



Arkansas Department of Health

4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000
Fay W. Boozman, M.D. Director
Mike Huckabee, Governor

August 8, 2000

Mr. Lloyd Bolling
State Agreements Program
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, Maryland 20852-2738

Dear Mr. Bolling:

Please find attached a copy of the Arkansas Rules and Regulations for Control of Sources of Ionizing Radiation. These revised regulations effective January 1, 1997, are our most current edition.

If additional copies are needed for the U.S. Nuclear Regulatory Commission (NRC) and/or its contractors, please advise. We will be more than willing to supply these documents.

Should you have ANY questions related to this letter, please feel free to call me. My telephone number is (501) 661-2107.

Sincerely,

Bernard Bevill, Supervisor
Division of Radiation Control &
Emergency Management Programs

pc: Snellings
Thompson
Powell

Attachment

Keeping Your Hometown Healthy

"An Equal Opportunity Employer"

DSP-006 Template

RIPS CRK: SP08

NOTICE TO EMPLOYEES

RH-2400

Arkansas Department of Health STANDARDS FOR PROTECTION AGAINST RADIATION

The Arkansas Department of Health (ADH) has adopted regulations with standards to protect you from hazards associated with radioactive materials and radiation emitting machines which are licensed or registered by ADH. In particular, the following information is available for your review:

Section 3: Standards for Protection Against Radiation
Part N: Notice, Instructions, and Reports to Workers
Any other documents your employer must provide, as noted below

These may be found at the following location:

YOUR EMPLOYER'S RESPONSIBILITY

Your employer is required to:

1. Comply with all applicable regulations and the conditions of the license or registration.
2. Post or otherwise make available to you a copy of the regulations, licenses, regulations, and operating procedures which apply to work in which you are engaged, and explain the provisions to you.

YOUR RESPONSIBILITY AS A WORKER

You should:

1. Know the provisions of the ADH regulations, the precautions, the operating procedures, and the emergency procedures which apply to your work.
2. Observe the provisions for your own protection and for the protection of your co-workers.
3. Report unsafe working conditions or violations of the license or registration conditions, or regulations to ADH.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY

1. The ADH regulations specify the occupational limits for radiation exposure including concentrations of radioactive material in air and water. These regulations require your employer to give you a written report if you receive an exposure in excess of any applicable limit. The limits on your exposure are contained in RH-1200, RH-1206, and RH-1207. While these are the maximum allowable limits, your employer should keep your radiation exposure below those limits as is reasonably achievable.
2. If you work where personnel monitoring is required and request information on your radiation exposures,
 - a. your employer must advise you annually of your exposure to radiation, and
 - b. upon termination of employment, your employer must give you a written report of your radiation exposures. A report of any exposure in excess of a limit must be reported to you.

INSPECTIONS: All licensed or registered activities are subject to inspection by the ADH.

INQUIRIES

Direct all inquiries on matters outlined above to: Radiation Control, Arkansas Department of Health, 4815 West Markham, Mail Slot #30, Little Rock, AR 72205-3867; (501) 661-2301 Emergencies only (800) 633-1735

POSTING REQUIREMENT: Copies of this notice must be posted in every establishment where employees are engaged in activities licensed or registered by the ADH. Posting must permit employees working in or frequenting any portion of a restricted area to observe a copy on the way to or from their place of employment.

**ARKANSAS
STATE BOARD OF HEALTH**

Radiation Control and Emergency Management Programs

**RULES AND REGULATIONS
FOR
CONTROL OF SOURCES OF IONIZING RADIATION**

Promulgated Under the Authority of Act 96 of 1913

and

Act 8 of the Second Extraordinary Session of 1961, As Amended

Effective Date January 1, 1963

This Revision Effective January 1, 1997

By the Arkansas State Board of Health

**Arkansas Department of Health
Little Rock, Arkansas**

Sandra B. Nichols, M.D., Director

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RADIOLOGICAL HEALTH

SECTION 1. REGISTRATION OF SOURCES OF RADIATION

PART A. GENERAL

- RH-1. Authority. Act 96 of 1913, Act 8 of Second Extraordinary Special Session of 1961, as Amended.
- RH-2. Effective Date. January 1, 1963.
- RH-3. Registration Requirement. Every person possessing a reportable source of radiation shall register in accordance with the provisions of these Regulations.
- RH-4. Communications. All communications concerning these Regulations shall be addressed to the Division of Radiation Control and Emergency Management, Arkansas Department of Health, 4815 West Markham, Mail Slot 30, Little Rock, Arkansas 72205-3867.
- RH-5. Additional Requirements. In addition to the requirements of this Part, all registrants are subject to the applicable provisions of other Parts of these Regulations.
- RH-6 - Reserved.
RH-9

PART B. DEFINITIONS

RH-10. General Definitions. As used in these Regulations. Additional definitions used only in a certain Part will be found in that Part.

- a. Act - Act 8 of Second Extraordinary Special Session of 1961, as amended.
- b. Decommission - To remove (as a facility) safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of license.
- c. Department - The Arkansas Department of Health.
- d. Inspection - An official examination or observation including but not limited to, tests, surveys and monitoring to determine compliance with rules, regulations, orders, requirements and conditions of the Department.
- e. Installation - The location where one or more reportable sources of radiation are used, operated or stored.
- f. Person - Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state or any other state or political subdivision or agency thereof and any legal successor, representative, agent or agency of the foregoing, other than the United States Nuclear Regulatory Commission and other federal government agencies.
- g. Possessing a source of radiation - Using, operating, storing, manufacturing or otherwise having control of a source of radiation in the State of Arkansas.
- h. Radiation - Ionizing radiation, i.e., gamma rays and x-rays, alpha and beta particles, high speed electrons, neutrons and other nuclear particles; but not sound or radio waves or visible, infrared or ultraviolet light.
- i. Radiation machine - Any device capable of producing radiation, but excluding particle accelerators and devices which produce radiation only by the use of radioactive material.

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RH-10 (Cont'd)

- j. Radioactive material - Any material, solid, liquid or gas which emits radiation spontaneously, including any natural radioactive material such as Radium.
- k. Registrant - Any person who is registering or who has registered with the Department pursuant to these Regulations.
- l. Reportable source of radiation - Any source of radiation as specified under RH-20 of these Regulations.
- m. Source of radiation - Any radioactive material or any device or equipment emitting or capable of producing radiation.
- n. These Regulations - The Arkansas State Board of Health Rules and Regulations for Control of Sources of Ionizing Radiation, Section 1.

RH-11 - Reserved.
RH-19

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PART C. REGISTRATION OF RADIATION MACHINES

- RH-20. Reportable Sources of Radiation. The following constitute reportable sources of radiation:
- Radiation machines, except when not installed in such manner as to be capable of producing radiation.
- RH-21. Initial Registration. Every person who possesses a reportable source of radiation on January 1, 1963 shall register with the Department prior to April 1, 1963. Every person not already registered who acquires possession of a reportable source of radiation subsequent to January 1, 1963 shall register with the Department within thirty (30) days of the date of acquisition.
- RH-22. Renewal of Registration. Every person possessing a registered source of radiation shall renew such registration with the Department during December of each year for the following year, as long as the activity requiring such registration continues and at such other times as the Department shall deem necessary.
- RH-23. Registration Form. Registration and renewal shall be made on forms furnished by the Department. The registration or renewal of registration shall set forth all applicable information called for by the form.
- RH-24. Separate Installations. Every person who registers shall complete a separate registration form for each installation.
- RH-25. Special Registration. If the reporting of each installation or other information called for is impractical, the Department, upon the request of a registrant, may approve registration in such special form as the Department may prescribe.
- RH-26. Report of Change. Within ten (10) days of change, the registrant shall report in writing to the Department any change in the name or address of the registrant or location of the installation, receipt, sale or disposal of any reportable source of radiation. In the case of disposition of the machine, such notification should specify the recipient of the machine.
- RH-27. Report of Discontinuance. Every registrant who permanently discontinues the use of or permanently disposes of, all his reportable sources of radiation at an installation, shall notify the Department within ten (10) days of such action.
- RH-28. Deleted.
- RH-29. Reserved.

PART D. REGISTRATION OF VENDOR SERVICES

- RH-30. Purpose and Scope. This Part provides for the registration of persons providing radiation machine installation, servicing and/or vendor services to licensees or registrants.
- RH-31. Installers of Radiation Machines. Each individual who is engaged in the business of installing or offering to install radiation machines, or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this state to a Department registrant, shall apply for registration of such services with the Department on July 1, 1983 or thereafter, prior to furnishing or offering to furnish any such services.
- RH-32. Registration Form. Registration and renewal shall be completed on forms furnished by the Department and shall contain all information required by the Department as indicated on the forms and accompanying instructions.
- RH-33. Training. Each person applying for registration under this Part shall specify the training and experience that qualify the individual to discharge the services for which the individual is applying for registration.
- RH-34. Services. Each registrant described in this Part shall not provide the services until such persons provide evidence that they have been registered with the Department. For the purpose of this Part, services may include but shall not be limited to:
- a. Installation or servicing of radiation machines and associated radiation machine components.
 - b. Installation or servicing of devices containing radioactive material.
 - c. Consulting services including surveys, and evaluation of Naturally Occurring Radioactive Material (NORM) sites or material.
 - d. Calibration of radiation machines or radiation measurement instruments or devices.

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e. Leak tests and leak test analysis.

Procedures must be submitted to this Department on how the test is performed and how the analysis is performed at the time of application.

f. Providing training to licensee or registrant personnel.

Training outline must be submitted to the Department at the time of application. Training includes but is not limited to:

1. Safe use and handling of X-ray equipment.
2. Safe use and handling of radioactive material.
3. Safe use and handling of Naturally Occurring Radioactive Material (NORM).
4. Training provided to Radiation Safety/Protection Officer.

g. Personnel Dosimetry Services.

1. Any individual offering or furnishing personnel dosimetry services to a Department licensee or registrant shall report each year to the Department all radiation exposure levels greater than limits set forth in RH-1200.a., within ten (10) days after the start of the next reporting period. This report shall include but is not limited to:

- A. Name of exposed individual.
- B. Name and address of the registrant or licensee employing the individual.
- C. Amount of the exposure.
- D. Monitoring year exposed.

2. Any individual offering or furnishing personnel dosimetry services shall not lower or amend radiation exposure reports except by authorization from the Department.

RH-34 (Cont'd)

3. Any individual offering or furnishing personnel dosimetry services shall comply with all additional requirements of quality assurance and control of personnel dosimetry, as deemed appropriate and necessary by the Department.

RH-35. Assembler and/or Transfer Requirement.

- a. Any person who sells, leases, transfers, lends, disposes, assembles or installs radiation machines in this state shall notify the Department within fifteen (15) days of:
 1. The name and address of persons who have received these machines;
 2. The manufacturer, model and serial number of each radiation machine transferred; and
 3. The date of transfer of each radiation machine.
- b. In the case of diagnostic x-ray systems which contain certified components, a copy of the assembler's report prepared in compliance with requirements of the Federal diagnostic x-ray standard (21 CFR 1020.30[d]) shall be submitted to the Department with fifteen (15) days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler.
- c. No person shall make, sell, lease, transfer, lend, assemble or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and used shall meet the requirements of these Regulations.

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RH-36. Deleted.

RH-37 - Reserved.

RH-39

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PART E. EXCLUSIONS FROM REGISTRATION

- RH-40. Excluded Material and Devices. The following materials and devices do not require registration:
- a. Domestic television receivers, providing the dose rate at 5 cm from any outer surface of 10 cm² area is less than 0.5 mrem per hour.
 - b. Other electrical equipment that produces radiation incidental to its operation from other purposes, providing the dose rate to the whole body at the point of nearest approach to such equipment when any external shielding is removed does not exceed 0.5 rem per year. The production testing or factory servicing of such equipment shall not be exempt.
 - c. Radiation machines while in transit or storage incident thereto.
- RH-41. Excluded Possessors. Common and contract carriers are exempt from the requirement to register to the extent that they transport or store reportable sources of radiation in the regular course of their carriage for another or storage incident thereto.
- RH-42 - Reserved.
RH-49

PART F. INSPECTION, EXEMPTIONS AND ADDITIONAL REQUIREMENTS

- RH-50. Radiation Protection Standards. Any person possessing a radiation machine that is a reportable source of radiation or who provides radiation machine installations and/or services shall be subject to the requirements of Section 3 of these Regulations (Radiation Protection Standards).
- RH-51. Records to be Maintained. Each person who possesses a reportable source of radiation shall keep records showing the receipt (for any source received after January 1, 1963), transfer or disposal of such source of radiation. Additional record requirements are specified elsewhere in these Regulations.
- RH-52. Access to Premises. The Department or its duly authorized representatives shall for reasonable cause have the power to enter at all reasonable times upon any private or public property for the purpose of determining whether or not there is compliance with or violation of the provisions of these rules and regulation, except that entry into areas under the jurisdiction of the federal government shall be effected only with the concurrence of the federal government or its duly designated representative.
- RH-53. Access to Records. Each registrant shall, upon reasonable notice, make available for inspection by the Department records kept by the registrant pertaining to his receipt, possession, use, transfer or disposal of sources of radiation.
- RH-54. Tests. Upon instruction from the Department, each registrant shall perform or cause to have performed and shall permit the Department to perform, such reasonable tests as the Department deems appropriate or necessary in the administration of the regulation, including, but not limited to, tests of:
- a. Sources of radiation.
 - b. Facilities wherein sources of radiation are used or stored.
 - c. Radiation detection and monitoring instruments.
 - d. Other equipment and devices used in connection with utilization or storage of registered sources of radiation.
- RH-55. Exemptions.
- a. The Department may, upon application therefore, or upon its own initiative, grant such exemptions or exceptions from the requirements of these Regulations as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

- b. U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors. Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this state is exempt from these Regulations to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:
1. Prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or -controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;
 2. Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the Department and the U.S. Nuclear Regulatory Commission jointly determine:
 - i. that the exemption of the prime contractor or subcontractor is authorized by law; and
 - ii. that under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

RH-56. Additional Requirements. The Department may, by rule, regulation or order, impose upon any registrant such requirements in addition to those established in this Regulation as it deems appropriate or necessary to minimize danger to public health and safety or property.

RH-57. Out-of-State Registration. Whenever any radiation machine is brought into the state for any temporary use, the persons proposing to bring such a machine into the state shall give written notice to the Department at least two (2) days before such a machine enters the state. The notice shall include the type of radiation machine; the nature, duration and scope of use; and the exact location where the radiation machine is to be used and state(s) in which this machine is registered. If for a specific case, the two (2) day period would impose an undue hardship on the person, upon application to the Department, permission to proceed sooner may be granted. In addition, the out-of-state person must:

RH-57 (Cont'd)

- a. Comply with all applicable regulations of the Department;
and
- b. Supply the Department with such other information as the
Department may reasonably request.

RH-58 Registration Fees

In accordance with Act 796 of 1995 - Codified as Arkansas Code
of 1987 Annotated, 20-21-217, annual fees for registration shall
be paid. Nonpayment of fees shall result in escalated
enforcement action and/or revocation of registration.

RH-59 Reserved.

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PART G. PROHIBITED USES

- RH-60. Hand-held Fluoroscopic Screens Prohibited. No hand-held fluoroscopic screen shall be used.
- RH-61. X-Ray Shoe-Fitting Equipment.
- a. X-Ray Shoe-Fitting Equipment Prohibited. No shoe-fitting device or shoe-fitting machine which uses fluoroscopic, x-ray or radiation principles shall be operated or maintained in this state.
 - b. Penalty for Use of X-ray Shoe-Fitting Machine. Any person violating the provisions of these Regulations shall be guilty of a misdemeanor and upon conviction shall be punished by a fine of not less than fifty dollars (\$50.00) and not more than five hundred dollars (\$500.00), and each day that such violation shall continue shall constitute a separate offense.
- RH-62 - Reserved.
RH-69

PART H. ENFORCEMENT

RH-70. Violations.

