalmic physicist under the license, except:
 - 1. For an authorized user, an individual who meets the requirements in RH-8319. and RH-8510.a., RH-8540.a., RH-8560.a., RH-8570.a., RH-8580.a., RH-8610.a., RH-8621.a., and RH-8660.a.;
 - 2. For an authorized nuclear pharmacist, an individual who meets the requirements in RH-8317.a. and RH-8319.;
 - 3. For an authorized medical physicist, an individual who meets the requirements in RH-8316.a. and c. and RH-8319.;
 - 4. An individual who is identified as an authorized user, an authorized nuclear pharmacist, ~~or~~ authorized medical physicist, or an ophthalmic physicist:
 - A. On a Nuclear Regulatory Commission ~~of~~ or Agreement State license or other equivalent permit or license recognized by the NRC that authorizes the use of ~~by product~~ radioactive material in medical use or in the practice of nuclear pharmacy;

- B. On a permit issued by an NRC or Agreement State specific licensee of broad scope that is authorized to permit the use of ~~byproduct~~ radioactive material in medical use or in the practice of nuclear pharmacy;
- C. On a permit issued by an NRC master material licensee that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy; or
- D. By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

5. Deleted.

- c. Before it changes Radiation Safety Officers, except as provided in RH-8300.c.;

RH-8011. (Cont'd)

- d. Before it receives radioactive material in excess of the amount, or in a different physical or chemical form than is authorized on the license;
- e. Before it adds to or changes the areas of use identified in the application or on the license;
- f. Before it changes the address(es) of use identified in the application or on the license;
- g. Before it changes statements, representations, and procedures which are incorporated into the license; ~~and~~
- h. Before it releases licensed facilities for unrestricted use; and
- i. Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

RH-8012. **Mobile Medical Service Administrative Requirements.**

- a. The Department shall license mobile medical services or clients of such services. The mobile medical service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile

medical service shall be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.

- b. Mobile medical service licensees shall obtain a letter signed by the management of each location where services are rendered that authorizes use of radioactive material at the client's address of use. This letter shall clearly delineate the authority and responsibility of both the client and the mobile medical service. If the client is licensed, the letter shall document procedures for notification, receipt, storage, and documentation of transfer of radioactive material delivered to the client's address for use by the mobile medical service.
- c. A mobile medical service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client, unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.
- d. A mobile medical service shall inform the client's management who is on site at each client's address of use at the time that radioactive material is being administered.
- e. A licensee providing mobile medical services shall retain the letter required in RH-8012.b. in accordance with RH-8711.

RH-8012. (Cont'd)

- f. A mobile medical service licensee shall, at a minimum, maintain the following documents on each mobile unit:
 - 1. The current operating and emergency procedures;
 - 2. A copy of the license;
 - 3. A copy of applicable sections of the Arkansas State Board of Health Rules and Regulations for Control of Sources of Ionizing Radiation.
 - 4. Copies of the letter required by RH-8012.b.;
 - 5. Current calibration records for each survey instrument and diagnostic equipment or dose delivery device in use; and
 - 6. Survey records covering uses associated with the mobile unit during, at a minimum, the preceding thirty (30) calendar days.

- g. A mobile medical service licensee shall maintain all records required by Section 3 and Section 9 ~~of these Regulations~~ at a location within the Department's jurisdiction that is:
 - 1. A single address of use:
 - A. Identified as the records retention location; and
 - B. Staffed at all reasonable hours by individual(s) authorized to provide the Department with access for purposes of inspection; or
 - 2. When no address of use is identified on the license for records retention, the mobile unit:
 - A. Identified in the license; and
 - B. Whose current client's address schedule and location schedule is reported to the Department.

RH-8013. License Issuance.

- a. The Department shall issue a license for the medical use of radioactive material if:
 - 1. The applicant has filed the Application for Radioactive Material License in accordance with the instructions in RH-8010;
 - 2. The applicant has paid any applicable fee;
 - 3. The applicant meets the requirements of Section 2 ~~of these regulations~~; and
 - 4. The Department finds the applicant equipped and committed to observe the safety standards established by the Department in these ~~Regulations~~ Rules for the protection of the public health and safety.
- b. The Department shall issue a license for mobile services if the applicant:
 - 1. Meets the requirements in RH-8013.a.; and

2. Assures that individuals to whom radioactive drugs or radiation from implants containing radioactive material will be administered may be released following treatment in accordance with RH-8420.

RH-8014.- RH-8019. Reserved.

RH-8020. **Notifications.**

- a. ~~A licensee shall provide to the Department a copy of the board certification and the written attestation(s), signed by a preceptor, the Nuclear Regulatory Commission or Agreement State license, the permit issued by an NRC master material licensee, the permit issued by an NRC or Agreement State licensee of broad scope, the permit issued by an NRC master material license broad scope permittee, and for each individual no later than thirty (30) days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under RH-8011.b. For individuals permitted to work under RH-8011.b.4., within the same 30-day time frame, the licensee shall also provide, as appropriate, verification of completion of:~~

- ~~1. Any additional case experience required in RH-8560.b.1.B.vii. for an authorized user under RH-8550.~~
- ~~2. Any additional training required in RH-8660.e. for an authorized user under RH-8630.~~
- ~~3. Any additional training required in RH-8316.c. for an authorized medical physicist.~~

A licensee shall provide to the Department, no later than thirty (30) days after the date that the licensee permits an individual to work under the provisions of RH-8011.b. as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist:

1. A copy of the board certification and, as appropriate, verification of completion of:
 - A. Training for the authorized medical physicist under RH-8316.c.;
 - B. Any additional case experience required in RH-8560.b.1.B.vii. for an authorized user under RH-8550.; or

C. Device specific training in RH-8660.c. for the authorized user under RH-8630.; or

2. A copy of the Nuclear Regulatory Commission or Agreement State license, the permit issued by an NRC master material licensee, the permit issued by an NRC or Agreement State licensee of broad scope, the permit issued by an NRC master material license broad scope permittee, or documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC for each individual whom the licensee permits to work under the provisions of this section.

b. A licensee shall notify the Department by letter no later than thirty (30) days after:

1. An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, an Associate Radiation Safety Officer, ~~or~~ an authorized medical physicist, or ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;

2. The licensee's mailing address changes;

~~3. The licensee's physical address changes;~~

~~4 3.~~ The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in RH-409.b. ~~of these regulations.; or~~

4. The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in RH-8011.i. The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

RH-8021.-RH-8024. Reserved.

RH-8025. **Exemptions Regarding Type A Specific Licenses of Broad Scope.**

A licensee possessing a Type A specific license of broad scope for medical use, issued under RH-406., is exempt from:

- a. The provisions of RH-8010.d. regarding the need to file an amendment to the license for medical uses of radioactive material as described in RH-8670.;
- b. The provisions of RH-8011.b.;
- c. The provisions of RH-8011.e. regarding additions to or changes in the areas of use at the addresses specified in the application or on the license;
- d. The provisions of RH-8020.a.;
- e. The provisions of RH-8020.b.1. for an authorized user, an authorized nuclear pharmacist, ~~or an authorized medical physicist,~~ or an ophthalmic physicist; and

RH-8025. (Cont'd)

- f. The provisions of RH-8310.a.

RH-8026. **Specific Exemptions.**

The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the ~~regulations~~ rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

RH-8027.-RH-8099. Reserved.

**PART B.
DEFINITIONS**

RH- 8100. **Definitions.**

Act – Act 8 of Second Extraordinary Session of 1961, as amended.

Address of use – The building or buildings that are identified on the license and where radioactive material may be received, prepared, used, or stored.

Agreement State – Any state with which the Atomic Energy Commission or the U.S. Nuclear Regulatory Commission has entered into an effective agreement under subsection 274 b. of the Atomic Energy Act of 1954 (68 Stat. 919), including any amendments thereto. Non-agreement State means any other State.

Area of use – A portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing radioactive material.

Associate Radiation Safety Officer means an individual who:

1. Meets the requirements in RH-8315. and RH-8319.; and
2. Is currently identified as an Associate Radiation Safety Officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on:
 - A. A specific medical use license issued by the Nuclear Regulatory Commission or an Agreement State; or
 - B. A medical use permit issued by a Nuclear Regulatory Commission master material licensee.

Authorized medical physicist means an individual who:

1. Meets the requirements in RH-8316.a. and RH-8319.; or
2. Is identified as an authorized medical physicist or teletherapy physicist on:
 - A. A specific medical use license issued by the Nuclear Regulatory Commission or Agreement State;
 - B. A medical use permit issued by a Nuclear Regulatory Commission master material licensee;

- C. A permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; or
- D. A permit issued by a Nuclear Regulatory Commission master material license broad scope medical use committee.

Authorized nuclear pharmacist means a pharmacist who:

- 1. Meets the requirements in RH-8317.a. and RH-8319.; or

RH-8100. (Cont'd)

- 2. Is identified as an authorized nuclear pharmacist on:
 - A. A specific license issued by the Nuclear Regulatory Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;
 - B. A permit issued by a Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;
 - C. A permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or
 - D. A permit issued by a Nuclear Regulatory Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or
- 3. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or
- 4. Is designated as an authorized nuclear pharmacist in accordance with RH-405.1.2.D.

Authorized user means a physician, dentist, or podiatrist who:

- 1. Meets the requirements in RH-8319. and RH-8510.a., RH-8540.a., RH-8560.a., RH-8570.a., RH-8580.a., RH-8610.a., RH-8615.a., RH-8621.a., or RH-8660.a.; or

2. Is identified as an authorized user on:
 - A. A Nuclear Regulatory Commission or Agreement State license that authorizes the medical use of radioactive material;
 - B. A permit issued by a Nuclear Regulatory Commission master material licensee that is authorized to permit the medical use of radioactive material;
 - C. A permit issued by a Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

RH-8100. (Cont'd)

- D. A permit issued by a Nuclear Regulatory Commission master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

Brachytherapy – A method of radiation therapy on which plated, embedded, activated, or sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal or interstitial application.

Brachytherapy source – A radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

Client's address (as used in this Section) – The address of use or a temporary jobsite for the purpose of providing mobile medical service in accordance with RH-8425.

Cyclotron – A particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

Dedicated check source – A radioactive source that is used to assure the consistent response of a radiation detection or measurement device over several months or years.

Dentist – An individual licensed to practice dentistry by the state in which the Department is located.

Diagnostic clinical procedures manual – A collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration, or in the case of sealed sources for diagnosis, the procedure.

High dose-rate remote afterloader – A brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Low dose-rate remote afterloader – A brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

RH-8100. (Cont'd)

Management – The chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

Manual brachytherapy – A type of therapy in which brachytherapy sources are manually applied or inserted.

Medical institution – An organization in which several medical disciplines are practiced.

Medical use – The intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

Medium dose-rate remote afterloader – A brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads) per hour, but less than or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Misadministration – An event that meets the criteria in RH-8800.a. or b.

Mobile medical service – The transportation of radioactive material or its medical use at the client's address.

Ophthalmic physicist means an individual who:

1. Meets the requirements in RH-8608.a.2. and RH-8319; and
2. Is identified as an ophthalmic physicist on a:

- A. Specific medical use license issued by the Nuclear Regulatory Commission or an Agreement State;
- B. Permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee;
- C. Medical use permit issued by a Nuclear Regulatory Commission master material licensee; or
- D. Permit issued by a Nuclear Regulatory Commission master material licensee broad scope medical use permittee.

Output – The exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source, or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

Patient intervention – Actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

Pharmacist (as used in this Section) – An individual licensed by the appropriate authority to practice pharmacy in the state in which the Department is located.

Physician – A doctor of medicine or doctor of osteopathy licensed by the Arkansas State Medical Board to prescribe drugs in the practice of medicine.

Podiatrist – An individual licensed by the appropriate authority to practice podiatry in the state in which the Department is located.

Positron Emission Tomography (PET) radionuclide production facility – A facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

RH-8100. (Cont'd)

Preceptor – An individual who provides, directs, or verifies the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, ~~or~~ a Radiation Safety Officer, or an Associate Radiation Safety Officer.

Prescribed dosage – the specified activity or range of activity of a radioactive drug as documented:

1. In a written directive as specified in RH-8307; or

2. In accordance with the directions of the authorized user for procedures performed pursuant to RH-8500. and RH-8530.

Prescribed dose:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
2. For teletherapy, the total dose and dose per fraction as documented in the written directive;
3. For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or
4. For remote brachytherapy, the total dose and dose per fraction as documented in the written directive.

Pulsed dose-rate remote afterloader – A special type of remote afterloading device that uses a single source capable of delivering dose rates in the “high dose-rate” range, but:

1. Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and
2. Is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

Radiation Safety Officer means an individual who:

1. Meets the requirements in RH-8315.a. or RH-8315.c.1. and RH-8319.; or

RH-8100. (Cont'd)

2. Is identified as a Radiation Safety Officer on:
 - A. A specific medical use license issued by the Nuclear Regulatory Commission or Agreement State; or
 - B. A medical use permit issued by a Nuclear Regulatory Commission master material licensee.

Radioactive drug – Any chemical compound containing radioactive material that may be used on or administered to patients or human research subjects as an aid in the diagnosis, treatment, or prevention of disease or other abnormal condition.

Sealed source (as used in this Section) – Any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

Sealed Source and Device Registry – The national registry that contains all the registration certificates, generated by both the Nuclear Regulatory Commission and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

Stereotactic radiosurgery – The use of external radiation in conjunction with a stereotactic guidance device to precisely deliver a dose to a treatment site.

Structured educational program – An educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

Teletherapy (as used in this Section) – A method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

Temporary jobsite (as used in this Section) – A location where mobile medical services are conducted other than the location(s) of use authorized on the license.

Therapeutic dosage – A dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

Therapeutic dose – A radiation dose delivered from a sealed source containing radioactive material to a patient or human research subject for palliative or curative treatment.

RH-8100. (Cont'd)

Treatment site – The anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

Type of use – Use of radioactive material as specified under RH-8500., RH-8530., RH-8550., RH-8600., RH-8620., RH-8630., or RH-8670.

Unit dosage – A dosage that:

1. Is obtained or prepared in accordance with the ~~regulations~~ rules for uses described in RH-8500., RH-8530., or RH-8550.; and
2. Is to be administered as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

Written directive – An authorized user’s written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in RH-8307.

RH-8101.- RH-8299. Reserved.

DRAFT

PART C.
GENERAL ADMINISTRATIVE REQUIREMENTS

RH-8300. Authority and Responsibilities for the Radiation Protection Program.

- a. In addition to the radiation protection program requirements of RH-1004. ~~of these regulations~~, a licensee's management must approve in writing:
1. Requests for license application, renewal, or amendments before submittal to the Department;
 2. Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist; and
 3. Radiation protection program changes that do not require a license amendment and are permitted under RH-8301.
- b. A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.
- c. For up to sixty (60) days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in ~~RH-8300.e. paragraph e. of this section~~, provided the licensee takes the actions required in ~~RH-8300.b., d., e., and h. paragraphs b., d., e., and h. of this section~~. A licensee may simultaneously appoint more than one (1) temporary RSO, if needed, to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different uses of radioactive material permitted by the license.

- d. A licensee shall establish ~~in writing~~ the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

RH-8300. (Cont'd)

- e. A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:
 - 1. Identify radiation safety problems;
 - 2. Initiate, recommend, or provide corrective actions;
 - 3. Stop unsafe operations; and,
 - 4. Verify implementation of corrective actions.
- f. Medical institutions that are authorized for radioactive material use under RH-8500., RH-8530., RH-8550., RH-8600., RH-8620., RH-8630., and RH-8670. shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license.
- g. The Committee shall:
 - 1. Include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members as the licensee deems appropriate;
 - 2. Meet as necessary, but at a minimum shall meet at intervals not to exceed six (6) months; and
 - 3. Maintain minutes of each meeting in accordance with RH-8700.
- h. A licensee shall retain a record of actions taken pursuant to ~~RH 8300.a., RH 8300.b. and RH 8300.d.~~ paragraphs a., b., and d. of this section in accordance with RH-8700.

RH-8301. **Radiation Protection Program Changes.**

- a. A licensee may revise its radiation protection program without Department approval if:
 - 1. The revision does not require an amendment under RH-8011.;
 - 2. The revision is in compliance with the ~~regulations~~ rules and the license;

RH-8301.a. (Cont'd)

- 3. The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee (if applicable); and
 - 4. The affected individuals are instructed on the revised program before the changes are implemented.
- b. A licensee shall retain a record of each change in accordance with RH-8701.

RH-8302.- RH-8304. Reserved.

RH-8305. **Duties of Authorized User and Authorized Medical Physicist.**

- a. A licensee shall assure that only authorized users for the type of radioactive material used:
 - 1. Prescribe the radiopharmaceutical dosage and/or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual; and
 - 2. Direct, as specified in RH-8306. and RH-8307., or in license conditions, the administration of radioactive material for medical use to patients or human research subjects;
 - 3. Prepare and administer, or supervise the preparation and administration of radioactive material for medical use, in accordance with RH-8005.b., RH-8005.c., and RH-8306.;

- b. A licensee shall assure that only authorized medical physicists perform, as applicable:
 - 1. Full calibration measurements as described in RH-8640., RH-8641., and RH-8642.;
 - 2. Periodic spot checks as described in RH-8643., RH-8644., and RH-8645.; and
 - 3. Radiation surveys as described in RH-8650.

RH-8306. **Supervision.**

- a. A licensee that permits the ~~receipts~~ receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by RH-8005.b. shall:
 - 1. In addition to the requirements in RH-2803. ~~of these regulations~~, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, ~~regulations~~ rules of Section 9, and license conditions with respect to the use of radioactive material; and
 - 2. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, ~~regulations~~ rules of Section 9, and license conditions with respect to the medical use of radioactive material.
- b. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by RH-8005.c., shall:
 - 1. Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and
 - 2. Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures, the ~~regulations~~ rules of Section 9, and license conditions.

- c. Unless physical presence as described in other sections of Section 9 is required, a licensee who permits supervised activities under RH-8306.a. and RH-8306.b. shall require an authorized user to be immediately available (by telephone within ten (10) minutes) to communicate with the supervised individual, and able to be physically present within one (1) hour of notification; and
- d. A licensee that permits supervised activities under RH-8306.a. and RH-8306.b. is responsible for the acts and omissions of the supervised individual.

RH-8307. **Written Directives.**

- a. A written directive must be dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 megabecquerels (30 μ Ci), any therapeutic dosage of radioactive material or any therapeutic dose of radiation from radioactive material.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented as soon as possible in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.

- b. The written directive must contain the patient or human research subject's name and the following:
 1. For any administration of quantities greater than 1.11 megabecquerels (30 μ Ci) of I-131 sodium iodide, the dosage;
 2. For an administration of a therapeutic dosage of radioactive drug containing radioactive material other than I-131 sodium iodide, the radioactive drug containing radioactive material, dosage, and route of administration;
 3. For gamma stereotactic radiosurgery, the total dose, treatment site, and number of values for the target coordinate settings per treatment for each anatomically distinct treatment site;
 4. For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;

- 4 5. For high dose-rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
6. For permanent implant brachytherapy:
- A. Prior to implantation: the treatment site, radionuclide, and total source strength; and
- B. After implantation but before the patient leaves the post-treatment recovery area: the treatment site, number of sources implanted, total source strength implanted, and the date; or
- 5 7. For all other brachytherapy, including ~~LDR, MDR, and PDR~~ low, medium, and pulsed dose-rate remote afterloaders:
- A. Prior to implantation: the treatment site, ~~the~~ radionuclide, and the dose; and
- B. After implantation but prior to completion of the procedure: ~~the radioisotope~~ radionuclide, treatment site, number of sources, ~~and~~ total source strength and exposure time (or, the total dose), and the date.

RH-8307. (Cont'd)

- c. A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

- d. The licensee shall retain the written directive in accordance with RH-8702.

RH-8308. **Procedures for Administrations Requiring a Written Directive.**

- a. For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:
 1. The patient's or human research subject's identity is verified before each administration; and
 2. Each administration is in accordance with the written directive.
- b. The procedures required by ~~RH-8308.a.~~ paragraph a. of this section must, at a minimum, address the following items that are applicable ~~for~~ to the licensee's use of radioactive material:
 1. Verifying the identity of the patient or human research subject;
 2. Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;
 3. Checking both manual and computer-generated dose calculations; ~~and~~
 4. Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by RH-8630 or RH-8670.;
 5. Determining if a misadministration, as defined in RH-8800., has occurred; and
 6. Determining, for permanent implant brachytherapy, within sixty (60) calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.
- c. A licensee shall retain a copy of the procedures required under paragraph a. of this section for the duration of the license.

RH-8309. Reserved.

RH-8310. **Suppliers for Sealed Sources or Devices for Medical Use.**

For medical use, a licensee ~~may~~ shall only use:

- a. Sealed sources or devices ~~initially~~ manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to Section 2 ~~of these regulations~~ or the equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; ~~or~~
- b. Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to Section 2 ~~of these regulations~~ or the equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; or
- c. Sealed sources or devices non-commercially transferred from a Section 9 licensee or a Nuclear Regulatory Commission ~~Part 35 licensee~~ or an Agreement State medical use licensee.

RH-8311.- RH-8314. Reserved.

RH-8315. Training for Radiation Safety Officer.

Except as provided in RH-8318., the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer or an individual assigned duties and tasks as an Associate Radiation Safety Officer as provided in RH-8300. to be an individual who:

- a. Is certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraphs ~~(d) and (e) of RH 8315 d. of this section.~~ ~~(The names of board certifications which that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be are posted on the NRC's Web page Medical Uses Licensee Toolkit web page.)~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:
 - 1. A. Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

RH-8315.a.1. (Cont'd)

- B. Have five (5) or more years of professional experience in health physics (graduate training may be substituted for no more than two (2) years of the required experience)

including at least three (3) years in applied health physics;
and

- C. Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or
- 2.
- A. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
 - B. Have two (2) years of full-time practical training and/or supervised experience in medical physics:
 - i. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Nuclear Regulatory Commission or an Agreement State; or
 - ii. In clinical nuclear medicine facilities providing diagnostic ~~and/or~~ therapeutic services under the direction of physicians who meet the requirements for authorized users in RH-8318., RH-8540., or RH-8560.; and
 - iii. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or
- b.
- 1. Has completed a structured educational program consisting of both:
 - A. 200 hours of classroom and laboratory training in the following areas:
 - i. Radiation physics and instrumentation;
 - ii. Radiation protection;

RH-8315.b.1.A. (Cont'd)

- iii. Mathematics pertaining to the use and measurement of radioactivity;
- iv. Radiation biology; and
- v. Radiation dosimetry; and

B. One (1) year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Nuclear Regulatory Commission or Agreement State license or permit issued by a Nuclear Regulatory Commission master material licensee that authorizes similar type(s) of use(s) of radioactive material ~~involving the following:~~ An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a Nuclear Regulatory Commission or an Agreement State license or permit issued by a Nuclear Regulatory Commission master material licensee. The full-time radiation safety experience must involve the following:

- i. Shipping, receiving, and performing related radiation surveys;
- ii. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
- iii. Securing and controlling radioactive material;
- iv. Using administrative controls to avoid mistakes in the administration of radioactive material;
- v. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
- vi. Using emergency procedures to control radioactive material; and
- vii. Disposing of radioactive material; ~~or~~ and

2. ~~Reserved.~~ This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects

of similar types of use of radioactive material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in paragraphs b.1. and d. of this section and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

RH-8315. (Cont'd)

- c. 1. Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under RH-8316.a., ~~and~~ has experience ~~in~~ with the radiation safety aspects for of similar types of use of radioactive material for which the licensee ~~is seeking~~ seeks the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer, and ~~who~~ meets the requirements in paragraphs ~~d. and e. of RH-8315. d. of this section;~~ d. of this section; or
2. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on ~~the licensee's license~~ a Nuclear Regulatory Commission or an Agreement State license, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or an Agreement State licensee of broad scope, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee, ~~and~~ has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as Radiation Safety Officer responsibilities as the Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements in paragraph d. of this section; and or
3. Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use license or new medical use permit issued by a Nuclear Regulatory Commission master material licensee. The individual must also meet the requirements in paragraph d. of this section.
- d. ~~Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph e. and in paragraphs a.1.A. and a.1.B. or a.2.A. and a.2.B. or~~

~~b.1. or c.1 or c.2 of RH-8315., and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and~~

- e d. Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, an Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

RH-8316. **Training for Authorized Medical Physicist.**

Except as provided in RH-8318., the licensee shall require the authorized medical physicist to be an individual who:

- a. Is certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraphs ~~b.2. and c. of RH-8316 c.~~ of this section. ~~(The names of board certifications which that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be are posted on the NRC's Web page Medical Uses Licensee Toolkit webpage.)~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:
1. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;
 2. Have two (2) years of full-time practical training and/or supervised experience in medical physics:
 - A. Under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under this section by the Nuclear Regulatory eCommission or an Agreement State; or
 - B. In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to one (1) million electron volts) and brachytherapy services under the direction of physicians who meet the requirements in RH-8318., RH-8610., or RH-8660.; and

3. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

RH-8316. (Cont'd)

- b.
 1. Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one (1) year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization.

This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to one (1) million electron volts) and brachytherapy services and must include:

- A. Performing sealed source leak tests and inventories;
 - B. Performing decay corrections;
 - C. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
 - D. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
2. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs ~~e. and a.1. and a.2., or b.1. and c. of RH-8316. this section;~~ and has achieved a level of competency sufficient to function independently is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in RH-8316., RH-8318., or equivalent Nuclear Regulatory

Commission or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; ~~and.~~

RH-8316. (Cont'd)

- c. Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

RH-8317. **Training for Authorized Nuclear Pharmacist.**

Except as provided in RH-8318, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

- a. Is certified by a specialty board whose certification process has been recognized by ~~the Department, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph b.2. of RH-8317.~~ ~~(The names of board certifications which that have been recognized by the Department, U.S. Nuclear Regulatory Commission or an Agreement State will be are posted on the NRC's Web page Medical Uses Licensee Toolkit web page.)~~ To have its certification process recognized, a specialty board shall require all candidates for certification to:
 - 1. Have graduated from a pharmacy program accredited by the American Accreditation Council on for Pharmaceutical Pharmacy Education (ACPE) (previously named the American Council on Pharmaceutical Education) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;
 - 2. Hold a current, active license to practice pharmacy;
 - 3. Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic

training may be substituted for no more than 2000 hours of the required training and experience; and

4. Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

RH-8317. (Cont'd)

- b.
 1. Has completed 700 hours in a structured educational program consisting of both:
 - A. 200 hours of classroom and laboratory training in the following areas:
 - i. Radiation physics and instrumentation;
 - ii. Radiation protection;
 - iii. Mathematics pertaining to the use and measurement of radioactivity;
 - iv. Chemistry of radioactive material for medical use; and
 - v. Radiation biology; and
 - B. Supervised practical experience in a nuclear pharmacy involving:
 - i. Shipping, receiving, and performing related radiation surveys;
 - ii. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha-or beta-emitting radionuclides;
 - iii. Calculating, assaying, and safely preparing dosages for patients or human research subjects;

- iv. Using administrative controls to avoid ~~medical events~~ misadministrations in the administration of radioactive material; and
- v. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

RH-8317.b. (Cont'd)

- 2. Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraphs ~~a.1, a.2., and a.3. or b.1.~~ of RH-8317. this section and has achieved a level of competency sufficient to function independently is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

RH-8318. **Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist.**

- a.
 - ~~1. An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Nuclear Regulatory Commission or Agreement State license or a permit issued by a Nuclear Regulatory Commission or Agreement State board scope licensee or master material license permit or by a master material license permittee of broad scope before October 1, 2006, need not comply with the training requirements of RH 8315., RH 8316., or RH 8317., respectively.~~
 - ~~2. An individual identified as a Radiation Safety Officer, an authorized medical physicist, or an authorized nuclear pharmacist on a Nuclear Regulatory Commission or Agreement State license or a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope between October 1, 2006 and October 1, 2012 need not comply with the training requirements of RH 8315., RH 8316., or RH 8317., respectively.~~

1. An individual identified on a Nuclear Regulatory Commission or an Agreement State license or a permit issued by a Nuclear Regulatory Commission or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before January 14, 2019, need not comply with the training requirements of RH-8315., RH-8316., or RH-8317., respectively, except the Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training requirements in RH-8315.d. or RH-8316.c., as appropriate, for any material or uses for which they were not authorized prior to this date.
2. Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of RH-8315. to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on a Nuclear Regulatory Commission or an Agreement State license or Nuclear Regulatory Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.
3. Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in RH-8316., for those materials and uses that these individuals performed on or before October 24, 2005.

RH-8318.a. (Cont'd)

- 3.4. A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or

Federally recognized Indian Tribe before November 30, ~~2007~~ 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of RH-8315., RH-8316, or RH-8317., respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of Section 9, "Use of Radionuclides in the Healing Arts." ~~these Rules.~~

- b. 1. Physicians, dentist, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee on or before October 1, 2006 January 14, 2019, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of RH-8510., RH-8540., RH-8560., RH-8570., RH-8580., RH-8590., RH-8610., RH-8615., RH-8621., and RH-8660. (Parts E through I of this Section).
2. Physicians, dentist, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or an Agreement State board scope licensee, or a permit issued by in accordance with a Nuclear Regulatory Commission master material broad scope license ~~broad scope permittee who perform only those medical uses for which they were authorized between October 1, 2006 and October 1, 2012~~ on or before October 24, 2005, need not comply with the training requirements of of RH-8510., RH-8540., RH-8560., RH-8570., RH-8580., RH-8590., RH-8610., RH-8615., RH-8621., and RH-8660. (Parts E through I of this Section) for those materials and uses that these individuals performed on or before October 24, 2005, as follows:-

- A. For uses authorized under RH-8500. or RH-8530., or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;
- B. For uses authorized under RH-8550., a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;
- C. For uses authorized under RH-8600. or RH-8630., a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and
- D. For uses authorized under RH-8620., a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.
3. Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training

requirements of RH-8510., RH-8540., RH-8560., RH-8570., RH-8580., RH-8590., RH-8610., RH-8615., RH-8621., and RH-8660. (Parts E through I of this Section) when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of these Rules.

RH-8318. (Cont'd)

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

RH-8319. **Recentness of Training.**

The training and experience specified in Section 9's Part C (General Administrative Requirements), Part E (Unsealed Radioactive Material – Written Directive Not Required), Part F (Unsealed Radioactive Material – Written Directive Required), Part G (Manual Brachytherapy), Part H (Sealed Sources for Diagnosis), and Part I (Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units) must have been obtained within the seven (7) years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

RH-8320.-RH-8399. Reserved.

**PART D:
GENERAL TECHNICAL REQUIREMENTS**

RH-8400. Quality Control of Diagnostic Equipment.

Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers or ~~procedures, which have been~~ approved by the Department. The licensee shall conduct quality control procedures in accordance with written procedures. Each licensee shall retain records of quality control of diagnostic equipment for three (3) years after the record is made.

RH-8401. Possession, Use, Checking, and Testing of Instruments Used to Measure the Activity of Unsealed Radioactive Material.

- a. For direct measurements performed in accordance with RH-8403., a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive material prior to administration to each patient or human research subject.
- b. A licensee shall:
 1. Check each instrument for constancy with a dedicated check source before use each day of use. The check shall be performed on a frequently used setting with a sealed source of not less than 50 microcuries (1.85 MBq) of any photon-emitting radionuclide with a half-life greater than 90 days.
 2. Test each instrument for accuracy at the time of installation and at least every 12 months thereafter. The test shall be completed by assaying at least two sealed sources containing different radionuclides, the activity of which has been determined by the National Institute of Standards and Technology (NIST) or by the manufacturer who has compared their source to a source calibrated by the NIST. The sources shall have a minimum activity of 50 microcuries (1.85 MBq) of any photon-emitting radionuclide. At least one of the sources shall have a principal photon energy between 100 keV and 500 keV.
 3. Test each instrument for linearity at the time of installation and at least every three months thereafter over the range of its use between the highest and lowest dosage that will be administered.

RH-8401.b. (Cont'd)

4. Test each instrument for geometry dependence at the time of installation over the range of volumes and volume configurations for which it will be used.
- c. A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds manufacturer's instructions, not to exceed ten percent (10%), if the dosage is greater than 30 microcuries (1.11 MBq) and shall repair or replace the instrument if the accuracy or constancy error exceeds manufacturer's instructions, not to exceed ten percent (10%).
- d. Prior to medical use, a licensee shall also perform checks and tests required by RH-8401. following adjustment, repair, or relocation of the instrument.
- e. Quality control methods not in accordance with RH-8401. must be authorized by the Department prior to use.
- f. A licensee shall retain a record of each instrument check or test required by RH-8401. in accordance with RH-8705.

RH-8402. **Calibration of Survey Instruments.**

- a. A licensee shall ensure that the survey instruments used to show compliance with Section 9 and Section 3 ~~of these regulations~~ have been calibrated before first use, annually, and following any repair that will affect the calibration.
- b. To satisfy the requirements of RH-8402.a., the licensee shall:
 1. Calibrate all required scale readings up to ten (10) millisieverts (1000 mrem) per hour with a radiation source;
 2. Have each radiation survey instrument calibrated:
 - A. At energies appropriate for use and at intervals not to exceed twelve (12) months or after instrument servicing, except for battery changes;

RH-8402.b.2. (Cont'd)

- B. For linear scale instruments, at two (2) points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two (2) points of at least one (1) decade; and for digital instruments, at three (3) points between 0.02 and 10 millisieverts (2 and 1000 mrem) per hour; and
 - C. For dose rate instruments, so that an accuracy within plus or minus twenty percent ($\pm 20\%$) of the true radiation dose rate can be demonstrated at each point checked.
3. Conspicuously note on the instrument the date of calibration.
- c. The licensee shall not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is greater than twenty percent (20%).
 - d. A licensee shall check each survey instrument for consistent response with a dedicated check source before each use. The licensee is not required to keep records of these checks.
 - e. The licensee shall retain a record of each survey instrument calibration in accordance with RH-8706.

RH-8403. **Determination of Dosages of Radioactive Material for Medical Use.**

- a. A licensee shall determine and record the activity of each dosage prior to medical use.
- b. For all radionuclides, this determination must be made by direct measurement.
- c. Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than twenty percent (20%).
- d. Dosage determination methods other than by direct measurement must be authorized by the Department prior to use.

- e. A licensee shall retain a record of the dosage determination required by Section 9 in accordance with RH-8707.

RH-8404. **Authorization for Calibration, Transmission, and Reference Sources.**

- a. Any person authorized by RH-8005. for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, transmission, and reference use:
1. Sealed sources, not exceeding 1.11 gigabecquerels (30 mCi) each, manufactured and distributed by a persons person specifically licensed pursuant to Part C of these regulations under RH-405.n. or equivalent provisions of the Nuclear Regulatory Commission or Agreement State regulations and that do not exceed 1.11 gigabecquerels (30 mCi) each;
 2. Sealed sources, not exceeding 1.11 gigabecquerels (30 mCi each), redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under RH-405.n. or equivalent Nuclear Regulatory Commission or Agreement State regulations, provided the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;
 3. Any radioactive material with a half-life of 120 days or less in individual amounts not to exceed ~~555 megabecquerels~~ 0.56 gigabecquerels (15 mCi);
 4. Any radioactive material with a half-life greater than 120 days in individual amounts not to exceed the smaller of:
 - A. 7.4 megabecquerels (200 µCi); or
 - B. 1000 times the quantities in Schedule B ~~of~~ to Section 2 (RH-901) ~~of these regulations; and or~~
 5. Technetium-99m in amounts as needed.
- b. Radioactive material in sealed sources authorized by this section shall not be:
1. Used for medical use as defined in RH-8100. except in accordance with the requirements in RH-8620.; or

2. Combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this section.

c. A licensee using calibration, transmission, and reference sources in accordance with the requirements in paragraph a. or b. of this section need not list these sources on a specific medical use license.

RH-8405. Requirements for Possession of Sealed Sources and Brachytherapy Sources.

a. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Department.

b. A licensee in possession of a sealed source shall:

1. Test the source for leakage in accordance with Section 3 ~~of these regulations.~~

2. Test the source for leakage at intervals not to exceed six (6) months or at other intervals approved by the Department, an Agreement State or the Nuclear Regulatory Commission in the Sealed Source and Device Registry.

RH-8405. (Cont'd)

c. The leak test shall be capable of detecting the presence of 185 becquerels (0.005 μCi) of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which contamination might be expected to accumulate. Records of the leak test results shall be kept in units of microcuries and maintained for inspection by the Department.

d. If the leak test reveals the presence of 185 becquerels (0.005 μCi) or more of removable contamination, the licensee shall:

1. Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements of Sections 2 and 3 ~~of these regulations;~~

2. File a report with the Department within five (5) days of receiving the leak tests results in accordance with RH-8802.
- e. A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotactic radiosurgery sources, shall conduct a quarterly physical inventory of all such sources. The licensee shall retain each inventory record in accordance with RH-8708.

RH-8406. Labels.

Each syringe and vial that contains a radioactive drug shall be labeled to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

RH-8407. Vial Shields.

A licensee shall require each individual preparing or handling a vial that contains a radioactive drug to keep the vial in a vial radiation shield.

RH-8408. Surveys for Ambient Radiation Dose Rate and Contamination.

- a. Except as provided in RH-8408.b., a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive drugs containing radioactive material were prepared for use or administered.

RH-8408. (Cont'd)

- b. A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radioactive drugs or radioactive wastes are stored.
- c. A licensee shall conduct the surveys required by RH-8408.a. and RH-8408.b. so as to be able to measure dose rates as low as one (1) microsievert (0.1 mrem) per hour.
- d. A licensee shall establish dose rate action levels for the surveys required by RH-8408.a. and RH-8408.b. and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

- e. A licensee shall survey for removable contamination each week of use all areas where radioactive drugs are prepared for use, administered, and where radioactive materials are stored.
- f. A licensee shall conduct the surveys required by RH-8408.e. so as to be able to detect contamination on each wipe sample of 33.3 becquerels (2000 dpm).
- g. A licensee shall establish removable contamination action levels for the surveys required by RH-8408.e. and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.
- h. A licensee does not need to perform the surveys required by RH-8408.a. in area(s) where patients or human research subjects are confined when they cannot be released pursuant to RH-8420.
- i. A licensee shall retain a record of each survey in accordance with RH-8709.

RH-8409. **Storage and Control of Volatiles and Gases.**

- a. A licensee shall store volatile radioactive materials and radioactive gases in a radiation shield and container.
- b. A licensee shall store and use a multi-dose container in a properly functioning fume hood.
- c. A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in Section 3 of these regulations.

RH-8409. (Cont'd)

- d. The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.
- e. A licensee shall check the operation of collection systems ~~monthly~~ at intervals recommended by the manufacturer or approved by the Department. The records of these checks shall be maintained for three (3) years.

RH-8410. **Decay-in-Storage.**

- a. A licensee may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
 - 1. Monitors radioactive material at the container surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;
 - 2. Removes or obliterates all radiation labels, except for material that will be handled as biomedical waste after release; and
 - 3. Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.
- b. For radioactive material disposed in accordance with RH-8410.a. of this section, the licensee shall retain a record of each disposal in accordance with RH-8712.

RH-8411.- RH-8419. Reserved.

RH-8420. **Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material.**

- a. A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (5 mSv) per year.

RH-8420. (Cont'd)

- b. A licensee shall provide the released individual, or the individual's parent or guardian, with oral and written instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 0.1 rem (1 mSv). If the total effective dose equivalent to a breast-feeding infant or child could exceed 0.1 rem (1 mSv) assuming there were no interruption of breast-feeding, the instructions shall also include:
 - 1. Guidance on the interruption or discontinuation of breast-feeding; and

2. Information on the potential consequences, if any, of failure to follow the guidance.
- c. Release of the individual shall be directly approved by an authorized user listed on the license, if the release requires a record under RH-8710. The authorized user must be approved for use of the type of radioactive material for which the individual being released has received.
- d. Records of the basis for authorizing the release of an individual shall be retained in accordance with RH-8710.
- e. Records of instructions provided to a breast-feeding woman shall be retained in accordance with RH-8710.

RH-8421- RH-8424. Reserved.

RH-8425. **Mobile Medical Service Technical Requirements.**

A licensee providing mobile medical service shall:

- a. Transport to each client's address only syringes or vials containing prepared drugs or radioactive materials that are intended for reconstitution of radioactive drug kits;
- b. Bring into each client's address all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;
- c. Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a client's address;

RH-8425. (Cont'd)

- d. Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function shall include a constancy check;
- e. Check survey instruments for consistent response with a dedicated check source before use at each client's address;

- f. Prior to leaving a client's address, perform area surveys and survey for removable contamination in all areas of use, to ensure compliance with Section 3 of these regulations;
- g. Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Department for compliance with airborne release standards; and,
- h. Retain a record of each survey required by RH-8425.f. in accordance with RH-8711.

RH-8426.- RH-8499. Reserved.

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**PART E:
UNSEALED RADIOACTIVE MATERIAL –
WRITTEN DIRECTIVE NOT REQUIRED**

RH-8500. Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive Is Not Required.

Except for quantities that require a written directive under RH-8307., a licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies that is:

- a. Obtained from:
 1. A manufacturer or preparer licensed under RH-405.1. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
 2. A PET radioactive drug producer licensed under RH-403.j. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
- b. Excluding production of PET radionuclides, prepared by:
 1. An authorized nuclear pharmacist;
 2. A physician who is an authorized user and who meets the requirements specified in RH-8540., or RH-8560. and RH-8540.c.1.B.vii.; or
 3. An individual under the supervision, as specified in RH-8306.; of the authorized nuclear pharmacist in paragraph b.1. of RH-8500. or the physician who is an authorized user in paragraph b.2. of RH-8500.; or
- c. Obtained from and prepared by a Department, Nuclear Regulatory Commission or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or
- d. Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA ~~for use in research.~~

RH-8501. Possession of Survey Instrument.

A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of one (1) microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrem) per hour. The instrument shall be operable and calibrated in accordance with RH-8402.

RH-8502.- RH-8509. Reserved.

RH-8510. Training for Uptake, Dilution, and Excretion Studies.

Except as provided in RH-8318., the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RH-8500. to be a physician who:

- a. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State ~~and who meets the requirements in paragraph c.2. of RH 8510.~~ (The names of board certifications ~~which~~ that have been recognized by the Nuclear Regulatory Commission or an Agreement State ~~will be~~ are posted on the NRC's ~~Web page~~ Medical Uses Licensee Toolkit web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:
 1. Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in paragraphs c.1.A. through c.1.B.vi. of ~~RH 8510.~~ this section; and
 2. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or
- b. Is an authorized user under RH-8540., RH-8560. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

RH-8510. (Cont'd)

- c. 1. Has completed 60 hours of training and experience, including a minimum of eight (8) hours of classroom and laboratory training in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:
 - A. Classroom and laboratory training in the following areas:
 - i. Radiation physics and instrumentation;
 - ii. Radiation protection;
 - iii. Mathematics pertaining to the use and measurement of radioactivity;
 - iv. Chemistry of radioactive material for medical use; and
 - v. Radiation biology; and
 - B. Work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8510., RH-8540., RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements, involving:
 - i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - ii. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - iii. Calculating, measuring, and safely preparing patient or human research subject dosages;
 - iv. Using administrative controls to prevent a ~~medical event~~ misadministration involving the use of unsealed ~~byproduct~~ radioactive material;

RH-8510.c.1.B. (Cont'd)

v. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

vi. Administering dosages of radioactive drugs to patients or human research subjects; and

2. ~~Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RH-8318., RH-8510., RH-8540., or RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph a.1. or c.1. of RH-8510. this section and has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under RH-8500. The attestation must be obtained from either:

A. A preceptor authorized user who meets the requirements in RH-8318., RH-8510., RH-8540., or RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8510., RH-8540., or RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph c.1. of this section.

RH-8511.- RH-8529. Reserved.

RH-8530. Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive Is Not Required.

Except for quantities that require a written directive under RH-8307., a licensee may use any unsealed radioactive material prepared for medical use for imaging and localization studies that is:

- a. Obtained from:
 - 1. A manufacturer or preparer licensed under RH-405.i. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
 - 2. A PET radioactive drug producer licensed under RH-403.j. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
- b. Excluding production of PET radionuclides, prepared by:
 - 1. An authorized nuclear pharmacist;
 - 2. A physician who is an authorized user and who meets the requirements in RH-8540, or RH-8560 and RH-8540.c.1.B.vii., or

RH-8530.b. (Cont'd)

- 3. An individual under the supervision, as specified in RH-8306, of the authorized nuclear pharmacist in paragraph b.1. of RH-8530. or the physician who is an authorized user in paragraph b.2. of RH-8530.;
- c. Obtained from and prepared by a Department, NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or
- d. Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.
- e. Deleted.

RH-8531. Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.

- a. A licensee shall not administer to humans a radiopharmaceutical that contains:
 1. More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 μ Ci of Mo-99 per mCi of Tc-99m); or
 2. More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 μ Ci of Sr-82 per mCi of Rb-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 μ Ci of Sr-85 per mCi of Rb-82).
 3. ~~Deleted.~~

- b. ~~To demonstrate compliance with RH 8531.a., the licensee preparing radiopharmaceuticals from radionuclide generators shall:~~
 1. ~~Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator;~~
 2. ~~Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems.~~

A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with paragraph a. of this section.

- c. A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with paragraph a. of this section.

RH-8531. (Cont'd)

- e d. ~~A licensee who must measure radionuclide contaminant concentration~~ If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-85 concentrations, the licensee shall retain a record of each measurement in accordance with RH-8713.
- d e. ~~A~~ The licensee shall report immediately to the Department each occurrence of radionuclide contaminant concentration exceeding the limits specified in RH 8531.a. any measurement that exceeds the limits in

paragraph a. of this section at the time of generator elution, in accordance with RH-8805.

RH-8532. Possession of Survey Instruments.

A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of one (1) microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of ten (10) microsieverts (1 mrem) per hour to ten (10) millisieverts (1000 mrem) per hour. The instruments shall be operable and calibrated in accordance with RH-8402.

RH-8533.- RH-8539. Reserved.

RH-8540. Training for Imaging and Localization Studies.

Except as provided in RH-8318., the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RH-8530. to be a physician who:

- a. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State ~~and who meets the requirements in paragraph c.2. of RH 8540.~~ (The names of board certifications ~~which that~~ have been recognized by the Nuclear Regulatory Commission or an Agreement State ~~will be~~ are posted on the NRC's ~~Web page~~ Medical Uses Licensee Toolkit web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:
 1. Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in paragraphs c.1.A. through c.1.B.vii. of ~~RH-8540.~~ this section; and
 2. Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

RH-8540. (Cont'd)

- b. Is an authorized user under RH-8560. and meets the requirements in RH-8540.c.1.B.vii., or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

- c. 1. Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum:
- A. Classroom and laboratory training in the following areas:
 - i. Radiation physics and instrumentation;
 - ii. Radiation protection;
 - iii. Mathematics pertaining to the use and measurement of radioactivity;
 - iv. Chemistry of radioactive material for medical use;
 - v. Radiation biology; and
 - B. Work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8540., or RH-8560. and RH-8540.c.1.B.vii., or equivalent Nuclear Regulatory Commission or Agreement State requirements; ~~involving.~~ An authorized nuclear pharmacist who meets the requirements in RH-8317. or RH-8318. may provide the supervised work experience for paragraph c.1.B.vii. of this section. Work experience must involve:
 - i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - ii. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - iii. Calculating, measuring, and safely preparing patient or human research subject dosages;
 - iv. Using administrative controls to prevent a ~~medical event~~ misadministration involving the use of unsealed radioactive material;

RH-8540.c.1.B. (Cont'd)

- v. Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
 - vi. Administering dosages of radioactive drugs to patients or human research subjects; and
 - vii. Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and
2. ~~Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RH-8318., RH-8540., or RH-8560. and RH-8540.c.1.B.vii., or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph a.1. or c.1. of RH-8540. this section and has achieved a level of competency sufficient to function independently is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under RH-8500. and RH-8530. The attestation must be obtained from either:~~
- A. A preceptor authorized user who meets the requirements in RH-8318., RH-8540., or RH-8560. and RH-8540.c.1.B.vii., or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
 - B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8540., or RH-8560. and RH-8540.c.1.B.vii., or equivalent Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph c.1. of this section.

RH-8541.- RH-8549. Reserved.

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**PART F:
UNSEALED RADIOACTIVE MATERIAL –
WRITTEN DIRECTIVE REQUIRED**

RH-8550. Use of Unsealed Radioactive Material for Which a Written Directive Is Required.

A licensee may use any unsealed radioactive material identified in RH-8560.b.1.B.vii. prepared for medical use and for which a written directive is required that is:

- a. Obtained from:
 1. A manufacturer or preparer licensed under RH-405.i. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
 2. A PET radioactive drug producer licensed under RH-403.j. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
- b. Excluding production of PET radionuclides, prepared by:
 1. An authorized nuclear pharmacist;
 2. A physician who is an authorized user and who meets the requirements specified in RH-8540. or RH-8560.; or
 3. An individual under the supervision, as specified in RH-8306., of the authorized nuclear pharmacist in paragraph b.1. of ~~RH-8550.~~ this section or the physician who is an authorized user in paragraph b.2. of ~~RH-8550.~~ this section; or
- c. Obtained from and prepared by a Department, Nuclear Regulatory Commission, or Agreement State licensee for use in research in accordance with a ~~Radioactive Drug Research Committee approved protocol~~ or an Investigational New Drug (IND) protocol accepted by the FDA ~~for use in research~~; or
- d. Prepared by the licensee for use in research in accordance with a ~~Radioactive Drug Research Committee approved application~~ or an Investigational New Drug (IND) protocol accepted by FDA ~~for use in research~~.

RH-8551. Safety Instruction.

In addition to the requirements of RH-2803. ~~of these regulations:~~

- a. A licensee shall provide radiation safety instruction to personnel caring for patients or human research subjects that have received therapy with a radioactive drug, and cannot be released in accordance with RH-8420. The training must be provided initially and at least annually. The instruction must be appropriate to the personnel's assigned duties and include the following:
 1. Patient or human research subject control;
 2. Visitor control to include the following:
 - A. Routine visitation to hospitalized individuals in accordance with Section 3 ~~of these regulations;~~
 - B. Contamination control;
 - C. Waste control; and
 - D. Notification of the RSO, or his or her designee, and the authorized user if the patient or the human research subject dies or has a medical emergency.
- b. A licensee shall retain a record of individuals receiving instruction in accordance with RH-8715.

RH-8552. Safety Precautions.

- a. For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with RH-8420., a licensee shall:
 1. Quarter the patient or the human research subject either in:
 - A. A private room with a private sanitary facility; or
 - B. A room, with a private sanitary facility, with another individual who also has received similar radiopharmaceutical therapy and who cannot be released in accordance with RH-8420.; and,

RH-8552.a. (Cont'd)

2. Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and
 2. Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle such material and items as radioactive waste.
- b. The Radiation Safety Officer, or his or her designee, and an authorized user shall be notified immediately if the patient or human research subject dies or has a medical emergency.

RH-8553. Possession of Survey Instruments.

A licensee authorized to use radioactive material for which a written directive is required shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of one (1) microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of ten (10) microsieverts (1 mrem) per hour to ten (10) millisieverts (1000 mrem) per hour. The instruments shall be operable and calibrated in accordance with RH-8402.

RH-8554.- RH-8559. Reserved.

RH-8560. **Training for Use of Unsealed Radioactive Material for Which a Written Directive Is Required.**

Except as provided by RH-8318, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RH-8550. to be a physician who:

- a. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in ~~paragraphs paragraph~~ b.1.B.vii. and b.2. of RH-8560 this section. ~~(Specialty boards whose certification processes~~ The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State will be are ~~posted on the NRC's Web page~~ Medical Uses Licensee Toolkit web page.)
To be recognized, a specialty board shall require all candidates for certification to:
 1. Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in paragraphs b.1.A. through b.1.B.v. of ~~RH-8560~~ this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the ~~Committee on Post-Graduate~~ Council on Postdoctoral Training of the American Osteopathic Association; and
 2. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or
- b.
 1. Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:
 - A. Classroom and laboratory training in the following areas:
 - i. Radiation physics and instrumentation;
 - ii. Radiation protection;

RH-8560.b.1.A. (Cont'd)

- iii. Mathematics pertaining to the use and measurement of radioactivity;
- iv. Chemistry of radioactive material for medical use; and
- v. Radiation biology; and

B. Work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in RH-8560.b., must also have experience in administering dosages in the same dosage category or categories (i.e., RH-8560.b.1.B.vii.) as the individual requesting authorized user status. The work experience must involve:

- i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- ii. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
- iii. Calculating, measuring, and safely preparing patient or human research subject dosages;
- iv. Using administrative controls to prevent a ~~medical event~~ misadministration involving the use of unsealed radioactive material;
- v. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
- vi. Reserved.

RH-8560.b.1.B. (Cont'd)

- vii. Administering dosages of radioactive drugs to patients or human research subjects from the three categories in this paragraph. Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under RH-8670. This work experience must involving involve a minimum of three (3) cases in each of the following categories for which the individual is requesting authorized user status:
- (a). Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;
 - (b). Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;
 - (c). Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its beta emitter, or a photon-emitting radionuclide with a electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required; and/or
 - (d). ~~Parenteral administration of any other radionuclide, for which a written directive is required; and~~

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs ~~a.1. and b.1.B.vii. or b.1. of RH-8560. this section~~ and has achieved a level of competency sufficient to function independently is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under RH-8550. for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in RH-8318., RH-8560., or equivalent

~~Nuclear Regulatory Commission or Agreement State requirements. The preceptor authorized user who meets the requirements in RH-8560.b. must have experience in administering dosages in the same dosage category or categories (i.e., RH 8560.b.1.B.vii.) as the individual requesting authorized user status. The attestation must be obtained from either:~~

- ~~A. A preceptor authorized user who meets the requirements in RH-8318., RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or~~
- ~~B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph b.1. of this section.~~

RH-8561.- RH-8569. Reserved.

RH-8570. Training for the Oral Administration of Sodium Iodide I-131 in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 millicuries) for Which a Written Directive Is Required.

Except as provided in RH-8318., the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), for which a written directive is required, to be a physician who:

- a. Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs c.1. and c.2. of ~~RH-8570. this section~~ and whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State ~~and who meets the requirements in paragraph c.3. of RH-8570.~~ (The names of board certifications ~~which that~~ have been recognized by the Nuclear Regulatory Commission or an Agreement State ~~will be~~ are posted on the NRC's ~~Web page~~ Medical Uses Licensee Toolkit web page); or
- b. Is an authorized user under RH-8560. for uses listed in RH-8560.b.1.B.vii.(a). or (b)., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
- c.
 1. Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:
 - A. Radiation physics and instrumentation;
 - B. Radiation protection;
 - C. Mathematics pertaining to the use and measurement of radioactivity;
 - D. Chemistry of radioactive material for medical use; and
 - E. Radiation biology; and

RH-8570.c. (Cont'd)

2. Has work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8560., RH-8570., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in RH-8560.b., must also have experience in administering dosages as specified in RH-8560.b.1.B.vii.(a). or (b). The work experience must involve:

- A. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - B. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - C. Calculating, measuring, and safely preparing patient or human research subject dosages;
 - D. Using administrative controls to prevent a ~~medical event~~ misadministration involving the use of radioactive material;
 - E. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
 - F. Administering dosages to patients or human research subjects, that includes at least three (3) cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and
3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs c.1. and c.2. of ~~RH-8570. this section;~~ and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under RH-8550. ~~The written attestation must be signed by a preceptor authorized user who meets the requirements in RH-8318., RH-8560., RH-8570., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirement in RH-8560.b., must also have experience in administering dosages as specified in RH-8560.b.1.B.vii.(a). or (b). The attestation must be obtained from either:~~
- A. A preceptor authorized user who meets the requirements in RH-8318., RH-8560., RH-8570., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements, and has experience in administering dosages as specified in RH-8560.b.1.B.vii.(a). or (b).; or
 - B. A residency program director who affirms in writing that the attestation represents the consensus of the residency

program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8560., RH-8570., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages as specified in RH-8560.b.1.B.vii.(a). or (b)., and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs c.1. and c.2. of this section.

RH-8571.- RH-8579. Reserved.