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

RH-71 - Reserved.
RH-99

SECTION 2. LICENSING OF RADIOACTIVE MATERIALS

(FOOTNOTES APPEAR AT THE END OF THIS SECTION)

PART A. GENERAL

- RH-100. Authority. Act 8 of Second Extraordinary Special Session of 1961, as amended.
- RH-101. Effective Date. The provisions of these Regulations shall become operative on the effective date of an agreement executed by the State of Arkansas and the Federal Government under the provisions of Section 274 of the Atomic Energy Act of 1954, as amended (73 STAT. 689).
- RH-102. License Requirement.
- a. No person shall receive, possess, use, transfer, own or acquire radioactive material except as authorized in a specific or general license issued pursuant to these Regulations or as otherwise provided in these Regulations. However, nothing in these Regulations shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission.^{1/}
 - b. In addition to the requirements of this Part, all licensees, except as otherwise noted in these Regulations, are subject to the requirements of Section 3 of these Regulations.
- RH-103. License Fee. In accordance with Act 796 of 1995, annual fees for licensing shall be paid. Nonpayment of fees shall result in escalated enforcement action and/or revocation of license.
- RH-104. Communications. All communications concerning these Regulations shall be addressed to the Division of Radiation Control and Emergency Management, Arkansas Department of Health, 4815 West Markham, Slot 30, Little Rock, Arkansas 72205-3867.

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PART B. DEFINITIONS

- RH-200. General Definitions as used in these Regulations: Additional definitions used in a certain part will be found in that part.
- a. Accelerator-produced material - Any material made radioactive by a particle accelerator.
 - b. Act - Act 8 of Second Extraordinary Special Session of 1961, as amended.
 - c. Active maintenance - Any significant remedial activity needed during the period of institutional control to maintain a reasonable assurance that the performance objectives in RH-407.c.2 and 3 are met. Such active maintenance includes ongoing activities such as the pumping and treatment of water from a disposal unit or one-time measures such as replacement of a disposal unit cover. Active maintenance does not include custodial activities such as repair of fencing, repair or replacement of monitoring equipment, revegetation, minor additions to soil cover, minor repair of disposal unit covers and general disposal site upkeep such as mowing grass.
 - d. Agreement State - Any state with which the U.S. Nuclear Regulatory Commission has entered into an effective agreement under Section 274 b. of the Atomic Energy Act of 1954, as amended (73 STAT. 689).
 - e. Alert - Events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.
 - f. Authorized nuclear pharmacist - A pharmacist who is:
 1. Board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or
 2. Identified as an authorized nuclear pharmacist on a Department, U.S. Nuclear Regulatory Commission, or other Agreement State license that authorizes the use of radioactive material in the practice of nuclear pharmacy; or

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3. Identified as an authorized nuclear pharmacist on a permit issued by the Department, the U.S. Nuclear Regulatory Commission, or other Agreement State specific license of broad scope that is authorized to permit the use of radioactive material in the practice of nuclear pharmacy.
- g. Authorized user - A physician, dentist, or podiatrist who is:
1. Board certified by at least one of the Boards listed in:
 - A. Nuclear medicine by the American Board of Nuclear Medicine; or
 - B. Diagnostic radiology by the American Board of Radiology; or
 - C. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
 - D. Radiology or therapeutic radiology by the American Board of Radiology; or
 - E. Radiation oncology by the American Osteopathic Board of Radiology; or
 - F. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
 - G. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
 2. Identified as an authorized user on a Department, U.S. Nuclear Regulatory Commission, or other Agreement State license that authorizes the medical use of radioactive material; or
 3. Identified as an authorized user on a permit issued by the Department, the U.S. Nuclear Regulatory Commission, or other Agreement State specific license of broad scope that is authorized to permit the medical use of radioactive material.

- h. Buffer Zone - A portion of the disposal site that is controlled by the licensee and that lies under the disposal units and between the disposal units and the boundary of the site.
- i. Byproduct material - Any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material.
- j. CFR - Code of Federal Regulations.
- k. Chelating agent - Amine polycarboxylic acids (e.g., EDTA, DTPA), hydroxycarboxylic acids and polycarboxylic acids (e.g., citric acid, carbolic acid and glucinic acid).
- l. Commencement of construction - Any clearing of land, excavation or other substantial action that would adversely affect the environment of a land disposal facility. The term does not mean disposal site exploration, necessary roads for disposal site exploration, borings to determine foundation conditions or other preconstruction monitoring or testing to establish background information related to the suitability of the disposal site or the protection of environmental values.
- m. Custodial Agency - An agency of the government designated to act on behalf of the government owner of the disposal site.
- n. Department - Arkansas Department of Health.
- o. Depleted Uranium - The source material Uranium in which the isotope Uranium-235 is less than 0.711 weight percent of the total Uranium present. Depleted Uranium does not include special nuclear material.
- p. Disposal - The isolation of radioactive wastes from the biosphere inhabited by man and containing his food chains by emplacement in a land disposal facility.
- q. Disposal site - That portion of a land disposal facility which is used for disposal of waste. It consists of disposal units and a buffer zone.
- r. Disposal unit - A discrete portion of the disposal site into which waste is placed for disposal. For near surface disposal the unit is usually a trench.

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- s. Effective Dose Equivalent - The sum of the products of the dose equivalent to the organ or tissue and the weighting factors applicable to each of the body organs or tissues that are irradiated. Weighting factors are: 0.25 for gonads, 0.15 for breast, 0.12 for red bone marrow, 0.12 for lungs, 0.03 for thyroid, 0.03 for bone surface, and 0.06 for each of the other five organs receiving the highest dose equivalent.
- t. Engineered barrier - A man-made structure or device that is intended to improve the land disposal facility's ability to meet the performance objectives in RH-407.c.
- u. Explosive material - Any chemical compound, mixture or device, which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.
- v. Hazardous waste - Those wastes designated as hazardous by Environmental Protection Agency regulations in 40 CFR Part 261.
- w. Human use - The internal or external administration of radiation or radioactive materials to human beings.
- x. Hydrogeologic unit - Any soil or rock unit or zone which by virtue of its porosity or permeability or lack thereof, has a distinct influence on the storage or movement of ground water.
- y. Inadvertent intruder - A person who might occupy the disposal site after closure and engage in normal activities, such as agriculture, dwelling construction or other pursuits in which the person might be unknowingly exposed to radiation from the waste.
- z. Individual - Any human being.
- aa. Inspection - An official examination or observation including but not limited to, tests, surveys and monitoring to determine compliance with rules, regulations, orders, requirements and conditions of the Department.
- ab. Intruder barrier - A sufficient depth of cover over the waste that inhibits contact with waste and helps to ensure that radiation exposures to an inadvertent intruder will meet the performance objectives set forth in this Part or engineered structures that provides equivalent protection to the inadvertent intruder.

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- ac. Land disposal facility - The land, buildings and equipment which are intended to be used for the disposal of the radioactive wastes into the subsurface of the land. For purposes of this Section, a geologic repository is not considered a land disposal facility.
- ad. License - Except where otherwise specified, a license issued pursuant to these Regulations.
- ae. Licensee - Any person who is licensed by the Department in accordance with these Regulations and the Act.
- af. Licensing State - Any state with regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and an effective program for, the regulatory control of Naturally-Occurring and Accelerator-Produced Radioactive Material (NARM).
- ag. Monitoring - Observing and making measurements to provide data to evaluate the performance and characteristics of the disposal site.
- ah. Near-surface disposal facility - A land disposal facility in which radioactive waste is disposed of in or within the upper 30 meters of the earth's surface.
- ai. Person - Any individual, corporation, partnership, firm, agency, political subdivision of this state, any other state or political subdivision or agency thereof and any legal successor, representative, agent or agency of the foregoing, other than the U.S. Nuclear Regulatory Commission and other federal government agencies.
- aj. Pharmacist - An individual registered by this State to compound and dispense drugs, prescriptions and poisons.
- ak. Physician - Any individual possessing a valid physician's and surgeon's certificate issued by this state.
- al. Pyrophoric liquid - Any liquid that ignites spontaneously in dry or moist air at or below 130° F (54.5° C). A pyrophoric solid is any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing or which can be ignited readily and when ignited, burns so vigorously and persistently as to create a serious transportation, handling or disposal hazard. Included are spontaneously combustible and water-reactive materials.

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- am. Radiation - Ionizing radiation, i.e., gamma rays and x-rays, alpha and beta particles, high speed electrons, neutrons and other nuclear particles; but not sound, radio waves, visible, infrared or ultraviolet light.
- an. Radioactive material - Any material, solid, liquid or gas which emits radiation spontaneously, including any natural radioactive material such as radium.
- ao. Radiographer - Any individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of these Regulations and the conditions of registration or of a license.
- ap. Radiographer's Assistant - Any individual who, under the personal supervision of a radiographer, uses sources of radiation, related handling tools or survey instruments in industrial radiography.
- aq. Radiographic exposure device - Any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.
- ar. Radiography - The examination of the macroscopic structure of materials by nondestructive methods utilizing sources of radiation.
- as. Registrant - Any person who is registered with the Department and is legally obligated to register with the Department pursuant to these Regulations and the Act.
- at. Registration - Registration with the Department in accordance with these Regulations adopted by the Department.
- au. Research and Development -
 - 1. Theoretical analysis, exploration or experimentation; or

(continued on next page)

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2. The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, material and processes.

Research and Development used in these Regulations does not include the internal or external administration of radiation or radioactive material to human beings.

- av. Sealed Source - Radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.
- aw. Site Area Emergency - Events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.
- ax. Site closure and stabilization - Those actions that are taken upon completion of operations that prepare the disposal site for custodial care and assure that the disposal site will remain stable and will not need ongoing active maintenance.
- ay. Source Material -
 1. Uranium or Thorium or any combination thereof in any physical or chemical form, or
 2. Ores which contain by weight one-twentieth of one percent (0.05 percent) or more of (A) Uranium, (B) Thorium or (C) any combination thereof.

Source material does not include special nuclear material.

- az. Source of radiation - Any radioactive material, device or equipment emitting or capable of producing radiation.

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- ba. Special nuclear material in quantities not sufficient to form a critical mass - Uranium enriched in the isotope 235 in quantities not exceeding 350 grams of contained Uranium-235; Uranium-233 in quantities not exceeding 200 grams; Plutonium in quantities not exceeding 200 grams or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula, as follows:

$$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

- bb. Stability - Structural stability.
- bc. Surveillance - Observation of the disposal site for purposes of visual detection of need for maintenance, custodial care, evidence of intrusion and compliance with other license and regulatory requirements.
- bd. These Regulations - The Arkansas State Board of Health Rules and Regulations for Control of Sources of Ionizing Radiation, Section 2.
- be. Unrefined and Unprocessed Ore - Ore in its natural form prior to any processing, such as grinding, roasting, beneficiating or refining.

Revision effective January 1, 1997

- bf. U.S. Department of Energy - The Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to Sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to Section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977.)

- bg. Waste - Those low-level radioactive wastes containing source, special nuclear or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as in the Federal Low-Level Waste Policy Act, that is radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel or byproduct material as defined in Section 11e.(2) of the Atomic Energy Act (Uranium or Thorium tailings and waste).

- bh. Waste handling licensees - Persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.

Revision effective January 1, 1997

PART C. EXEMPTIONS

RH-300. Source Material.

- a. Any person is exempt from these Regulations to the extent that such person receives, possesses, uses or transfers source material in any chemical mixture, compound, solution or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution or alloy.
- b. Any person is exempt from this Regulation to the extent that such person receives, possesses, uses or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.
- c. Any person is exempt from this regulation to the extent that such person receives, possesses, uses or transfers:
 1. Any quantity of Thorium contained in:
 - A. Incandescent gas mantles; or
 - B. Vacuum tubes; or
 - C. Welding rods; or
 - D. Electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of Thorium; or
 - E. Germicidal lamps, sunlamps and lamps for outdoor or industrial lighting provided that each lamp does not contain more than 2 grams of Thorium; or
 - F. Rare earth metals and compounds, mixtures and products containing not more than 0.25% by weight Thorium, Uranium or any combination of these.
 - G. Personnel neutron dosimeters; provided, that each dosimeter does not contain more than 50 milligrams of Thorium.
 2. Source material contained in the following products:
 - A. Glazed ceramic tableware, provided that the glaze contains not more than 20 percent by weight source material;

- B. Piezoelectric ceramic containing not more than two (2) percent by weight source material;
3. Photographic film, negatives and prints containing Uranium or Thorium;
4. Any finished product or part fabricated of or containing Tungsten or Magnesium-Thorium alloys; provided that the Thorium content of the alloy does not exceed four (4) percent by weight and that the exemption contained in this Subparagraph shall not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such product or part; and
5. Uranium contained in counterweights installed in rockets, projectiles and missiles or stored or handled in connection with installation or removal of such counterweights; provided that:
 - A. The counterweights are manufactured in accordance with a specific license issued by the Department, the U.S. Nuclear Regulatory Commission or any Agreement State authorizing distribution by the licensee pursuant to this Subparagraph or equivalent regulations of the NRC or any Agreement State;
 - B. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM;"^{2/}
 - C. Each counterweight is durably and legibly labelled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED;"^{2/} and
 - D. The exemption contained in this Subparagraph shall not be deemed to authorize the chemical, physical or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.
6. Uranium used as shielding constituting part of any shipping container which is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM" and which meets the

specifications for containers for radioactive materials prescribed by Section 173.394 or 173.395 of 49 CFR Part 173, of the regulations published by the U.S. Department of Transportation.

7. Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of Thorium; and that the exemption contained in this Subparagraph shall not be deemed to authorize either:
 - A. The shaping, grinding or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens; or
 - B. The receipt, possession, use or transfer of Thorium contained in contact lenses or in spectacles or in eyepieces in binoculars or other optical instruments.
8. Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of Uranium.
9. Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:
 - A. The Thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (Thorium Dioxide); and
 - B. The Thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.
- d. The exemption contained in RH-300.c shall not be deemed to authorize manufacture, processing or production of any of the products described herein.

RH-301. Other Radioactive Materials.

a. Exempt concentrations.

1. Except as provided in RH-301.a.2 below, any person is exempt from this Part to the extent that such person receives, possesses, uses, transfers, owns or

acquires products materials containing radioactive material in concentrations not in excess of those listed in Part I, RH-902, Schedule C.

2. No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under RH-301.a.1 or equivalent regulations of the U.S. Nuclear Regulatory Commission or any Agreement State, except in accordance with a license issued pursuant to RH-405.g or the general license provided in RH-402 of this Section.
- b. Certain items containing radioactive material. Except for persons who apply radioactive material to or persons who incorporate radioactive material into, the following products, any person is exempt from these Regulations to the extent that he receives, possesses, uses, transfers, owns or acquires the following products. ^{3/}
1. Time pieces or hands or dials containing Radium or not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:
 - A. 25 millicuries of Tritium per timepiece;
 - B. 5 millicuries of Tritium per hand;
 - C. 15 millicuries of Tritium per dial (bezels when used shall be considered as part of the dial);
 - D. 100 microcuries of Promethium-147 per watch or 200 microcuries of Promethium-147 per other timepiece hand;
 - E. 20 microcuries of Promethium-147 per watch hand or 40 microcuries of Promethium-147 per other timepiece hand;
 - F. 60 microcuries of Promethium-147 per watch dial or 120 microcuries of Promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial);

- G. The levels of radiation from hands and dials containing Promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:
 - i. For wrist watches, 0.1 millirad per hour at 10 centimeters from any surface;
 - ii. For any other timepiece, 0.1 millirad per hour at 1 centimeter from any surface;
 - iii. For any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface.
- 2. Lock illuminators containing not more than 15 millicuries of Tritium or not more than 2 millicuries of Promethium-147 installed in automobile locks. The levels of radiation from each lock illuminator containing Promethium-147 will not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.
- 3. Balances of precision containing not more than 1 millicuries of Tritium per balance or not more than 0.5 millicurie of Tritium per balance part.
- 4. Automobile shift quadrants containing not more than 25 millicuries of Tritium.
- 5. Marine compasses containing not more than 750 millicuries of Tritium gas and other marine navigational instruments containing not more than 250 millicuries of Tritium gas.
- 6. Thermostat dials and pointers containing not more than 25 millicuries of Tritium per thermostat.
- 7. Electron tubes: Provided, that each tube does not contain more than one of the following specified quantities of radioactive material:
 - A. 150 millicuries of Tritium per microwave receiver protector tube or 10 millicuries of Tritium per any electron tube;
 - B. 1 microcurie of Cobalt-60;

- C. 5 microcuries of Nickel-63;
- D. 30 microcuries of Krypton-85;
- E. 5 microcuries of Cesium-137;
- F. 30 microcuries of Promethium-147;

And provided further, that the level of radiation due to radioactive material contained in each electron tube does not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber. ^{4/}

- 8. Spark gap irradiators containing not more than 1 microcurie of Cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons per hour (11.4 liters per hour).
- 9. Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material; provided that:
 - A. Each source contains no more than one exempt quantity set forth in Schedule B, and
 - B. Each instrument contains no more than ten (10) exempt quantities. For purposes of RH-301.b.9, an instrument's source(s) may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Schedule B, provided that the sum of each fractions shall not exceed unity.
 - C. For purposes of this RH-301.b.9, 0.05 microcurie of Americium-241 is considered an exempt quantity under Schedule B.
- c. Resins containing Scandium-46 and designed for sand consolidation in oil wells. Any person is exempt from these Regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing Scandium-46 which are designed for sand consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a

specific license issued by the U.S. Nuclear Regulatory Commission or shall have been manufactured in accordance with the specifications contained in a specific license or equivalent licensing document issued by the Department or any Agreement State to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Section 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the Nuclear Regulatory Commission. This exemption does not authorize the manufacture of any resins containing Scandium-46.