RH-8580. **Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 millicuries) for Which a Written Directive Is Required.**

Except as provided in RH-8318., the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries) to be a physician who:

- a. Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs c.1. and c.2. of ~~RH-8580., this section~~ and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State, ~~and who meets the requirements in paragraph c.3. of RH-8580.~~ (The names of board certifications ~~which that~~ have been recognized by the Nuclear Regulatory Commission or an Agreement State ~~will be~~ are posted on the NRC's ~~Web page~~ Medical Uses Licensee Toolkit web page); or
- b. Is an authorized user under RH-8560. for uses listed in RH-8560.b.1.B.vii.(b). or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
- c. 1. Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:
 - A. Radiation physics and instrumentation;

- B. Radiation protection;
- C. Mathematics pertaining to the use and measurement of radioactivity;
- D. Chemistry of radioactive material for medical use; and
- E. Radiation biology; and

RH-8580.c. (Cont'd)

2. Has work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8560., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in RH-8560.b., must also have experience in administering dosages as specified in RH-8560.b.1.B.vii.(b). The work experience must involve:
 - A. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - B. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - C. Calculating, measuring, and safely preparing patient or human research subject dosages;
 - D. Using administrative controls to prevent a ~~medical event~~ misadministration involving the use of radioactive material;
 - E. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

- F. Administering dosages to patients or human research subjects, that includes at least three (3) cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and
3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs c.1. and c.2. of ~~RH-8580. this section,~~ and has achieved a level of competency sufficient to function independently is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under RH-8550. The written attestation must be signed by a preceptor authorized user who meets the requirements in RH-8318., RH-8560., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirements in RH-8560.b., must also have experience in administering dosages as specified in RH-8560.b.1.B.vii.(b). The attestation must be obtained from either:
- A. A preceptor authorized user who meets the requirements in RH-8318., RH-8560., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages as specified in RH-8560.b.1.B.vii.(b).; or
- B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8560., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages as specified in RH-8560.b.1.B.vii.(b)., and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs c.1. and c.2. of this section.

RH-8581.- RH-8589. Reserved.

RH-8590. Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive.

a. Except as provided in RH-8318., the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

- a 1. Is an authorized user under RH-8560. for uses listed in RH-8560.b.1.B.vii.(c), ~~or RH-8560.b.1.B.vii.(d)~~, or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
- b 2. Is an authorized user under RH-8610., RH-8660., or equivalent Nuclear Regulatory Commission or Agreement State requirements, and who meets the requirements in paragraph ~~d.~~ of RH-8590. b. of this section; or
- c 3. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under RH-8610. or RH-8660., and who meets the requirements in paragraph ~~d.~~ of RH-8590. b. of this section.

d b. The physician:

1. Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, ~~for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required~~ listed in RH-8560.b.1.B.vii.(c). The training must include:
 - A. Radiation physics and instrumentation;
 - B. Radiation protection;
 - C. Mathematics pertaining to the use and measurement of radioactivity;
 - D. Chemistry of radioactive material for medical use; and
 - E. Radiation biology; and

RH-8590.d. (Cont'd).

2. Has work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH- 8560., RH-8590., or equivalent Nuclear Regulatory Commission or Agreement State requirements, in the parenteral administrations listed in RH-8560.b.1.B.vii.(c), for which a written directive is required, of any beta emitter, or any photon emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in RH-8560., RH-8590., or equivalent Nuclear Regulatory Commission or Agreement State requirements, must have experience in administering dosages as specified in RH-8560.b.1.B.vii.(c) and/or RH-8560.b.1.B.vii.(d) in the same category or categories as the individual requesting authorized user status. The work experience must involve:
 - A. Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;
 - B. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
 - C. Calculating, measuring, and safely preparing patient or human research subject dosages;
 - D. Using administrative controls to prevent a medical event misadministration involving the use of unsealed radioactive material;
 - E. Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and
 - F. Administering dosages to patients or human research subjects, that include at least three (3) cases involving of the parenteral administrations as specified in RH-8560.b.1.B.vii.(c), for which a written directive is required, of any beta emitter, or any photon emitting radionuclide with a photon energy less than 150 keV and/or at least three (3) cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and

RH-8590.d. (Cont'd)

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs ~~b. or c.~~ b.1. and b.2. of RH-8590. this section; and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. ~~The written attestation must be signed by a preceptor authorized user who meets the requirements in RH-8318., RH-8560., RH-8590., or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirements in RH-8560., must have experience in administering dosages as specified in RH-8560.b.1.B.vii.(c) and/or RH-8560.b.1.B.vii.(d).~~ The attestation must be obtained from either:
- A. A preceptor authorized user who meets the requirements in RH-8318., RH-8560., RH-8590., or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user who meets the requirements in RH-8560., RH-8590., or equivalent Nuclear Regulatory Commission or Agreement State requirements must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or
- B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8560., RH-8590., or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs b.1. and b.2. of this section.

RH-8591.- RH-8599. Reserved.

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**PART G:
MANUAL BRACHYTHERAPY**

RH-8600. Use of Sealed Sources for Manual Brachytherapy.

A licensee shall use only brachytherapy sources ~~for therapeutic medical uses:~~

- a. As approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or
- b. In research to deliver therapeutic doses for medical use in accordance with an effective active Investigational Device Exemption (IDE) application accepted by the ~~FDA~~ U.S. Food and Drug Administration provided the requirements of RH-8310.a. are met.

RH-8601. Surveys After Source Implant and Removal.

- a. Immediately after implanting sources in a patient or a human research subject, the licensee shall perform a survey to locate and account for all sources that have not been implanted.
- b. Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.
- c. A licensee shall retain a record of the surveys in accordance with RH-8716.

RH-8602. Brachytherapy Sources Inventory.

- a. A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.
- b. Promptly after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

- c. A licensee shall maintain a record of the brachytherapy source accountability in accordance with RH-8717.

RH-8603. Safety Instruction.

In addition to the requirements of RH-2803.:

- a. The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with RH-8420. Instruction must be commensurate with the duties of the personnel and shall include the following:
 - 1. Size and appearance of the brachytherapy sources;
 - 2. Safe handling and shielding instructions;
 - 3. Patient or human research subject control;
 - 4. Visitor control, including both:
 - A. Routine visitation of hospitalized individuals in accordance with RH-1208.a.1.; and
 - B. Visitation authorized in accordance with RH-1208.c.; and
 - 5. Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject dies or has a medical emergency.
- b. Records of individuals receiving instruction shall be maintained in accordance with RH-8715.

RH-8604. Safety Precautions for Patients or Human Research Subjects Receiving Brachytherapy.

- a. For each patient or human research subject that is receiving brachytherapy and cannot be released in accordance with RH-8420., a licensee shall:
 - 1. Not place the patient or human research subject in the same room as an individual who is not receiving brachytherapy;

2. Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

RH-8604. (Cont'd)

- b. A licensee shall have emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:
 1. Dislodged from the patient; or
 2. Lodged within the patient following removal of the source applicators.
- c. The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

RH-8605. **Calibration Measurements of Brachytherapy Sealed Sources.**

- a. Prior to the first medical use of a brachytherapy sealed source on or after October 1, 2006, a licensee shall perform the following:
 1. Determine the source output or activity using a dosimetry system that meets the requirements of RH-8635.a.;
 2. Determine source positioning accuracy within applicators; and
 3. Use published protocols accepted by nationally recognized bodies to meet the requirements of paragraphs RH-8605-a.1.; and RH-8605-a.2. of this section.
- b. A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with paragraph RH-8605-a. of this section.
- c. A licensee shall mathematically correct the outputs or activities determined in paragraph RH-8605-a. of this section for physical decay at intervals consistent with one percent (1%) physical decay.

- d. An authorized medical physicist shall perform or review the calculation measurements made pursuant to paragraphs a., b., or c. of this section RH-8605.a., RH-8605.b., or RH-8605.e.
- e. Notwithstanding paragraph d. of this section, an ophthalmic physicist, as defined in RH-8100., may perform or review measurements made pursuant to paragraphs a., b., and c. of this section, in relation to strontium-90 sources for ophthalmic treatments.
- ~~e. Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined in accordance with paragraphs RH-8605.a., RH-8605.b., and RH-8605.e.~~
- f. A licensee shall retain a record of each calibration in accordance with RH-8718.
- ~~g. A licensee shall retain a record of decay calculations required by RH-8605.e. in accordance with RH-8719.~~

RH-8606. Therapy-Related Computer Systems.

The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

- a. The source-specific input parameters required by the dose calculation algorithm;
- b. The accuracy of dose, dwell time, and treatment time calculations at representative points;
- c. The accuracy of isodose plots and graphic displays; and
- d. The accuracy of the software used to determine radioactive source positions from radiographic images.

RH-8607. Possession of Survey Instruments.

A licensee authorized to use manual brachytherapy sources shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of one (1) microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrem) per hour, and a portable radiation measurement survey instrument capable

of measuring dose rates over the range of ten (10) microsieverts (1 mrem) per hour to ten (10) millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with RH-8402.

RH-8608. Strontium-90 Sources for Ophthalmic Treatments.

a. Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in paragraph b. of this section are performed by either:

1. An authorized medical physicist; or

2. An individual who:

A. Is identified as an ophthalmic physicist on a specific medical use license issued by the Nuclear Regulatory Commission or an Agreement State; permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; medical use permit issued by a Nuclear Regulatory Commission master material licensee; or permit issued by a Nuclear Regulatory Commission master material licensee broad scope medical use permittee; and

B. Holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

C. Has successfully completed one (1) year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

D. Has documented training in:

i. The creation, modification, and completion of written directives;

ii. Procedures for administrations requiring a written directive; and

iii. Performing the calibration measurements of brachytherapy sources as detailed in RH-8605.

b. The individuals who are identified in paragraph a. of this section must:

1. Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under RH-8605.; and
 2. Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in paragraph a. of this section will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.
- c. Licensees must retain a record of the activity of each strontium-90 source in accordance with RH-8719.

~~RH-8608.~~ RH-8609. Reserved.

RH-8610. **Training for Use of Manual Brachytherapy Sources.**

Except as provided in RH-8318., the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under RH-8600. to be a physician who:

- a. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State, ~~and who meets the requirements in paragraph b.3. of RH 8610.~~ (The names of board certifications ~~which that~~ have been recognized by the Nuclear Regulatory Commission or an Agreement State ~~will be~~ are posted on the NRC's ~~Web page~~ Medical Uses Licensee Toolkit web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:
 1. Successfully complete a minimum of three (3) years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee~~ Council on Post-

~~Graduate Postdoctoral~~ Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or
- b. 1. Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:
- A. 200 hours of classroom and laboratory training in the following areas:
 - i. Radiation physics and instrumentation;
 - ii. Radiation protection;
 - iii. Mathematics pertaining to the use and measurement of radioactivity; and
 - iv. Radiation biology; and

RH-8610.b.1. (Cont'd)

- B. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8610., or equivalent Nuclear Regulatory Commission or Agreement State requirements, at a medical ~~institution~~ facility authorized to use radioactive material under RH-8600., involving:
 - i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - ii. Checking survey meters for proper operation;
 - iii. Preparing, implanting, and removing brachytherapy sources;

- iv. Maintaining running inventories of material on hand;
 - v. Using administrative controls to prevent a ~~medical event~~ misadministration involving the use of radioactive material;
 - vi. Using emergency procedures to control radioactive material; and
2. Has completed three (3) years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in RH-8318., RH-8610., or equivalent Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee~~ Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph b.1.B. of ~~RH-8610.~~ this section; and
3. Has obtained written attestation, ~~signed by a preceptor authorized user who meets the requirements in RH-8318., RH-8610. or equivalent Nuclear Regulatory Commission or Agreement State requirements,~~ that the individual has satisfactorily completed the requirements in paragraphs ~~a.1., or~~ b.1. and b.2., of ~~RH-8610.~~ this section and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under RH-8600. The attestation must be obtained from either:
- A. A preceptor authorized user who meets the requirements in RH-8318., RH-8610., or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
 - B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8610., or equivalent Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the

Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs b.1. and b.2. of this section.

RH-8611.- RH-8614. Reserved.

RH-8615. Training for Ophthalmic Use of Strontium-90.

Except as provided in RH-8318., the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

- a. Is an authorized user under RH-8610. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or
- b.
 1. Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:
 - A. Radiation physics and instrumentation;
 - B. Radiation protection;
 - C. Mathematics pertaining to the use and measurement of radioactivity; and
 - D. Radiation biology; and
 2. Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:
 - A. Examination of each individual to be treated;
 - B. Calculation of the dose to be administered;
 - C. Administration of the dose; and
 - D. Follow up and review of each individual's case history; and

RH-8615.b. (Cont'd)

3. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RH-8318., RH-8610., RH-8615., or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs b.1. and b.2. of ~~RH-8615. this section~~ and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

RH-8616.- RH-8619. Reserved.

**PART H:
SEALED SOURCES FOR DIAGNOSIS**

RH-8620. **Use of Sealed Sources and Medical Devices for Diagnosis.**

~~A licensee shall use only sealed sources for diagnostic medical uses:~~

~~a. Approved in the Sealed Source and Device Registry; and~~

~~b. Handled in accordance with the manufacturer's radiation safety instructions.~~

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

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

c. Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RH-8310.a. are met.

RH-8621. **Training for Use of Sealed Sources and Medical Devices for Diagnosis.**

Except as provided in RH-8318., the licensee shall require the authorized user of a diagnostic sealed source ~~for use in~~ or a device authorized under RH-8620. to be a physician, dentist, or podiatrist who:

a. Is certified by a specialty board whose certification process includes all of the requirements in paragraphs ~~b. and c. and d. of RH-8621.~~ this section and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State. ~~(The names of board certifications which that have been recognized by the Nuclear Regulatory Commission~~

or an Agreement State ~~will be~~ are posted on the NRC's ~~Web page~~ Medical Uses Licensee Toolkit web page); or

b. Is an authorized user for uses listed in RH-8530. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

b c. Has completed eight (8) hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity; and
4. Radiation biology; and

e d. Has completed training in the use of the device for the uses requested.

RH-8622.- RH-8629. Reserved.

**PART I:
PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS,
AND GAMMA STEREOTACTIC RADIOSURGERY UNITS**

RH-8630. Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.

~~A licensee shall use sealed sources in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:~~

- ~~a. As approved in the Sealed Source and Device Registry; or~~
 - ~~b. In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of RH 8310.a. are met.~~
- a. A licensee shall only use sealed sources:
- 1. Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses: or
 - 2. In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RH-8310.a. are met.
- b. A licensee shall use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:
- 1. Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or
 - 2. In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RH-8310.a. are met.

RH-8631. **Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit.**

- a. Before releasing a patient or a human research subject from licensee control, a licensee shall make a survey of the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe, shielded position.
- b. A licensee shall retain a record of the surveys in accordance with RH-8716.

RH-8632. **Installation, Maintenance, Adjustment, and Repair.**

- a. Only a person specifically licensed by the Department, the Nuclear Regulatory Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

RH-8632. (Cont'd)

- b. Except for low dose-rate remote afterloader units, only a person specifically licensed by the Department, an Agreement State or the Nuclear Regulatory Commission shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.
- c. For a low dose-rate remote afterloader unit, only a person specifically licensed by the Department, an Agreement State or the Nuclear Regulatory Commission, or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.
- d. A licensee shall retain a record of the installation, maintenance, adjustment, and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with RH-8720.

RH-8633. **Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.**

- a. A licensee shall:
1. Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;
 2. Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);
 3. Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and
 4. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. This procedure must include:
 - A. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
 - B. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
 - C. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

RH-8633.a.4. (Cont'd)

- b. A copy of the procedures required by ~~RH-8633.a.4.~~ paragraph a.4. of this section must be physically located at the unit console.
- c. A licensee shall post instructions at the unit console to inform the operator of:
 1. The location of the procedures required by ~~RH-8633.a.4.~~ paragraph a.4. of this section; and
 2. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

- d. 1. Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.
- 2. A licensee shall provide operational and safety instructions, initially and at least annually, to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties, in: The instructions shall include instruction in:
 - 1 A. The procedures identified in ~~RH-8633.a.4.~~ paragraph a.4. of this section; and
 - 2 B. The operating procedures for the unit.
- e. A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.
- f. A licensee shall retain a record of individuals receiving instruction required by ~~RH-8633.d.~~ paragraph d. of this section, in accordance with RH-8715.
- g. A licensee shall retain a copy of the procedures required by paragraphs a.4. and d.2.B. of this section until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

RH-8634. **Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.**

- a. A licensee shall control access to the treatment room by a door at each entrance.
- b. A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:
 - 1. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

RH-8634.b. (Cont'd)

2. Cause the source(s) to be shielded promptly when an entrance door is opened; and
 3. Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.
- c. A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.
- d. Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.
- e. For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.
- f. In addition to the requirements specified in ~~RH-8634.a. through RH-8634.e.~~ paragraphs a. through e. of this section, a licensee shall:
1. For ~~low dose-rate~~, medium dose-rate, and pulsed dose-rate remote afterloader units, require:
 - A. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during initiation of all patient treatments involving the unit; and
 - B. An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.
 2. For high dose-rate remote afterloader units, require:
 - A. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

RH-8634.f.2. (Cont'd)

- B. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.
- 3. For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.
- 4. Notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.
- g. A licensee shall have emergency response equipment available near each treatment room, to respond to a source that inadvertently:
 - 1. Remains in the unshielded position; or
 - 2. Lodges within the patient following completion of the treatment.

RH-8635. **Dosimetry Equipment.**

- a. Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two (2) conditions must be met.
 - 1. The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; 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

RH-8635.a. (Cont'd)

2. The system must have been calibrated within the previous four (4) years; 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must have indicated that the calibration factor of the licensee's system had not changed by more than two percent (2%). The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.
- b. The licensee shall have available for use a dosimetry system for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with RH-8635.a. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in RH-8635.a.
- c. The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with RH-8721.

RH-8636.- RH-8639. Reserved.

RH-8640. **Full Calibration Measurements on Teletherapy Units.**

- a. A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:
 1. Before the first medical use of the unit; and
 2. Before medical use under the following conditions:
 - A. Whenever spot-check measurements indicate that the output differs by more than five percent (5%) from the output obtained at the last full calibration corrected mathematically for radioactive decay;

RH-8640.a.2. (Cont'd)

- B. Following replacement of the source or following reinstallation of the teletherapy unit in a new location;
 - C. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
3. At intervals not exceeding one (1) year.
- b. To satisfy the requirement of RH-8640.a., full calibration measurements must include determination of:
- 1. The output within plus or minus three percent ($\pm 3\%$) for the range of field sizes and for the distance or range of distances used for medical use;
 - 2. The coincidence of the radiation field and the field indicated by the light beam localizing device;
 - 3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;
 - 4. Timer accuracy and linearity over the range of use;
 - 5. On-off error; and
 - 6. The accuracy of all distance measuring and localization devices in medical use.
- c. A licensee shall use the dosimetry system described in RH-8635.a. to measure the output for one set of exposure conditions. The remaining radiation measurements required in RH-8640.b.1. may be made using a dosimetry system that indicates relative dose rates.
- d. A licensee shall make full calibration measurements required by RH-8640.a. in accordance with published protocols accepted by nationally recognized bodies.
- e. A licensee shall mathematically correct the outputs determined in RH-8640.b.1. for physical decay for intervals not exceeding one (1) month for cobalt-60, six (6) months for cesium-137, or at intervals consistent with one percent (1%) decay for all other nuclides.

- f. Full calibration measurements required by RH-8640.a. and physical decay corrections required by RH-8640.e. must be performed by the authorized medical physicist.
- g. A licensee shall retain a record of each calibration in accordance with RH-8722.

RH-8641. Full Calibration Measurements on Remote Afterloader Units.

- a. A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:
 - 1. Before the first medical use of the unit;
 - 2. Before medical use under the following conditions:
 - A. Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
 - B. Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
 - 3. At intervals not exceeding one (1) quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and
 - 4. At intervals not exceeding one (1) year for low dose-rate remote afterloader units.
- b. To satisfy the requirement of RH-8641.a., full calibration measurements must include, as applicable, determination of:
 - 1. The output within plus or minus five percent ($\pm 5\%$);
 - 2. Source positioning accuracy to within plus or minus one (± 1) millimeter;
 - 3. Source retraction with backup battery upon power failure;
 - 4. Length of the source transfer tubes;

RH-8641.b. (Cont'd)

5. Timer accuracy and linearity over the typical range of use;
 6. Length of the applicators; and
 7. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.
- c. In addition to the requirements for full calibrations for low dose-rate remote afterloader units in RH-8641.b., a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one (1) quarter.
 - d. A licensee shall use the dosimetry system described in RH-8635.a. to measure the output.
 - e. A licensee shall make full calibration measurements required by RH-8641.a. of this section in accordance with published protocols accepted by nationally recognized bodies.
 - f. For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with RH-8641.a. through RH-8641.e.
 - g. A licensee shall mathematically correct the outputs determined in RH-8641.b.1. for physical decay at intervals consistent with one percent (1%) physical decay.
 - h. Full calibration measurements required by RH-8641.a. and physical decay corrections required by RH-8641.g. must be performed by the authorized medical physicist.
 - i. A licensee shall retain a record of each calibration in accordance with RH-8722.

RH-8642. Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.

- a. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:
 1. Before the first medical use of the unit;

RH-8642.a. (Cont'd)

2. Before medical use under the following conditions:
 - A. Whenever spot-check measurements indicate that the output differs by more than five percent (5%) from the output obtained at the last full calibration corrected mathematically for radioactive decay;
 - B. Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and
 - C. Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and
 3. At intervals not exceeding one (1) year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.
- b. To satisfy the requirement of RH-8642.a., full calibration measurements must include determination of:
1. The output within plus or minus three percent ($\pm 3\%$);
 2. Relative helmet factors;
 3. Isocenter coincidence;
 4. Timer accuracy and linearity over the range of use;
 5. On-off error;
 6. Trunnion centricity;
 7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
 8. Helmet microswitches;
 9. Emergency timing circuits; and
 10. Stereotactic frames and localizing devices (trunnions).

RH-8642. (Cont'd)

- c. A licensee shall use the dosimetry system described in RH-8635.a. to measure the output for one (1) set of exposure conditions. The remaining radiation measurements required in RH-8642.b.1. may be made using a dosimetry system that indicates relative dose rates.
- d. A licensee shall make full calibration measurements required by RH-8642.a. in accordance with published protocols accepted by nationally recognized bodies.
- e. A licensee shall mathematically correct the outputs determined in RH-8642.b.1. at intervals not exceeding one (1) month for cobalt-60 and at intervals consistent with one percent (1%) physical decay for all other radionuclides.
- f. Full calibration measurements required by RH-8642.a. and physical decay corrections required by RH-8642.e. must be performed by the authorized medical physicist.
- g. A licensee shall retain a record of each calibration in accordance with RH-8722.

RH-8643. Periodic Spot-Checks for Teletherapy Units.

- a. A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:
 1. Timer accuracy, and timer linearity over the range of use;
 2. On-off error;
 3. The coincidence of the radiation field and the field indicated by the light beam localizing device;
 4. The accuracy of all distance measuring and localization devices used for medical use;
 5. The output for one (1) typical set of operating conditions measured with the dosimetry system described in RH-8635.b.; and
 6. The difference between the measurement made in RH-8643.a.5. 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).

RH-8643. (Cont'd)

- b. A licensee shall perform measurements required by RH-8643.a. in accordance with procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.
- c. A licensee shall have the authorized medical physicist review the results of each spot-check within fifteen (15) days. The authorized medical physicist shall promptly notify the licensee in writing of the results of each spot-check.
- d. A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:
 - 1. Electrical interlocks at each teletherapy room entrance;
 - 2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);
 - 3. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
 - 4. Viewing and intercom systems;
 - 5. Treatment room doors from inside and outside the treatment room; and
 - 6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.
- e. If the results of the checks required in RH-8643.d. indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
- f. A licensee shall retain a record of each spot-check required by RH-8643.a. and RH-8643.d., in accordance with RH-8723.

RH-8644. Periodic Spot-Checks for Remote Afterloader Units.

- a. A licensee authorized to use remote afterloader units for medical use shall perform spot-checks of each remote afterloader facility and on each unit:
 1. At the beginning of each day of use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit;
 2. Prior to each patient treatment with a low dose-rate remote afterloader unit; and
 3. After each source installation.
- b. The licensee shall have the authorized medical physicist establish written procedures for performing the spot-checks required in RH-8644.a. The authorized medical physicist need not actually perform the spot-check measurements.
- c. A licensee shall have the authorized medical physicist review the results of each spot-check within fifteen (15) days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.
- d. To satisfy the requirements of RH-8644.a., spot-checks must, at a minimum, assure proper operation of:
 1. Electrical interlocks at each remote afterloader unit room entrance;
 2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
 3. Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;
 4. Emergency response equipment;
 5. Radiation monitors used to indicate the source position;
 6. Timer accuracy;
 7. Clock (date and time) in the unit's computer; and
 8. Decayed source(s) activity in the unit's computer.

- e. If the results of the checks required in RH-8644.d. indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
- f. A licensee shall retain a record of each check required by RH-8644.d. in accordance with RH-8724.

RH-8645. Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

- a. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:
 - 1. Monthly;
 - 2. At the beginning of each day of use; and
 - 3. After each source installation.
- b. The licensee shall have the authorized medical physicist:
 - 1. Establish written procedures for performing the spot-checks required in RH-8645.a.; and
 - 2. Review the results of each spot-check required by RH-8645.a. within fifteen (15) days of the check. The authorized medical physicist need not actually perform the spot-check measurements. The authorized medical physicist shall notify the licensee as soon as possible, in writing, of the results of the spot-check.
- c. To satisfy the requirements of RH-8645.a.1., spot-checks must, at a minimum:
 - 1. Assure proper operation of:
 - A. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
 - B. Helmet microswitches;
 - C. Emergency timing circuits; and

RH-8645.c.1. (Cont'd)

- D. Stereotactic frames and localizing devices (trunnions).
2. Determine:
- A. The output for one (1) typical set of operating conditions measured with the dosimetry system described in RH-8635.b.;
 - B. The difference between the measurement made in RH-8645.c.2.A. 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);
 - C. Source output against computer calculation;
 - D. Timer accuracy and linearity over the range of use;
 - E. On-off error; and
 - F. Trunnion centricity.
- d. To satisfy the requirements of RH-8645.a.2. and RH-8645.a.3., spot-checks must assure proper operation of:
- 1. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
 - 2. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
 - 3. Viewing and intercom systems;
 - 4. Timer termination;
 - 5. Radiation monitors used to indicate room exposures; and
 - 6. Emergency off buttons.
- e. A licensee shall arrange for prompt repair of any system identified in RH-8645.c. that is not operating properly.

- f. If the results of the checks required in RH-8645.d. indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
- g. A licensee shall retain a record for each check required by RH-8645.c. and RH-8645.d. in accordance with RH-8725.

RH-8646. **~~Five-Year Inspection~~ Full-Inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units.**

- a. A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement ~~or at intervals not to exceed five (5) years, whichever comes first,~~ to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed five (5) years for each teletherapy unit and shall not exceed seven (7) years for each gamma stereotactic radiosurgery unit.
- b. This inspection and servicing may only be performed by persons specifically licensed to do so by the Department, the Nuclear Regulatory Commission, or an Agreement State ~~or the Nuclear Regulatory Commission.~~
- c. A licensee shall keep a record of the inspection and servicing in accordance with RH-8728.

RH-8647. **Additional Technical Requirements for Mobile Remote Afterloader Units.**

- a. A licensee providing mobile remote afterloader service shall:
 1. Check survey instruments for consistent response before medical use at each address of use or on each day of use, whichever is more frequent; and
 2. Account for all sources before departure from a client's address of use.
- b. In addition to the periodic spot-checks required by RH-8644., a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:

1. Electrical interlocks on treatment area access points;

RH-8647.b. (Cont'd)

2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
 3. Viewing and intercom systems;
 4. Applicators, source transfer tubes, and transfer tube-applicator interfaces;
 5. Radiation monitors used to indicate room exposures;
 6. Source positioning (accuracy); and
 7. Radiation monitors used to indicate whether the source has returned to a safe shielded position.
- c. In addition to the requirements for checks in RH-8647.b., a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.
 - d. If the results of the checks required in RH-8647.b. indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
 - e. A licensee shall retain a record of each check required by RH-8647.b. in accordance with RH-8726.

RH-8648. **Therapy-Related Computer Systems.**

The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

- a. The source-specific input parameters required by the dose calculation algorithm;
- b. The accuracy of dose, dwell time, and treatment time calculations at representative points;

- c. The accuracy of isodose plots and graphic displays;

RH-8648. (Cont'd)

- d. The accuracy of the software used to determine radioactive source positions from radiographic images; and
- e. The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

RH-8649. **Possession of Survey Instruments.**

A licensee authorized to use radioactive material in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of one (1) microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrem) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of ten (10) microsieverts (1 mrem) per hour to ten (10) millisieverts (1000 mrem) per hour. The instruments shall be operable and calibrated in accordance with RH-8402.