- d. Gas and aerosol detectors containing radioactive material.
1. Except for persons who manufacture, process or produce gas and aerosol detectors containing radioactive material, any person is exempt from these Regulations to the extent such person receives, possesses, uses, transfers, owns or acquires byproduct material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission^{5/} pursuant to Section 32.26 of 10 CFR Part 32, or any Agreement State, which license authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.
 2. Gas and aerosol detectors previously manufactured and distributed to general licensees in accordance with a specific license issued by an Agreement State shall be considered exempt under RH-301.d.1, provided that the device is labeled in accordance with the specific license authorizing distribution of the generally licensed device and provided further that they meet the requirements of RH-405.g.
 3. Gas and aerosol detectors containing Naturally Occurring Radioactive Material (NORM) previously manufactured and distributed in accordance with a specific license issued by a Licensing State shall be considered exempt under RH-301.d.A, provided that the device is labeled in accordance with the specific license authorizing distribution and provided further that they meet the requirements of RH-405.g.

- e. Self-luminous products containing Tritium, Krypton-85 or Promethium-147. Except for persons who manufacture, process or produce self-luminous products containing Tritium, Krypton-85 or Promethium-147, any person is exempt from these Regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires Tritium, Krypton-85 or Promethium-147 in self-luminous products manufactured, processed, produced, imported or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR 32 which authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in this Paragraph e does not apply to Tritium, Krypton-85 or Promethium-147 used in products for frivolous purposes or in toys or adornments.

RH-302. Carriers. Common and contract carriers, freight forwarders and warehousemen operating within this state are exempt from these Regulations to the extent that they transport or store sources of radiation in the regular course of their carriage for another or storage incident thereto.

RH-303. U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors. Any U.S. Department of Energy (DOE) contractor or subcontractor and any U.S. Nuclear Regulatory Commission (NRC) contractor or subcontractor of the following categories operating within this state is exempt from these Regulations to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

- a. Prime contractors performing work for the DOE at U.S. Government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;
- b. Prime contractors of the DOE performing research in or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof;
- c. Prime contractors of the DOE using or operating nuclear reactors or other nuclear devices in a U.S. Government owned vehicle or vessel; and
- d. Any other prime contractor or subcontractor of the DOE or of the NRC when the State and the NRC jointly determine
 - i. that the exemption of the prime contractor or subcontractor is authorized by law; and

- ii. that under the terms of the contract of subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

RH-304. Other Exemptions. The Department may, upon application therefor or upon its own initiative, grant such exemptions or exceptions from the requirements of these Regulations as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

RH-305. Exempt Quantities.

- a. Except as provided in Subparagraphs c and d of this Paragraph, any person is exempt from these Regulations to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in RH-901, Schedule B.
- b. Any person who possesses radioactive material received or acquired under the general license formerly provided in RH-402.a is exempt from the requirements for a license set forth in this Part to the extent that such person possesses, uses, transfers or owns such radioactive material.
- c. This RH-305 does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution or the incorporation of radioactive material into products intended for commercial distribution.
- d. No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Schedule B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this Paragraph or equivalent regulations of the U.S. Nuclear Regulatory Commission or any Agreement State, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR Part 32 which license states that the radioactive material may be transferred by the licensee to persons exempt under this RH-305 or the equivalent regulations of the U.S. Nuclear Regulatory Commission or any Agreement State.^{5/}

PART D. LICENSES

RH-400. Types of Licensees. Licenses for radioactive materials are of two types: general and specific.

General Licenses provided in these Regulations are effective without the filing of an application with the Department or the issuance of licensing documents to particular persons.

Specific Licenses are issued to named persons upon application filed pursuant to these Regulations.

RH-401. General Licenses - Source Material.

- a. A general license is hereby issued authorizing use and transfer of not more than fifteen (15) pounds of source material at any one time by persons in the following categories:
1. Pharmacists using the source material solely for the compounding of medicinals;
 2. Physicians using the source material for medicinal purposes;
 3. Persons receiving possession of source material from pharmacists and physicians in the form of medicinals or drugs;
 4. Commercial and industrial firms and research, educational and medical institutions for research, development, educational or commercial purposes; and provided, that no person shall pursuant to this general license, receive more than a total of 150 pounds of source material in any one (1) calendar year.
- b. Persons who receive, possess, use or transfer source material pursuant to the general license issued in RH-401.a are exempt from the provisions of Section 3 of these Regulations to the extent that such receipt, possession, use or transfer is within the terms of such general license. Provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific license issued pursuant to these Regulations.
- c. A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, use or transfer source material.

RH-402. General Licenses - Other Radioactive Materials.

- a. Certain Devices and Equipment. A general license is hereby issued to transfer, receive, acquire, own, possess and use radioactive material incorporated in a device or equipment which is listed in Part I, RH-900, Schedule A and has been manufactured pursuant to a specific license or equivalent licensing document, issued to the supplier by the Department, the U.S. Nuclear Regulatory Commission or any Agreement State and authorizing distribution under the general license of this Paragraph or its equivalent.

The general license provided in this RH-402.a is subject to the provision of RH-56, RH-60, RH-301.a.2, RH-409, RH-416, RH-500, RH-501, RH-600, RH-601, RH-602, RH-4012, Section 3 ^{6/} and Section 4 of these Regulations.

- b. 1. Certain Measuring, Gauging or Controlling Devices. A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of RH-402.b.2, 3, 4, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage or qualitative or quantitative chemical composition or for producing light or an ionized atmosphere.
2. The general license in RH-402.b.1 applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes distribution of devices to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.
3. Any person who owns, receives, acquires, possesses, uses or transfers radioactive material in a device pursuant to the general license in RH-402.b.1:
- A. Shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is

prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;

- B. Shall assure that the device is tested for leakage of radioactive material and proper operations of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label, however;
 - i. Devices containing only Krypton need not be tested for leakage of radioactive material, and
 - ii. Devices containing only Tritium or not more than 100 microcuries of other beta and/or gamma emitting material or 10 microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation, need not be tested for any purpose;
- C. Shall assure that the tests required by RH-402.b.3.B and other testing, installation, servicing and removal from installation involving the radioactive materials, its shielding or containment, are performed;
 - i. In accordance with the instructions provided by the labels; or
 - ii. By a person holding a specific license from the Department, the U.S. Nuclear Regulatory Commission or an Agreement State to perform such activities;
- D. Shall maintain records showing compliance with the requirements of RH-402.b.3.B and 3.C. The records shall show the results of tests. The records also shall show the dates of performance and the names of persons performing, testing, installation servicing and removal from installation concerning the radioactive material, its shielding or containment;

- E. Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding a specific license from the Department, the U.S. Nuclear Regulatory Commission or an Agreement State, to repair such devices or disposed of by transfer to a person authorized by a specific license to receive the radioactive material contained in the device and within thirty (30) days, furnish to the Department a report containing a brief description of the event and the remedial action taken;
- F. Shall not abandon the device containing radioactive material;
- G. Except as provided in RH-402.b.3.H, shall transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the Department, the U.S. Nuclear Regulatory Commission or an Agreement State, whose specific license authorizes him to receive the device and within thirty (30) days after transfer of a device to a specific licensee, shall furnish to the Department a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee in order to obtain a replacement device;
- H. Shall transfer the device to another general licensee only;
 - i. Where the device remains in use at a particular location. In such case the transferor shall give a transferee a copy of these Regulations and any safety documents identified in the label on the device and within thirty (30) days of the transfer, report to the Department the manufacturer's name and model number

of device transferred, the name and address of the transferee and the name and/or position of an individual who may constitute a point of contact between the Department and the transferee; or

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

I. Shall comply with the provisions of RH-1501 and RH-1502 for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of Section 3 of these Regulations.

4. The general license in RH-402.b.1 does not authorize the manufacture of devices containing radioactive material.

5. The general license provided in this Paragraph is subject to the provisions of RH-56, RH-60, RH-409, RH-416, RH-500, RH-501, RH-600, RH-601, RH-602, RH-4012 and Section 4.

c. 1. Luminous Safety Devices in Aircraft. A general license is hereby issued to own, receive, acquire, possess and use Tritium or Promethium-147 contained in luminous safety devices for use in aircraft, provided each device contains not more than ten (10) curies of Tritium or 300 millicuries of Promethium-147 and that each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured or assembled in accordance with the specifications contained in a specific license or equivalent licensing document issued by the Department or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of CFR Part 32 of the Regulations of the U.S. Nuclear Regulatory Commission.

2. Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in RH-402.c.1 are exempt from the

requirements of Section 3, except that they shall comply with the provisions of Section 3, Part F, RH-1501 and RH-1502.

3. This general license does not authorize the manufacture, assembly or repair of luminous safety devices containing Tritium or Promethium-147.
 4. This general license does not authorize the ownership, receipt, acquisition, possession or use of Promethium-147 contained in instrument dials.
 5. The general license provided in this Paragraph is subject to the provisions of RH-56, RH-60, RH-409, RH-416, RH-500, RH-501, RH-600, RH-601, RH-602, RH-4012 and Section 4.
- d. 1. Calibration and Reference Sources. A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use and transfer, in accordance with provisions of Subparagraphs 4 and 5 of this Paragraph d, Americium-241 in the form of calibration or reference sources:
- A. Any person who holds a specific license issued by the Department which authorizes him to receive, possess, use and transfer radioactive material; and
 - B. Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes him to receive, possess, use and transfer special nuclear material.
2. A general license is hereby issued to receive, possess, use and transfer Plutonium in the form of calibration or reference sources in accordance with the provisions of Subparagraphs 4 and 5 of this Paragraph d to any person who holds a specific license issued by the Department which authorizes him to receive, possess, use and transfer radioactive material.
 3. A general license is hereby issued to own, receive, possess, use and transfer Radium-226 in the form of calibration or reference sources in accordance with the provisions of Subparagraphs 4 and 5 of this Paragraph d to any person who holds a specific

license issued by the Department which authorizes him to receive, possess, use and transfer radioactive material.

4. The general licenses in Subparagraphs 1 and 2 of this Paragraph apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license or equivalent licensing document issued to the manufacturer by the Department or any Agreement State pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 of these Regulations of the U.S. Nuclear Regulatory Commission.
5. The general licenses in Subparagraphs 1 and 2 of this Paragraph are subject to the provisions of RH-56, RH-60, RH-409, RH-416, RH-500, RH-501, RH-600, RH-601, RH-602, RH-4012, Section 3 and Section 4. In addition, persons who own, receive, acquire, possess, use and transfer one or more calibration or reference sources pursuant to these general licenses:
 - A. Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries of Americium-241 and 5 microcuries of Plutonium in such sources; or 5 microcuries of Radium-226 in such sources;
 - B. Shall not receive, possess, use or transfer such source unless the source or the storage container bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement:

The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the Commission

has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION -- RADIOACTIVE MATERIAL -- THIS SOURCE CONTAINS (AMERICIUM-241) (PLUTONIUM)*. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

(Name of Manufacturer or Importer);

- C. Shall not transfer, abandon or dispose of such source except by transfer to a person authorized by a license from the Department, the U.S. Nuclear Regulatory Commission or an Agreement State to receive the source;
 - D. Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain Americium-241, Plutonium or Radium-226 which might otherwise escape during storage; and
 - E. Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.
6. These general licenses do not authorize the manufacture of calibration or reference sources containing Americium-241, Plutonium or Radium-226.
- e. Ownership of Radioactive Material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this Part, this general license does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.
 - f. Ice Detection Devices.
 - 1. A general license is hereby issued to own, receive, acquire, possess, use and transfer Strontium-90 contained in ice detection devices, provided each

*Showing only the name of the appropriate material

device contains not more than 50 microcuries of Strontium-90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license or equivalent licensing document issued by the Department or any Agreement State to the manufacturer of such device pursuant to licensing requirements equivalent to those in Section 32.61 of 10 CFR Part 32 of the Regulations of the U.S. Nuclear Regulatory Commission.

2. Persons who own, receive, acquire, possess, use or transfer Strontium-90 contained in ice detection devices pursuant to the general license in Subparagraph 1 of this Paragraph f:
 - A. Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating, to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license or equivalent licensing document from the U.S. Nuclear Regulatory Commission or any Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of these Regulations;
 - B. Shall assure that all labels affixed to the device at the time of receipt and which bear a statement which prohibits removal of the labels, are maintained thereon;
 - C. Are exempt from the requirements of Section 3 except that such persons shall comply with the provisions of RH-1400, RH-1501 and RH-1502 of these Regulations.
3. This general license does not authorize the manufacture, assembly, disassembly or repair of Strontium-90 in ice detection devices.
4. The general license in this RH-402.f is subject to the provisions of RH-56, RH-60, RH-409, RH-416, RH-500, RH-501, RH-600, RH-601, RH-602, RH-4012 and Section 4.

g. Intrastate Transportation of Radioactive Material. A general license is hereby issued to any common or contract carrier to transport and store radioactive material in the regular course of their carriage for another or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements of these Regulations, appropriate to the mode of transport, of the U.S. Department of Transportation insofar as such regulations relate to the loading and storage of packages, placarding of the transporting vehicle and incident reporting.^{7/} Persons who transport and store radioactive material pursuant to the general license in this Paragraph are exempt from the requirements of Section 3 of these Regulations.

h. General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing.^{8/}

1. A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of RH-402.h, 2, 3, 4, 5 and 6 of this Section, the following radioactive materials in prepackaged units:

A. Carbon-14, in units not exceeding 10 microcuries each for use In Vitro clinical or laboratory tests not involving internal or external administration of radioactive material or the radiation therefrom, to human beings or animals.

B. Cobalt-57, in units not exceeding 10 microcuries each for use in In Vitro clinical or laboratory tests not involving internal or external administration of radioactive material or the radiation therefrom, to human beings or animals.

C. Hydrogen-3 (Tritium), in units not exceeding 50 microcuries each for use in In Vitro clinical or laboratory tests not involving internal or external administration of radioactive material or the radiation therefrom, to human beings or animals.

- D. Iodine-125 in units not exceeding 10 microcuries each for use in In Vitro clinical or laboratory tests not involving internal or external administration of radioactive material or the radiation therefrom, to human beings or animals.
 - E. Iodine-131, in units not exceeding 10 microcuries each for use in In Vitro clinical or laboratory tests not involving internal or external administration of radioactive material or the radiation therefrom, to human beings or animals.
 - F. Iron-59, in units not exceeding 20 microcuries each for use in In Vitro clinical or laboratory tests not involving internal or external administration of radioactive material or the radiation therefrom, to human beings or animals.
 - G. Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of Iodine-129 and 0.005 microcurie of Americium-241 each for use in In Vitro clinical or laboratory tests not involving internal or external administration of radioactive material or the radiation therefrom, to human beings or animals.
 - H. Selenium-75, in units not exceeding 10 microcuries each for use in In Vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.
2. No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by RH-402.h.1 until the individual has filed Department Form RH-102 "Registration Certificate - In Vitro Testing With Radioactive Material Under General License" with the Radiation Control Programs, Arkansas Department of Health and received from the Department a validated copy of Department Form RH-102 with registration number assigned or until he has been authorized pursuant to RH-405.C.3 to use radioactive material under the general license in RH-402.h. The

registrant shall furnish on Department Form RH-102 the following information and such other information as may be required by that form:

- A. Name and address of the registrant;
 - B. The location of use; and
 - C. A statement that the registrant has appropriate radiation measuring instruments to carry out In Vitro clinical or laboratory tests with radioactive materials as authorized under the general license in RH-402.h, and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive materials.
3. A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by RH-402.h.1 shall comply with the following:
- A. The general licensee shall not possess at any one time, pursuant to the general license established by RH-402.h.1 at any one location of storage or use, a total amount of Iodine-125, Iodine-131, Selenium-75, Cobalt-57 and/or Iron-59 in excess of 200 microcuries.
 - B. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.
 - C. The general licensee shall use the radioactive material only for the uses authorized by RH-402.h.1.
 - D. The general licensee shall not transfer the radioactive material except by transfer to a person authorized to receive it pursuant to a license issued by the Department, the U.S. Nuclear Regulatory Commission or any Agreement State nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

- E. The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in RH-402.h.1.G as required by RH-1400.
- 4. The general licensee shall not receive, acquire, possess or use radioactive material pursuant to RH-402.h.1:
 - A. Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission or any Agreement State that authorizes manufacture and distribution of Iodine-125, Iodine-131, Carbon-14, Hydrogen-3 (Tritium), Selenium-75, Iron-59, Cobalt-57 or Mock Iodine-125 for distribution to persons generally licensed under RH-402.h.1.