RH-8650. **Radiation Surveys.**

- a. In addition to the survey requirements in RH-1300.b. ~~of these regulations,~~ a person licensed pursuant to Section 9 shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry.
- b. The licensee shall make the survey required by RH-8650.a. at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).
- c. A licensee shall retain a record of the radiation surveys required by RH-8650.a. in accordance with RH-8727.

RH-8651.- RH-8659. Reserved.

RH-8660. **Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.**

Except as provided in RH-8318., the licensee shall require an authorized user of a sealed source for a use authorized under RH-8630. to be a physician who:

- a. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraphs ~~b.3. and c.~~ of ~~RH-8660~~ this section. (The names of board certifications ~~which~~ that have been recognized by the Nuclear Regulatory Commission or an Agreement State ~~will be~~ are posted on the NRC's ~~web page~~ Medical Uses Licensee Toolkit web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:
 1. Successfully complete a minimum of three (3) years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee~~ Council on ~~Post-Graduate~~ Postdoctoral Training of the American Osteopathic Association; and
 2. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders, and external beam therapy; or
- b.
 1. Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:
 - A. 200 hours of classroom and laboratory training in the following areas:
 - i. Radiation physics and instrumentation;
 - ii. Radiation protection;
 - iii. Mathematics pertaining to the use and measurement of radioactivity; and

- iv. Radiation biology; and

RH-8660.b.1. (Cont'd)

- B. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8660., or equivalent Nuclear Regulatory Commission or Agreement State requirements, at a medical institution facility that is authorized to use radioactive material in RH-8630., involving:
 - i. Reviewing full calibration measurements and periodic spot-checks;
 - ii. Preparing treatment plans and calculating treatment doses and times;
 - iii. Using administrative controls to prevent a ~~medical event~~ misadministration involving the use of radioactive material;
 - iv. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
 - v. Checking and using survey meters; and
 - vi. Selecting the proper dose and how it is to be administered; and
- 2. Has completed three (3) years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in RH-8318., RH-8660., or equivalent Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the ~~Committee~~ Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph b.1.B. of ~~RH-8660. this~~ section; and

RH-8660.b. (Cont'd)

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in ~~paragraph a.1. or paragraphs b.1. and b.2.; and paragraph c. of RH-8660. this section;~~ and has achieved a level of competency sufficient to function independently is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in RH-8318., RH-8660., or equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and The attestation must be obtained from either:
 - A. A preceptor authorized user who meets the requirements in RH-8318., RH-8660., or equivalent Nuclear Regulatory Commission or Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or
 - B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8660., or equivalent Nuclear Regulatory Commission or Agreement State requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic

Association and must include training and experience specified in paragraphs b.1. and b.2. of this section.

- c. Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

RH-8661.- RH-8669. Reserved.

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**PARTS J – K
[RESERVED]**

**PART L:
OTHER MEDICAL USES OF RADIOACTIVE MATERIAL
OR RADIATION FROM RADIOACTIVE MATERIAL**

RH-8670. Other Medical Uses of Radioactive Material or Radiation from Radioactive Material.

A licensee may use radioactive material or a radiation source approved for medical use that is not specifically addressed in Section 9 if:

- a. The applicant or licensee has submitted the information required by RH-8010.b., RH-8010.c., and RH-8010.d; and
- b. The applicant or licensee has received written approval from the Nuclear Regulatory Commission, or an Agreement State in a license and uses the material in accordance with the ~~regulations~~ rules and specific conditions the Nuclear Regulatory Commission or Agreement State considers necessary for the medical use of the material.

RH-8671.- RH-8699. Reserved.

**PART M:
RECORDS**

RH-8700. Records of Authority and Responsibilities for Radiation Protection Programs.

- a. A licensee shall retain a record of actions taken by the licensee's management in accordance with RH-8300.a. for five (5) years. The record must include a summary of the actions taken and a signature of licensee management.
- b. The licensee shall retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by RH-8300.d, and a signed copy of ~~the~~ each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by RH-8300.b. The record must include the signature of the Radiation Safety Officer and licensee management.
- c. For each Associate Radiation Safety Officer appointed under RH-8300.b., the licensee shall retain, for five (5) years after the Associate Radiation Safety Officer is removed from the license, a copy of the written document appointing the Associate Radiation Safety Officer signed by the licensee's management.
- ed. The minutes of each Radiation Safety Committee meeting held in accordance with RH-8300.g. shall include:
 - 1. The date of the meeting;
 - 2. Members present;
 - 3. Members absent; and
 - 4. Summary of deliberations and discussions.

RH-8701. Records of Radiation Protection Program Safety Changes.

A licensee shall retain a record of each radiation protection program change made in accordance with RH-8301.a. for five (5) years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

RH-8702. Records of Written Directives.

A licensee shall retain a copy of each written directive as required by RH-8307. for three (3) years.

RH-8703. Records of Misadministrations.

A licensee shall retain a record of misadministrations reported in accordance with RH-8800. for three (3) years. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration; a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

RH-8704. Record of a Dose to an Embryo/Fetus or a Nursing Child.

A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with RH-8801 for three (3) years. The record must contain the licensee's name; names of all the individuals involved; social security number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

RH-8705. Records of Checks and Tests of Instruments Used to Measure the Activity of Unsealed Radioactive Material.

A licensee shall maintain a record of instrument checks and tests required by RH-8401. for three (3) years, excluding geometry test records where only the most current record must be maintained. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

RH-8706. Records of Survey Instrument Calibrations.

A licensee shall maintain a record of survey instrument calibrations required by RH-8402. for three (3) years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

RH-8707. Records of Dosages of Unsealed Radioactive Material for Medical Use.

A licensee shall maintain a record of dosage determinations required by RH-8403. for three (3) years. The record must contain the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.1 megabecquerel (30 μ Ci); the date and time of the dosage determination; and the name of the individual who determined the dosage.

RH-8708. Records of Possession of Sealed Sources and Brachytherapy Sources.

A licensee shall retain a record of the quarterly physical inventory of sealed sources and brachytherapy sources required by RH-8405.e. for three (3) years. The inventory record must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

RH-8709. Records of Surveys for Ambient Radiation ~~Exposure~~ Dose Rate and Contamination.

A licensee shall retain a record of each survey required by RH-8408. for three (3) years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

RH-8710. Records of the Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material.

- a. A licensee shall retain a record, signed by the authorized user, of the basis for authorizing the release of an individual pursuant to RH-8420.a., if the total effective dose equivalent is calculated by:
 1. Using the retained activity rather than the activity administered;
 2. Using an occupancy factor less than 0.25 at 1 meter;

3. Using the biological or effective half-life; or
4. Considering the shielding by tissue.

RH-8710. (Cont'd)

- b. A licensee shall retain a record that the instructions required by RH-8420.b. were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 0.1 rem (1 mSv).
- c. Records required by paragraphs a. and b. of this section shall be retained for three (3) years after the date of release of the individual.

RH-8711. **Records of Administrative and Technical Requirements that Apply to the Provision of Mobile Services.**

- a. A licensee shall retain a copy of the letter(s) that permits the use of radioactive material at a client's address of use, as required by RH-8012.b., for three (3) years after the last provision of service.
- b. A licensee shall retain the record of each survey required by RH-8425.f. for three (3) years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

RH-8712. **Records of Decay-in-Storage.**

A licensee shall maintain records of the disposal of licensed materials, as required by RH-8410., for three (3) years. The record must include the date the container was sealed, the date of the disposal, the radionuclides disposed, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

RH-8713. **Records of Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.**

A licensee shall maintain a record of the radionuclide contaminant concentration tests required by RH-8531. for three (3) years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcuries/millicuries), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicuries), the time and date of the measurement, and the name of the individual who made the measurement.

RH-8714. Reserved.

RH-8715. **Records of Safety Instruction and ~~Training~~ Operational Instruction.**

A licensee shall maintain a record of safety instructions ~~and training~~ required by RH-8551.; and RH-8603.; and the operational and safety instructions required by RH-8633. for three (3) years. The record must include a list of the topics covered, the date of the instruction ~~or training~~, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

RH-8716. **Records of Radiation Surveys of Patients and Human Research Subjects.**

A licensee shall maintain a record of the surveys required by RH-8601. and RH-8631. for three (3) years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

RH-8717. **Records of Brachytherapy Source Inventory.**

- a. A licensee shall maintain a record of brachytherapy source accountability required by RH-8602. for three (3) years.
- b. For temporary implants, the record must include:
 1. The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and
 2. The number and activity of sources not implanted, the time and date they were returned to storage, and the name of the individual who returned them to storage.
- c. For permanent implants, the record must include:

1. The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;
2. The number and activity of sources returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and
3. The number and activity of sources permanently implanted in the patient or human research subject.

RH-8718. Records of Calibration Measurements on Brachytherapy Sources.

A licensee shall maintain a record of the calibrations on brachytherapy sources required by RH-8605. for three (3) years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist, or ophthalmic physicist, as appropriate.

RH-8719. Records of Decay of Strontium-90 Sources for Ophthalmic Treatments.

A licensee shall maintain a record of the activity of a strontium-90 source required by RH-~~8605.~~ 8608. for the life of the source. The record must include the date and initial activity of the source as determined under RH-8605., and for each decay calculation, the date, and the source activity as determined under RH-8608., and the signature of the authorized medical physicist, or ophthalmic physicist, as appropriate.

RH-8720. Records of Installation, Maintenance, Adjustment, and Repair.

A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by RH-8632. for three (3) years. For each installation, maintenance, adjustment, and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

RH-8721. Records of Dosimetry Equipment.

- a. A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with RH-8635. for the duration of the license.
- b. For each calibration, intercomparison, or comparison, the record must include:
 1. The date;
 2. The manufacturer's name, model numbers, and serial numbers of the instruments that were calibrated, intercompared, or compared as required by RH-8635.a. and RH-8635.b.;

RH-8721.b. (Cont'd)

3. The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and
4. The names of the individuals who performed the calibration, intercomparison, or comparison.

RH-8722. **Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations.**

- a. A licensee shall maintain a record of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations required by RH-8640., RH-8641., and RH-8642. for three (3) years.
- b. The record must include:
 1. The date of the calibration;
 2. The manufacturer's name, model number, and serial number for the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and instruments used to calibrate the unit;
 3. The results and assessments of the full calibrations;
 4. The results of the autoradiograph required for low dose-rate remote afterloader units; and

5. The signature of the authorized medical physicist who performed the full calibration.

RH-8723. Records of Periodic Spot-Checks for Teletherapy Units.

- a. A licensee shall retain a record of each periodic spot-check for teletherapy units required by RH-8643. for three (3) years.
- b. The record must include:
 1. The date of the spot-check;

RH-8723.b. (Cont'd)

2. The manufacturer's name, model number, and serial number for the teletherapy unit, source, and instrument used to measure the output of the teletherapy unit;
3. An assessment of timer linearity and constancy;
4. The calculated on-off error;
5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
6. The determined accuracy of each distance measuring and localization device;
7. The difference between the anticipated output and the measured output;
8. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors;
and
9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

RH-8724. Records of Periodic Spot-Checks for Remote Afterloader Units.

- a. A licensee shall retain a record of each spot-check for remote afterloader units required by RH-8644. for three (3) years.
- b. The record must include, as applicable:
 - 1. The date of the spot-check;
 - 2. The manufacturer's name, model number, and serial number for the remote afterloader unit and source;
 - 3. An assessment of timer accuracy;

RH-8724.b. (Cont'd)

- 4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and
- 5. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

RH-8725. **Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.**

- a. A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by RH-8645. for three (3) years.
- b. The record must include:
 - 1. The date of the spot-check;
 - 2. The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;
 - 3. An assessment of timer linearity and accuracy;
 - 4. The calculated on-off error;
 - 5. A determination of trunnion centricity;

6. The difference between the anticipated output and the measured output;
7. An assessment of source output against computer calculations;
8. Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

RH-8725.b. (Cont'd)

9. The name of the individual, who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

RH-8726. **Records of Additional Technical Requirements for Mobile Remote Afterloader Units.**

- a. A licensee shall retain a record of each check for mobile remote afterloader units required by RH-8647.b. for three (3) years.
- b. The record must include:
 1. The date of the check;
 2. The manufacturer's name, model number, and serial number of the remote afterloader unit;
 3. Notations accounting for all sources before the licensee departs from a facility;
 4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and
 5. The signature of the individual who performed the check.

RH-8727. **Records of Surveys of Therapeutic Treatment Units.**

- a. A licensee shall maintain a record of radiation surveys of treatment units made in accordance with RH-8650.a. for the duration of use of the unit.
- b. The record must include:
 - 1. The date of the measurements;
 - 2. The manufacturer's name, model number, and serial number of the treatment unit, source, and instrument used to measure radiation levels;
 - 3. Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

RH-8727.b. (Cont'd)

- 4. The signature of the individual who performed the test.

RH-8728. **Records of ~~Five (5) Year Inspection~~ Full-Inspection Servicing for Teletherapy and Gamma Stereotactic Surgery Radiosurgery Units.**

- a. A licensee shall maintain a record of the ~~five (5) year inspections~~ full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units required by RH-8646. for the duration of use of the unit.
- b. The record must contain:
 - 1. The inspector's radioactive materials license number;
 - 2. The date of inspection;
 - 3. The manufacturer's name and model number and serial number of both the treatment unit and source;
 - 4. A list of components inspected and serviced, and the type of service; and
 - 5. The signature of the inspector.

RH-8729.- RH-8799. Reserved.

**PART N:
REPORTS**

RH-8800. **Reports and Notifications of Misadministrations.**

- a. ~~Other than events that result from intervention by a patient or human research subject, a licensee shall report any event in which the administration of radioactive material or radiation from radioactive material results in~~ A licensee shall report any event as a misadministration, except for an event that results from patient intervention, in which:
1. The administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in:
- ~~±~~ A. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sievert (5 rem) effective dose equivalent, 0.5 Sievert (50 rem) to an organ or tissue, or 0.5 Sievert (50 rem) shallow dose equivalent to the skin; and ~~either~~
- A i. The total dose delivered differs from the prescribed dose by twenty percent (20%) or more;
- ~~B~~ ii. The total dosage delivered differs from the prescribed dosage by twenty percent (20%) or more or falls outside the prescribed dosage range; or
- ~~C~~ iii. The fractionated dose delivered differs from the prescribed dose; for a single fraction, by fifty percent (50%) or more.
2. B. A dose that exceeds 0.05 Sievert (5 rem) effective dose equivalent, 0.5 Sievert (50 rem) to an organ or tissue, or 0.5 Sievert (50 rem) shallow dose equivalent to the skin from any of the following:
- A i. An administration of a wrong radioactive drug containing radioactive material or the wrong radionuclide for a brachytherapy procedure;
- ~~B~~ ii. An administration of a radioactive drug containing radioactive material by the wrong route of administration;

- € iii. An administration of a dose or dosage to the wrong individual or human research subject;
- Ð iv. An administration of a dose or dosage delivered by the wrong mode of treatment; or
- £ v. A leaking sealed source.

RH-8800.a. (Cont'd)

3 C. A dose to the skin or an organ or tissue other than the treatment site that exceeds by ~~0.5 Sievert (50 rem) to an organ or tissue and fifty percent (50%) of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).~~:

- i. 0.5 Sievert (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and
- ii. Fifty percent (50%) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

2. For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

- A. The total source strength administered differing by twenty percent (20%) or more from the total source strength documented in the post-implantation portion of the written directive;
- B. The total source strength administered outside of the treatment site exceeding twenty percent (20%) of the total source strength documented in the post-implantation portion of the written directive; or
- C. An administration that includes any of the following:

- i. The wrong radionuclide;
 - ii. The wrong individual or human research subject;
 - iii. Sealed source(s) implanted directly into a location discontinuous from the treatment site, as documented in the post-implantation portion of the written directive; or
 - iv. A leaking sealed source resulting in a dose that exceeds 0.5 Sievert (50 rem) to an organ or tissue.
- b. A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.
- c. The licensee shall notify the Department by telephone no later than the next calendar day after discovery of the misadministration.
- d. The licensee shall submit a written report to the Department within fifteen (15) days after discovery of the misadministration.
 1. The written report must include:
 - A. The licensee's name;
 - B. The name of the prescribing physician;
 - C. A brief description of the event;
 - D. Why the event occurred;
 - E. The effect, if any, on the individual who received the administration;
 - F. Actions, if any, that have been taken, or are planned, to prevent recurrence; and
 - G. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

2. The report may not contain the individual's name or any other information that could lead to identification of the individual.

RH-8800. (Cont'd)

- e. The licensee shall provide notification of the misadministration to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

- f. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.
- g. A licensee shall retain a record of a misadministration in accordance with RH-8703. A copy of the record required under RH-8703. shall be provided to the referring physician, if other than the licensee, within fifteen (15) days after discovery of the misadministration.

RH-8801. **Reports and Notifications of a Dose to an Embryo/Fetus or a Nursing Child.**

- a. A licensee shall report any dose to an embryo/fetus that is greater than five (5) millisievert (500 mrem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

RH-8801. (Cont'd)

- b. A licensee shall report any dose to a nursing child, that was not specifically approved, in advance, by the authorized user, that is a result of an administration of radioactive material to a breast-feeding individual that:
 1. Is greater than five (5) millisievert (500 mrem) total effective dose equivalent; or
 2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.
- c. The licensee shall notify by telephone the Department no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in RH-8801.a. or RH-8801.b.
- d. The licensee shall submit a written report to the Department within fifteen (15) days after discovery of a dose to the embryo/fetus or nursing child that requires a report in RH-8801.a. or RH-8801.b.
 1. The written report must include:
 - A. The licensee's name;
 - B. The name of the prescribing physician;
 - C. A brief description of the event;
 - D. Why the event occurred;
 - E. The effect, if any, on the embryo/fetus or the nursing child;
 - F. What actions, if any, have been taken or are planned to prevent recurrence; and
 - G. Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

2. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

RH-8801. (Cont'd)

- e. The licensee shall notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under RH-8801.a. or RH-8801.b., unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care of the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification.

To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

- f. A licensee shall retain a record of a dose to an embryo/fetus or a nursing child in accordance with RH-8704. A copy of the record required under RH-8704 shall be provided to the referring physician, if other than the licensee, within fifteen (15) days after discovery of the event.

RH-8802. **Reports of Leaking Sources.**

A licensee shall file a report with the Department within five (5) days if a leakage test required by RH-8405. reveals the presence of 185 Becquerel (0.005 μCi) or more of removable contamination. The written report must include the model number and serial number, if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

RH-8803. Deleted.

RH-8804. Deleted.

RH-8805. Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.

- a. The licensee shall notify by telephone the Department and the distributor of the generator within 24 hours after discovery that an eluate exceeded the permissible concentration listed in RH-8531.a. at the time of generator elution. The telephone report to the Department must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects; when the distributor was notified; and the action taken.
- b. The licensee shall submit a written report to the Department within thirty (30) calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; the probable cause and an assessment of failure in the licensee's equipment, procedures, or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by paragraph a. of this section.

RH-8805 8806.- RH-8899. Reserved.

**PART O:
ENFORCEMENT**

RH-8900. Violations.

a. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any ~~regulation~~ rule or order issued thereunder. Any person who willfully violates any provision of the Act or any ~~regulation~~ rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

b. **Impounding.**

Sources of radiation shall be subject to impounding pursuant to Section 5 of these ~~Regulations~~ Rules.

RH-8901.- RH-8999. Reserved.

FOOTNOTES TO SECTION 9

1/

Experience with at least three (3) cases in category vii.(b). also satisfies the requirement in category vii.(a).

**SECTION 10.
[RESERVED]**

DRAFT

**SECTION 11.
THERAPEUTIC RADIATION MACHINES**

**PART A.
GENERAL**

RH-10000. Purpose and Scope.

- a. This Section establishes requirements, for which the licensee or registrant is responsible, for use of therapeutic radiation machines. The provisions of this Section are in addition to, and not in substitution for, other applicable provisions of these ~~Regulations~~ Rules.
- b. Therapeutic radiation machines meeting the definition of a particle accelerator are subject to Section 6, "Licenses and Radiation Safety Requirements for Particle Accelerators." Electronic brachytherapy devices and other therapeutic radiation machines not meeting the definition of a particle accelerator are subject to Section 1, "Registration of ~~Sources of Radiation~~ Machine Facilities and Vendor Services." RH-10308. devices are licensed or registered as determined by the Department.
- c. The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the healing arts who meets the training and experience criteria in RH-10200.c.

RH-10001. Provisions for Research Involving Human Subjects.

A licensee or registrant may use therapeutic radiation machines to conduct research involving human subjects, provided the research is conducted, funded, supported, or regulated by a Federal Agency that has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee or registrant shall apply for and receive approval of a specific amendment to its Department license or registration before conducting such research. Both types of licensees/registrants shall, at a minimum, obtain prior informed consent from the human subjects and obtain prior review and approval of the research activities by an Institutional Review Board in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

RH-10002. **U.S. Food and Drug Administration, Federal, and State Requirements.**

Nothing in this Section relieves the licensee or registrant from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing therapeutic radiation machines or auxiliary devices.

RH-10003. **Communications.**

Except where otherwise specified, all communications concerning these ~~Regulations~~ Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-10004. **Interpretations.**

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the ~~regulations~~ rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-10005. **Specific Exemptions.**

The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the ~~regulations~~ rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

RH-10006.- RH-10099. Reserved.

PART B. DEFINITIONS

RH-10100. **Definitions.**

Absorbed dose (D) - The mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM , where dE is the mean energy imparted by ionizing radiation to matter of mass dM . The SI unit of absorbed dose is joule per kilogram, and the special name of the unit of absorbed dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.

Absorbed dose rate - Absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

Accessible surface - Surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

Act - Act 8 of Second Extraordinary Session of 1961, as amended.

Added filtration - Any filtration which is in addition to the inherent filtration.

Air kerma (K) - The kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM , where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM . The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

Barrier - See "protective barrier."

Beam axis - The axis of rotation of the beam limiting device.

Beam-limiting device - A field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

Beam monitoring system - A system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

Beam scattering foil - A thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

Bent beam linear accelerator - A linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

Beam quality - A term that describes the penetrating power of the x-ray beam. This is identified numerically by half-value layer and is influenced by kilovolt peak (kVp) and filtration.

Beam quality (accelerator) - A term that describes the type and penetrating power of the ionizing radiation produced for certain machine settings.

Central axis of the beam - An imaginary line passing through the center of the useful beam and the center of the plane figure formed by the edge of the first beam-limiting device.

Changeable filters - Any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

Collimator - A device or mechanism by which the x-ray beam is restricted in size.

Contact therapy system - A therapeutic radiation machine with a short target-skin distance (TSD), usually less than 5 centimeters.

Conventional simulator - Any x-ray system designed to reproduce the geometric conditions of the radiation therapy equipment.

Detector - See "radiation detector."

Diaphragm - A device or mechanism by which the x-ray beam is restricted in size.

Dose monitor unit (DMU) - A unit response from the beam monitoring system from which the absorbed dose can be calculated.

Dosimetry system - A system of devices used for the detection, measurement, and display of qualitative and quantitative radiation exposures.

Electronic brachytherapy - A method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage.

RH-10100. (Cont'd)

Electronic brachytherapy device - The system used to produce and deliver therapeutic radiation including the x-ray tube, the control mechanism, the cooling system, and the power source.

Electronic brachytherapy source - The x-ray tube component used in an electronic brachytherapy device.

External beam radiation therapy - Therapeutic irradiation in which the source of radiation is at a distance from the body.

Field-flattening filter - A filter used to homogenize the absorbed dose rate over the radiation field.

Field size - The dimensions along the major axes of an area in a plane perpendicular to the central axis of the beam at the normal treatment or examination source to image distance and defined by the intersection of the major axes and the 50% isodose line.

Filter - Material placed in the useful beam to change beam quality in therapeutic radiation machines subject to RH-10301.

Gantry - That part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

Gray (Gy) - The SI unit of absorbed dose, kerma, and specific energy imparted equal to 1 joule per kilogram. The previous unit of absorbed dose (rad) is being replaced by the gray (1 Gy=100 rad).

Half-value layer (HVL) - The thickness of a specified substance which, when introduced into the path of a given beam of radiation, reduces the radiation field quantity to one-half its original value.

Healing arts - Any treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury, or unhealthy or abnormal physical or mental condition.

Institutional Review Board (IRB) - Any board, committee, or other group formally designated by an institution to review, approve the initiation of, and conduct periodic review of biomedical research involving human subjects.

Intensity Modulated Radiation Therapy (IMRT) - Radiation therapy that uses non-uniform radiation beam intensities which have been determined by various computer-based optimization techniques.

RH-10100. (Cont'd)

Interlock - A device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

Interruption of irradiation - The stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

Irradiation - The exposure of a living being or matter to ionizing radiation.

Isocenter - The center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

Kilovolt (kV) [kilo electron volt (keV)] - The energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. (Note: current convention is to use kV for photons and keV for electrons.)

Kilovolt peak (kVp) - See "peak tube potential."

Lead equivalence - The thickness of lead affording the same attenuation, under specified conditions, as the material in question.

Leakage radiation - Radiation emanating from the radiation therapy system except for the useful beam.

Light field - The area illuminated by light, simulating the radiation field.

mA - Milliampere.

Megavolt (MV) [mega electron volt (MeV)] - The energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum. (Note: current convention is to use MV for photons and MeV for electrons.)

Misadministration - An event that meets the criteria in RH-10201.b.

Mobile Electronic Brachytherapy Service - Transportation of an electronic brachytherapy device to provide electronic brachytherapy at an address that is not the address of record.

Monitor unit (MU) - See "dose monitor unit."

Moving beam radiation therapy - Radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation, and rotational therapy.

Nominal treatment distance -

- a. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.
- b. For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

Output - The exposure rate (air kerma rate), dose rate, or a quantity related to these rates from a therapeutic radiation machine.

Patient - An individual subjected to machine produced radiation for the purposes of medical therapy. The term "patient" also applies to a human research subject.

Patient intervention - Actions by the patient or human research subject, whether intentional or unintentional, such as prematurely terminating the administration.

Peak tube potential - The maximum value of the potential difference in kilovolts across the x-ray tube during an exposure.

Periodic quality assurance check - A procedure which is performed to ensure that a previous parameter or condition continues to be valid.

Phantom - An object behaving in essentially the same manner as tissue, with respect to absorption or scattering of the ionizing radiation in question.

Physician - A doctor of medicine or doctor of osteopathy licensed by the Arkansas State Medical Board to prescribe drugs in the practice of medicine.

Prescribed dose - The total dose and dose per fraction as documented in the written directive. The prescribed dose is an estimation from measured data from a specified therapeutic machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique.

RH-10100. (Cont'd)

Primary dose monitoring system - A system that will monitor the useful beam during irradiation and that will terminate irradiation when a pre-selected number of dose monitor units have been delivered.

Primary protective barrier - See "protective barrier."

Protective barrier - A barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

- a. Primary protective barrier - The radiation absorbing material, excluding filters, placed in the useful beam.
- b. Secondary protective barrier - The radiation absorbing material that attenuates stray radiation.

Qualified Medical Physicist - An individual qualified in accordance with RH-10200.d.

Radiation detector - A device that 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.

Radiation field - See "useful beam."

Radiation head - The structure from which the useful beam emerges.

Radiation therapy system - An x-ray system that utilizes prescribed doses of ionizing radiation for treatment.

Redundant beam monitoring system - A combination of two independent dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

Scattered radiation - Ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

Secondary dose monitoring system - A system which will terminate irradiation in the event of failure of the primary dose monitoring system.

Secondary protective barrier - See "protective barrier."

Shutter - A device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

Sievert (Sv) - The SI unit of dose equivalent. The unit of dose equivalent is the joule per kilogram. The previous unit of dose equivalent (rem) is being replaced by the sievert (1 Sv=100 rem).

Simulator (radiation therapy simulation system) - Any x-ray system intended for localizing the volume to be exposed during radiation therapy and establishing the position and size of the therapeutic irradiation field. (See "conventional simulator" and "virtual simulator.")

Source - The region and/or material from which the radiation emanates.

Source-skin distance (SSD) - See "target-skin distance."

Stationary beam radiation therapy - Radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

Stray radiation - The sum of leakage and scattered radiation.

Target - That part of an x-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

Target-skin distance (TSD) - The distance measured along the beam axis from the center of the front surface of the x-ray target and/or electron virtual source to the surface of the irradiated object or patient.

Tenth-value layer (TVL) - The thickness of a specified substance which, when introduced into the path of a given beam of radiation, reduces the radiation field quantity to one-tenth of its original value.

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.

Therapeutic radiation machine - X-ray or electron-producing equipment designed and used for external beam radiation therapy. For the purpose of these ~~Regulations~~ Rules, devices used to administer electronic brachytherapy shall also be considered therapeutic radiation machines.

Tube - An x-ray tube, unless otherwise specified.

RH-10100. (Cont'd)

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.

Useful beam - The radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the therapeutic radiation machine to produce radiation.

Virtual simulator - A computed tomography (CT) unit used in conjunction with relevant software which recreates the treatment machine; and that allows import, manipulation, display, and storage of images from CT and/or other imaging modalities.

Virtual source - A point from which radiation appears to originate.

Wedge filter - A filter which effects continuous change in transmission over all or a part of the useful beam.

Written directive - An order in writing for the administration of radiation to a specific patient or human research subject. Written directives shall meet the requirements in RH-10201.

X-ray tube - Any electron tube which is designed to be used primarily for the production of x-rays.

RH-10101.- RH-10199. Reserved.

PART C.
ADMINISTRATIVE REQUIREMENTS

RH-10200. **General Administrative Requirements for Facilities Using Therapeutic Radiation Machines.**

a. **Administrative controls.**

The licensee or registrant shall be responsible for directing the operation of the therapeutic radiation machines that have been licensed/registered with the Department. The licensee or registrant or an agent of the licensee/registrant shall ensure that the requirements of Section 11 are met in the operation of the therapeutic radiation machine(s).

b. A therapeutic radiation machine that does not meet the provisions of these ~~Regulations~~ Rules shall not be used for irradiation of patients.

c. **Training for therapeutic radiation machine Authorized Users.**

1. The licensee or registrant for any therapeutic radiation machine shall require the Authorized User to be a physician who:

A. Is certified by:

- i. The American Board of Radiology in Radiation Oncology or Therapeutic Radiology; or
- ii. The American Board of Radiology in Radiology, prior to 1976 (combined diagnostic and therapeutic radiology program); or
- iii. The American Osteopathic Board of Radiology in Radiation Oncology; or
- iv. The Faculty of Radiologists of the Royal College of Surgeons in Ireland in Radiation Oncology; or
- v. The Royal College of Radiologists in Clinical Oncology; or
- vi. The Royal College of Physicians and Surgeons of Canada in Radiation Oncology or Therapeutic Radiology; or

- B. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, five hundred (500) hours of supervised work experience, and a minimum of three (3) years of supervised clinical experience.
- i. To satisfy the requirement for instruction, the classroom and laboratory training shall include:
 - (a). Radiation physics and instrumentation;
 - (b). Radiation protection;
 - (c). Mathematics pertaining to the use and measurement of ionization radiation; and
 - (d). Radiation biology.
 - ii. To satisfy the requirement for supervised work experience, training shall be under the supervision of an Authorized User and shall include:
 - (a). Review of the full calibration measurements and periodic quality assurance checks;
 - (b). Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings;
 - (c). Using administrative controls to prevent misadministrations;
 - (d). Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and
 - (e). Checking and using radiation survey meters.

- iii. To satisfy the requirement for a period of supervised clinical experience, training shall include one (1) year in a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education (ACGME) or the Council on Postdoctoral Training (COPT) of the American Osteopathic Association and an additional two (2) years of clinical experience in therapeutic radiology under the supervision of an Authorized User. The supervised clinical experience shall include:
 - (a). Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;
 - (b). Selecting proper dose and how it is to be administered;
 - (c). Calculating the therapeutic radiation machine doses and collaborating with the Authorized User in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reaction to radiation; and
 - (d). Post-administration follow-up and review of case histories.
2. Notwithstanding the requirements of RH-10200.c.1., the registrant for any therapeutic radiation machine subject to RH-10301. or RH-10307. may also submit the training and experience of the prospective Authorized User physician for Department review on a case-by-case basis, provided the training and experience is substantially equivalent to that described in RH-10200.c.1. and includes significant emphasis on dosimetry calculation.
3. A physician shall not act as an Authorized User for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the Department.

d. Training for Qualified Medical Physicists.

1. The licensee or registrant for any therapeutic radiation machine shall require the Qualified Medical Physicist to be an individual who:

A. Is certified by:

i. The American Board of Radiology in:

- (a). Therapeutic Medical Physics; or
- (b). Therapeutic Radiologic Physics; or
- (c). Roentgen-Ray & Gamma-Ray Physics; or
- (d). X-ray and Radium Physics; or
- (e). Radiologic Physics; or

ii. The American Board of Medical Physics in Radiation Oncology Physics; or

iii. The Canadian College of Physicists in Medicine in Radiation Oncology Physics; or

B. Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one (1) year of full time training in medical physics; and an additional year of full time work experience under the supervision of an individual who meets the requirements for a Qualified Medical Physicist.

This training and work experience shall be conducted in clinical radiation facilities that provide high-energy external beam radiation therapy (photons and electrons with energies greater than or equal to one MV/one MeV). During the year of work experience, the tasks listed in RH-10300.a., RH-10301.p./RH-10302.t., and RH-10301.q./RH-10302.u. shall have been performed under the supervision of an individual who meets the requirements for a Qualified Medical Physicist.

RH-10200.d. (Cont'd)

2. An individual identified as a qualified expert on an Arkansas medical particle accelerator license on or before November 30, 2014 shall be considered as meeting the requirements for a Qualified Medical Physicist for the purposes of these ~~Regulations~~ Rules.
3. An individual shall not act as a Qualified Medical Physicist for any therapeutic radiation machine until such time as said individual's training has been reviewed and approved by the Department.

e. **Qualifications of operators.**

1. Individuals who operate therapeutic radiation machines for human use shall meet the appropriate Radiologic Technology Licensure requirements issued in accordance with the Rules and Regulations Pertaining to Radiologic Technology Licensure promulgated under the authority of Act 1071 of 1999, as amended – codified at Arkansas Code Annotated §§ 17-106-101 –17-106-111 and 17-106-201 – 17-106-204. The original licensure document or a notarized copy of the document shall be maintained at the location(s) where the individual is working.
2. Operator qualifications of all personnel currently operating a therapeutic radiation machine shall be kept on file at the facility. Information on former operators shall be retained for a period of at least five (5) years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

- f. Written operating and safety procedures shall be developed by a Qualified Medical Physicist and shall include any restrictions required for the safe operation of the particular therapeutic radiation machine. These procedures shall be available in the control area of the therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these procedures. Written operating and safety procedures for a therapeutic radiation machine subject to RH-10301. shall be in accordance with RH-10301.r. Procedures for a therapeutic radiation machine subject to RH-10302. shall be in accordance with RH-10302.s. Procedures for an electronic brachytherapy device shall be in accordance with RH-10307.h.
- g. Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a therapeutic radiation machine Authorized User. This provision specifically prohibits deliberate exposure of an individual for training, demonstration, or other non-healing-arts purposes.

h. Visiting Authorized User.

Notwithstanding the provisions of RH-10200.g., a licensee or registrant may permit any physician to act as a Visiting Authorized User under the terms of the licensee's or registrant's license/registration for up to sixty (60) days per calendar year under the following conditions:

1. The Visiting Authorized User has the prior written permission of the licensee's/registrator's management and, where applicable, the facility's Radiation Safety Committee; and
2. The Visiting Authorized User meets the training requirements established for Authorized Users in RH-10200.c.1.; and
3. The licensee or registrant maintains copies of all records generated pursuant to RH-10200.h.1. and h.2. for five (5) years from the date of the last visit.

i. All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the licensee's or registrant's quality management program. In addition to the requirements of Section 11, these individuals are also subject to the requirements of RH-1200., RH-1302., and RH-1500.d. ~~of these Regulations.~~

j. Information and maintenance record and associated information.

The licensee or registrant shall maintain the following information in a separate file for each therapeutic radiation machine, for inspection by the Department:

1. Report of acceptance testing;
2. Records of all surveys, calibrations, and periodic quality assurance checks required by this Section for the therapeutic radiation machine, including the names of persons who performed the activities;
3. Records of maintenance and/or modifications performed on the therapeutic radiation machine, including the names of persons who performed the services; and

4. Signature of person authorizing the return of the therapeutic radiation machine to clinical use after service, repair, or upgrade.

RH-10200. (Cont'd)

k. Report and notification of a dose to an embryo/fetus.

1. A licensee or registrant shall report any dose to an embryo/fetus that is greater than five (5) millisievert (500 mrem) dose equivalent that is a result of an administration of radiation to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the referring physician.
2. The licensee or registrant shall notify the Department by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus that requires a report pursuant to RH-10200.k.1.
3. The licensee or registrant shall submit a written report to the Department within fifteen (15) days after discovery of a dose to the embryo/fetus that requires a report pursuant to RH-10200.k.1.
 - A. The written report shall include:
 - i. The licensee's or registrant's name and license/registration number;
 - ii. The name of the referring physician and of the prescribing physician;
 - iii. A brief description of the event;
 - iv. Why the event occurred;
 - v. The effect, if any, on the embryo/fetus;
 - vi. What actions, if any, have been taken or are planned to prevent recurrence; and
 - vii. Certification that the licensee or registrant notified the pregnant individual (or the pregnant individual's responsible relative or guardian), and if not, why not.
 - B. The report must not contain the individual's name or any other information that could lead to identification of the individual.

RH-10200.k. (Cont'd)

4. The licensee or registrant shall provide notification of the event to the referring physician and also to the pregnant individual, no later than 24 hours after discovery of an event that would require reporting under RH-10200.k.1., unless the referring physician personally informs the licensee or registrant either that he or she will inform the pregnant individual or that, based on medical judgment, telling the pregnant individual would be harmful. The licensee or registrant is not required to notify the pregnant individual without first consulting with the referring physician. If the referring physician or pregnant individual cannot be reached within 24 hours, the licensee or registrant shall make the appropriate notifications as soon as possible thereafter. The licensee or registrant may not delay any appropriate medical care for the embryo/fetus, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this subparagraph, the notification may be made to the pregnant individual's responsible relative or guardian instead of to the pregnant individual. If a verbal notification is made, the licensee or registrant shall inform the pregnant individual, or the pregnant individual's responsible relative or guardian, that a written description of the event can be obtained from the licensee/registrant upon request. The licensee or registrant shall provide such a written description if requested.
5. A licensee or registrant shall retain a record of a dose to an embryo/fetus for five (5) years. The record must contain the information required by RH-10200.k.3.A. plus the name of the pregnant individual who is the subject of the event and her social security number or other identification number, if one has been assigned. A copy of this record shall be provided to the referring physician, if other than the licensee or registrant, within fifteen (15) days after the discovery of the event.
1. Licensees or registrants with equipment that has been issued variances by the United States Food and Drug Administration (FDA) to Title 21, CFR Part 1020 shall maintain copies of those variances at the pertinent authorized use locations until transfer or disposal of the therapeutic radiation machine or termination of the license or registration.

m. **Record retention periods.**

1. Each licensee or registrant shall retain each record that is required by this Section or by license condition for the period specified by the appropriate ~~regulation~~ rule or license condition. If a retention period is not otherwise specified by ~~regulation~~ rule or license condition, the record must be retained until the Department terminates each license or registration that authorizes the activity that is subject to the recordkeeping requirement.
2. If there is a conflict between the Department's ~~regulations~~ rules in this Section, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the ~~regulations~~ rules in this Section for such records shall apply unless the Department, pursuant to RH-10005., has granted a specific exemption from the record retention requirements specified in the ~~regulations~~ rules in this Section.

n. **Record maintenance.**

Each record required by this Section 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-10201. **Quality Management Program.**

Each licensee, registrant, or applicant subject to RH-10301., RH-10302., or RH-10307. shall develop, implement, and maintain a quality management program to provide high confidence that radiation will be administered as directed by the Authorized User.

a. **Scope and applicability.**

The quality management program shall address, at a minimum, the following specific objectives:

1. **Written directives.**

- A. A written directive must be dated and signed by an Authorized User prior to the administration of radiation.

If because of the patient's/human research subject's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's/human research subject's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the patient's/human research subject's record and a revised written directive is signed by an Authorized User within 48 hours of the oral revision.

- B. The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions.

- C. A written revision to an existing written directive may be made, provided that the revision is dated and signed by an Authorized User prior to the administration of the therapeutic radiation machine dose, or the next fractional dose.

- D. The licensee or registrant shall retain a copy of the written directive for five (5) years.

2. **Procedures for administrations.**

The licensee or registrant shall develop, implement, and maintain written procedures to provide high confidence that:

- A. Prior to the administration of each course of radiation treatments, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;
- B. Each administration is in accordance with the written directive;
- C. Therapeutic radiation machine final plans of treatment and related calculations are in accordance with the respective written directives by:
 - i. Checking both manual and computer generated dose calculations to verify they are correct and in accordance with the written directive; and
 - ii. Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;
- D. Any unintended deviation from the written directive is identified, evaluated, and appropriate action is taken; and
- E. The licensee or registrant retains a copy of the procedures for administrations for the duration of the license or registration.

b. **Reports and notifications of misadministrations.**

- 1. A licensee or registrant shall report any event resulting from intervention of a patient or human research subject in which the administration of therapeutic radiation machine radiation results, or will result in, unintended permanent functional damage to an organ or a physiological system as determined by a physician.

RH-10201.b. (Cont'd)

2. Other than events that result from intervention by a patient or human research subject, a licensee or registrant shall report any event in which the administration of a therapeutic radiation machine therapy dose:
 - A. Involves the wrong patient, wrong treatment modality, or wrong treatment site; or
 - B. Consists of three (3) or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than ten percent (10%) of the total prescribed dose; or
 - C. The calculated weekly administered dose differs from the weekly prescribed dose by more than thirty percent (30%) of the weekly prescribed dose; or
 - D. The calculated total administered dose differs from the total prescribed dose by more than twenty percent (20%) of the total prescribed dose.
3. The licensee or registrant shall notify the Department by telephone no later than the next calendar day after the discovery of a misadministration.
4. The licensee or registrant shall provide notification of the event to the referring physician and also notify the individual who is the subject of 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 or 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 affected individual 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 for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this subparagraph, the notification of the individual who is the subject of the misadministration may be made instead to that

RH-10201.b. (Cont'd)

individual's responsible relative or guardian. If a verbal notification is made, the licensee or registrant shall inform the

individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee/registrant upon request. The licensee or registrant shall provide such a written description if requested.

5. The licensee or registrant shall submit a written report to the Department within fifteen (15) days after the discovery of a misadministration. The report shall not contain the individual's name or any other information that could lead to the identification of the individual. The written report shall include the following:
 - A. The licensee's or registrant's name;
 - B. The name of the prescribing physician;
 - C. A brief description of the event;
 - D. Why the event occurred;
 - E. The effect, if any, on the individual who received the administration;
 - F. What actions, if any, that have been taken, or are planned, to prevent recurrence;
 - G. Certification that the licensee or registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not; and
 - H. What information was provided to the individual (or the individual's responsible relative or guardian) when notified.
6. The licensee or registrant shall retain a record of a misadministration in accordance with RH-10201.c. A copy of this record shall be provided to the referring physician, if other than the licensee or registrant, within fifteen (15) days after discovery of the misadministration.
7. Aside from the notification requirement in RH-10201.b.4., nothing in this section affects any rights or duties of licensees or registrants and physicians in relation to each other, to individuals affected by

the misadministration, or to that individual's responsible relatives or guardians.

RH-10201. (Cont'd)

c. **Records of misadministrations.**

A licensee or registrant shall retain a record of misadministrations reported in accordance with RH-10201.b. for five (5) years. The record shall contain the following:

1. The licensee's or registrant's name;
2. The names of all persons involved (including the individual who is the subject of the misadministration);
3. The social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration;
4. A brief description of the event; why it occurred; the effect, if any, on the individual;
5. The actions, if any, that have been taken, or are planned, to prevent recurrence; and
6. Whether the licensee or registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not.

RH-10202.- RH-10299. Reserved.

PART D.
TECHNICAL REQUIREMENTS

RH-10300. General Technical Requirements for Facilities Using Therapeutic Radiation Machines.

a. Protection surveys.

1. The licensee or registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with RH-10304. The radiation protection survey shall be performed by, or under the direction of, a Qualified Medical Physicist and shall verify, via the use of nationally recognized shielding evaluation survey procedures, that:
 - A. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in RH-1200.a. ~~of these Regulations~~; and
 - B. Radiation levels in unrestricted areas do not exceed the limits specified in RH-1208.a. and RH-1208.b. ~~of these Regulations~~.
2. In addition to the requirements of RH-10300.a.1., a radiation protection survey shall also be performed prior to any subsequent medical use and:
 - A. After making any change in the treatment room shielding;
 - B. After making any change in the location of the therapeutic radiation machine within the treatment room;
 - C. After relocating the therapeutic radiation machine;
 - D. Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room;
 - E. After making a change in the occupancy of areas adjacent to the treatment room; and
 - F. At least annually to check for unknown changes and malfunctioning equipment.

3. Initial radiation protection surveys of therapeutic radiation machine installations subject to RH-10302. shall be performed by, or under the direction of, a Qualified Medical Physicist who did not consult in the design of the therapeutic radiation machine installation and is not employed by or within any corporation or partnership with the individual who consulted in the design of the installation.
4.
 - A. The survey record shall indicate all instances where the facility, in the opinion of the Qualified Medical Physicist, is in violation of applicable regulations rules. Any deficiencies detected during the survey shall be corrected prior to using the therapeutic radiation machine.
 - B. The survey record shall include, but not be limited to, the following:
 - i. The date of the measurements;
 - ii. The reason the survey is required;
 - iii. A description of the therapeutic radiation machine including the manufacturer's name, model number and serial number, beam type, and beam energy;
 - iv. A diagram of the facility that details building structures; areas surrounding the treatment room that were surveyed; and the position of the therapeutic radiation machine, control panel, and associated equipment;
 - v. A description of the instrumentation used to determine radiation measurements, including the date of the most recent calibration and who performed the calibration for each instrument used;
 - vi. The conditions under which radiation measurements were taken;
 - vii. Survey data including:
 - (a). The measured dose rate at several points in each area expressed in millirems (microsieverts) per hour;

- (b). The projected maximum “in-any-one-hour” dose equivalent in each unrestricted area adjacent to the therapeutic radiation machine;
 - (c). The projected maximum annual total effective dose equivalent (TEDE) in each restricted and unrestricted area adjacent to the therapeutic radiation machine; and
 - (d). A description of workload, use, and occupancy factors employed in determining the projected annual TEDE; and
 - viii. The signature of the individual responsible for conducting the survey.
- 5. If the results of the surveys required by RH-10300.a.1. or RH-10300.a.2. indicate any radiation levels in excess of the respective limit specified in RH-10300.a.1., the licensee or registrant shall lock the control in the "OFF" position and not use the unit:
 - A. Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or
 - B. Until the licensee or registrant has received a specific exemption from the Department.
- 6. Initial radiation protection survey reports shall be maintained for the duration of the license or registration. Other radiation protection survey reports shall be maintained for five (5) years.
- b. **Modification of radiation therapy unit or room before beginning a treatment program.**

If the survey required by RH-10300.a. indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by RH-1208.a. and RH-1208.b., before beginning the treatment program the licensee or registrant shall ensure the following:

- 1. The unit is equipped with beam direction interlocks or additional radiation shielding is added to ensure compliance with RH-1208.a. and RH-1208.b.;

RH-10300.b. (Cont'd)

2. The survey required by RH-10300.a. is performed again; and
3. The survey report generated is in accordance with RH-10300.a.4.B. and includes the results of the initial survey, a description of the modification made in order to comply with this paragraph, and the results of the second survey; or
4. A license or registration amendment is requested and received under RH-1208.d. that authorizes radiation levels in unrestricted areas greater than those permitted by RH-1208.a. and RH-1208.b.

c. **Dosimetry equipment.**

1. The licensee or registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous twenty-four (24) months; after any servicing that may have affected the system's calibration; and after any constancy checks performed on the system indicated the need.
 - A. For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for cobalt-60;
 - B. For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured;
2. The licensee or registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with RH-10300.c.1. This comparison shall have been performed within the previous twelve (12) months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in RH-10300.c.1.;

RH-10300.c. (Cont'd)

3. The licensee or registrant shall maintain a record of each dosimetry system calibration and comparison for five (5) years. For each calibration or comparison, the record shall include the following: the date of the calibration or comparison; the manufacturer's name, model numbers, and serial numbers of the instruments that were calibrated or compared as required by RH-10300.c.1. and RH-10300.c.2.; the correction factors that were determined; the names of the individuals who performed the calibration or comparison; and evidence that the comparison was performed by, or under the direct supervision and in the physical presence of, a Qualified Medical Physicist.

d. **Reports of external beam radiation therapy surveys and measurements.**

The licensee or registrant for any therapeutic radiation machine subject to RH-10301. or RH-10302. shall furnish a copy of the records required in RH-10300.a.. and RH-10300.b. to the Department within thirty (30) days following completion of the action that initiated the record requirement. Annual radiation protection surveys shall not be submitted unless it is discovered that radiation levels in unrestricted and/or restricted areas exceed the dose limits specified in Section 3 of these Regulations.

RH-10301. **Therapeutic Radiation Machines of Less Than 500 kV.^{1/}**

a. **Leakage radiation.**

When the x-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

1. **5-50 kV systems.**

The leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly shall not exceed 100 mrad (1 mGy) in any one hour.

2. **>50 and <500 kV systems.**

The leakage air kerma rate measured at a distance of 1 meter from the target in any direction shall not exceed 1 rad (1 cGy) in any 1 hour. This air kerma rate measurement may be averaged over areas no larger than one hundred square centimeters (100 cm²). In addition, the air kerma rate at a distance of 5 centimeters from the surface of the tube housing assembly shall not exceed 30 rad (30 cGy) per hour.

3. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in RH-10301.a.1. and RH-10301.a.2. for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the Department.

b. **Permanent beam limiting devices.**

Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

c. **Adjustable or removable beam limiting devices.**

1. All adjustable or removable beam limiting devices, diaphragms, cones, or blocks shall not transmit more than five percent (5%) of the useful beam for the most penetrating beam used; and
2. When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

d. **Filter system.**

The filter system shall be so designed that:

1. Filters cannot be accidentally displaced at any possible tube orientation;
2. For equipment installed after an interlock system prevents irradiation if the proper filter is not in place;

3. The air kerma rate escaping from the filter slot shall not exceed 1 rad (1 cGy) per hour at one (1) meter under any operating conditions; and
4. Each filter shall be marked as to its material of construction and its thickness.

e. **Tube immobilization.**

1. The x-ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and
2. The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

f. **Source marking.**

The tube housing assembly shall be so marked that it is possible to determine the location of the source to within five (5) millimeters, and such marking shall be readily accessible for use during calibration procedures.

g. **Beam block.**

Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, that can be positioned over the entire useful beam exit port during periods when the beam is not in use.

h. **Timer.**

A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

1. A timer with a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time or time remaining indicator;
2. The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" 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 reset the elapsed time indicator;

3. The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;
4. The timer shall permit accurate pre-setting and determination of exposure times as short as 1 second;
5. The timer shall not permit an exposure if set at zero;
6. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and
7. Timer shall be accurate to within one percent (1%) of the selected value or 1 second, whichever is greater.

i. **Control panel.**

In addition to other applicable requirements specified in Section 11, the control panel shall also:

1. Provide an indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;
2. Provide an indication of whether x-rays are being produced;
3. Provide a means for indicating x-ray tube potential and current;
4. Provide the means for terminating an exposure at any time;
5. Provide a positive display of specific filter(s) in the beam;
6. Include an access control (locking) device that will prevent unauthorized use of the therapeutic radiation machine; and
7. Include emergency buttons/switches that shall be clearly labeled as to their functions.

j. **Multiple tubes.**

When a control panel may energize more than one x-ray tube:

1. It shall be possible to activate only one x-ray tube at any time;

2. There shall be an indication at the control panel identifying which x-ray tube is activated; and
3. There shall be an indication at the tube housing assembly when that tube is energized.

k. **Target-skin distance (TSD).**

There shall be a means of determining the central axis TSD to within one (1) centimeter and of reproducing this measurement to within two (2) millimeters thereafter.

l. **Shutters.**

Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds after the x-ray "ON" switch is energized, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

m. **Low filtration x-ray tubes.**

Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

n. **Facility design requirements for therapeutic radiation machines capable of operating in the range 50 kV to 500 kV.**

In addition to shielding adequate to meet requirements of RH-10305., the treatment room shall meet the following design requirements:

1. **Aural communication.**

Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible.

2. **Viewing systems.**

Provision shall be made to permit continuous observation of the patient during irradiation, and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless at least one viewing system is operational.

o. **Additional requirements.**

Treatment rooms that contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

1. All protective barriers shall be fixed except for entrance doors or beam interceptors;
2. The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;
3. Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. 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; and
4. When any door referred to in RH-10301.o.3. is opened while the x-ray tube is activated, the air kerma rate at a distance of 1 meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

p. **Full calibration measurements.**

1. Full calibration of a therapeutic radiation machine subject to RH-10301. shall be performed by, or under the direct supervision of, a Qualified Medical Physicist who is physically present at the facility during the calibration:
 - A. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;
 - B. At intervals not exceeding one (1) year; and

C. Before medical use under the following conditions:

- i. Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent (5%) from the value obtained at the last full calibration and the difference cannot be reconciled; and
- ii. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

D. Notwithstanding the requirements of RH-10301.p.1.C.:

- i. Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes and/or energies that are not within their acceptable range; and
 - ii. If the repair, replacement, or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in RH-10301.p.1.C.i.
2. To satisfy the requirement of RH-10301.p.1., full calibration shall include all measurements recommended for annual calibration by NCRP Report No. 69, "Dosimetry of X-Ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV."
 3. The registrant shall use a dosimetry system described in RH-10300.c.1. to measure the radiation output of a therapeutic radiation machine subject to RH-10301.
 4. A copy of the most recent calibration performed pursuant to RH-10301.p.1. shall be available at a designated area within the therapy facility housing the therapeutic radiation machine.

5. The registrant shall maintain a record of each calibration for five (5) years. The record shall include the following: the date of the calibration; the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the x-ray tube; the manufacturer's name, model numbers, and serial numbers of the instruments used to calibrate the therapeutic radiation machine; the results and an assessment of the full calibration; and the signature of the Qualified Medical Physicist responsible for the calibration.

q. **Periodic quality assurance checks.**

1. Periodic quality assurance checks shall be performed on those therapeutic radiation machines subject to RH-10301. that are capable of operation at greater than or equal to 50 kV.
2. The registrant shall perform periodic quality assurance checks required by RH-10301.q.1. in accordance with written procedures established by the Qualified Medical Physicist. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed and that the quality assurance check shall be performed during the calibration specified in RH-10301.p.1. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in RH-10301.p.1., shall be stated.
3. The cause for a parameter exceeding a tolerance set by the Qualified Medical Physicist shall be investigated and corrected before the system is used for patient irradiation.
4. Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Qualified Medical Physicist's quality assurance check procedures, the system shall be recalibrated as required in RH-10301.p.1.
5. The registrant shall use a dosimetry system described in RH-10300.c.2. to perform periodic quality assurance checks involving measurement of radiation output.
6. The registrant shall have the Qualified Medical Physicist review and sign the results of each quality assurance check within thirty (30) days of the date that the check was performed.

RH-10301.q. (Cont'd)

7. The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to RH-10301. are performed at intervals not to exceed thirty (30) days.
8. Notwithstanding the requirements of RH-10301.q.6. and RH-10301.q.7., the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to a human unless the quality assurance checks required by RH-10301.q.6. and RH-10301.q.7. have been performed within the thirty (30) day period immediately prior to said administration.
9. To satisfy the requirement of RH-10301.q.7., safety quality assurance checks shall, at a minimum, ensure proper operation of:
 - A. Electrical interlocks at each external beam radiation therapy room entrance, if applicable;
 - B. The "BEAM-ON" and termination switches;
 - C. Beam condition indicator lights on the access door(s) and in the radiation therapy room, if applicable, and on the control console;
 - D. Viewing and intercom systems, if applicable;
 - E. Radiation area monitors, if applicable; and
 - F. Electrically operated treatment room doors from inside and outside the treatment room, if applicable.
10. A copy of the most recent quality assurance checks performed pursuant to RH-10301.q. shall be available at a designated area within the therapy facility housing the therapeutic radiation machine.
11. If the results of the safety quality assurance checks required in RH-10301.q.9. indicate the malfunction of any system, a registrant shall secure the control console in the OFF position and not use the therapeutic radiation machine except as may be necessary to repair, replace, or check the malfunctioning system.