Unless one of the following statements or a substantially similar statement which contains the information called for in the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

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

Name of Manufacturer

5. The registrant possessing or using radioactive materials under the general license of RH-402.h.1 shall report in writing to the Director, Division of Radiation Control and Emergency Management, any changes in the information furnished by him in the "Registration Certificate - In Vitro Testing with Radioactive Material Under General License", Department Form RH-102. The report shall be furnished within thirty (30) days after the effective date of such change.
6. Any person using radioactive material pursuant to the general license of RH-402.h.1 is exempt from the requirements of Section 3, "Standards for Protection Against Radiation" with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in RH-402.1.G shall comply with the provisions of RH-1400, RH-1501 and RH-1502.

RH-403. Specific Licenses.

- a. Application for specific licenses shall be filed on forms supplied by the Division of Radiation Control and Emergency Management, Arkansas Department of Health, 4815 West Markham, Slot 30, Little Rock, Arkansas 72205-3867. The application shall set forth all applicable information called for by the form. An application for a license may request a license for one or more activities.
- 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 an individual duly authorized to act for and on his behalf.
- d. In the application, the applicant may incorporate, by reference, information contained in previous applications, statements or reports filed with the Department: Provided, that such references are clear and specific.
- e. Applications and documents submitted to the Department in connection with the applications 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.

f. The Department may verify information contained in applications and secure additional information deemed necessary to make a reasonable determination as to whether to issue a license and whether special conditions should be attached thereto by visiting the facility or location where radioactive materials would be possessed or used and by discussing details of proposed possession or use of the radioactive materials with the applicant or his designated representative.

g. Requirements For Emergency Response Plans For Certain Licensees

1. Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in RH-905, Schedule F - "Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must contain either:

- i. An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 0.5 rem effective dose equivalent or 5 rems to the thyroid; or
- ii. An emergency plan for responding to a release of radioactive material.

2. One or more of the following factors may be used to support an evaluation submitted under g.1.i of this section:

- i. The radioactive material is physically separated so that only a portion could be involved in an accident;
- ii. All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;
- iii. The release fraction in the respirable size range would be lower than the release fraction shown in RH-905 due to the chemical or physical form of the material;

- iv. The solubility of the radioactive material would reduce the dose received;
 - v. Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in RH-905;
 - vi. Operating restrictions or procedures would prevent a release fraction as large as that shown in RH-905; or
 - vii. Other factors appropriate for the specific facility.
3. An emergency plan for responding to a release of radioactive material submitted under RH-403.g. must include the following information:
- i. Facility description. A brief description of the licensee's facility and area near the site.
 - ii. Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.
 - iii. Classification of accidents. A system for classifying each accident as "alert" or "site area emergency."
 - iv. Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.
 - v. Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.
 - vi. Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

- vii. Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the Department; also responsibilities for developing, maintaining, and updating the plan.
- viii. Notification and coordination. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the Department immediately and ensure notification of other appropriate offsite response organizations "and not later than one hour after the licensee declares an emergency."
- ix. Information to be communicated. A brief description of the types of information regarding facility status, radioactive releases and, if necessary, recommended protective actions.
- x. Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their

responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

- xi. Safe shutdown. A brief description of the means of restoring the facility to a safe condition after an accident.
- xii. Exercises. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises, although recommended, is not required. Exercises must use accident scenarios postulated as most probable for the specific site; the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.
- xiii. Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

4. The licensee shall allow the Department and the offsite response organizations expected to respond in case of an accident sixty (60) days to comment on the licensee's emergency plan before submitting it in final form to the Department. The licensee shall provide any comments received within the sixty (60) days to the Department with the emergency plan.

RH-404. General 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 material in question for the purpose requested in accordance with Section 3 of these Regulations 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 protect health and minimize danger to public health and safety or property; and
 3. The issuance of the license will not be inimical to the health and safety of the public; and the applicant satisfies any applicable special requirements in RH-405 of these Regulations.
- b. Additional requirements for the issuance of specific licenses for human use of radioactive material.
 1. A person shall not manufacture, produce, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a specific license issued by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State, or as allowed in RH-404.b.2 or RH-404.b.3.
 2. An individual may receive, possess, use, or transfer radioactive material in accordance with these Regulations under the supervision of an authorized user as provided in RH-404.b.7 through RH-404.b.9, unless prohibited by license condition.

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3. An individual may prepare unsealed radioactive material for medical use in accordance with these Regulations under the supervision of an authorized nuclear pharmacist or authorized user as provided in RH-404.b.7 through RH-404.b.9.
4. A licensee shall provide to the Department a copy of the board certification; the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State license; or the permit issued by a licensee of broad scope for each individual no later than 30 (thirty) days after the date that the licensee permits the individual to work as an authorized user or an authorized nuclear pharmacist pursuant to RH-412.
5. A licensee shall notify the Department by letter no later than 30 (thirty) days after:
 - A. An authorized user, an authorized nuclear pharmacist, Radiation Safety Officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change; or
 - B. The licensee's mailing address changes.
6. The licensee shall mail the documents required in this Section to the appropriate address identified in RH-104.
7. A licensee that permits the receipt, possession, use or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by RH-404.b.2 of this Part shall:
 - A. Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material and in the licensee's written quality management program;
 - B. Require the supervised individual to follow the instructions of the supervising authorized user, follow the written radiation safety and quality management procedures established by the licensee, and comply with the Regulations and the license conditions with respect to the use of radioactive material; and

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- C. Periodically review the supervised individual's use of radioactive material and the records kept to reflect this use.
8. 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-404.b.3. shall:
- A. Instruct the supervised individual in the preparation of radioactive material for medical use and the principles of and procedures for radiation safety and in the licensee's written quality management program, as appropriate to that individual's use of radioactive material;
 - B. Require the supervised individual to follow the instructions given pursuant to RH-404.b.8.A and to comply with the Regulations and license conditions; and
 - C. Require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing radioactive material for medical use and the records kept to reflect that work.
9. A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.
10. A licensee may use for medical use only:
- A. Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 10 CFR Part 30 and 10 CFR 32.74 or RH-405.n; or
 - B. Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 10 CFR Part 30 or RH-405.n.

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RH-405. Special Requirements for Issuance of Certain Specific Licenses.

- a. Human use of radioactive materials in institutions. In addition to the requirements set forth in Part D, RH-404, a specific license for human use of radioactive material in an institution will be issued only if:
 1. Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of radioactive material.
 - A. Each Committee must meet the following administrative requirements:
 - i. Membership must consist of at least three (3) individuals and must include an authorized user of each type of use permitted by the licensee, the Radiation Safety Officer, a representative of the nursing service, and representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.
 - ii. The Committee must meet at least semi-annually.
 - iii. To establish a quorum and to conduct business, at least one-half of the Committee's membership must be present, including the Radiation Safety Officer and the management's representative.
 - iv. The minutes of each Radiation Safety Committee meeting must include:
 - (a). The date of the meeting;
 - (b). Members present;
 - (c). Members absent;
 - (d). Summary of deliberations and discussions;
 - (e). Recommended actions and the numerical results of all ballots; and
 - (f). ALARA program reviews.
 - v. The Committee must promptly provide each member with a copy of the meeting minutes, and retain one copy for the duration of the license.

- B. To oversee the use of licensed material, the Committee must:
- i. Review recommendations on ways to maintain individual and collective doses ALARA;
 - ii. (a). Review, on the basis of safety and with regard to the training and experience standards, and approve or disapproved any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or a teletherapy physicist before submitting a license application or request for amendment or renewal; or
(b). Review, pursuant to RH-412, on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist.
 - iii. Review, on the basis of safety, and approve or disapprove with the advice and consent of the Radiation Safety Officer and the management representative, minor changes in radiation safety procedures that are not potentially important to safety;
 - iv. Review quarterly, with the assistance of the Radiation Safety Officer, a summary of the occupational radiation dose records of all personnel working with radioactive material;
 - v. Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving radioactive material with respect to cause and subsequent actions taken; and
 - vi. Review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

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2. The applicant possesses adequate facilities for the clinical care of patients;
3. The physician designated on the application as the individual user has substantial experience in the handling and administration of radioactive material and, where applicable, the clinical management of radioactive patients; and
4. If the application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant's staff has substantial experience in the use of a variety of radioactive materials for a variety of human uses.

b. Licensing of Individual Physicians for Human Use of Radioactive Materials.

1. An application by an individual physician or group of physicians for a specific license for human use of radioactive material will be approved if:
 - A. The applicant satisfies the general requirements specified in RH-404.
 - B. The application is for use in the applicant's practice in an office outside a medical institution;
 - C. The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and
 - D. The applicant has extensive experience in the proposed use, the handling and administration of radioisotopes and where applicable, the clinical management of radioactive patients.
2. The Department will not approve an application by an individual physician or group of physicians for a specific license to receive, possess or use radioactive material on the premises of a medical institution unless:
 - A. The use of radioactive material is limited to:

- i. The administration of radiopharmaceuticals for diagnostic or therapeutic purposes;
 - ii. The performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered;
 - iii. The performance of In Vitro diagnostic studies; or
 - iv. The calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation and diagnostic instrumentation.
 - B. The physician brings the radioactive material with him/her and removes the radioactive material when he/she departs. (The institution cannot receive, possess or store radioactive material other than the amount of material remaining in the patient); and
 - C. The medical institution does not hold a radioactive material license under RH-405.a.
 - D. The physician obtains written approval from the institution's administration authorizing him/her to bring radioactive material into the institution.
- c. Specific Licenses for Certain Groups of Medical Uses of Radioactive Material.
 1. Subject to the provisions of RH-405.c.2, 3 and 4, an application for a specific license pursuant to Paragraphs a, b or d of this Section for any medical use or uses of radioactive material specified in one or more of Groups I to V, inclusive, of Schedule D will be approved for all of the uses within the group or groups which include the use or uses specified in the application if:
 - A. The applicant satisfies the requirements of Paragraphs a, b or d of this Section;
 - B. The applicant or the physician designated in the application as the individual user has

adequate clinical experience in the types of uses included in the Group or Groups;

- C. The applicant or the physicians and all other personnel who will be involved in the preparation and use of the radioactive material have adequate training and experience in the handling of radioactive material appropriate to their participation in the uses included in the Group or Groups;
- D. The applicant's radiation detection and measuring instrumentation is adequate for conducting the procedures involved in the uses included in the Group or Groups; and
- E. The applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the uses included in the Group or Groups.

2. Any licensee who is authorized to use radioactive material pursuant to one or more Groups in RH-405.c.1 and Schedule D is subject to the following conditions:

- A.
 - i. For Groups I, II, IV and V, no licensee shall receive, possess or use radioactive material except as a radiopharmaceutical manufactured in the form to be administered to the patient, labeled, packaged and distributed in accordance with a specific license issued by the Department, the U.S. Nuclear Regulatory Commission pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued by an Agreement State pursuant to equivalent regulations; or
 - ii. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user, or an individual under the supervision of either as specified in RH-404.b.8.
- B. For Group III, no licensee shall receive, possess or use generators or reagent kits that do not contain radioactive material to prepare radiopharmaceuticals containing radioactive material, except:
 - i. Reagent kits not containing radioactive material that are approved by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State for use by persons licensed pursuant to RH-405.c and Schedule D or equivalent regulations; or

- ii. Generators or reagent kits containing radioactive material that are manufactured, labeled, packaged and distributed in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Sec. 32.73 of 10 CFR Part 32 or a specific license issued by an Agreement State pursuant to equivalent regulations.
- C. For Group III, any licensee using generators or reagent kits shall:
- i. Elute the generator or process radioactive material with the reagent kit, in accordance with instructions approved by the Nuclear Regulatory Commission or an Agreement State and furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit;
 - ii. Before administration to patients, cause each elution or extraction of Technetium-99m from a Molybdenum-99/Technetium-99m generator to be tested to determine either the total Molybdenum-99 activity or the concentration of Molybdenum-99. This testing shall be conducted according to written procedures and by personnel who have been specifically trained to perform the test;
 - iii. Prohibit the administration to patients of Technetium-99m containing more than 0.15 microcurie of Molybdenum-99 per millicurie of Technetium-99m, and
 - iv. Maintain for two years, for Department inspection, records of the Molybdenum-99 test conducted on each elution from the generator.
3. Any licensee who is licensed pursuant to RH-405.c.1 for one or more of the medical use groups in Schedule D also is authorized to use radioactive material under the general license in RH-402.h for the specified In Vitro uses without filing Department Form RH-102 as required by RH-402.h

provided, that the licensee is subject to the other provisions of RH-402.h.

4. Any licensee who is licensed pursuant to RH-405.c.1 for one or more of the medical use groups in Schedule D also is authorized, subject to the provisions of RH-405.c.4 and 5 to receive, possess and use for calibration and reference standards:
 - A. Any radioactive material listed in Group I, Group II or Group III of Schedule D of this part with a half-life not longer than one hundred (100) days, in amounts not to exceed 15 millicuries total;
 - B. Any radioactive material listed in Group I, Group II or Group III of Schedule D of this Part with half-life greater than one hundred (100) days in amounts not to exceed 200 microcuries total;
 - C. Technetium-99m in amounts not to exceed 50 millicuries; and
 - D. Any radioactive material, in amounts not to exceed 6 millicuries per source, contained in calibration or reference sources that have been manufactured, labeled, packaged and distributed in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent regulations.
5. A. Any licensee who possesses sealed sources as calibration or reference sources pursuant to RH-405.c.4 shall cause each sealed source containing radioactive material, other than Hydrogen-3, with a half-life greater than 30 days in any form other than gas, to be tested for leakage and/or contamination at intervals not to exceed six (6) months. Prior to the transfer, the sealed sources should not be used until tested, provided, however, that no leak tests are required when:

- i. The source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material, or
 - ii. The sealed source is stored and is not being used; such sources shall, however, be tested for leakage prior to any use or transfer unless they have been leak tested within six (6) months prior to the date of use or transfer.
 - B. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which contamination might be expected to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Department.
 - C. If the leak test reveals the presence of 0.005 microcurie or more of removable contamination the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Section 2 and Section 3 of these Regulations. A report shall be filed within five (5) days of the test with the Department describing the equipment involved, the test results and the corrective action taken.
6. Any licensee who possesses and uses calibration and reference sources pursuant to RH-405.c.4.D shall:
- A. Follow the radiation safety and handling instructions approved by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State and furnished by the manufacturer on the label attached to the source or permanent container thereof or in the leaflet or brochure that accompanies the source and maintain such instruction in a legible and conveniently available form; and

- B. Conduct a quarterly physical inventory to account for all sources received and possessed. Records of the inventories shall be maintained for inspection by the Department and shall include the quantities and kinds of radioactive material, location of sources, and the date of the inventory.
7. Provisions for research involving human subjects. A licensee who is licensed in accordance with RH-405.c.1 may conduct research involving human subjects using radioactive material provided 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 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.
8. Nothing in this Part relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs or devices.
- d. Human Use of Sealed Sources. In addition to the requirements set forth in Part D, RH-404, a specific license for human use of sealed sources will be issued only if the applicant or if the application is made by an institution, the individual user:
1. Has specialized training in the therapeutic use of the sealed source considered or has experience equivalent to such training, and
 2. Is a physician.

e. Manufacture and Distribution of Devices to Persons Generally Under Part D, RH-402.b. In addition to the requirements set forth in Part D, RH-404, a specific license to distribute certain devices of the types enumerated in Part D, RH-402.b to persons generally licensed under Part D, RH-402.b will be issued only if:

1. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions and potential hazards of the device to provide reasonable assurance that:
 - A. The device can be safely operated by persons not having training in radiological protection;
 - B. Under ordinary conditions of handling, storage and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device and it is unlikely that any person will receive in any period of one (1) calendar year a dose in excess of 10% of the limits specified in RH-1200.a; and
 - C. Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk;
active blood-forming organs;
gonads; or lens of eye 15 rems

Hands and forearms; feet and
ankles; localized areas of skin
averaged over areas no larger
than 1 square centimeters 200 rems

Other organs 50 rems

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- D. Each device bears a durable, legible, clearly visible label or labels approved by the Department, which contain in a clearly identified and separate statement:
- i. Instructions and precautions necessary to assure safe installation, operation and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);
 - ii. The requirement or lack of requirement, for leak testing or for testing any on-off mechanism and indicator, including the maximum time interval for such testing and the identification of radioactive material by isotope, quantity or radioactivity and date of determination of the quantity; and
 - iii. The information called for in the following statement in the same or substantially similar form:

The receipt, possession, use and transfer of this device Model _____, ^{9/} Serial No. _____ ^{9/} are subject to a general license or the equivalent and the regulations of the U.S. NRC or a State with which the NRC has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

(name of manufacturer or distributor)

2. In the event the applicant desires that the device be required to be tested at intervals longer than six (6) months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the

device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Department will consider information which includes, but is not limited to:

- A. Primary containment (source capsule);
 - B. Protection of primary containment;
 - C. Method of sealing containment;
 - D. Containment construction materials;
 - E. Form of contained radioactive material;
 - F. Maximum temperature withstood during prototype test;
 - G. Maximum pressure withstood during prototype tests;
 - H. Maximum quantity of contained radioactive material;
 - I. Radiotoxicity of contained radioactive material; and
 - J. Operating experience with identical devices or similarly designed and constructed devices.
3. In the event the applicant desires that the general licensee under RH-402.b, or under equivalent regulations of the NRC or an Agreement State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator or remove the device from installation, he shall include in his application written instructions to be followed by the general licensee, estimated calendar year doses associated with such activity or activities and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in

radiological protection, in addition to other handling, storage and use of devices under the general license, is unlikely to cause that individual to receive a calendar year dose in excess of 10% of the limits specified in RH-1200.a.