12. The registrant shall maintain a record of each quality assurance check required by RH-10301.q. for five (5) years. The record shall include the results of the check plus the following: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name, model numbers, and serial numbers for the instruments used to measure the radiation output of the therapeutic radiation machine; the name of the individual who performed the periodic quality assurance check; and the signature of the Qualified Medical Physicist who reviewed the quality assurance check.

r. **Operating procedures.**

1. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.
2. Operating procedures shall include, but are not limited to, the following:
 - A. Therapeutic radiation machines shall not be used for irradiation of patients unless all applicable requirements of Section 11 have been met;
 - B. Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;
 - C. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;
 - D. The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV; and
 - E. No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual in the treatment room, other than the patient, shall be protected by a barrier sufficient to meet the dose limit requirements specified in Section 3 of these Regulations.

RH-10301. (Cont'd)

s. **Possession of survey instrument(s).**

Each facility location authorized to use a therapeutic radiation machine in accordance with RH-10301. shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μ Sv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable in accordance with RH-10303. and shall be calibrated in accordance with RH-10304.

RH-10302. **Therapeutic Radiation Machines - Photon Therapy Systems (500 kV and Above) and Electron Therapy Systems (500 keV and Above).**

a. **Possession of survey instrument(s).**

Each facility location authorized to use a therapeutic radiation machine in accordance with RH-10302. shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 mrem (10 μ Sv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable in accordance with RH-10303. and shall be calibrated in accordance with RH-10304.

b. **Leakage radiation outside the maximum useful beam in photon and electron modes.**

1. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius two (2) meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e., patient plane), shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding one hundred square centimeters (100 cm²) at a minimum of sixteen (16) points uniformly distributed in the plane.

RH-10302.b. (Cont'd)

2. Except for the area defined in RH-10302.b.1., the absorbed dose due to leakage radiation (excluding neutrons) at 1 meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding one hundred square centimeters (100 cm²).
3. For equipment manufactured after November 30, 2014, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1 (most current revision).
4. For each therapeutic radiation machine, the licensee shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in RH-10302.b.1. through RH-10302.b.3. for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the Department.

c. **Leakage radiation through beam limiting devices.**

1. **Photon radiation.**

All adjustable or interchangeable beam limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) shall not exceed two percent (2%) of the maximum absorbed dose on the central axis of the useful beam measured in a 100 cm² radiation field, or maximum available field size if less than 100 cm²;

2. **Electron radiation.**

All adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

- A. A maximum of two percent (2%) and average of 0.5 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven (7) centimeters outside the periphery of the useful beam; and
- B. A maximum of ten percent (10%) of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two (2) centimeters outside the periphery of the useful beam.

3. **Measurement of leakage radiation.**

A. **Photon radiation.**

Measurements of leakage radiation through the beam limiting devices shall be made with the beam limiting devices closed and any residual aperture blocked by at least two (2) tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding ten square centimeters (10 cm²);

B. Electron radiation.

Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one (1) square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one (1) centimeter of water equivalent build up material.

d. Filters/wedges.

1. Each wedge filter that is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined.
2. If the absorbed dose rate information required by RH-10302.i. relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter shall be removable only by the use of tools.
3. For equipment which utilizes wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils:
 - A. Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;
 - B. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
 - C. A display shall be provided at the treatment control panel showing the wedge filter(s), interchangeable field flattening filter(s), and/or interchangeable beam scattering foil(s) in use; and

- D. An interlock shall be provided to prevent irradiation if any filter and/or beam scattering foil selection operation carried out in the treatment room does not agree with the filter and/or beam scattering foil selection operation carried out at the treatment control panel.

e. **Stray radiation in the useful beam.**

For equipment manufactured after November 30, 2014, the licensee shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that x-ray stray radiation in the useful electron beam, absorbed dose at the surface during x-ray irradiation, and stray neutron radiation in the useful x-ray beam are in compliance with the most current revision of International Electrotechnical Commission (IEC) Document 60601-2-1.

f. **Beam monitors.**

All therapeutic radiation machines subject to RH-10302. shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

1. A therapeutic radiation machine subject to RH-10302. shall be provided with at least two (2) independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.
2. The detector and the system into which that detector is incorporated shall meet the following requirements:
 - A. Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;
 - B. Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;
 - C. Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation;

- D. The design of the beam monitoring systems shall ensure that the:
 - i. Malfunctioning of one system shall not affect the correct functioning of the other system(s); and
 - ii. Failure of either system shall terminate irradiation or prevent the initiation of radiation; and
- E. Each beam monitoring system shall have a legible display at the treatment control panel. Each display shall:
 - i. Maintain a reading until intentionally reset;
 - ii. Have only one scale and no electrical or mechanical scale multiplying factors;
 - iii. Utilize a design such that increasing dose is displayed by increasing numbers; and
 - iv. In the event of power failure, the beam monitoring information required in RH-10302.f.2.E.iii. 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.

g. Beam symmetry.

- 1. A bent-beam linear accelerator with beam flattening filter(s) subject to RH-10302. shall be provided with auxiliary device(s) to monitor beam symmetry;
- 2. The device(s) referenced in RH-10302.g.1. shall be able to detect field asymmetry greater than ten percent (10%); and
- 3. The device(s) referenced in RH-10302.g.1. shall be configured to terminate irradiation if the specifications in RH-10302.g.2. cannot be maintained.

h. Selection and display of dose monitor units.

- 1. Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel;

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2. The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation;
3. After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and
4. After termination of irradiation, it shall be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

i. **Air kerma rate/absorbed dose rate.**

A system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. The radiation detectors specified in RH-10302.f. may form part of this system. In addition:

1. The dose monitor unit rate shall be displayed at the treatment control panel;
2. If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the licensee;
3. If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten (10) times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad); and
4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in RH-10302.i.2. and RH-10302.i.3. for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the Department.

j. **Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy.**

1. Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.
2. If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than fifteen percent (15%) or forty (40) dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and
3. An indicator on the control panel shall show which monitoring system has terminated irradiation.

k. **Termination of irradiation.**

It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

l. **Interruption of irradiation.**

If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from 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, irradiation and equipment movements shall be automatically terminated.

m. **Timer.**

A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

1. A timer shall be provided which has a display at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator;

2. The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" 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 reset the elapsed time indicator; and
3. The timer shall terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

n. **Selection of radiation type.**

Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

1. Irradiation shall not be possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel;
2. The radiation type selected shall be displayed at the treatment control panel before and during irradiation;
3. An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type that has been selected;
4. An interlock system shall be provided to prevent irradiation with x-rays, except to obtain an image, when electron applicators are fitted;
5. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and
6. 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.

o. **Selection of energy.**

Equipment capable of generating radiation beams of different energies shall meet the following requirements:

1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

2. The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;
3. Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and
4. For equipment manufactured after November 30, 2014, the selection of energy shall be in compliance with the most current revision of International Electrotechnical Commission (IEC) Document 60601-2-1.

p. **Selection of stationary beam radiation therapy or moving beam radiation therapy.**

Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

1. Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;
2. The mode of operation shall be displayed at the treatment control panel;
3. An interlock system shall be provided to ensure that the equipment can operate only in the mode that has been selected;
4. An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

5. Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For all equipment:
 - A. An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten (10) degrees of rotation or one (1) cm of linear motion differs by more than twenty percent (20%) from the selected value;
 - B. Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than five percent (5%) from the dose monitor unit value selected;
 - C. An interlock shall be provided to prevent motion of more than five (5) degrees or one (1) cm beyond the selected limits during moving beam radiation therapy;
 - D. An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy; and
 - E. Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement;
6. Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by RH-10302.j.; and
7. An interlock system shall be provided to terminate irradiation if movement:
 - A. Occurs during stationary beam radiation therapy; or
 - B. Does not start or stops during moving beam radiation therapy unless such stoppage is a pre-planned function.

q. **Facility design requirements for therapeutic radiation machines operating above 500 kV.**

In addition to shielding adequate to meet requirements of RH-10305., the following design requirements shall apply:

1. **Protective barriers.**

All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors;

2. **Control panel.**

In addition to other applicable requirements specified in Section 11, the control panel shall also:

- A. Be located outside the treatment room;
- B. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;
- C. Provide an indication of whether radiation is being produced; and
- D. Include an access control (locking) device that will prevent unauthorized use of the therapeutic radiation machine;

3. **Viewing systems.**

Windows, mirrors, closed-circuit television, or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless at least one viewing system is operational;

4. **Aural communications.**

Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible;

5. **Room entrances.**

Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors. These warning lights shall indicate when the useful beam is "ON" and when it is "OFF";

6. **Entrance interlocks.**

Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel;

7. **Beam interceptor interlocks.**

If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with RH-1208.a. and RH-1208.b., interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s);

8. **Emergency cutoff switches.**

At least 1 emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by RH-10302.k. All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch;

9. **Safety interlocks.**

All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine; and

10. **Surveys for residual activity.**

Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating energies above 10 MV (10 MeV) prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production. Records of surveys pursuant to this subparagraph shall be maintained for five (5) years.

r. **Qualified Medical Physicist support.**

1. The services of a Qualified Medical Physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The Qualified Medical Physicist shall be responsible for:

- A. Full calibrations required by RH-10302.t.;
- B. Radiation protection surveys required by RH-10300.a.;
- C. Supervision and review of beam and clinical dosimetry;
- D. Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;
- E. Establishment of quality assurance procedures and performance of quality assurance check review required by RH-10302.u.
- F. Consultation with the Authorized User in treatment planning, as needed; and
- G. Performing of calculations/assessments regarding patient treatments that may constitute misadministrations.

2. If the Qualified Medical Physicist is not a full-time employee of the licensee, the operating procedures required by RH-10302.s. shall also specifically address how the Qualified Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Qualified Medical Physicist can be reached for instruction.

s. **Operating procedures.**

1. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.
2. Operating procedures shall include, but are not limited to, the following:
 - A. No individual, other than the patient, shall be in the treatment room during treatment. No individual shall be in the treatment room during any irradiation for testing or calibration purposes;
 - B. Therapeutic radiation machines shall not be used for irradiation of patients unless all applicable requirements of Section 11 have been met;
 - C. Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;
 - D. When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light field; and
 - E. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

t. **Acceptance testing, commissioning, and full calibration measurements.**

1. Acceptance testing, commissioning, and full calibration of a therapeutic radiation machine subject to RH-10302. shall be performed by, or under the direct supervision of, a Qualified Medical Physicist who is physically present at the facility during the calibration.

2. Acceptance testing and commissioning shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators" – AAPM Report No. 47, prepared by Radiation Therapy Task Group No. 45, and the manufacturer's contractual specifications. Acceptance testing and commissioning shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.
3. Full calibration shall include measurement of all applicable parameters recommended in "Task Group 142 Report: Quality Assurance of Medical Accelerators" – AAPM Report No. 142, prepared by the Quality Assurance and Outcome Improvement Subcommittee Task Group No. 142. Full calibration shall be performed in accordance with Report No. 142 and with "AAPM Code of Practice for Radiotherapy Accelerators" – AAPM Report No. 47, prepared by Radiation Therapy Task Group No. 45. Although it is not necessary to complete all elements of a full calibration at the same time, all applicable parameters (for all energies) shall be completed at intervals not exceeding twelve (12) months, unless a more frequent interval is referenced in Report No. 142.
4. The Qualified Medical Physicist shall perform or directly supervise, while being physically present at the facility, all elements of a full calibration necessary to determine that all parameters are within acceptable limits:
 - A. Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent (5%) from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy and/or multi-mode capabilities shall only require measurements for those modes and/or energies that are not within their acceptable range; and
 - B. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement, or modification does not affect all modes and/or energies, measurements shall be performed on the effected mode/energy that is in most frequent clinical use at the facility. The remaining energies/modes may be validated with quality assurance check procedures against the criteria in RH-10302.t.4.A.

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5. The licensee shall use a dosimetry system described in RH-10300.c.1. to measure the radiation output of a therapeutic radiation machine subject to RH-10302.
6. A copy of the most recent calibration performed pursuant to RH-10302.t. shall be available at a designated area within the therapy facility housing the therapeutic radiation machine.
7. The licensee shall maintain a record of each calibration for five (5) years. The record shall include the following: the date of the calibration; the manufacturer's name, model number, and serial number for the therapeutic radiation machine and for the instruments used to calibrate the therapeutic radiation machine; the results and an assessment of the full calibration; and the signature of the Qualified Medical Physicist responsible for the calibration.

u. **Periodic quality assurance checks.**

1. Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to RH-10302. These quality assurance checks shall be performed in accordance with "Task Group 142 Report: Quality Assurance of Medical Accelerators" – AAPM Report No. 142, prepared by the Quality Assurance and Outcome Improvement Subcommittee Task Group No. 142, at intervals not to exceed those specified in Report No. 142. All periodic quality assurance checks with an annual frequency do not have to be performed at the same time but shall be completed within an interval not to exceed twelve (12) months.
2. To satisfy the requirement of RH-10302.u.1., periodic quality assurance checks shall include determination of central axis radiation output and all other applicable quality assurance checks contained in "Task Group 142 Report: Quality Assurance of Medical Accelerators" – AAPM Report No. 142, prepared by the Quality Assurance and Outcome Improvement Subcommittee Task Group No. 142.
3. The licensee shall use a dosimetry system described in RH-10300.c.2. to perform periodic quality assurance checks involving measurement of radiation output.

4. The licensee shall perform periodic quality assurance checks required by RH-10302.u.1. in accordance with written procedures established by the Qualified Medical Physicist. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the quality assurance check when compared to the value for that parameter determined in the full calibration.
5. The licensee shall review the results of each periodic quality assurance check according to the following procedures:
 - A. The Authorized User and Qualified Medical Physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances;
 - B. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the Authorized User or Qualified Medical Physicist within three (3) treatment days; and
 - C. The Qualified Medical Physicist shall review and sign the results of each quality assurance check at intervals not to exceed thirty (30) days.
6. Applicable safety quality assurance checks shall be performed on all therapeutic radiation machines subject to RH-10302. at intervals not to exceed those specified in "Task Group 142 Report: Quality Assurance of Medical Accelerators" – AAPM Report No. 142, prepared by the Quality Assurance and Outcome Improvement Subcommittee Task Group No. 142. Safety quality assurance checks performed pursuant to RH-10302.u.7. shall be performed at intervals not to exceed three (3) months, unless a more frequent interval is referenced in Report No. 142.
7. To satisfy the requirement of RH-10302.u.6., safety quality assurance checks shall, at a minimum, ensure proper operation of:
 - A. Electrical interlocks at each external beam radiation therapy room entrance;

- B. Proper operation of the "BEAM-ON," interrupt, and termination switches;
 - C. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;
 - D. Viewing and intercom systems;
 - E. Radiation area monitors;
 - F. Electrically operated treatment room door(s) from inside and outside the treatment room; and
 - G. At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.
8. If the results of the safety quality assurance checks required in RH-10302.u.7. indicate the malfunction of any system, a licensee shall secure the control console in the OFF position and not use the therapeutic radiation machine except as may be necessary to repair, replace, or check the malfunctioning system.
9. A copy of the most recent quality assurance checks performed pursuant to RH-10302.u. shall be available at a designated area within the therapy facility housing the therapeutic radiation machine.
10. The licensee shall maintain a record of each quality assurance check required by RH-10302.u. for five (5) years. The record shall include the results of the check plus the following: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name, model numbers, and serial numbers for the instruments used to measure the radiation output of the therapeutic radiation machine; the name of the individual who performed the periodic quality assurance check; and the signature of the Qualified Medical Physicist who reviewed the quality assurance check.

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v. **Quality assurance for Intensity-Modulated Radiation Therapy.**

Quality assurance for Intensity-Modulated Radiation Therapy (IMRT) shall:

1. Include commissioning and testing (if applicable) of the treatment planning and delivery systems, routine quality assurance of the delivery system, and patient-specific validation for each treatment plan utilizing IMRT; and
2. Be performed in accordance with:
 - A. Department ~~regulations~~ rules;
 - B. The licensee's procedures;
 - C. "Guidance Document on Delivery, Treatment Planning, and Clinical Implementation of IMRT: Report of the IMRT Subcommittee of the AAPM Radiation Therapy Committee" - AAPM Report No. 82, prepared by the IMRT Subcommittee of the Radiation Therapy Committee, or current published recommendations from a recognized national professional association with expertise in IMRT;^{2/} and
 - D. Manufacturer's contractual specifications.

RH-10303. **Operability of Survey Instruments.**

- a. Portable monitoring equipment shall be tested for proper operation by way of a reference check performed at the following frequencies:
 1. At the time of calibration;
 2. Before each use and also after each survey to ensure the equipment was operational during the survey;
 3. After each maintenance and/or battery change; and
 4. At least quarterly.

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- b. If any reference check performed using a pre-defined geometry yields a reading that is not within +/- 20% of the reading measured immediately after calibration, the instrument shall be recalibrated.
- c. Records of portable monitoring equipment operability shall be maintained for five (5) years.

RH-10304. **Calibration of Survey Instruments.**

- a. The licensee or registrant shall ensure that the survey instruments used to show compliance with this Section have been calibrated before first use, at intervals not to exceed twelve (12) months, and following any repair that will affect the calibration.
- b. To satisfy the requirements of RH-10304.a., the licensee or registrant shall ensure:
 - 1. Calibration of all scales with readings up to 1000 mrem (10 mSv) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);
 - 2. Calibration of at least two (2) points located at approximately 1/3 and 2/3 of full scale on each scale of a linear scale instrument; calibration at midrange for each decade and at two (2) points of at least one decade on each scale of a logarithmic scale instrument; calibration at three (3) points between 2 and 1000 mrem (0.02 and 10 mSv) per hour for digital instruments.
- c. To satisfy the requirements of RH-10304.b., the licensee or registrant shall:
 - 1. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent (10%); and
 - 2. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent (20%) if a correction factor or graph is conspicuously attached to the instrument and is used to interpret readings to within 10 percent (10%).

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- d. The licensee or registrant shall retain a record of each calibration required in RH-10304.a. for five (5) years. The record shall include:
 - 1. A description of the calibration procedure; and
 - 2. A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.
- e. The licensee or registrant may obtain the services of individuals licensed by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform calibrations of survey instruments. Records of calibrations that contain information required by RH-10304.d. shall be maintained by the licensee or registrant.
- f. The licensee or registrant shall conspicuously note on the instrument the date of calibration.

RH-10305. **Shielding and Safety Design Requirements.**

- a. Each therapeutic radiation machine shall be provided with such primary and/or secondary barriers as are necessary to ensure compliance with RH-1200. and RH-1208.
- b. Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for Department approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in Appendix A to Section 11.

RH-10306. **Quality Assurance for Radiation Therapy Simulation Systems.**

Quality assurance for a conventional or virtual simulator shall:

- a. Include acceptance testing and periodic verification of system performance; and

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- b. Be performed in accordance with current published recommendations from a recognized national professional association with expertise in simulation systems.^{3/}

RH-10307. **Electronic Brachytherapy.**

- a. An electronic brachytherapy device that does not meet the requirements of RH-10307. shall not be used for irradiation of patients; and
- b. An electronic brachytherapy device shall only be utilized for human use applications specifically approved by the U.S. Food and Drug Administration (FDA) unless participating in a research study approved by the registrant's Institutional Review Board (IRB).

c. **Possession of survey instrument(s).**

Each facility location authorized to use an electronic brachytherapy device in accordance with RH-10307. shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 mrem (10 μ Sv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable in accordance with RH-10303. and shall be calibrated in accordance with RH-10304. for the applicable electronic brachytherapy source energy.

d. **Facility design requirements for electronic brachytherapy devices.**

In addition to shielding adequate to meet requirements of RH-10305., the treatment room shall meet the following design requirements:

1. If applicable, provision shall be made to prevent simultaneous operation of more than one therapeutic radiation machine in a treatment room;
2. Access to the treatment room shall be controlled by a door at each entrance;
3. Each treatment room shall have provisions to permit continuous two-way aural communication between the patient and the operator at the control panel. The electronic brachytherapy device shall not be used for irradiation of patients unless continuous two-way aural communication is possible;

4. Each treatment room shall have provisions to permit continuous visual observation of the patient from the treatment control panel during irradiation. The electronic brachytherapy device shall not be used for irradiation of patients unless the patient can be observed;
5. For electronic brachytherapy devices operating at or below 150 kV, radiation shielding for the staff in the treatment room shall be available, either as a portable shield and/or as localized shielding material around the treatment site; and
6. For electronic brachytherapy devices capable of operating above 150 kV:
 - A. The control panel shall be located outside the treatment room; and
 - B. Electrical interlocks shall be provided for all door(s) to the treatment room. These interlocks shall:
 - i. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
 - ii. Cause the source to be shielded when an entrance door is opened; and
 - iii. Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console.

e. **Control panel.**

In addition to other applicable requirements specified in Section 11, the control panel shall also:

1. Provide an indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;
2. Provide an indication of whether x-rays are being produced;

3. Provide a means for indicating electronic brachytherapy source potential and current;
4. Provide the means for terminating an exposure at any time;
5. Include an access control (locking) device that will prevent unauthorized use of the electronic brachytherapy device; and
6. Include emergency buttons/switches that shall be clearly labeled as to their functions.

f. **Timer.**

A suitable irradiation control device (timer) shall be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor.

1. A timer shall be provided at the treatment control panel. The timer shall indicate the planned setting and the time elapsed or remaining;
2. The timer shall not permit an exposure if set at zero;
3. The timer shall be a cumulative device that activates with an indication of "BEAM-ON" 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 reset the elapsed time indicator;
4. The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system has not previously terminated irradiation.
5. The timer shall permit setting of exposure times as short as 0.1 second; and
6. The timer shall be accurate to within one percent (1%) of the selected value or 0.1 second, whichever is greater.

g. **Qualified Medical Physicist support.**

1. The services of a Qualified Medical Physicist shall be required in facilities having electronic brachytherapy devices. The Qualified Medical Physicist shall be responsible for:
 - A. Evaluation of the output from the electronic brachytherapy source;
 - B. Radiation protection surveys required by RH-10300.a.;
 - C. Generation of the necessary dosimetric information;
 - D. Supervision and review of treatment calculations prior to initial treatment of any treatment site;
 - E. Establishment of quality assurance procedures and performance of quality assurance check review required by RH-10307.k.;
 - F. Consultation with the Authorized User in treatment planning, as needed;
 - G. Performing calculations/assessments regarding patient treatments that may constitute misadministrations; and
 - H. Implementation of shield locations and safe distances for individuals present in the treatment room during electronic brachytherapy treatments.
2. If the Qualified Medical Physicist is not a full-time employee of the registrant, the operating procedures required by RH-10307.h. shall also specifically address how the Qualified Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Qualified Medical Physicist can be reached for instruction.

h. **Operating procedures.**

1. A copy of the current operating and emergency procedures shall be maintained at the electronic brachytherapy device control console.

2. Operating procedures shall include, but are not limited to, the following:
 - A. Only individuals approved by the Authorized User, Radiation Safety Officer, or Qualified Medical Physicist shall be present in the treatment room during treatment;
 - B. Electronic brachytherapy devices shall not be used for irradiation of patients unless all applicable requirements of Section 11 have been met;
 - C. The electronic brachytherapy device shall be inoperable, either by hardware or password, when unattended by qualified staff or service personnel;
 - D. During operation, the Qualified Medical Physicist shall ensure that all persons in the treatment room, and all persons entering the treatment room, are prevented from exceeding the dose limits specified in Section 3 of these Regulations;
 - E. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used;
 - F. Written procedures shall be developed, implemented, and maintained for responding to an abnormal situation. These procedures shall include:
 - i. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions; and
 - ii. The names and telephone numbers of the Authorized Users, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.
 - G. Instructions shall be posted at the electronic brachytherapy device control console to inform the operator of the names and telephone numbers of the Authorized Users, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally; and

H. The Radiation Safety Officer, or his/her designee, and an Authorized User shall be notified as soon as possible if the patient has a medical emergency, suffers injury, or dies. The Department shall be notified as soon as possible if the patient expires during a treatment.

i. **Safety precautions for electronic brachytherapy devices.**

1. In accordance with RH-1302., "Conditions Requiring Individual Monitoring of External and Internal Occupational Dose," each registrant shall monitor exposures to radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Section 3, "Standards for Protection Against Radiation."
2. An Authorized User and a Qualified Medical Physicist shall be physically present during the initiation of all patient treatments involving the electronic brachytherapy device;
3. A Qualified Medical Physicist and either an Authorized User or a physician or electronic brachytherapy device operator shall be physically present during continuation of all patient treatments involving the electronic brachytherapy device, provided the physician or operator is under the supervision of an Authorized User. All individuals present pursuant to RH-10307.i.2. or i.3. shall be trained in the operation and emergency response for the electronic brachytherapy device;
4. A Qualified Medical Physicist shall designate shield locations or safe distances sufficient to meet the dose limit requirements of Section 3 of these Regulations for any individual, other than the patient, in the treatment room; and
5. All personnel in the treatment room are required to remain behind shielding or at a safe distance during treatment. A Qualified Medical Physicist shall approve any deviation from this requirement and shall designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.

j. Electronic brachytherapy source calibration measurements.

1. Calibration of the electronic brachytherapy source output for an electronic brachytherapy device shall be performed by, or under the direct supervision of, a Qualified Medical Physicist who is physically present at the facility during the calibration.
2. Calibration of the electronic brachytherapy source output shall be made for each electronic brachytherapy source, after any repair affecting the x-ray beam generation, when indicated by the electronic brachytherapy source quality assurance checks, and in accordance with RH-10307.j.5.
3. Calibration of the electronic brachytherapy source output shall utilize a dosimetry system described in RH-10300.c.1.
4. Calibration of the electronic brachytherapy source output shall include, as applicable, determination of:
 - A. The output within two percent (2%) of the expected value, if applicable, or determination of the output if there is no expected value;
 - B. Timer accuracy and linearity over the typical range of use;
 - C. Proper operation of back-up exposure control devices;
 - D. Evaluation that the relative dose distribution about the source is within five percent (5%) of that expected; and
 - E. Source positioning accuracy to within one (1) millimeter within the applicator.
5. Calibration of the x-ray source output, as described in RH-10307.j.1. through j.4., shall be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of a calibration protocol published by a national professional association, the manufacturer's calibration protocol shall be followed.
6. A copy of the most recent calibration performed pursuant to RH-10307.j. shall be available at a designated area within the therapy facility housing the therapeutic radiation machine.

7. The registrant shall maintain a record of each calibration for five (5) years. The record shall include the following: the date of the calibration; the manufacturer's name, model number, and serial number for the electronic brachytherapy device and a unique identifier for its electronic brachytherapy source; the manufacturer's name, model numbers, and serial numbers of the instruments used to calibrate the electronic brachytherapy device; the results and an assessment of the calibration; and the signature of the Qualified Medical Physicist responsible for the calibration.

k. **Periodic quality assurance checks for electronic brachytherapy devices.**

1. Quality assurance checks shall be performed on each electronic brachytherapy device:
 - A. At the beginning of each day of use;
 - B. Each time the device is moved to a new room within the same facility or to a different site (i.e., different address of use); and
 - C. After each x-ray tube installation.
2. The registrant shall perform periodic quality assurance checks required by RH-10307.k.1. in accordance with written procedures established by the Qualified Medical Physicist. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the quality assurance check.
3. To satisfy the requirements of RH-10307.k.1., periodic quality assurance checks shall include, at a minimum:
 - A. Verification that output of the electronic brachytherapy source falls within three percent (3%) of expected values, as appropriate for the device, as determined by:
 - i. Output as a function of time, or
 - ii. Output as a function of setting on a monitor chamber.