4. Each person licensed under RH-405.e to distribute devices to generally licensed persons shall:
 - A. Furnish a copy of the general license contained in RH-402.b to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license contained in RH-402.b.
 - B. Furnish a copy of the general license contained in the NRC or Agreement State's regulation equivalent to RH-402.b or alternatively, furnish a copy of the general license contained in RH-402.b to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the NRC or the Agreement State. If a copy of the general license in RH-402.b is furnished to such a person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. NRC or Agreement State under requirements substantially the same as those in RH-402.b.
 - C. Report to the Department all transfers of such devices to persons for use under the general license in RH-402.b. Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Department and the general licensee, the type and model number of device transferred and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the

report shall include identification of each intermediate person by name, address, contact and relationship to the intended user. If no transfers have been made to persons generally licensed under RH-402.b during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within thirty (30) days thereafter.

- D.
- i. Report to the NRC all transfers of such devices to persons for use under the NRC general license in Section 31.5 of 10 CFR Part 31.
 - ii. Report to the responsible State Agency all transfers of such devices to persons for use under a general license in an Agreement State's Regulations equivalent to RH-402.b.
 - iii. Such reports shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Department and the general licensee, the type and model of the device transferred and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact and relationship to the intended user. The report shall be submitted within thirty (30) days after the end of each calendar quarter in which such a device is transferred to the generally licensed person.

- iv. If no transfers have been made to NRC licensees during the reporting period, this information shall be reported to the NRC.
 - v. If no transfers have been made to a particular state during the reporting period, this information shall be reported to the responsible State Agency upon request of the Department.
- E. Keep records showing the name, address and the point of contact for each general licensee to whom the applicant directly or through an intermediate person transfers radioactive material in devices for use pursuant to the generally license provided in RH-402.b or equivalent regulations of the NRC or an Agreement State. The records should show the date of each transfer, the isotope and the quantity of radioactivity in each device transferred, the identity of any intermediate person and compliance with the report requirements of this Section.
- f. Use of Sealed Sources in Non-medical Radiography. A specific license for use of sealed sources in radiography will be issued only if:
- 1. The applicant satisfies the general requirements specified in Part D, RH-404; and
 - 2. The applicant will have an adequate program for training radiographers and radiographers' assistants and submits to the Department a schedule or description of such program which specifies the:
 - A. Initial training;
 - B. Periodic training;
 - C. On-the-job training;

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- D. Means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with, Department Regulations and licensing requirements and the operating and emergency procedures of the applicant; and
 - E. Means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant; and
- 3. The applicant has established and submits to the Department satisfactory written operating and emergency procedures as described in RH-1802.b; and
 - 4. The applicant has established and submits to the Department a description of its internal audit program in accordance with RH-1802.d; and
 - 5. The applicant submits to the Department a description of his overall organizational structure pertaining to the industrial radiography program including specified delegations of authority and responsibility for operation of the program; and
 - 6. The applicant who desires to conduct his own leak tests has established adequate procedures to be followed in leak testing sealed sources for possible leakage and contamination and submits to the Department a description of such procedures including:
 - A. Instrumentation to be used;
 - B. Methods of performing test, e.g., points on equipment to be smeared and method of taking smear; and
 - C. Pertinent experience of the person who will perform the tests.

g. Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations. In addition to the requirements set forth in Section RH-404 above, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under RH-301.a.1 will be issued only if:

1. The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material and estimated concentration of the radioactive material in the product or material at the time of transfer; and
2. The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in RH-902, Schedule C, that reconcentration of the radioactive material in concentrations exceeding those in RH-902, Schedule C, is not likely, that use of lower concentrations is not feasible and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by or application to, a human being.

Each person licensed under this Paragraph g shall file an annual report with the Department which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial

concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee. If no transfers of radioactive material have been made pursuant to this Paragraph g during the reporting period, the report shall so indicate. The report shall cover the year ending June 30 and shall be filed within thirty (30) days thereafter.

- h. Licensing of the Manufacture, Assembly or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble or repair luminous safety devices containing Tritium or Promethium-147 for use in aircraft, for distribution to persons generally licensed under RH-402.c will be approved if:
1. The applicant satisfies the general requirements specified in RH-404 and
 2. The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, 32.556 and 32.101 of 10 CFR Part 32 or their equivalent.
- i. Licensing of the Manufacture of Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed Under RH-402.d. An application for a specific license to manufacture calibration and reference sources containing Americium-241, Plutonium or Radium-226 to persons generally licensed under RH-402.d will be approved if:
1. The applicant satisfies the general requirement of RH-401; and
 2. The applicant satisfies the requirements of Sections 32.57, 32.58, 32.59 and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.
- j. Licensing of the Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of RH-402.h will be approved if:
1. The applicant satisfies the general requirements specified RH-404.

2. The radioactive material is to be prepared for distribution in prepackaged units of:
 - A. Carbon-14 in units not exceeding 10 microcuries each.
 - B. Cobalt-57 in units not exceeding 10 microcuries each.
 - C. Hydrogen-3 (Tritium) in units not exceeding 50 microcuries each.
 - D. Iodine-125 in units not exceeding 10 microcuries each.
 - E. Mock Iodine-125 in units not exceeding 0.05 microcurie of Iodine-129 and 0.005 microcurie of Americium-241 each.
 - F. Iodine-131 in units not exceeding 10 microcuries each.
 - G. Iron-59 in units not exceeding 20 microcuries each.
 - H. Selenium-75 in units not exceeding 10 microcuries each.
3. Each prepackaged unit bears a durable, clearly visible label:
 - A. Identifying the radioactive contents as to chemical form and radionuclide and indicating that the amount of radioactivity does not exceed 10 microcuries of Iodine-125, Iodine-131, Carbon-14, Cobalt-57 or Selenium-75; 50 microcuries of Hydrogen-3 (Tritium); 20 microcuries of Iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcurie of Iodine-129 and 0.005 microcurie of Americium-241 each; and
 - B. Displaying the radiation caution symbol described in RH-1303.a.1 and 2 and the words, **"CAUTION, RADIOACTIVE MATERIAL"**, and **"Not for Internal or External Use in Humans or Animals"**.

4. The following statement, as appropriate or a substantially similar statement which contains the information called for in the statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

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

Name of Manufacturer

5. The label affixed to the unit or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in Part E, Section 3 of these Regulations.
- k. Licensing the Manufacture and Distribution of Ice Detection Devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under RH-402.f will be approved if:
1. The applicant satisfies the general requirements of RH-404; and
 2. The criteria of Sections 32.61, 32.62 and 32.103 of 10 CFR Part 32 are met.

1. Manufacture, Preparation, or Transfer for Commercial Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Group Licenses.
 1. An application for a specific license to manufacture, prepare, or transfer for commercial distribution radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to RH-405.c for the uses listed in RH-903 Schedule D Group I, Group II, Group IV or Group V of this Part will be approved if:
 - A. The applicant satisfies the general requirements specified in RH-404 of this Part;
 - B. The applicant submits evidence that the applicant is at least one of the following:
 - i. Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;
 - ii. Registered or licensed with a State Agency as a drug manufacturer;
 - iii. Licensed as a pharmacy by a State Board of Pharmacy; or
 - iv. Operating as a nuclear pharmacy within a Federal medical institution.
 - C. The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per vial, syringe, generator, or other container of the radiopharmaceutical; and the shielding provided by the packaging to show it is appropriate for safe handling and storage of radiopharmaceuticals by group licensees; and
 - D. The applicant satisfies the following labeling requirements:
 - i. A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material,

of a radiopharmaceutical to be transferred for commercial distribution. The label must include the radiation symbol and the words "**CAUTION, RADIOACTIVE MATERIAL**" or "**DANGER, RADIOACTIVE MATERIAL**"; the name of the radiopharmaceutical or its abbreviation; and the quantity of radioactivity at a specified date and time. For radiopharmaceuticals with a half life greater than 100 (one hundred) days, the time may be omitted.

- ii. A label is affixed to each syringe, vial, or other container used to hold a radiopharmaceutical to be transferred for commercial distribution. The label must include the radiation symbol and the words "**CAUTION, RADIOACTIVE MATERIAL**" or "**DANGER, RADIOACTIVE MATERIAL**" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.
2. A licensee described by RH-405.1.1.B.iii or RH-405.1.1.B.iv of this Section:
- A. May prepare radiopharmaceuticals for medical use, as defined in RH-200, provided that the radiopharmaceutical is prepared by either an authorized nuclear pharmacist, as specified in RH-405.1.2.B and RH-405.1.2.C of this Section, or an individual under the supervision of an authorized nuclear pharmacist as specified in RH-404.b.8.
 - B. May allow a pharmacist to work as an authorized nuclear pharmacist if:
 - i. This individual qualifies as an authorized nuclear pharmacist as defined in RH-200;
 - ii. The licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist.

- C. The actions authorized in RH-405.1.2.A and RH-405.1.2.B of this Section are permitted in spite of more restrictive language in license conditions.
 - D. May designate a pharmacist (as defined in RH-200) as an authorized nuclear pharmacist if the individual is identified as of December 2, 1994, as an "authorized user" on a nuclear pharmacy license issued by the Department under this Part.
 - E. Shall provide to the Department a copy of each individual's certification by the Board of Pharmaceutical Specialties, the Department, the U.S. Nuclear Regulatory Commission, or other Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the State pharmacy licensure or registration, no later than 30 (thirty) days after the date that the licensee allows, pursuant to RH-405.1.2.B.i and RH-405.1.2.B.iii of this Section, the individual to work as an authorized nuclear pharmacist.
3. A licensee shall possess and use instrumentation to measure the radioactivity of radiopharmaceuticals. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radiopharmaceuticals prior to transfer for commercial distribution. In addition, the licensee shall:
- A. Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and
 - B. Check each instrument for constancy and proper operation at the beginning of each day of use.
4. 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.

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m. Deleted.

- n. Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to RH-402 for use as a calibration or reference source or for human use of sealed sources will be approved if:
1. The applicant satisfies the general requirements in RH-404 of this Part;
 2. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:
 - A. The radioactive material contained, its chemical and physical form and amount,
 - B. Details of design and construction of the source or device,
 - C. Procedures for and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,
 - D. For devices containing radioactive material, the radiation profile of a prototype device,
 - E. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,
 - F. Procedures and standards for calibrating sources and devices,

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- G. Legend and methods for labeling sources and devices as to their radioactive content, and
 - H. Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;
- 3. The label affixed to the source or device or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay and a statement that the name of source or device is licensed by the Department for distribution to persons licensed pursuant to RH-405.d of this Part or under equivalent licenses of the U.S. Nuclear Regulatory Commission or an Agreement State, provided, that such labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source;
 - 4. In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six (6) months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and
 - 5. In determining the acceptable interval for test of leakage of radioactive material, the Department will consider information that includes, but is not limited to:
 - A. Primary containment or source capsule,
 - B. Protection of primary containment,
 - C. Method of sealing containment,

- D. Containment construction materials,
- E. Form of contained radioactive material,
- F. Maximum temperature withstood during prototype tests,
- G. Maximum pressure withstood during prototype tests,
- H. Maximum quantity of contained radioactive material,
- I. Radiotoxicity of contained radioactive material,
- J. Operation experience with identical sources or devices or similarly designed and constructed sources or devices.

RH-406 Special Requirements for Specific Licenses of Broad Scope. This Paragraph prescribes requirements for the issuance of specific licenses of broad scope for radioactive material ("broad licenses")^{11/} and certain regulations governing holders of such licenses.

- a. The different types of broad licenses are set forth below:
 - 1. A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.
 - 2. A "Type B specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in RH-904, Schedule E, for any authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in RH-904, Schedule E, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio

of the quantity possessed to the applicable quantity specified in RH-904, Schedule E, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

3. A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in RH-904, Schedule E, for any authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in RH-904, Schedule E, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in RH-904, Schedule E, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

b. An application for a Type A specific license of broad scope will be approved if:

1. The applicant satisfies the general requirements specified in RH-404 of this Part;
2. The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and
3. The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting and management review that are necessary to assure safe operations, including:
 - A. The establishment of a radiation safety committee composed of such persons as a radiological safety officer, a representative of management and persons trained and experienced in the safe use of radioactive materials;
 - B. The appointment of a radiological safety officer who is qualified by training and experience in radiation protection and who is

available for advice and assistance on radiological safety matters; and

- C. The establishment of appropriate administrative procedures to assure:
 - i. Control of procurement and use of radioactive material;
 - ii. Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user and the operating or handling procedures; and
 - iii. Review, approval and recording by the radiation safety committee of safety evaluation of proposed uses prepared in accordance with Subdivision ii of this Subparagraph C prior to use of the radioactive material.

- c. An application for a Type B specific license of broad scope will be approved if:
 - 1. The applicant satisfies the general requirements specified in RH-404 of this Part; and
 - 2. The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting and management review that are necessary to assure safe operations, including:
 - A. The appointment of a radiological safety officer who is qualified by training and experience in radiation protection and who is available for advice and assistance on radiological safety matters; and
 - B. The establishment of appropriate administrative procedures to assure:
 - i. Control of procurement and use of radioactive material;

- ii. Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user and the operating or handling procedures; and
 - iii. Review, approval and recording by the radiological safety officer of safety evaluations of proposed uses prepared in accordance with Subdivision ii of the Subparagraph B prior to use of the radioactive material.
- d. An application for a Type C specific license of broad scope will be approved if:
- 1. The applicant satisfied the general requirements specified in RH-404 of this Part; and
 - 2. The applicant submits a statement that radioactive material will be used only by or under the direct supervision of, individuals who have received:
 - A. A college degree at the bachelor level or equivalent training and experience in the physical or biological sciences or in engineering; and
 - B. At least forty (40) hours of training and experience in the safe handling of radioactive material and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and
 - 3. The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting and management review necessary to assure safe operations.
- e. Specific license of broad scope are subject to the following conditions:

1. Persons licensed pursuant to the RH-406 shall not:
 - A. Conduct tracer studies in the environment involving direct release of radioactive material;
 - B. Receive, acquire, own, possess, use or transfer devices containing 100,000 curies or more of radioactive material in sealed sources used for irradiation of materials;
 - C. Conduct activities for which a specific license issued by the Department under RH-405 of this Part is required; or
 - D. Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug or other product designed for ingestion or inhalation by or application to, a human being.
2. Each Type A specific license of broad scope issued under this Part shall be subject to the condition that radioactive material possessed under the license may only be used by or under the direct supervision of, individuals approved by the licensee's radiation safety committee.
3. Each Type B specific license of broad scope issued under this Part shall be subject to the condition that radioactive material possessed under the license may only be used by or under the direct supervision of, individuals approved by the licensee's radiological safety officer.
4. Each Type C specific license of broad scope issued under this Part shall be subject to the condition that radioactive material possessed under the license may only be used by or under the direct supervision of, individuals who satisfy the requirements of Subparagraph d of this RH-406.

RH-407. Special Requirements for Land Disposal of Radioactive Waste

- a. Each person shall file an application with the Department and obtain a license as provided in this Paragraph before commencing construction of a land disposal facility. Failure to comply with this requirement may be grounds for denial of a license.

- b. Content of Application. An application to receive from others, possess and dispose of wastes containing or contaminated with radioactive material by land disposal must consist of general information, specific technical information, institutional information and financial information as set forth in this Paragraph. An environmental report prepared in accordance with Subpart A of 10 CFR Part 51 must accompany the application.
 1. The general information must include each of the following:
 - A. Identity of the applicant including:
 - i. The full name, address, telephone number and description of the business or occupation of the applicant;
 - ii. If the applicant is a partnership, the name and address of each partner and the principal location where the partnership does business;
 - iii. If the applicant is a corporation or an unincorporated association, the state where it is incorporated or organized and the principal location where it does business and the names and addresses of its directors and principal officers; and
 - iv. If the applicant is acting as an agent or representative of another person in filing the application, all information required under this Paragraph must be supplied with respect to the other person.
 - B. Qualifications of the applicant:
 - i. The organizational structure of the applicant, both offsite and onsite, including a description of lines of authority and assignments of responsibilities, whether in the form of administrative directives, contract provisions, or otherwise;

- ii. The technical qualifications, including training and experience, of the applicant and members of the applicant's staff to engage in the proposed activities. Minimum training and experience requirements for personnel filling key positions described in RH-407.b.1.B.i. must be provided;
 - iii. A description of the applicant's personnel training program; and
 - iv. The plan to maintain an adequate complement of trained personnel to carry out waste receipt, handling and disposal operations in a safe manner.
- C. A description of:
- i. The location of the proposed disposal site;
 - ii. The general character of the proposed activities;
 - iii. The types and quantities of radioactive waste to be received, possessed and disposed of;
 - iv. Plans for use of the land disposal facility for purposes other than disposal of radioactive wastes; and
 - v. The proposed facilities and equipment.
- D. Proposed schedules for construction, receipt of waste and first emplacement of waste at the proposed land disposal facility.
2. The specific technical information must include the following information needed for demonstration that the performance objectives of Subpart c of this Paragraph and the applicable technical requirements of Subpart d of this Paragraph will be met:
- A. A description of the natural and demographic disposal site characteristics as determined by disposal site selection and characterization activities. The description must include

geologic, geotechnical, hydrologic, meteorologic, climatologic and biotic features of disposal site and vicinity.

- B. A description of the design features of the land disposal facility and the disposal units. For near-surface disposal, the description must include those design features related to infiltration of water; integrity of covers for disposal units; structural stability of backfill, waste and covers; contact of wastes with standing water; disposal site drainage; disposal site closure and stabilization; elimination to the extent practicable of long-term disposal site maintenance; inadvertent intrusion; occupational exposures; disposal site monitoring; and adequacy of the size of the buffer zone for monitoring and potential mitigative measures.
- C. A description of the principal design criteria and their relationship to the performance objectives.
- D. A description of the design basis natural events or phenomena and their relationship to the principal design criteria.
- E. A description of codes and standards which the applicant has applied to the design and which will apply to construction of the land disposal facilities.
- F. A description of the construction and operation of the land disposal facility. The description must include as a minimum the methods of construction of disposal units; waste emplacement; the procedures for and areas of waste segregation; types of intruder barriers; onsite traffic and drainage systems; survey control program; methods and areas of waste storage; and methods to control surface water and groundwater access to the wastes. The description must also include a description of the methods to be employed in the handling and disposal of wastes containing chelating agents or other non-radiological substances that might affect meeting the performance objectives in Subpart C of this Paragraph.

- G. A description of the disposal site closure plan, including those design features which are intended to facilitate disposal site closure and to eliminate the need for ongoing active maintenance.
- H. An identification of the known natural resources at the disposal site, the exploitation of which could result in inadvertent intrusion into the low-level wastes after removal of active institutional control.
- I. A description of the kind, amount, classification and specifications of the radioactive material proposed to be received, possessed and disposed of at the land disposal facility.
- J. A description of the quality control program for the determination of natural disposal site characteristics and for quality control during the design, construction, operation and closure of the land disposal facility and the receipt, handling and emplacement of waste. Audits and managerial controls must be included.
- K. A description of the radiation safety program for control and monitoring of radioactive effluents to ensure compliance with the performance objective in RH-407.c.2. and occupational radiation exposure to ensure compliance with the requirements of Section 3 of these Regulations and to control contamination of personnel, vehicles, equipment, buildings and the disposal site. Both routine operations and accidents must be addressed. The program description must include procedures, instrumentation, facilities and equipment.
- L. A description of the environmental monitoring program to provide data to evaluate potential health and environmental impacts and the plan for taking corrective measures if migration of radionuclides is indicated.
- M. A description of the administrative procedures that the applicant will apply to control activities at the land disposal facility.

- N. Technical analyses. The specific technical information must also include the following analyses needed to demonstrate that the performance objectives of Subpart c of this Paragraph will be met:
- i. Pathways analyzed in demonstrating protection of the general population from releases of radioactivity must include air, soil, groundwater, surface water, plant uptake and exhumation by burrowing animals. The analyses must clearly identify and differentiate between the roles performed by the natural disposal site characteristics and design features in isolating and segregating the wastes. The analyses must clearly demonstrate that there is reasonable assurance that the exposure to humans from the release of radioactivity will not exceed the limits set forth in RH-407.c.2.
 - ii. Analyses of the protection of individuals from inadvertent intrusion must include demonstration that there is reasonable assurance the waste classification and segregation requirements will be met and that adequate barriers to inadvertent intrusion will be provided.
 - iii. Analyses of the protection of individuals during operations must include assessments of expected exposures due to routine operations and likely accidents during handling, storage and disposal of waste. The analyses must provide reasonable assurance that exposures will be controlled to meet the requirements of Section 3 of these Regulations.
 - iv. Analyses of the long-term stability of the disposal site and the need for ongoing active maintenance after closure must be based upon analyses of active natural processes such as erosion, mass wasting, slope failure, settlement of wastes and backfill, infiltration through covers over disposal areas and

adjacent soils and surface drainage of the disposal site. The analyses must provide reasonable assurance that there will not be a need for ongoing active maintenance of the disposal site following closure.

3. The institutional information must include:
 - A. A certification by the Federal or State government which owns the disposal site that the Federal or State government is prepared to accept transfer of the license when the provisions of RH-407.b.7. are met and will assume responsibility for custodial care after site closure and post-closure observation and maintenance.
 - B. Where the proposed disposal site is on land not owned by the Federal or a State government, the applicant must submit evidence that arrangements have been made for assumption of ownership in fee by the Federal or a State government before the Department issues a license.
4. The financial information must be sufficient to demonstrate that the financial qualifications of the applicant are adequate to carry out the activities for which the license is sought and meet other financial assurance requirements as specified in Subpart e of this Part.
5. Any expiration date on a license applies only to the above ground activities and to the authority to dispose of waste. Failure to renew the license shall not relieve the licensee of responsibility for carrying out site closure, post-closure observation and transfer of the license to the site owner. An application for renewal or an application for closure must be filed at least thirty (30) days prior to license expiration.
6. Contents of a application for closure.
 - A. Prior to final closure of the disposal site or as otherwise directed by the Department, the applicant shall submit an application to amend the license for closure. This closure

application must include a final revision and specific details of the disposal site closure plan included as part of the license application submitted under RH-407.b.2.G. that includes each of the following:

- i. Any additional geologic, hydrologic or other disposal site data pertinent to the long-term containment of emplaced radioactive wastes obtained during the operational period.
 - ii. The results of tests, experiments or other analyses relating to backfill of excavated areas, closure and sealing, waste migration and interaction with emplacement media, or any other tests, experiments or analysis pertinent to the long-term containment of emplaced waste within the disposal site.
 - iii. Any proposed revision of plans for:
 - Decontamination and/or dismantlement of surface facilities;
 - Backfilling of excavated areas; or
 - Stabilization of the disposal site for post-closure care.
- B. An environmental report or a supplement to an environmental report prepared in accordance with Subpart A of 10 CFR, Part 51 must accompany the application.
- C. Upon review and consideration of an application to amend the license for closure submitted in accordance with Subparagraph G.4 of this Paragraph, the Department shall issue an amendment authorizing closure if there is reasonable assurance that the long-term performance objectives of Subpart c of this Paragraph will be met.
- D. Following completion of closure authorized in RH-407.b.6, the licensee shall observe, monitor and carry out necessary maintenance and repairs at the disposal site until the license is transferred by the Department in

accordance with RH-407.b.7. Responsibility for the disposal site must be maintained by the licensee for five (5) years. A shorter or longer time period for post-closure observation and maintenance may be established and approved as part of the site closure plan, based on site-specific conditions.

7. Transfer of license. Following closure and the period of post-closure observation and maintenance, the licensee may apply for an amendment to transfer the license to the disposal site owner. The license shall be transferred when the Department finds:
 - A. That the closure of the disposal site has been made in conformance with the licensee's disposal site closure plan, as amended and approved as part of the license;
 - B. That reasonable assurance has been provided by the licensee that the performance objectives of Subpart c of this Paragraph are met;
 - C. That any funds and necessary records for care will be transferred to the disposal site owner;
 - D. That the post-closure monitoring program is operational for implementation by the disposal site owner; and
 - E. That the Federal or State government agency which will assume responsibility for institutional control of the disposal site is prepared to assume responsibility and ensure that the institutional requirements found necessary under RH-407.d.10.B will be met.

c. Performance Objectives

1. General requirement. Land disposal facilities must be sited, designed, operated, closed and controlled after closure so that reasonable assurance exists that exposures to humans are within the limits established in the performance objectives in RH-407.c.2 through 5.

2. Protection of the general population from releases of radioactivity. Concentrations of radioactive material which may be released to the general environment in ground water, surface water, air, soil, plants or animals must not result in an annual dose exceeding an equivalent of 25 millirems to the whole body, 75 millirems to the thyroid and 25 millirems to any other organ of any member of the public. Reasonable effort should be made to maintain releases of radioactivity in effluents to the general environment as low as is reasonably achievable.
 3. Protection of individuals from inadvertent intrusion. Design, operation and closure of the land disposal facility must ensure protection of any individual inadvertently intruding into the disposal site and occupying the site or contacting the waste at any time after active institutional controls over the disposal site are removed.
 4. Protection of individuals during operations. Operations at the land disposal facility must be conducted in compliance with the standards for radiation protection set out in Section 3 of these Regulations, except for releases of radioactivity in effluents from the land disposal facility which shall be governed by RH-407.c.2. Every reasonable effort shall be made to maintain radiation exposures as low as is reasonably achievable.
 5. Stability of the disposal site after closure. The disposal facility must be sited, designed, used, operated and closed to achieve long-term stability of the disposal site and to eliminate to the extent practicable the need for ongoing active maintenance of the disposal site following closure so that only surveillance, monitoring or minor custodial care are required.
- d. Technical Requirements for Land Disposal Facilities.
1. Disposal site suitability for near-surface disposal.
 - A. The purpose of this section is to specify the minimum characteristics a disposal site must have to be acceptable for use as a near-surface disposal facility. The primary emphasis in disposal site suitability is given to

isolation of wastes, a matter having long-term impacts and to disposal site features that ensure that the long-term performance objectives of Subpart c of this Paragraph are met, as opposed to short-term convenience or benefits.

- B. The disposal site shall be capable of being characterized, modeled, analyzed and monitored.
- C. Within the region or state where the facility is to be located, a disposal site should be selected so that projected population growth and future developments are not likely to affect the ability of the disposal facility to meet the performance objectives of Subpart c of this Paragraph.
- D. Areas must be avoided having known natural resources which, if exploited, would result in failure to meet the performance objectives of Subpart c of this Paragraph.
- E. The disposal site must be generally well drained and free of areas of flooding or frequent ponding. Waste disposal shall not take place in a 100-year flood plain, coastal high-hazard area or wetland.
- F. Upstream drainage areas must be minimized to decrease the amount of runoff which could erode or inundate waste disposal units.
- G. The disposal site must provide sufficient depth to the water table that ground water intrusion, perennial or otherwise, into the waste will not occur. The Department will consider an exception to this requirement to allow disposal below the water table if it can be conclusively shown that disposal site characteristics will result in molecular diffusion being the predominant means of radionuclide movement and the rate of movement will result in the performance objectives of Subpart c of this Paragraph being met. In no case will waste disposal be permitted in the zone of fluctuation of the water table.

- H. The hydrogeologic unit used for disposal shall not discharge ground water to the surface within the disposal site.
 - I. Areas must be avoided where tectonic processes such as faulting, folding, seismic activity or vulcanism may occur with such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of Subpart c of this Paragraph or may preclude defensible modeling and prediction of long-term impacts.
 - J. Areas must be avoided where surface geologic processes such as mass wasting, erosion, slumping, landsliding or weathering occur with such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of Subpart c of this Paragraph or may preclude defensible modeling and prediction of long-term impacts.
 - K. The disposal site must not be located where nearby facilities or activities could adversely impact the ability of the site to meet the performance objectives of Subpart c of this Paragraph or significantly mask the environmental monitoring program.
2. Disposal site design for near-surface disposal.
- A. Site design features must be directed toward long-term isolation and avoidance of the need for continuing active maintenance after site closure.
 - B. The disposal site design and operation must be compatible with the disposal site closure and stabilization plan and lead to disposal site closure that provides reasonable assurance the performance objectives of Subpart c of this Paragraph will be met.
 - C. The disposal site must be designed to complement and improve, where appropriate, the ability of the disposal site's natural characteristics to assure that the performance objectives of Subpart c of this Paragraph will be met.

- D. Covers must be designed to minimize to the extent practicable water infiltration, to direct percolating or surface water away from the disposed waste and to resist degradation by surface geologic processes and biotic activity.
 - E. Surface features must direct surface water drainage away from disposal units at velocities and gradients which will not result in erosion that will require ongoing active maintenance in the future.
 - F. The disposal site must be designed to minimize to the extent practicable the contact of water with waste during storage, the contact of standing water with waste during disposal and the contact of percolating or standing water with wastes after disposal.
3. Near-surface disposal facility operation and disposal site closure.
- A. Wastes designated as Class A pursuant to RH-407.d.6, must be segregated from other wastes by placing in disposal units which are sufficiently separated from disposal units for the other waste classes so that any interaction between Class A wastes and other wastes will not result in the failure to meet the performance objectives in Subpart c of this Paragraph. This segregation is not necessary for Class A wastes if they meet the stability requirements in RH-407.d.7.B of this Part.
 - B. Wastes designated as Class C pursuant to RH-407.d.6 must be disposed of so that the top of the waste is a minimum of 5 meters below the top surface of the cover or must be disposed of with intruder barriers that are designed to protect against an inadvertent intrusion for at least 500 years.
 - C. All wastes shall be disposed of in accordance with the requirements of RH-407.d.3.D through K.

- D. Wastes must be emplaced in a manner that maintains the package integrity during emplacement, minimizes the void spaces between packages and permits the void spaces to be filled.
- E. Void spaces between waste packages must be filled with earth or other material to reduce future subsidence within the fill.
- F. Waste must be placed and covered in a manner that limits the radiation dose rate at the surface of the cover to levels that at a minimum will permit the licensee to comply with all provisions of RH-1208 at the time the license is transferred pursuant to RH-407.b.7.
- G. The boundaries and locations of each disposal unit (e.g., trenches) must be accurately located and mapped by means of a land survey. Near-surface disposal units must be marked in such a way that the boundaries of each unit can be easily defined. Three permanent survey marker control points, referenced to United States Geological Survey (USGS) or National Geodetic Survey (NGS) survey control stations, must be established in the site to facilitate surveys. The USGS or NGS control stations must provide horizontal and vertical controls as checked against USGS or NGS record files.
- H. A buffer zone of land must be maintained between any buried waste and the disposal site boundary and beneath the disposed waste. The buffer zone shall be of adequate dimensions to carry out environmental monitoring activities specified in RH-407.d.4 and take mitigative measures if needed.
- I. Closure and stabilization measures as set forth in the approved site closure plan must be carried out as each disposal unit (e.g., each trench) is filled and covered.
- J. Active waste disposal operations must not be have an adverse effect on completed closure and stabilization measures.