- B. Verification of the consistency of the dose distribution to within three percent (3%) of that found during calibration required by RH-10307.j. If within three percent (3%) is unachievable, manufacturer's specifications shall be followed ; and
 - C. Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within two (2) mm.
4. The registrant shall use a dosimetry system described in RH-10300.c.2. to perform periodic quality assurance checks involving measurement of radiation output.
5. The registrant shall review the results of each quality assurance check according to the following procedures:
- A. An Authorized User and Qualified Medical Physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The electronic brachytherapy device shall not be made available for subsequent medical use until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances;
 - B. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the Authorized User or Qualified Medical Physicist within two (2) days; and
 - C. The Qualified Medical Physicist shall review and sign the results of each quality assurance check at intervals not to exceed thirty (30) days.
6. To satisfy the requirements of RH-10307.k.1., safety quality assurance checks shall, at a minimum, ensure:
- A. Proper operation of radiation exposure indicator lights on the control console and, if applicable, on the electronic brachytherapy device;
 - B. Proper operation of viewing and intercom systems, if applicable, in each electronic brachytherapy facility;
 - C. Proper operation of radiation area monitors, if applicable;

RH-10307.k.6. (Cont'd)

- D. Proper operation of electrical interlocks at each treatment room entrance, if applicable;
 - E. The integrity of all cables, catheters, or parts of the device that carry high voltages; and
 - F. Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.
7. If the results of the safety quality assurance checks required in RH-10307.k.6. indicate the malfunction of any system, a registrant shall secure the control console in the OFF position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning system.
8. A copy of the most recent quality assurance checks performed pursuant to RH-10307.k. shall be available at a designated area within the therapy facility housing the therapeutic radiation machine.
9. The registrant shall maintain a record of each quality assurance check required by RH-10307.k. for five (5) years.
- A. The record shall include the results of the check plus the following: the date of the quality assurance check; the manufacturer's name, model number, and serial number for the electronic brachytherapy device; the name of the individual who performed the periodic quality assurance check; and the signature of the Qualified Medical Physicist who reviewed the quality assurance check.
 - B. For radiation output quality assurance checks required by RH-10307.k.3., the record shall also include the unique identifier for the electronic brachytherapy source; and the manufacturer's name, model numbers, and serial numbers for the instruments used to measure the radiation output of the electronic brachytherapy device.

1. **Therapy-related computer systems.**

The registrant shall perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of an acceptance testing protocol published by a national professional association, the manufacturer's acceptance testing protocol shall be followed.

1. Acceptance testing shall be performed by, or under the direct supervision of, a Qualified Medical Physicist who is physically present at the facility during the testing. At a minimum, the acceptance testing shall include, as applicable, verification of:
 - A. The source-specific input parameters required by the dose calculation algorithm;
 - B. The accuracy of dose, dwell time, and treatment time calculations at representative points;
 - C. The accuracy of isodose plots and graphic displays;
 - D. The accuracy of the software used to determine radiation source positions from radiographic images; and
 - E. If the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.
2. The position indicators in the applicator shall be compared to the actual position of the source or planned dwell positions, as appropriate, at the time of commissioning.
3. Prior to each patient treatment regimen, the parameters for the treatment shall be evaluated and approved by the Authorized User or the Qualified Medical Physicist for correctness through means independent of that used for the determination of the parameters.

m. **Training.**

The following training requirements are in addition to the training and experience requirements of RH-10200.c. for therapeutic radiation machine Authorized Users and RH-10200.d. for Qualified Medical Physicists:

1. A registrant shall provide instruction initially, at least annually, and upon significant procedural changes to all individuals who operate the electronic brachytherapy device, as appropriate to the individual's assigned duties. Instruction shall be provided in the operating procedures specified in RH-10307.h. and in the device's emergency procedures. If the interval between patients exceeds one (1) year, retraining of the individuals shall be provided.
2. Authorized Users, Qualified Medical Physicists, and electronic brachytherapy device operators shall receive device specific instruction initially from the manufacturer and annually from either the manufacturer or other qualified trainer. The training shall be of a duration recommended by the manufacturer's training protocol. The training shall include, but not be limited to:
 - A. Device-specific radiation safety requirements;
 - B. Device operation;
 - C. Clinical use for the types of use approved by the FDA;
 - D. Emergency procedures, including an emergency drill; and
 - E. The registrant's quality assurance program.
3. A registrant shall retain a record of individuals receiving instruction required by this paragraph for five (5) years. The record shall include a list of the topics covered, the date of the instruction, the names of the attendees, and the names of the individuals who provided the instruction.

RH-10307. (Cont'd)

n. **Mobile electronic brachytherapy service.**

A registrant providing mobile electronic brachytherapy service shall, at a minimum:

1. Obtain a memorandum of understanding addressing radiation safety if the device is to be used at sites that are not under the control of the mobile service itself, prior to operation at those sites;
2. Check all radiation survey instruments for operability before medical use at each address of use or on each day of use, whichever is more frequent;
3. Account for the electronic brachytherapy source in the electronic brachytherapy device before departure from the client's address; and
4. Perform, at each location on each day of use, all of the required quality assurance checks specified in RH-10307.k. to ensure proper operation of the device.

RH-10308. **Other Use of Electronically-Produced Radiation to Deliver Therapeutic Radiation ~~Dosage~~ Dose.**

A person shall not utilize any device which is designed to electrically generate a source of ionizing radiation to deliver therapeutic radiation ~~dosage~~ dose, and which is not appropriately regulated under any existing device category of ~~therapeutic radiation machine~~, until:

- a. The applicant, licensee, or registrant has, at a minimum, provided the Department with:
 1. A completed RC FORM 200, "Radiation Machine Facility Registration" form or "Application for Medical Particle Accelerator," as applicable;
 2. A copy of the device manufacturer's U.S. Food and Drug Administration clearance or approval;
 - ~~3.~~ 3. A detailed description of the device and its intended applications;
 - ~~3~~ 4. Facility design requirements information, including shielding and access control;

- ~~4~~ 5. Documentation of appropriate training and experience for prospective Authorized User physicians and Qualified Medical Physicists;
 - ~~6~~. Quality management program procedures;
 - ~~5~~ 7. Methodology for measurement of ~~dosages~~ dose to be administered to patients or human research subjects;
 - ~~6~~. Radiation safety precautions instructions;
 - ~~8~~. Operating and safety procedures;
 - ~~7~~ 9. Documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for radiation safety;
 - ~~8~~ 10. Quality assurance program procedures;
 - ~~11~~. Acceptance testing protocol to be followed;
 - ~~12~~. A copy of any memorandums of understanding addressing radiation safety; and
 - ~~9~~ 13. Other information requested by the Department in its review of the application; and
- b. The applicant, licensee, or registrant has received written approval from the Department to utilize the device in accordance with the ~~regulations~~ rules and specific conditions the Department considers necessary for the medical use of the device.

RH-10309.- RH-10399. Reserved.

PART E.
[RESERVED]

RH-10400.- RH-10499. Reserved.

**PART F.
ENFORCEMENT**

RH-10500. **Violations.**

a. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any ~~regulation~~ rule or order issued thereunder. Any person who willfully violates any provision of the Act or any ~~regulation~~ rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

b. **Impounding.**

Sources of radiation shall be subject to impounding pursuant to Section 5 of these ~~Regulations~~ Rules.

RH-10501.- RH-10999. Reserved.

APPENDIX A TO SECTION 11

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

I. All Therapeutic Radiation Machines

- A. Submit basic facility information including the following: name, telephone number, and Department vendor registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; the street address of the therapeutic radiation machine facility; and the room number of the therapeutic radiation machine. The plan should also indicate whether this is a new structure or a modification to an existing structure.
- B. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.
- C. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

II. Therapeutic Radiation Machines up to 150 Kv (photons only)

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, at a minimum, the following additional information:

- A. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors;
- B. The maximum design workload for the facility including total weekly radiation output (expressed in gray [rad] or air kerma at 1 meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;
- C. A facility blueprint/drawing indicating the following: scale (0.25 inch = 1 foot is typical); direction of North; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with RH-1200. ~~of these Regulations;~~

Appendix A to Section 11. (Cont'd)

- D. The structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;
- E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest areas where it is likely that individuals may be present; and
- F. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary/leakage barriers, restricted and unrestricted areas, and entry doors) and shielding material in the facility:
 - 1. If commercial software is used to generate shielding requirements, identify the software used and the version/revision date.
 - 2. If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

III. Therapeutic Radiation Machines Over 150 kV

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities that produce photons with a maximum energy in excess of 150 kV and/or electrons shall submit shielding plans which contain, at a minimum, the following additional information:

- A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced (i.e., photon, electron). The target to isocenter distance shall be specified;
- B. The maximum design workload for the facility including total weekly radiation output (expressed in gray [rad] at 1 meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;
- C. A facility blueprint/drawing (including both floor plan and elevation views) indicating the following: relative orientation of the therapeutic radiation machine; scale (0.25 inch = 1 foot is typical); type(s), thickness, and minimum density of shielding materials; direction of North; the locations and size of all penetrations through each shielding barrier (ceiling, walls, and floor), as well as details of the doors and maze;

Appendix A to Section 11. (Cont'd)

- D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;
- E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest areas where it is likely that individuals may be present;
- F. A description of all assumptions that were in shielding calculations, including, but not limited to, the following: design energy (i.e., room may be designed for 6 MV unit although only a 4 MV unit is currently proposed), workload, presence of integral beam-stop in unit, occupancy and uses of adjacent areas, fraction of time that useful beam will intercept each permanent barrier (walls, floor, and ceiling), and "allowed" radiation exposure in both restricted and unrestricted areas; and
- G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary/leakage barriers, restricted and unrestricted areas, small angle scatter, entry doors, and maze] and shielding material in the facility:
 - 1. If commercial software is used to generate shielding requirements, identify the software used and the version/revision date; and
 - 2. If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

IV. Neutron Shielding

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities that are capable of generating energies above 10 MV (10 MeV) shall submit shielding plans which contain, at a minimum, the following additional information:

- A. The structural composition, thickness, minimum density, and location of all neutron shielding material;
- B. A description of all assumptions that were used in neutron shielding calculations, including, but not limited to, the following: neutron spectra as a function of energy, neutron fluence rate, and absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas;

Appendix A to Section 11. (Cont'd)

- C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition (i.e., restricted and unrestricted areas, entry doors, and maze) and neutron shielding material utilized in the facility:
 - 1. If commercial software is used to generate shielding requirements, identify the software used and the version/revision date; and
 - 2. If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.
- D. The method(s) and instrumentation that will be used to verify the adequacy of all neutron shielding installed in the facility.

V. References

- A. NCRP Report No. 49, "Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV" (1976).
- B. NCRP Report No. 79, "Neutron Contamination from Medical Electron Accelerators" (1984).
- C. NCRP Report No. 144, "Radiation Protection for Particle Accelerator Facilities" (2003).
- D. NCRP Report No. 151, "Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities" (2005).

FOOTNOTES TO SECTION 11

- ^{1/} Electronic brachytherapy devices are subject to the requirements of RH-10307. and are exempt from the requirements of RH-10301.
- ^{2/} “IMRT Commissioning: Multiple Institution Planning and Dosimetry Comparisons, a Report from AAPM Task Group 119” – AAPM Report No. 119, prepared by the Work Group on IMRT Task Group No. 119, and “Dosimetry Tools and Techniques for IMRT” – AAPM Report No. 120, prepared by the Work Group on IMRT Task Group No. 120, provide further recommendations.
- ^{3/} “Comprehensive QA for Radiation Oncology,” – AAPM Report No. 46, prepared by the Radiation Therapy Committee Task Group No. 40, provides recommendations regarding conventional simulators. “Quality Assurance for Computed-Tomography Simulators and the Computed-Tomography-Simulation Process: Report of the AAPM Radiation Therapy Committee Task Group No. 66,” – AAPM Report No. 83, prepared by the Radiation Therapy Committee Task Group No. 66, provides recommendations regarding virtual simulators.

SECTION 12.
PHYSICAL PROTECTION OF CATEGORY 1 AND
CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

PART A.
GENERAL

RH-11000. Reserved.

RH-11001. **Purpose.**

This Section has been established to provide the requirements for the physical protection program for any licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material listed in Appendix A to this Section. These requirements provide reasonable assurance of the security of category 1 or category 2 quantities of radioactive material by protecting these materials from theft or diversion. Specific requirements for access to material, use of material, transfer of material, and transport of material are included. No provision of this Section authorizes possession of licensed material.

RH-11002. Reserved.

RH-11003. **Scope.**

- a. Parts B and C of this Section apply to any person who, under these ~~Regulations~~ Rules, possesses or uses at any site, an aggregated category 1 or category 2 quantity of radioactive material.
- b. Part D of this Section applies to any person who:
 1. Transports or delivers to a carrier for transport in a single shipment, a category 1 or category 2 quantity of radioactive material, under these ~~Regulations~~ Rules; or
 2. Imports or exports a category 1 or category 2 quantity of radioactive material; the provisions only apply to the domestic portion of the transport.

RH-11004. Reserved.

RH-11005. **Definitions.**

Access control - A system for allowing only approved individuals to have unescorted access to the security zone and for ensuring that all other individuals are subject to escorted access.

Act - Act 8 of the Second Extraordinary Session of 1961, as amended.

Aggregated - Accessible by the breach of a single physical barrier that would allow access to radioactive material in any form, including any devices that contain the radioactive material, when the total activity equals or exceeds a category 2 quantity of radioactive material.

Agreement State - Any state with which the Atomic Energy Commission or the U.S. Nuclear Regulatory Commission has entered into an effective agreement under subsection 274 b. of the Atomic Energy Act of 1954 (68 Stat. 919), including any amendments thereto. Non-agreement State means any other State.

Approved individual - An individual whom the licensee has determined to be trustworthy and reliable for unescorted access in accordance with Part B of this Section and who has completed the training required by RH-11043.c.

Background investigation - The investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.

Carrier - A person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

Category 1 quantity of radioactive material - A quantity of radioactive material meeting or exceeding the category 1 threshold in Table 1 of Appendix A to this Section. This is determined by calculating the ratio of the total activity of each radionuclide to the category 1 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a category 1 quantity. Category 1 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

Category 2 quantity of radioactive material - A quantity of radioactive material meeting or exceeding the category 2 threshold but less than the category 1 threshold in Table 1 of Appendix A to this Section. This is determined by calculating the ratio of the total activity of each radionuclide to the category 2 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a category 2 quantity. Category 2 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

Diversion - The unauthorized movement of radioactive material subject to this Section to a location different from the material's authorized destination inside or outside of the site at which the material is used or stored.

Escorted access - Accompaniment while in a security zone by an approved individual who maintains continuous direct visual surveillance at all times over an individual who is not approved for unescorted access.

Fingerprint orders - The orders issued by the U.S. Nuclear Regulatory Commission or the legally binding requirements issued by Agreement States that require fingerprints and criminal history records checks for individuals with unescorted access to category 1 and category 2 quantities of radioactive material or safeguards information-modified handling.

Government agency - Any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government.

License issuing authority - The licensing agency that issued the license, i.e., the Department, the appropriate agency of an Agreement State, or the U.S. Nuclear Regulatory Commission.

Local law enforcement agency (LLEA) - A public or private organization that has been approved by a federal, state, or local government to carry firearms and make arrests, and is authorized and has the capability to provide an armed response in the jurisdiction where the licensed category 1 or category 2 quantity of radioactive material is used, stored, or transported.

Lost or missing licensed material - Licensed material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

Mobile device - A piece of equipment containing licensed radioactive material that is either mounted on wheels or casters, or otherwise equipped for moving without a need for disassembly or dismounting; or designed to be hand carried. Mobile devices do not include stationary equipment installed in a fixed location.

Movement control center - An operations center that is remote from transport activity and that maintains position information on the movement of radioactive material, receives reports of attempted attacks or thefts, provides a means for reporting these and other problems to appropriate agencies and can request and coordinate appropriate aid.

No-later-than arrival time - The date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than arrival time may not be more than six (6) hours after the estimated arrival time for shipments of category 2 quantities of radioactive material.

Person -

1. Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency of this state, political subdivision of this state, any other state or political subdivision or agency thereof; and
2. Any legal successor, representative, agent, or agency of the foregoing, but not including United States Government agencies.

Reviewing official - The individual who shall make the trustworthiness and reliability determination of an individual to determine whether the individual may have, or continue to have, unescorted access to the category 1 or category 2 quantities of radioactive materials that are possessed by the licensee.

Sabotage - Deliberate damage, with malevolent intent, to a category 1 or category 2 quantity of radioactive material, a device that contains a category 1 or category 2 quantity of radioactive material, or the components of the security system.

Safe haven - A readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the local law enforcement authorities.

Security zone - Any temporary or permanent area determined and established by the licensee for the physical protection of category 1 or category 2 quantities of radioactive material during use or storage.

State - A State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

RH-11005. (Cont'd)

Telemetric position monitoring system - A data transfer system that captures information by instrumentation and/or measuring devices about the location and status of a transport vehicle or package between the departure and destination locations.

Trustworthiness and reliability - Characteristics of an individual considered dependable in judgment, character, and performance, such that unescorted access to category 1 or category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or security. A determination of trustworthiness and reliability for this purpose is based upon the results from a background investigation.

Unescorted access - Solitary access to an aggregated category 1 or category 2 quantity of radioactive material or the devices that contain the material.

United States – When used in a geographical sense, includes Puerto Rico and all territories and possessions of the United States.

RH-11006. Reserved.

RH-11007. **Communications.**

Except where otherwise specified, all communications concerning these ~~Regulations~~ Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-11008. Reserved.

RH-11009. **Interpretations.**

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the ~~regulations~~ rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-11010. Reserved.

RH-11011. **Specific Exemptions.**

- a. The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the ~~regulations~~ rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

- b. A licensee that possesses radioactive waste that contains category 1 or category 2 quantities of radioactive material is exempt from the requirements of Parts B, C, and D of this Section – except that any radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 lbs) is not exempt from the requirements of this Section. The licensee shall implement the following requirements to secure the radioactive waste:
 1. Use continuous physical barriers that allow access to the radioactive waste only through established access control points;
 2. Use a locked door or gate with monitored alarm at the access control point;
 3. Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and
 4. Immediately notify the LLEA and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste that contains category 1 or category 2 quantities of radioactive material.

RH-11012.- RH-11019. Reserved.

PART B.
BACKGROUND INVESTIGATIONS AND ACCESS AUTHORIZATION PROGRAM

RH-11020. Reserved.

RH-11021. **Personnel Access Authorization Requirements for Category 1 or Category 2 Quantities of Radioactive Material.**

a. **General.**

1. Each licensee that possesses an aggregated quantity of radioactive material at or above the category 2 threshold shall establish, implement, and maintain its access authorization program in accordance with the requirements of this Part.
2. An applicant for a new license and each licensee that would become newly subject to the requirements of this Part upon application for modification of its license shall implement the requirements of this Part, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.
3. Any licensee that has not previously implemented the Security Orders or been subject to the provisions of this Part B shall implement the provisions of this Part B before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

b. **General performance objective.**

The licensee's access authorization program must ensure that the individuals specified in paragraph c.1. of this section are trustworthy and reliable.

c. **Applicability.**

1. Licensees shall subject the following individuals to an access authorization program:
 - A. Any individual whose assigned duties require unescorted access to category 1 or category 2 quantities of radioactive material or to any device that contains the radioactive material; and

RH-11021.c.1. (Cont'd)

B. Reviewing officials.

2. Licensees need not subject the categories of individuals listed in RH-11029.a. to the investigation elements of the access authorization program.
3. Licensees shall approve for unescorted access to category 1 or category 2 quantities of radioactive material only those individuals with job duties that require unescorted access to category 1 or category 2 quantities of radioactive material.
4. Licensees may include individuals needing access to safeguards information-modified handling under 10 CFR Part 73 in the access authorization program under this Part B.

RH-11022. Reserved.

RH-11023. **Access Authorization Program Requirements.**

a. **Granting unescorted access authorization.**

1. Licensees shall implement the requirements of this Part for granting initial or reinstated unescorted access authorization.
2. Individuals who have been determined to be trustworthy and reliable shall also complete the security training required by RH-11043.c. before being allowed unescorted access to category 1 or category 2 quantities of radioactive material.

b. **Reviewing officials.**

1. Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to category 1 or category 2 quantities of radioactive materials possessed by the licensee.

2. Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. Provide oath or affirmation certifications to the Department by an appropriate method listed in RH-11007. The fingerprints of the named reviewing official must be taken by a law enforcement agency, Federal or State agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a State to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every ten (10) years in accordance with RH-11025.c.
3. Reviewing officials must be permitted to have unescorted access to category 1 or category 2 quantities of radioactive material or access to safeguards information or safeguards information-modified handling, if the licensee possesses safeguards information or safeguards information-modified handling. Reviewing officials permitted unescorted access to category 1 or category 2 quantities of radioactive material shall receive appropriate radiation safety training, initially and at a frequency not to exceed twelve (12) months. The licensee shall maintain records of the initial and refresher training for three (3) years from the date of the training.
4. Reviewing officials cannot approve other individuals to act as reviewing officials.
5. A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:
 - A. The individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy and reliable by the licensee; or
 - B. The individual is subject to a category listed in RH-11029.a.

c. **Informed consent.**

1. Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. This consent must include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed during the background investigation. Licensees do not need to obtain signed consent from those individuals that meet the requirements of RH-11025.b. A signed consent must be obtained prior to any reinvestigation.
2. The subject individual may withdraw his or her consent at any time. Licensees shall inform the individual that:
 - A. If an individual withdraws his or her consent, the licensee may not initiate any elements of the background investigation that were not in progress at the time the individual withdrew his or her consent; and
 - B. The withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

d. **Personal history disclosure.**

Any individual who is applying for unescorted access authorization shall disclose the personal history information that is required by the licensee's access authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any personal history information required by this Part is sufficient cause for denial or termination of unescorted access.

e. **Determination basis.**

1. The reviewing official shall determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access authorization based on an evaluation of all of the information collected to meet the requirements of this Part.

2. The reviewing official may not permit any individual to have unescorted access until the reviewing official has evaluated all of the information collected to meet the requirements of this Part and determined that the individual is trustworthy and reliable. The reviewing official may deny unescorted access to any individual based on information obtained at any time during the background investigation.
3. The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.
4. The reviewing official may terminate or administratively withdraw an individual's unescorted access authorization based on information obtained after the background investigation has been completed and the individual granted unescorted access authorization.
5. Licensees shall maintain a list of persons currently approved for unescorted access authorization. When a licensee determines that a person no longer requires unescorted access or meets the access authorization requirement, the licensee shall remove the person from the approved list as soon as possible, but no later than seven (7) working days, and take prompt measures to ensure that the individual is unable to have unescorted access to the material.

f. **Procedures.**

Licensees shall develop, implement, and maintain written procedures for implementing the access authorization program. The procedures must include provisions for the notification of individuals who are denied unescorted access. The procedures must include provisions for the review, at the request of the affected individual, of a denial or termination of unescorted access authorization. The procedures must contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

g. Right to correct and complete information.

1. Prior to any final adverse determination, licensees shall provide each individual subject to this Part with the right to complete, correct, and explain information obtained as a result of the licensee's background investigation. Confirmation of receipt by the individual of this notification must be maintained by the licensee for a period of one (1) year from the date of the notification.
2. If, after reviewing his or her criminal history record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, update, or explain anything in the record, the individual may initiate challenge procedures. These procedures include direct application by the individual challenging the record to the law enforcement agency that contributed the questioned information or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, ATTN: SCU, Mod. D-2, 1000 Custer Hollow Road, Clarksburg, WV 26306 as set forth in 28 CFR 16.30 through 16.34. In the latter case, the Federal Bureau of Investigation (FBI) will forward the challenge to the agency that submitted the data, and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division makes any changes necessary in accordance with the information supplied by that agency. Licensees must provide at least ten (10) days for an individual to initiate action to challenge the results of an FBI criminal history records check after the record being made available for his or her review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

h. Records.

1. The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for three (3) years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

RH-11023.h. (Cont'd)

2. The licensee shall retain a copy of the current access authorization program procedures as a record for three (3) years after the procedure is no longer needed. If any portion of the procedure is superseded, the licensee shall retain the superseded material for three (3) years after the record is superseded.
3. The licensee shall retain the list of persons approved for unescorted access authorization for three (3) years after the list is superseded or replaced.

RH-11024. Reserved.

RH-11025. **Background Investigations.**

a. **Initial investigation.**

Before allowing an individual unescorted access to category 1 or category 2 quantities of radioactive material or to the devices that contain the material, licensees shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation must encompass at least the seven (7) years preceding the date of the background investigation or since the individual's eighteenth birthday, whichever is shorter. The background investigation must include at a minimum:

1. Fingerprinting and an FBI identification and criminal history records check in accordance with RH-11027.;
2. **Verification of true identity.**

Licensees shall verify the true identity of the individual who is applying for unescorted access authorization to ensure that the applicant is who he or she claims to be. A licensee shall review official identification documents (e.g., driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth) and compare the documents to personal information data provided by the individual to identify any discrepancy in the information. Licensees shall document the type, expiration, and identification number of the identification document, or maintain a photocopy of identifying documents on file in accordance with RH-11031. Licensees shall certify in writing that the identification was properly reviewed, and shall

maintain the certification and all related documents for review upon inspection;

3. **Employment history verification.**

Licensees shall complete an employment history verification, including military history. Licensees shall verify the individual's employment with each previous employer for the most recent seven (7) years before the date of application;

4. **Verification of education.**

Licensees shall verify that the individual participated in the education process during the claimed period;

5. **Character and reputation determination.**

Licensees shall complete reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks under this Part must be limited to whether the individual has been and continues to be trustworthy and reliable;

6. The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the individual (e.g., seek references not supplied by the individual); and

7. If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide information or indicates an inability or unwillingness to provide information within a time frame deemed appropriate by the licensee but at least after ten (10) business days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness, or inability in the record of investigation; and attempt to obtain the information from an alternate source.

RH-11025. (Cont'd)

b. Grandfathering.

1. Individuals who have been determined to be trustworthy and reliable for unescorted access to category 1 or category 2 quantities of radioactive material under the Fingerprint Orders may continue to have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. These individuals shall be subject to the reinvestigation requirement.
2. Individuals who have been determined to be trustworthy and reliable under the provisions of 10 CFR Part 73 or the security orders for access to safeguards information, safeguards information-modified handling, or risk-significant material may have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. The licensee shall document that the individual was determined to be trustworthy and reliable under the provisions of 10 CFR Part 73 or a security order. Security order, in this context, refers to any order that was issued by the NRC that required fingerprints and an FBI criminal history records check for access to safeguards information, safeguards information-modified handling, or risk significant material such as special nuclear material or large quantities of uranium hexafluoride. These individuals shall be subject to the reinvestigation requirement.

c. Reinvestigations.

Licensees shall conduct a reinvestigation every 10 years for any individual with unescorted access to category 1 or category 2 quantities of radioactive material. The reinvestigation shall consist of fingerprinting and an FBI identification and criminal history records check in accordance with RH-11027. The reinvestigations must be completed within ten (10) years of the date on which these elements were last completed.

RH-11026. Reserved.

RH-11027. **Requirements for Criminal History Records Checks of Individuals Granted Unescorted Access to Category 1 or Category 2 Quantities of Radioactive Material.**

a. **General performance objective and requirements.**

1. Except for those individuals listed in RH-11029. and those individuals grandfathered under RH-11025.b., each licensee subject to the provisions of this Part shall fingerprint each individual who is to be permitted unescorted access to category 1 or category 2 quantities of radioactive material. Licensees shall transmit all collected fingerprints to the U.S. Nuclear Regulatory Commission for transmission to the FBI. The licensee shall use the information received from the FBI as part of the required background investigation to determine whether to grant or deny further unescorted access to category 1 or category 2 quantities of radioactive materials for that individual.
2. The licensee shall notify each affected individual that his or her fingerprints will be used to secure a review of his or her criminal history record and shall inform him or her of the procedures for revising the record or adding explanations to the record.
3. Fingerprinting is not required if a licensee is reinstating an individual's unescorted access authorization to category 1 or category 2 quantities of radioactive materials if:
 - A. The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his or her unescorted access authorization; and
 - B. The previous access was terminated under favorable conditions.
4. Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to category 1 or category 2 quantities of radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee, based upon a background investigation conducted under this Part, the Fingerprint Orders, or 10 CFR Part 73. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the provisions of RH-11031.c.

5. Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to category 1 or category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

b. Prohibitions.

1. Licensees may not base a final determination to deny an individual unescorted access authorization to category 1 or category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:
 - A. An arrest more than one (1) year old for which there is no information of the disposition of the case; or
 - B. An arrest that resulted in dismissal of the charge or an acquittal.
2. Licensees may not use information received from a criminal history records check obtained under this Part in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

c. Procedures for processing of fingerprint checks.

1. For the purpose of complying with this Part, licensees shall submit to the U.S. Nuclear Regulatory Commission, Director, Division of Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop T-07D04M, Rockville, Maryland 20852, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by emailing MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at <https://www.nrc.gov/security/chp.html>.