- K. Only wastes containing or contaminated with radioactive materials shall be disposed of at the disposal site.
4. Environmental monitoring.
- A. At the time a license application is submitted, the applicant shall have conducted a preoperational monitoring program to provide basic environmental data on the disposal site characteristics. The applicant shall obtain information about the ecology, meteorology, climate, hydrology, geology, geochemistry and seismology of the disposal site. For those characteristics that are subject to variation, data must cover at least a twelve (12) month period.
 - B. The licensee must have plans for taking corrective measures if migration of radionuclides would indicate that the performance objectives of Subpart c may not be met.
 - C. During the land disposal facility site construction and operation, the licensee shall maintain a monitoring program. Measurements and observations must be made and recorded to provide data to evaluate the potential health and environmental impacts during both the construction and the operation of the facility and to enable the evaluation of long-term effects and the need for mitigative measures. The monitoring system must be capable of providing early warning of releases of radionuclides from the disposal site before they leave the site boundary.
 - D. After the disposal site is closed, the licensee responsible for post-operational surveillance of the disposal site shall maintain a monitoring system based on the operating history and the closure and stabilization of the disposal site. The monitoring system must be capable of providing early warning of releases of radionuclides from the disposal site before they leave the site boundary.

5. The Department may, upon request or on its own initiative, authorize provisions other than those set forth in RH-407.d.2 through 4 for the segregation and disposal of waste and for the design and operation of a land disposal facility on a specific basis, if it finds reasonable assurance of compliance with the performance objectives of Subpart c of this Paragraph.
6. Classification of waste for near-surface disposal. Determination of the classification of radioactive waste involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form and disposal methods are effective.

A. Classes of waste:

- i. Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in RH-407.d.7.A. If Class A waste also meets the stability requirements set forth in RH-407.d.7.B, it is not necessary to segregate the waste for disposal.
- ii. Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in RH-407.d.7.

- iii. Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in RH-407.d.7.
- iv. Waste that is not generally acceptable for near-surface disposal is waste for which waste form and disposal methods must be different and in general more stringent, than those specified for Class C waste. In the absence of specific requirements in this Part, proposals for disposal of this waste may be submitted to the Department for approval, pursuant to RH-407.d.9 of this Part.

- B. Classification determined by long-lived radionuclides. If radioactive waste contains only radionuclides listed in Table 1, classification shall be determined as follows:
- i. If the concentration does not exceed 0.1 times the value in Table 1, the waste is Class A.
 - ii. If the concentration exceeds 0.1 times the value in Table 1 but does not exceed the value in Table 1, the waste is Class C.
 - iii. If the concentration exceeds the value in Table 1, the waste is not generally acceptable for near-surface disposal.
 - iv. For wastes containing mixtures of radionuclides listed in Table 1, the total concentration shall be determined by the sum of fractions rule described in RH-407.d.6.F.

Revision effective January 1, 1997

TABLE 1.

Radionuclide	Concentration, curies per cubic meter
C-14	8
C-14 in activated metal	80
Ni-59 in activated metal	220
Nb-94 in activated metal	0.2
Tc-99	3
I-129	0.08
Alpha emitting transuranic nuclides with half-life greater than five years	¹ 100
Pu-241	13,500
Cm-242	¹ 20,000

¹Units are nanocuries per gram.

- C. Classification determined by short-lived radionuclides. If radioactive waste does not contain any of the radionuclides listed in Table 1, classification shall be determined based on the concentrations shown in Table 2. However, as specified in RH-407.d.6.E of this Section, if radioactive waste does not contain any nuclides listed in either Table 1 or 2, it is Class A.
- i. If the concentration exceeds the value in Column 1, the waste is Class A.
 - ii. If the concentration exceeds the value in Column 1, but does not exceed the value in Column 2, the waste is Class B.
 - iii. If the concentration exceeds the value in Column 2, but does not exceed the value in Column 3, the waste is Class C.
 - iv. If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.
 - v. For wastes containing mixtures of the nuclides listed in Table 2, the total concentration shall be determined by the sum of fractions rule described in RH-407.d.6.F.

TABLE 2.

Radionuclide	Concentration, curies per cubic meter		
	Col. 1	Col. 2	Col. 3
Total of all nuclides less than 5 year half life	700	(1)	(1)
H-3	40	(1)	(1)
Co-60	700	(1)	(1)
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000
Cs-137	1	44	4600

¹ There are no limits established for these radionuclides in Class B or C wastes. Practical consideration such as the effects of external radiation and internal heat generation on transportation, handling and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other nuclides in Table 2 determine the waste to the Class C independent of these nuclides.

D. Classification determined by both long and short-lived radionuclides. If radioactive waste contains a mixture of radionuclides, some of which are listed in Table 1 and some of which are listed in Table 2, classification shall be determined as follows:

- i. If the concentration of a nuclide listed in Table 1 does not exceed 0.1 times the value listed in Table 1, the class shall be that determined by the concentration of nuclides listed in Table 2.
- ii. If the concentration of a nuclide listed in Table 1 exceeds 0.1 times the value listed in Table 1 but does not exceed the value in Table 1, the waste shall be Class C, provided the concentration of nuclides listed in Table 2 does not exceed the value shown in Column 3 of Table 2.

- E. Classification of wastes with radionuclides other than those listed in Tables 1 and 2. If radioactive waste does not contain any nuclides listed in either Table 1 or 2, it is Class A.
 - F. The sum of the fractions rule for mixtures of radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each nuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 50 Ci/m³ and Cs-137 in a concentration of 22 Ci/m³. Since the concentrations both exceed the values in Column 1, Table 2, they must be compared to Column 2 values. For Sr-90 fraction $50/150 = 0.33$; for Cs-137 fraction, $22/44 = 0.5$; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.
 - G. Determination of concentrations in wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste or weight of the waste if the units are expressed as nanocuries per gram.
7. Waste characteristics.
- A. The following requirements are minimum requirements for all classes of waste and are intended to facilitate handling at the disposal site and provide protection of health and safety of personnel at the disposal site.

- i. Waste must not be packaged for disposal in cardboard or fiberboard boxes.
 - ii. Liquid waste must be solidified or packaged in sufficient absorbent material to absorb twice the volume of the liquid.
 - iii. Solid waste containing liquid shall contain as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume.
 - iv. Waste must not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.
 - v. Waste must not contain or be capable of generating, quantities of toxic gases, vapors or fumes harmful to persons transporting, handling or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with RH-407.d.6.G.
 - vi. Waste must not be pyrophoric. Pyrophoric materials contained in waste shall be treated, prepared and packaged to be nonflammable.
 - vii. Waste in a gaseous form must be packaged at a pressure that does not exceed 1.5 atmospheres at 20° C. Total activity must not exceed 100 curies per container.
 - viii. Waste containing hazardous, biological, pathogenic or infectious material must be treated to reduce to the maximum extent practicable the potential hazard from the non-radiological materials.
- B. The requirements in this Section are intended to provide stability of the waste. Stability is intended to ensure that the waste does not structurally degrade and affect overall stability of the site through slumping, collapse or

other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

- i. Waste must have a structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form or placing the waste in a disposal container or structure that provides stability after disposal.
 - ii. Notwithstanding the provisions in RH-407.d.7.A.ii and iii, liquid wastes or wastes containing liquid, must be converted into a form that contains as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5% of the volume of the waste for waste processed to a stable form.
 - iii. Void spaces within the waste and between the waste and its package must be reduced to the extent practicable.
8. Each package must be clearly labeled to identify whether it is Class A waste, Class B waste or Class C waste in accordance with RH-407.d.6.
 9. The Department may, upon request or on its own initiative, authorize other provisions for the classification and characteristics of waste on a specific basis, if, after evaluation of the specific characteristics of the waste, disposal

site, and method of disposal, it finds reasonable assurance of compliance with the performance objectives in Subpart c of this Paragraph.

10. Institutional requirements.

A. Land ownership. Disposal of radioactive waste received from other persons may be permitted only on land owned in fee by the Federal or a State government.

B. Institutional control. The land owner or custodial agency shall carry out an institutional control program to physically control access to the disposal site following transfer of control of the disposal site from the disposal site operator. The institutional control program must also include, but not be limited to, carrying out an environmental monitoring program at the disposal site, periodic surveillance, minor custodial care and other requirements as determined by the Department, and administration of funds to cover the costs for these activities. The period of institutional controls will be determined by the Department, but institutional controls may not be relied upon for more than 100 years following transfer of control of the disposal site to the owner.

e. Funding for Disposal Site Closure and Stabilization.

1. The applicant shall provide assurance that sufficient funds will be available to carry out disposal site closure and stabilization, including decontamination or dismantlement of land disposal facility structures; and closure and stabilization of the disposal site so that following transfer of the disposal site to the site owner, the need for ongoing active maintenance is eliminated to the extent practicable and only minor custodial care, surveillance and monitoring are required. These assurances shall be based on Department-approved cost estimates reflecting the Department-approved plan for disposal site closure and stabilization. The applicant's cost estimates must take into account total capital costs that would be incurred if an independent contractor were hired to perform the closure and stabilization work.

2. In order to avoid unnecessary duplication and expense, the Department will accept financial sureties that have been consolidated with earmarked financial or surety arrangements established to meet requirements of other Federal or State agencies and/or local governing bodies for such decontamination, closure and stabilization. The Department will accept this arrangement only if they are considered adequate to satisfy these requirements and that the portion of the surety which covers the closure of the disposal site is clearly identified and committed for use in accomplishing these activities.
3. The licensee's surety mechanism will be annually reviewed by the Department to assure that sufficient funds are available for completion of the closure plan, assuming that the work has to be performed by an independent contractor.
4. The amount of surety liability should change in accordance with the predicted cost of future closure and stabilization. Factors affecting closure and stabilization cost estimates include inflation; increases in the amount of disturbed land; changes in engineering plans; closure and stabilization that has already been accomplished and any other conditions affecting costs. This will yield a surety that is at least sufficient at all times to cover the costs of closure of the disposal units that are expected to be used before the next license renewal.
5. The term of the surety mechanism must be open-ended unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. This assurance could be provided with a surety mechanism which is written for a specified period of time (e.g., five years) yet which must be automatically renewed unless the party who issues the surety notifies the Department and the beneficiary (the licensee) not less than 90 days prior to the renewal date of its intention not to renew. In such a situation the licensee must submit a replacement surety within thirty (30) days after notification of cancellation. If the licensee fails to provide a replacement surety acceptable to the Department, the site owner may collect on the original surety.

6. Proof of forfeiture must not be necessary to collect the surety so that in the event that the licensee could not provide an acceptable replacement surety within the required time, the surety shall be automatically collected prior to its expiration. The conditions described above would have to be clearly stated on any surety instrument which is not open-ended and must be agreed to by all parties. Liability under the surety mechanism must remain in effect until the closure and stabilization program has been completed and approved by the Department and the license has been transferred to the site owner.
7. Financial surety arrangements generally acceptable to the Department include surety bonds, cash deposits, certificates of deposits, deposits of government securities, escrow accounts, irrevocable letters or lines of credit, trust funds and combinations of the above or such other types of arrangements as may be approved by the Department. However, self-insurance or any arrangement which essentially constitutes pledging the assets of the licensee, will not satisfy the surety requirement for private sector applicants since this provides no additional assurance other than that which already exists through license requirements.

RH-408. Issuance of Specific Licenses.

- a. Upon a determination that an application meets the requirements of the Act and these Regulations 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 and necessary to effectuate the purposes of the Act.
- b. The Department may incorporate in any license at the time of issuance or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of licensed material as it deems appropriate or necessary in order to:
 1. Protect health or to minimize danger to life or property;

2. Require such reports and the keeping of such records and to provide for such inspection of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and these Regulations thereunder; and
3. Prevent loss or theft of licensed material.

RH-409. Specific Terms and Conditions of Licenses.

- a. Each license issued pursuant to these Regulations 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.
- b. No license issued or granted under this Part and no right to possess or utilize radioactive material granted by any license issued pursuant to this Part 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.
- c. Each person licensed by the Department pursuant to these Regulations shall confine their use and possession of the material licensed to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to these Regulations in Section 2, shall carry with it the right to receive, acquire, own and possess radioactive material. Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of Section 4 of these Regulations.
- d. The Department may incorporate, in any license issued pursuant to Section 2 of these Regulations, at the time of issuance or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of radioactive material as it deems appropriate or necessary in order to:
 1. Protect health or to minimize danger to life 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 necessary or appropriate to effectuate the purposes of the Act and these Regulations thereunder.
- e. Each licensee shall notify the Department in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license. This notification requirement applies to all specific licenses issued under Section 2 of these Regulations.
- f. Licensees required to submit emergency plans by RH-403.g shall follow the emergency plan approved by the Department. Proposed changes to the plan may not be implemented without prior application to and prior approval by the Department.
- g. Bankruptcy notification
 1. Each licensee shall notify the Department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title II (Bankruptcy) of the United States Code by or against:
 - A. the licensee;
 - B. an entity (as that term is defined in 11 U.S.C. 101 (14)) controlling the licensee or listing the licensee or licensee as property of the estate; or
 - C. an affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.
 2. This notification must indicate:
 - A. the bankruptcy court in which the petition for bankruptcy was filed; and,
 - B. the date of the filing of the petition.
- h. Financial assurance and record keeping for decommissioning
 1. Each applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in

quantities exceeding 10^5 times the applicable quantities set forth in RH-2300, Appendix B, shall submit a decommissioning funding plan as described in RH-409.h.5 of this section. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix B.

2. Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and in quantities specified in RH-409.h.4 of this section shall either:
 - A. Submit a decommissioning funding plan as described in RH-409.h.5 of this section; or
 - B. Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by RH-409.h.4 of this section using one of the methods described in RH-409.h.6 of this section. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of RH-409.h.6 of this section is to be submitted to the Department.
3.
 - A. Each holder of a specific license issued on or after July 27, 1993, which is of a type described in RH-409.h.1 of this section, shall provide financial assurance for decommissioning in accordance with the criteria set forth in this section.
 - B. Each holder of a specific license issued before July 27, 1993, and of a type described in RH-409.h.3 of this section shall submit, on or before July 27, 1993, a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount at least equal to \$750,000 in accordance with the

criteria set forth in this section. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

C. Each holder of a specific license issued before July 27, 1993, and of a type described in RH-409.h.2 of this section shall submit, on or before July 27, 1993, a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in this section.

4. Table of required amounts of financial assurance for decommissioning by quantity of material.

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of Appendix B of RH-2300 in unsealed form. (For a combination of isotopes, if R, as defined in RH-409.h.1 divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.). \$750,000

Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of Appendix B of RH-2300 in unsealed form. (For a combination of isotopes, if R, as defined in RH-409.h.1. divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.). \$150,000

Greater than 10^{10} times the applicable quantities of Appendix B of RH-2300 in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in RH-409.h.1., divided by 10^{10} is greater than 1.). \$ 75,000

5. Each decommissioning funding plan must contain a cost estimate for decommissioning and a description of the method of assuring funds for decommissioning from RH-409.h.6, including means of adjusting cost estimates as associated funding levels periodically over the life of the facility.
6. Financial assurance for decommissioning must be provided by one or more of the following methods:
 - A. Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.
 - B. A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix A of this Part. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this Section. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are contained in Appendix B of this Part. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this Section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method of insurance used to provide financial assurance for decommissioning must contain the following conditions:

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- i. The surety method or insurance must be open-ended or, if written for a specified term, such as five (5) years, must be renewed automatically unless 90 (ninety) days or more prior to the renewal date, the issuer notifies the Department, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Department within 30 (thirty) days after receipt of notification of cancellation.
 - ii. The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Department. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.
 - iii. The surety method or insurance must remain in effect until the Department has terminated the license.
- C. An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of

government securities. The surety or insurance provisions must be as stated in RH-409.h.6.B.

- D. In the case of State or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in RH-409.h.4 of this Section, and indicating that funds for decommissioning will be obtained when necessary.
7. Facilities or individuals licensed under Section 2 shall keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the Department. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the Department considers important to decommissioning consists of:
- A. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.
 - B. As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

- C. Except for areas containing only sealed sources (provided the sources have not leaked and no contamination remains after any leak) or radioactive materials having only half-lives of less than 65 (sixty-five) days, a list contained in a single document and updated every two (2) years, consisting of the following:
- i. All areas designed and formerly designated restricted areas as defined in RH-1100;
 - ii. All areas outside of restricted areas that require documentation under RH-409.h.7.A;
 - iii. All areas outside of restricted areas where current and previous wastes have been buried as documented under RH-1500.g; and
 - iv. All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to unrestricted release levels or apply for approval for disposal under RH-1401.
- D. Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning and records of the funding method used for assuring funds if either a funding plan or certification is used.

RH-410. Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas.

- a. Except as provided in Part D, RH-411.b, each specific license shall expire at the end of the day, in the month and year stated therein.