RH-11027.c. (Cont'd)

2. Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." (For guidance on making electronic payments, contact the Division of Physical and Cyber Security Policy by emailing Crimhist.Resource@nrc.gov.) Combined payment for multiple applications is acceptable. The U.S. Nuclear Regulatory Commission publishes the amount of the fingerprint check application fee on the NRC's public Web site. (To find the current fee amount, go to the Licensee Criminal History Records Checks & Firearms Background Check Information page at <https://www.nrc.gov/security/chp.html> and see the link for "How do I determine how much to pay for the request?")
3. The U.S. Nuclear Regulatory Commission will forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

RH-11028. Reserved.

RH-11029. **Relief from Fingerprinting, Identification, and Criminal History Records Checks and Other Elements of Background Investigations for Designated Categories of Individuals Permitted Unescorted Access to Certain Radioactive Materials.**

- a. Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, and other elements of the background investigation are not required for the following individuals prior to granting unescorted access to category 1 or category 2 quantities of radioactive materials:
 1. An employee of the U.S. Nuclear Regulatory Commission or of the Executive Branch of the U.S. Government who has undergone fingerprinting for a prior U.S. Government criminal history records check;
 2. A Member of Congress;
 3. An employee of a member of Congress or Congressional committee who has undergone fingerprinting for a prior U.S. Government criminal history records check;

RH-11029.a. (Cont'd)

4. The Governor of a State or his or her designated State employee representative;
5. Federal, State, or local law enforcement personnel;
6. State Radiation Control Program Directors and State Homeland Security Advisors or their designated State employee representatives;
7. Agreement State employees conducting security inspections on behalf of the NRC under an agreement executed under section 274.i. of the Atomic Energy Act;
8. Representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement who have been certified by the NRC;
9. Emergency response personnel who are responding to an emergency;
10. Commercial vehicle drivers for road shipments of category 1 and category 2 quantities of radioactive material;
11. Package handlers at transportation facilities such as freight terminals and railroad yards;
12. Any individual who has an active Federal security clearance, provided that he or she makes available the appropriate documentation. Written confirmation from the agency/employer that granted the Federal security clearance or reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of three (3) years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material; and

13. Any individual employed by a service provider licensee for which the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to category 1 or category 2 quantities of radioactive material. Written verification from the service provider must be provided to the licensee. The licensee shall retain the documentation for a period of three (3) years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

b. Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, are not required for an individual who has had a favorably adjudicated U.S. Government criminal history records check within the last five (5) years, under a comparable U.S. Government program involving fingerprinting and an FBI identification and criminal history records check provided that he or she makes available the appropriate documentation. Written confirmation from the agency/employer that reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of three (3) years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material. These programs include, but are not limited to:

1. National Agency Check;
2. Transportation Worker Identification Credentials (TWIC) under 49 CFR part 1572;
3. Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under 27 CFR part 555;
4. Health and Human Services security risk assessments for possession and use of select agents and toxins under 42 CFR part 73;
5. Hazardous Material security threat assessment for hazardous material endorsement to commercial driver's license under 49 CFR part 1572; and
6. Customs and Border Protection's Free and Secure Trade (FAST) Program.

RH-11030. Reserved.

RH-11031. **Protection of Information.**

- a. Each licensee who obtains background information on an individual under this Part shall establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.
- b. The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his or her representative, or to those who have a need to have access to the information in performing assigned duties in the process of granting or denying unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling. No individual authorized to have access to the information may disseminate the information to any other individual who does not have a need to know.
- c. The personal information obtained on an individual from a background investigation may be provided to another licensee:
 1. Upon the individual's written request to the licensee holding the data to disseminate the information contained in his or her file; and
 2. The recipient licensee verifies information such as name, date of birth, social security number, gender, and other applicable physical characteristics.
- d. The licensee shall make background investigation records obtained under this Part available for examination by an authorized representative of the Department to determine compliance with the ~~regulations~~ rules and laws.
- e. The licensee shall retain all fingerprint and criminal history records (including data indicating no record) received from the FBI, or a copy of these records if the individual's file has been transferred, on an individual for three (3) years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

RH-11032. Reserved.

RH-11033. **Access Authorization Program Review.**

- a. Each licensee shall be responsible for the continuing effectiveness of the access authorization program. Each licensee shall ensure that access authorization programs are reviewed to confirm compliance with the requirements of this Part and that comprehensive actions are taken to correct any noncompliance that is identified. The review program shall evaluate all program performance objectives and requirements. Each licensee shall periodically (at least annually) review the access program content and implementation.
- b. The results of the reviews, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the access authorization program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.
- c. Review records must be maintained for three (3) years.

RH-11034.- RH-11039. Reserved.

PART C.
PHYSICAL PROTECTION REQUIREMENTS DURING USE

RH-11040. Reserved.

RH-11041. **Security Program.**

a. **Applicability.**

1. Each licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements of this Part.
2. An applicant for a new license and each licensee that would become newly subject to the requirements of this Part upon application for modification of its license shall implement the requirements of this Part, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.
3. Any licensee that has not previously implemented the security requirements or been subject to the provisions of Part C shall provide written notification to the Department as specified in RH-11007. at least ninety (90) days before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

b. **General performance objective.**

Each licensee shall establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to category 1 or category 2 quantities of radioactive material.

c. **Program features.**

Each licensee's security program must include the program features, as appropriate, described in RH-11043., RH-11045., RH-11047., RH-11049., RH-11051., RH-11053., and RH-11055.

RH-11042. Reserved.

RH-11043. **General Security Program Requirements.**

a. **Security plan.**

1. Each licensee identified in RH-11041.a. shall develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by this Part. The security plan must, at a minimum:
 - A. Describe the measures and strategies used to implement the requirements of this Part; and
 - B. Identify the security resources, equipment, and technology used to satisfy the requirements of this Part.
2. The security plan must be reviewed and approved by the individual with overall responsibility for the security program.
3. A licensee shall revise its security plan as necessary to ensure the effective implementation of Department requirements. The licensee shall ensure that:
 - A. The revision has been reviewed and approved by the individual with overall responsibility for the security program; and
 - B. The affected individuals are instructed on the revised plan before the changes are implemented.
4. The licensee shall retain a copy of the current security plan as a record for three (3) years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for three (3) years after the record is superseded.

b. **Implementing procedures.**

1. The licensee shall develop and maintain written procedures that document how the requirements of this Part and the security plan will be met.
2. The implementing procedures and revisions to these procedures must be approved in writing by the individual with overall responsibility for the security program.

3. The licensee shall retain a copy of the current procedure as a record for three (3) years after the procedure is no longer needed. Superseded portions of the procedure must be retained for three (3) years after the record is superseded.

c. **Training.**

1. Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training must include instruction in:
 - A. The licensee's security program and procedures to secure category 1 or category 2 quantities of radioactive material, and in the purposes and functions of the security measures employed;
 - B. The responsibility to report promptly to the licensee any condition that causes or may cause a violation of Department requirements;
 - C. The responsibility of the licensee to report promptly to the local law enforcement agency and licensee any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material; and
 - D. The appropriate response to security alarms.
2. In determining those individuals who shall be trained on the security program, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of category 1 or category 2 quantities of radioactive material. The extent of the training must be commensurate with the individual's potential involvement in the security of category 1 or category 2 quantities of radioactive material.

3. Refresher training must be provided at a frequency not to exceed twelve (12) months and when significant changes have been made to the security program. This training must include:
 - A. Review of the training requirements of paragraph c. of this section and any changes made to the security program since the last training;
 - B. Reports on any relevant security issues, problems, and lessons learned;
 - C. Relevant results of Department inspections; and
 - D. Relevant results of the licensee's program review and testing and maintenance.
4. The licensee shall maintain records of the initial and refresher training for three (3) years from the date of the training. The training records must include dates of the training, topics covered, a list of licensee personnel in attendance, and related information.

d. **Protection of information.**

1. Licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.
2. Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.
3. Before granting an individual access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access, licensees shall:
 - A. Evaluate an individual's need to know the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access; and

- B. If the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in RH-11025.a.2. through a.7.
- 4. Licensees need not subject the following individuals to the background investigation elements for protection of information:
 - A. The categories of individuals listed in RH-11029.a.; or
 - B. Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in RH-11025.a.2. through a.7., has been provided by the security service provider.
 - 5. The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.
 - 6. Licensees shall maintain a list of persons currently approved for access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access. When a licensee determines that a person no longer needs access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access, or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than seven (7) working days, and take prompt measures to ensure that the individual is unable to obtain the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

RH-11043.d. (Cont'd)

7. When not in use, the licensee shall store its security plan, implementing procedures, and the list of individuals that have been approved for unescorted access in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.
8. The licensee shall retain as a record for three (3) years after the document is no longer needed:
 - A. A copy of the information protection procedures; and
 - B. The list of individuals approved for access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

RH-11044. Reserved.

RH-11045. **LLEA Coordination.**

- a. A licensee subject to this Part shall coordinate, to the extent practicable, with an LLEA for responding to threats to the licensee's facility, including any necessary armed response. The information provided to the LLEA must include:
 1. A description of the facilities and the category 1 and category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with this Part; and
 2. A notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of material.
- b. The licensee shall notify the Department as specified in RH-11007. within three (3) business days if:
 1. The LLEA has not responded to the request for coordination within sixty (60) days of the coordination request; or
 2. The LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.

RH-11045. (Cont'd)

- c. The licensee shall document its efforts to coordinate with the LLEA. The documentation must be kept for three (3) years.
- d. The licensee shall coordinate with the LLEA at a frequency not to exceed twelve (12) months and when changes to the facility design or operation adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

RH-11046. Reserved.

RH-11047. **Security Zones.**

- a. Licensees shall ensure that all aggregated category 1 and category 2 quantities of radioactive material are used or stored within licensee-established security zones. Security zones may be permanent or temporary.
- b. Temporary security zones must be established as necessary to meet the licensee's transitory or intermittent business activities, such as periods of maintenance, source delivery, and source replacement.
- c. Security zones must, at a minimum, allow unescorted access only to approved individuals through:
 - 1. Isolation of category 1 and category 2 quantities of radioactive materials by the use of continuous physical barriers that allow access to the security zone only through established access control points. A physical barrier is a natural or man-made structure or formation sufficient for the isolation of the category 1 or category 2 quantities of radioactive material within a security zone; or
 - 2. Direct control of the security zone by approved individuals at all times; or
 - 3. A combination of continuous physical barriers and direct control.

RH-11047. (Cont'd)

- d. For category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, at a minimum, provide sufficient individuals approved for unescorted access to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities.
- e. Individuals not approved for unescorted access to category 1 or category 2 quantities of radioactive material must be escorted by an approved individual when in a security zone.

RH-11048. Reserved.

RH-11049. **Monitoring, Detection, and Assessment.**

- a. **Monitoring and detection.**
 - 1. Licensees shall establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones. Licensees shall provide the means to maintain continuous monitoring and detection capability in the event of a loss of the primary power source, or provide for an alarm and response in the event of a loss of this capability to continuously monitor and detect unauthorized entries.
 - 2. Monitoring and detection must be performed by:
 - A. A monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility; or
 - B. Electronic devices for intrusion detection alarms that will alert nearby facility personnel; or
 - C. A monitored video surveillance system; or
 - D. Direct visual surveillance by approved individuals located within the security zone; or
 - E. Direct visual surveillance by a licensee designated individual located outside the security zone.

3. A licensee subject to this Part shall also have a means to detect unauthorized removal of the radioactive material from the security zone. This detection capability must provide:
 - A. For category 1 quantities of radioactive material, immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. Such immediate detection capability must be provided by:
 - i. Electronic sensors linked to an alarm; or
 - ii. Continuous monitored video surveillance; or
 - iii. Direct visual surveillance.
 - B. For category 2 quantities of radioactive material, weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

b. **Assessment.**

Licensees shall immediately assess each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.

c. **Personnel communications and data transmission.**

For personnel and automated or electronic systems supporting the licensee's monitoring, detection, and assessment systems, licensees shall:

1. Maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and
2. Provide an alternative communication capability for personnel, and an alternative data transmission and processing capability, in the event of a loss of the primary means of communication or data transmission and processing. Alternative communications and data transmission systems may not be subject to the same failure modes as the primary systems.

RH-11049. (Cont'd)

d. **Response.**

Licensees shall immediately respond to any actual or attempted unauthorized access to the security zones, or actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material at licensee facilities or temporary job sites. For any unauthorized access involving an actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material, the licensee's response shall include requesting, without delay, an armed response from the LLEA.

RH-11050. Reserved.

RH-11051. **Maintenance and Testing.**

- a. Each licensee subject to this Part shall implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition and are capable of performing their intended function when needed. The equipment relied on to meet the security requirements of this Part must be inspected and tested for operability and performance in accordance with manufacturer's specifications and at the manufacturer's suggested frequency. The licensee shall maintain documentation providing the manufacturer's specifications regarding inspections and testing as well as the recommended inspection and testing frequencies. If the manufacturer's specifications are unobtainable, documentation of the effort to obtain the specifications shall be maintained. If there is no manufacturer's suggested frequency, inspections and testing must be performed at a frequency not to exceed twelve (12) months.
- b. The licensee shall maintain a record of each maintenance, inspection, or testing activity for three (3) years. The record must include the date of the activity; what type of activity was performed; the equipment involved; the results of the activity; the name of the individual who conducted the activity; and what repair and/or maintenance, if any, was performed.

RH-11052. Reserved.

RH-11053. **Requirements for Mobile Devices.**

Each licensee that possesses mobile devices containing category 1 or category 2 quantities of radioactive material must:

- a. Have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee; and
- b. For devices in or on a vehicle or trailer, unless the health and safety requirements for a site prohibit the disabling of the vehicle, the licensee shall utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. Licensees shall not rely on the removal of an ignition key to meet this requirement.

RH-11054. Reserved.

RH-11055. **Security Program Review.**

- a. Each licensee shall be responsible for the continuing effectiveness of the security program. Each licensee shall ensure that the security program is reviewed to confirm compliance with the requirements of this Part and that comprehensive actions are taken to correct any noncompliance that is identified. The review must include the radioactive material security program content and implementation. Each licensee shall periodically (at least annually) review the security program content and implementation.
- b. The results of the review, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the security program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.
- c. The licensee shall maintain the review documentation for three (3) years.

RH-11056. Reserved.

RH-11057. **Reporting of Events.**

- a. The licensee shall immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the Department by telephone at 1-800-633-1735. In no case shall the notification to the Department be later than four (4) hours after the discovery of any attempted or actual theft, sabotage, or diversion.
- b. The licensee shall assess any suspicious activity related to possible theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material and notify the LLEA as appropriate. As soon as possible but not later than four (4) hours after notifying the LLEA, the licensee shall notify the Department by telephone at 1-800-633-1735.
- c. The initial telephone notification required by paragraph a. of this section must be followed within a period of thirty (30) days by a written report submitted to the Department by an appropriate method listed in RH-11007. The report must include sufficient information for Department analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

RH-11058.- RH-11069. Reserved.

PART D.
PHYSICAL PROTECTION IN TRANSIT

RH-11070. Reserved.

RH-11071. **Additional Requirements for Transfer of Category 1 and Category 2 Quantities of Radioactive Material.**

A licensee transferring a category 1 or category 2 quantity of radioactive material to a licensee of the Department, U.S. Nuclear Regulatory Commission, or an Agreement State shall meet the license verification provisions listed below instead of those listed in RH-501.c.:

- a. Any licensee transferring category 1 quantities of radioactive material to a licensee of the Department, U.S. Nuclear Regulatory Commission, or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and that the licensee is authorized to receive radioactive material at the location requested for delivery. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.
- b. Any licensee transferring category 2 quantities of radioactive material to a licensee of the Department, U.S. Nuclear Regulatory Commission, or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

RH-11071. (Cont'd)

- c. In an emergency where the licensee cannot reach the license issuing authority and the license verification system is nonfunctional, the licensee may accept a written certification by the transferee that it is authorized by license to receive the type, form, and quantity of radioactive material to be transferred. The certification must include the license number, current revision number, issuing agency, expiration date, and for a category 1 shipment the authorized address. The licensee shall keep a copy of the certification. The certification must be confirmed by use of the NRC's license verification system or by contacting the license issuing authority by the end of the next business day.
- d. The transferor shall keep a copy of the verification documentation as a record for three (3) years.

RH-11072. Reserved.

RH-11073. **Applicability of Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Transit.**

- a. For shipments of category 1 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in RH-11075.a. and e.; RH-11077.; RH-11079.a.1., b.1., and c.; and RH-11081.a., c., e., g., and h.
- b. For shipments of category 2 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in RH-11075.b. through e.; RH-11079.a.2., a.3., b.2., and c.; and RH-11081.b., d., f., g., and h. For those shipments of category 2 quantities of radioactive material that meet the criteria of RH-3509.b., the shipping licensee shall also comply with the advance notification provisions of RH-3509.
- c. The shipping licensee shall be responsible for meeting the requirements of this Part unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under this Part.
- d. Each licensee that imports or exports category 1 quantities of radioactive material shall comply with the requirements for physical protection during transit contained in RH-11075.a.2. and e.; RH-11077.; RH-11079.a.1., b.1., and c.; and RH-11081.a., c., e., g., and h. for the domestic portion of the shipment.

RH-11073. (Cont'd)

- e. Each licensee that imports or exports category 2 quantities of radioactive material shall comply with the requirements for physical protection during transit contained in RH-11079.a.2., a.3., and b.2.; and RH-11081.b., d., f., g., and h. for the domestic portion of the shipment.

RH-11074. Reserved.

RH-11075. **Preplanning and Coordination of Shipment of Category 1 or Category 2 Quantities of Radioactive Material.**

- a. Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall:
 - 1. Preplan and coordinate shipment arrival and departure times with the receiving licensee;
 - 2. Preplan and coordinate shipment information with the Department and with the governor or the governor's designee of any State through which the shipment will pass to:
 - A. Discuss the State's intention to provide law enforcement escorts; and
 - B. Identify safe havens; and
 - 3. Document the preplanning and coordination activities.
- b. Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.
- c. Each licensee who receives a shipment of a category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

RH-11075. (Cont'd)

- d. Each licensee, who transports or plans to transport a shipment of a category 2 quantity of radioactive material, and determines that the shipment will arrive after the no-later-than arrival time provided pursuant to paragraph b. of this section, shall promptly notify the receiving licensee of the new no-later-than arrival time.
- e. The licensee shall retain a copy of the documentation for preplanning and coordination and any revision thereof, as a record for three (3) years.

RH-11076. Reserved.

RH-11077. **Advance Notification of Shipment of Category 1 Quantities of Radioactive Material.**

As specified in paragraphs a. and b. of this section, each licensee shall provide advance notification to the Department and to the governor of a State, or the governor's designee, of the shipment of licensed material in a category 1 quantity, through or across the boundary of the State, before the transport, or delivery to a carrier for transport, of the licensed material outside the confines of the licensee's facility or other place of use or storage.

a. **Procedures for submitting advance notification.**

- 1. The notification must be made to the Department and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of the Department and of governors and governors' designees, is available on the U.S. Nuclear Regulatory Commission website at <https://scp.nrc.gov/special/designee.pdf>. A list of the contact information is also available upon request from the Department. The notification to the Department may be made by email to Communication.Center@arkansas.gov.
- 2. A notification delivered by mail must be postmarked at least seven (7) days before transport of the shipment commences at the shipping facility.
- 3. A notification delivered by any means other than mail must reach the Department at least four (4) days before the transport of the shipment commences and must reach the office of the governor or the governor's designee at least four (4) days before transport of a shipment within or through the State.

b. Information to be furnished in advance notification of shipment.

Each advance notification of shipment of category 1 quantities of radioactive material must contain the following information, if available at the time of notification:

1. The name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;
2. The license numbers of the shipper and receiver;
3. A description of the radioactive material contained in the shipment, including the radionuclides and quantity;
4. The point of origin of the shipment and the estimated time and date that shipment will commence;
5. The estimated time and date that the shipment is expected to enter each State along the route;
6. The estimated time and date of arrival of the shipment at the destination; and
7. A point of contact, with a telephone number, for current shipment information.

c. Revision notice.

1. The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the governor of the State or the governor's designee and to the Department.
2. A licensee shall promptly notify the governor of the State or the governor's designee of any changes to the information provided in accordance with paragraphs b. and c.1. of this section. The licensee shall also immediately notify the Department of any such changes.

RH-11077. (Cont'd)

d. **Cancellation notice.**

Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified and to the Department. The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled.

e. **Records.**

The licensee shall retain a copy of the advance notification and any revision and cancellation notices as a record for three (3) years.

f. **Protection of information.**

State officials, State employees, and other individuals, whether or not licensees of the Department, the NRC, or of an Agreement State, who receive schedule information of the kind specified in RH-11077.b. shall protect that information against unauthorized disclosure as specified in RH-11043.d.

RH-11078. Reserved.

RH-11079. **Requirements for Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Shipment.**

a. **Shipments by road.**

1. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:
 - A. Ensure that movement control centers are established that maintain position information from a remote location. These control centers must monitor shipments 24 hours a day, 7 days a week, and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies.

- B. Ensure that redundant communications are established that allow the transport to contact the escort vehicle (when used) and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication.
- C. Ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center must provide positive confirmation of the location, status, and control over the shipment. The movement control center must be prepared to promptly implement preplanned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.
- D. Provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the Department of Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver.
- E. Develop written normal and contingency procedures to address:
 - i. Notifications to the communication center and law enforcement agencies;
 - ii. Communication protocols. Communication protocols must include a strategy for the use of authentication codes and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost;
 - iii. Loss of communications; and
 - iv. Responses to an actual or attempted theft or diversion of a shipment.

- F. Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.
- 2. Each licensee that transports category 2 quantities of radioactive material shall maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.
 - 3. Each licensee who delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:
 - A. Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.
 - B. Use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and
 - C. Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.
- b. **Shipments by rail.**
- 1. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:
 - A. Ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center. The communications center shall provide positive confirmation of the location of the shipment and its status. The communications center shall

implement preplanned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

B. Ensure that periodic reports to the communications center are made at preset intervals.

2. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

A. Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.

B. Use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

C. Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

c. **Investigations.**

Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall immediately conduct an investigation upon the discovery that a category 1 shipment is lost or missing. Each licensee who makes arrangements for the shipment of category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

RH-11080. Reserved.

RH-11081. **Reporting of Events.**

- a. The shipping licensee shall notify the appropriate LLEA and the Department (1-800-633-1735) within one (1) hour of its determination that a shipment of category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law enforcement agency in the area of the shipment's last confirmed location. During the investigation required by RH-11079.c., the shipping licensee will provide agreed upon updates to the Department on the status of the investigation.
- b. The shipping licensee shall notify the Department (1-800-633-1735) within four (4) hours of its determination that a shipment of category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secured, the licensee shall immediately notify the Department.
- c. The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the Department (1-800-633-1735) upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment of category 1 radioactive material.
- d. The shipping licensee shall notify the Department (1-800-633-1735) as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of a category 2 quantity of radioactive material.
- e. The shipping licensee shall notify the Department (1-800-633-1735) and the LLEA as soon as possible upon recovery of any lost or missing category 1 quantities of radioactive material.
- f. The shipping licensee shall notify the Department (1-800-633-1735) as soon as possible upon recovery of any lost or missing category 2 quantities of radioactive material.
- g. The initial telephone notification required by paragraphs a. through d. of this section must be followed within a period of thirty (30) days by a written report submitted to the Department by an appropriate method listed in RH-11007. A written report is not required for notifications on

RH-11081.g. (Cont'd)

suspicious activities required by paragraphs c. and d. of this section. The report must set forth the following information, as appropriate:

1. A description of the licensed material involved, including kind, quantity, and chemical and physical form;
 2. A description of the circumstances under which the loss, theft, etc. occurred;
 3. A statement of disposition, or probable disposition, of the licensed material involved;
 4. Actions that have been taken, or will be taken, to recover the material; and
 5. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of this type of event.
- h. Subsequent to filing the written report, the licensee shall also report, by an appropriate method listed in RH-11007., any additional substantive information on the event within thirty (30) days after the licensee learns of such information.

RH-11082.- RH-11099. Reserved.

PART E.
[RESERVED]

RH-11100.- RH-11199. Reserved.

**PART F.
RECORDS**

RH-11200. Form of Records.

Each record required by this Section must be legible throughout the retention period specified by each Department ~~regulation~~ rule. 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 shall maintain adequate safeguards against tampering with and loss of records.

RH-11201. Reserved.

RH-11202. Record Retention.

Licensees shall maintain the records that are required by the ~~regulations~~ rules in this Section for the period specified by the appropriate ~~regulation~~ rule. If a retention period is not otherwise specified, these records must be retained until the Department terminates the facility's license. All records related to this Section may be destroyed upon Department termination of the facility license.

RH-11203.- RH-11299. Reserved.

**PART G.
ENFORCEMENT**

RH-11300. Inspections.

- a. Each licensee shall afford to the Department at all reasonable times opportunity to inspect category 1 or category 2 quantities of radioactive material and the premises and facilities wherein such radioactive material is used, produced, or stored.
- b. Each licensee shall make available to the Department for inspection, upon reasonable notice, records kept by the licensee pursuant to these ~~Regulations~~ Rules.

RH-11301. Violations.

An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any ~~regulation rule~~ rule or order issued thereunder. Any person who willfully violates any provision of the Act or any ~~regulation rule~~ rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

RH-11302.- RH-11999. Reserved.

APPENDIX A TO SECTION 12

CATEGORY 1 AND CATEGORY 2 RADIOACTIVE MATERIALS

TABLE 1—CATEGORY 1 AND CATEGORY 2 THRESHOLDS

The terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only.

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Americium-241.....	60	1,620	0.6	16.2
Americium-241/Be.....	60	1,620	0.6	16.2
Californium-252.....	20	540	0.2	5.40
Cobalt-60.....	30	810	0.3	8.10
Curium-244.....	50	1,350	0.5	13.5
Cesium-137.....	100	2,700	1	27.0
Gadolinium-153.....	1,000	27,000	10	270
Iridium-192.....	80	2,160	0.8	21.6
Plutonium-238.....	60	1,620	0.6	16.2
Plutonium-239/Be.....	60	1,620	0.6	16.2
Promethium-147.....	40,000	1,080,000	400	10,800
Radium-226.....	40	1,080	0.4	10.8
Selenium-75.....	200	5,400	2	54.0
Strontium-90.....	1,000	27,000	10	270
Thulium-170.....	20,000	540,000	200	5,400
Ytterbium-169.....	300	8,100	3	81.0

Note: Calculations Concerning Multiple Sources or Multiple Radionuclides

The “sum of fractions” methodology for evaluating combinations of multiple sources or multiple radionuclides is to be used in determining whether a location meets or exceeds the threshold and is thus subject to the requirements of this Section.

- I. If multiple sources of the same radionuclide and/or multiple radionuclides are aggregated at a location, the sum of the ratios of the total activity of each of the radionuclides must be determined to verify whether the activity at the location is less than the category 1 or category 2 thresholds of Table 1, as appropriate. If the calculated sum of the ratios, using the equation below, is greater than or equal to 1.0, then the applicable requirements of this Section apply.

- II. First, determine the total activity for each radionuclide from Table 1. This is done by adding the activity of each individual source, material in any device, and any loose or bulk material that contains the radionuclide. Then use the equation below to calculate the sum of the ratios by inserting the total activity of the applicable radionuclides from Table 1 in the numerator of the equation and the corresponding threshold activity from Table 1 in the denominator of the equation. Calculations must be performed in metric values (i.e., TBq) and the numerator and denominator values must be in the same units.

R_1 = total activity for radionuclide 1
 R_2 = total activity for radionuclide 2
 R_N = total activity for radionuclide n

AR_1 = activity threshold for radionuclide 1
 AR_2 = activity threshold for radionuclide 2
 AR_N = activity threshold for radionuclide n

$$\sum_{i=1}^n \left[\frac{R_i}{AR_i} \right] \geq 1.0$$

$$\frac{R_1}{AR_1} + \frac{R_2}{AR_2} + \dots + \frac{R_n}{AR_n} \geq 1.0$$

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SEVERABILITY

If any provision of these Rules or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of these Rules which can give effect without the invalid provisions or applications, and to this end the provisions hereto are declared severable.

REPEAL

All rules and parts of rules in conflict herewith are hereby repealed.

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CERTIFICATION

This will certify that the foregoing Rules for Control of Sources of Ionizing Radiation were adopted by the Arkansas Board of Health at a regular session of the Board held in Little Rock, Arkansas, on the 22nd day of July, 2021 XX^{xx} day of XXXXXXXX, 2023.

José Romero, MD, FAAP, FIDSA, FPIDS, FAAAS
Secretary of Health
Arkansas Board of Health
Jennifer Dillaha, MD
Secretary of the Board of Health
Director of the Department of Health

Date