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- b. Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the Department notifies the licensee in writing that the license is terminated. During this time, the licensee shall:
1. Limit actions involving radioactive material to those related to decommissioning; and
 2. Continue to control entry to restricted areas until they are suitable for release in accordance with Department requirements.
- c. Within 60 (sixty) days of the occurrence of any of the following, each licensee shall provide notification to the Department in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Department requirements, or submit within 12 (twelve) months of notification a decommissioning plan, and begin decommissioning upon approval of that plan if:
1. The license has expired pursuant to RH-410,a; or
 2. The licensee has decided to permanently cease principal activities, as defined in this Part, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Department requirements; or
 3. No principal activities under the license have been conducted for a period of 24 (twenty-four) months; or
 4. No principal activities have been conducted for a period of 24 (twenty-four) months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Department requirements.

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RH-411. Renewal of Licenses.

- a. Application for renewal of specific licenses shall be filed in accordance with Part D, RH-403.
- b. In any case in which a licensee, not less than 30 days prior to expiration of this 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 the application has been finally approved or disapproved by the Department.

RH-412. Amendment of License at Request of Licensee. Applications for amendment of a license shall be filed in accordance with Part D, RH-403 and shall specify the respects in which the licensee desires his license to be amended and the grounds for such amendment.

RH-413. Department Action on Application to Renew or Amend. In considering an application by a licensee to renew or amend his license, the Department will apply the criteria set forth in Part D, RH-404 and Part D, RH-405, as applicable.

RH-414. Inalienability of Licenses. No license issued or granted under these Regulations and no right to possess or utilize radioactive material granted by any license issued pursuant to these Regulations 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.

RH-415. Reserved.

RH-416. Modification, Revocation and Termination 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 of these Regulations or because of conditions revealed by such application or statement 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 the license or of any rule, regulation or order of the Department.
- c. Except in cases of willful violation 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 therefor, 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 opportunity to demonstrate or achieve compliance with all lawful requirements.
- d. The Department may terminate a specific license upon request submitted by the licensee to the Department in writing.

PART E. TRANSFER OF MATERIAL

RH-500. Authorization for Transfer. No licensee shall transfer radioactive material except as authorized pursuant to this Part.

RH-501. Condition of Transfer. Any licensee may transfer radioactive material subject to acceptance by the transferee, to:

- a. The Department;
- b. The U.S. Department of Energy, the U.S. Nuclear Regulatory Commission or any successor thereto;
- c. Any person exempt from these Regulations to the extent permitted under such exemption;
- d. Any person licensed to receive such material under terms of a general license or its equivalent or specific license or equivalent licensing document issued by the Department, the U.S. Nuclear Regulatory Commission or any Agreement State or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Department or any other state having an agreement with the U.S. Nuclear Regulatory Commission, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended; or
- e. Any other person authorized by the Department in writing.
- f. Before transferring radioactive material to a specific licensee of the Department, the Nuclear Regulatory Commission (NRC) or an Agreement State, or to a general licensee who is required to register with the NRC or an Agreement State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form and quantity of radioactive material to be transferred.
- g. The following methods for the verification required by RH-501.f are acceptable:
 1. The transferor may have in his possession and read, a current copy of the transferee's specific license or registration certificate.
 2. The transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date;

3. For emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date; provided, that the oral certification is confirmed in writing within ten (10) days;
4. The transferor may obtain other sources of information compiled by a reporting service from official records of the Department, the NRC or the licensing agency of an Agreement State as to the identity of licensees and the scope and expiration dates of licenses and registration; or
5. When none of the methods of verification in RH-501.g.1 to 4 are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Department, the NRC or the licensing agency of an Agreement State that the transferee is licensed to receive the radioactive material.

RH-502. Preparation of Material. Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of RH-3200 of these Regulations.

PART F. RECORDS, REPORTS AND INSPECTIONS

RH-600. Records. Each person who receives a source of radiation pursuant to a license under this Section shall keep records showing the receipt, transfer and disposal of such sources of radiation.

RH-601. Inspections.

- a. Each licensee shall afford, at all reasonable times, to the Department opportunity to inspect radioactive materials and the installation wherein such radioactive materials are used 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.

RH-602. Tests. Upon instruction from the Department, each licensee shall perform or cause to have performed and shall permit the Department to perform, such reasonable tests as the Department deems appropriate or necessary, including, but not limited to, tests of:

- a. Sources of radiation;
- b. Facilities wherein radioactive materials are used or stored;
- c. Radiation detection and monitoring instruments; and
- d. Other equipment and devices used in connection with utilization or storage of licensed material.

PART G. ENFORCEMENT

- RH-700. a. Violations. Any person who violates any of the provisions of the Act or rules, regulations or orders in effect pursuant thereto, of the Department shall, upon conviction thereof, be punished by a fine of not less than one hundred dollars (\$100.00) nor more than two thousand dollars (\$2,000.00) or by imprisonment for not more than six (6) months or be both fined and imprisoned.
- b. Impounding. Sources of radiation shall be subject to impounding pursuant to Section 5 of these Regulations.

PART H. RECIPROCITY

RH-750. Reciprocal Recognition of Licenses.

- a. Subject to the provisions of these Regulations, any person who possesses a specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or any Agreement State, other than this state, may conduct the activities authorized in such licensing document within this state for a period not in excess of one hundred eighty (180) days in any period of twelve (12) consecutive months without obtaining a specific license from the Department, provided that:
1. The licensing document does not limit the activity authorized by such document to specified installations or locations; and
 2. The out-of-state licensee notifies the Department in writing at least two (2) days prior to engaging in such activity. Such notification shall indicate the exact location, period and type of proposed possession and use within this state and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the two day period would impose an undue hardship on the out-of-state licensee, he may, upon application to the Department, obtain permission to proceed sooner; and
 3. The out-of-state licensee complies with all applicable regulations of the Department and with all the terms and conditions of his licensing document, except any such terms and conditions which may be inconsistent with applicable regulations of the Department; and
 4. Provided further that the Department may require the out-of-state licensee to supply such other information as the Department may reasonably request.
- b. To the extent provided in RH-300, RH-301 and RH-402, any person may transfer, receive, acquire, own, possess and use any equipment, device, commodity or other product containing radioactive material which has been manufactured, processed or produced in accordance with a specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or any Agreement State.

RH-750 (Cont'd)

c. Notwithstanding the provisions of Paragraph a of this Section RH-750, any person who holds a specific license or equivalent licensing document issued by the U.S. Nuclear Regulatory Commission or an Agreement State authorizing the holder to manufacture, install or service a device described in RH-402.b.1 within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install and service such device in this state provided that:

1. Such person shall file a report with the Department within thirty (30) days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general licensee by names and address, the type of device transferred and the quantity and type of radioactive material contained in the device;
2. The device has been manufactured, labeled, installed and serviced in accordance with applicable provisions of the specific license or equivalent licensing document issued to such person by the U.S. Nuclear Regulatory Commission or an Agreement State;
3. Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited"; and
4. The holder of the specific license or equivalent licensing document shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in RH-402.b.

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

RH-751. Additional Requirements. The Department may, by rule, regulation or order, impose upon any licensee such requirements in addition to those established in these Regulations as it deems appropriate or necessary to minimize danger to public health and safety or property.

PART I. SCHEDULES

RH-900. Schedule A.

Generally Licensed Equipment, When Manufactured in Accordance With Specific License.

The following devices and equipment incorporating radioactive material, when manufactured, tested and labeled by the manufacturer in accordance with the specifications contained in a specific license or equivalent licensing document issued by the Department, the U.S. Nuclear Regulatory Commission or any Agreement State, are placed under a general license pursuant to Section 2, Part D, RH-402.a.

- a. Static Elimination Device. Devices designed for use as static eliminators which contain, as a sealed source or sources radioactive material consisting of a total of not more than 500 microcuries of Polonium-210 per device.
- b. Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of Polonium 210 per device or of a total of not more than 50 millicuries of Hydrogen-3 (Tritium) per device.

RH-901. Schedule B. Exempt Quantities.

Radioactive Material	Micro-curies	Radioactive Material	Micro-curies
Antimony-122 (Sb 122)	100	Gallium-67 (Ga 67)	100
Antimony-124 (Sb 124)	10	Gallium-72 (Ga 72)	10
Antimony-125 (Sb 125)	10	Germanium-68 (Ge 68)	10
Arsenic-73 (As 73)	100	Germanium-71 (Ge 71)	100
Arsenic-74 (As 74)	10	Gold-195 (Au 195)	10
Arsenic-76 (As 76)	10	Gold-198 (Au 198)	100
Arsenic-77 (As 77)	100	Gold-199 (Au 199)	100
Barium-131 (Ba 131)	10	Hafnium-181 (Hf 181)	10
Barium-133 (Ba 133)	10	Holmium-166 (Ho 166)	100
Barium-140 (Ba 140)	10	Hydrogen-3 (H 3)	1,000
Bismuth-210 (Bi 210)	1	Indium-111 (In 111)	100
Bromine-82 (Br 82)	10	Indium-113m (In 113m)	100
Cadmium-109 (Cd 109)	10	Indium-114m (In 114m)	10
Cadmium-115m (Cd 115)	10	Indium-115m (In 115m)	100
Cadmium-115 (Cd 115)	100	Indium-115 (In 115)	10
Calcium-45 (Ca 45)	10	Iodine-123 (I 123)	100
Calcium-47 (Ca 47)	10	Iodine-125 (I 125)	1
Carbon-14 (C 14)	100	Iodine-126 (I 126)	1
Cerium-141 (Ce 141)	100	Iodine-129 (I 129)	0.1
Cerium-143 (Ce 143)	100	Iodine-131 (I 131)	1
Cerium-144 (Ce 144)	1	Iodine-132 (I 132)	10
Cesium-129 (Cs 129)	100	Iodine-133 (I-133)	1
Cesium-131 (Cs 131)	1,000	Iodine-134 (I-134)	10
Cesium-134m (Cs 134m)	100	Iodine-135 (I-135)	10
Cesium-134 (Cs 134)	1	Iridium-192 (Ir 192)	10
Cesium-135 (Cs 135)	10	Iridium-194 (Ir 194)	10
Cesium-136 (Cs 136)	10	Iron-52 (Fe 52)	10
Cesium-137 (Cs 137)	10	Iron-55 (Fe 55)	100
Chlorine-36 (Cl 36)	10	Iron-59 (Fe 59)	10
Chlorine-38 (Cl 38)	10	Krypton-85 (Kr 85)	100
Chromium-51 (Cr 51)	1,000	Krypton-87 (Kr 87)	10
Cobalt-57 (Co 57)	100	Lanthanum-140 (La 140)	10
Cobalt-58m (Co 58m)	10	Lutetium-177 (Lu 177)	100
Cobalt-58 (Co 58)	10	Manganese-52 (Mn 52)	10
Cobalt-60 (Co 60)	1	Manganese-54 (Mn 54)	10
Copper-64 (Cu 64)	100	Manganese-56 (Mn 56)	10
Dysprosium-165 (Dy 165)	10	Mercury-197m (Hg 197m)	100
Dysprosium-166 (Dy 166)	100	Mercury-197 (Hg 197)	100
Erbium-169 (Er 169)	100	Mercury-203 (Hg 203)	10
Erbium-171 (Er 171)	100	Molybdenum-99 (Mo 99)	100
Europium-152 (Eu 152) 9.2 h	100	Neodymium-147 (Nd 147)	100
Europium-152 (Eu 152) 13 yr	1	Neodymium-149 (Nd 149)	100
Europium-154 (Eu 154)	1	Nickel-59 (Ni 59)	100
Europium-155 (Eu 155)	10	Nickel-63 (Ni 63)	10
Fluorine-18 (F 18)	1,000	Nickel-65 (Ni 65)	100
Gadolinium-153 (Gd 153)	10	Niobium-93m (Nb 93m)	10
Gadolinium-159 (Gd 159)	100	Niobium-95 (Nb 95)	10

RH-901. Schedule B. Exempt Quantities. (Continued)

Radioactive Material	Micro-curies	Radioactive Material	Micro-curies
Niobium-97 (Nb 97)	10	Strontium-91 (Sr 91)	10
Osmium-185 (Os 185)	100	Strontium-92 (Sr 92)	10
Osmium-191m (Os 191m)	100	Sulphur-35 (S 35)	100
Osmium-191 (Os 191)	10	Tantalum-182 (Ta 182)	10
Osmium-193 (Os 193)	100	Technetium-96 (Tc 96)	10
Palladium-103 (Pd 103)	100	Technetium-97m (Tc 97m)	100
Palladium-109 (Pd 109)	100	Technetium-97 (Tc 97)	100
Phosphorus-32 (P 32)	10	Technetium-99m (Tc 99m)	100
Platinum-191 (Pt 191)	100	Technetium-99 (Tc 99)	10
Platinum-193m (Pt 193m)	100	Tellurium-125m (Te 125m)	10
Platinum-193 (Pt 193)	100	Tellurium-127m (Te 127m)	10
Platinum-197m (Pt 197m)	100	Tellurium-127 (Te 127)	100
Platinum-197 (Pt 197)	100	Tellurium-129m (Te 129m)	10
Polonium-210 (Po 210)	0.1	Tellurium-129 (Te 129)	100
Potassium-42 (K 42)	10	Tellurium-131m (Te 131m)	10
Potassium-43 (K 43)	10	Tellurium-132 (Te 132)	10
Praseodymium-142 (Pr 142)	100	Terbium-160 (Tb 160)	10
Praseodymium-143 (Pr 143)	100	Thallium-200 (Tl 200)	100
Promethium-147 (Pm 147)	10	Thallium-201 (Tl 201)	100
Promethium-149 (Pm 149)	10	Thallium-202 (Tl 202)	100
Rhenium-186 (Re 186)	100	Thallium-204 (Tl 204)	10
Rhenium-188 (Re 188)	100	Thulium-170 (Tm 170)	10
Rhodium-103m (Rh 103m)	100	Thulium-171 (Tm 171)	10
Rhodium-105 (Rh 105)	100	Tin-113 (Sn 113)	10
Rubidium-81 (Rb 81)	10	Tin-125 (Sn 125)	10
Rubidium-86 (Rb 86)	10	Tungsten-181 (W 181)	10
Rubidium-87 (Rb 87)	10	Tungsten-185 (W 185)	10
Ruthenium-97 (Ru 97)	100	Tungsten-187 (W 187)	100
Ruthenium-103 (Ru 103)	10	Vanadium-48 (V 48)	10
Ruthenium-105 (Ru 105)	10	Xenon-131m (Xe 131m)	1,000
Ruthenium-106 (Ru 106)	1	Xenon-133 (Xe 133)	100
Samarium-151 (Sm 151)	10	Xenon-135 (Xe 135)	100
Samarium-153 (Sm 153)	100	Ytterbium-175 (Yb 175)	100
Scandium-46 (Sc 46)	10	Yttrium-87 (Y 87)	10
Scandium-47 (Sc 47)	100	Yttrium-88 (Y 88)	10
Scandium-48 (Sc 48)	10	Yttrium-90 (Y 90)	10
Selenium-75 (Se 75)	10	Yttrium-91 (Y 91)	10
Silicon-31 (Si 31)	100	Yttrium-92 (Y 92)	100
Silver-105 (Ag 105)	10	Yttrium-93 (Y 93)	100
Silver-110m (Ag 110m)	1	Zinc-65 (Zn 65)	10
Silver-111 (Ag 111)	100	Zinc-69m (Zn 69m)	100
Sodium-22 (Na 22)	10	Zinc-69 (Zn 69)	1,000
Sodium-24 (Na 24)	10	Zirconium-93 (Zr 93)	10
Strontium-85 (Sr 85)	10	Zirconium-95 (Zr 95)	10
Strontium-89 (Sr 89)	1	Zirconium-97 (Zr 97)	10
Strontium-90 (Sr 90)	0.1		

RH-901. Schedule B. Exempt Quantities. (Continued)

Radioactive Material	Micro-curies	Radioactive Material	Micro-curies
		Alpha emitting radioactive material not listed above	0.01
		Any radioactive material listed above other than alpha emitting radioactive material	0.1

Note 1: For purposes of RH-305.a, where there is involved a combination of isotopes, the limit for the combination should be derived as follows:

Determine the amount of each isotope possessed and 1,000 times the amount in Schedule B for each of those isotopes when not in combination. The sum of the ratios of those quantities may not exceed 1.
Example.

$$\frac{\text{Amt. of Isotope A possessed}}{1000 \times \text{Schedule B quantity for Isotope A}} + \frac{\text{Amt. of Isotope B possessed}}{1000 \times \text{Schedule B quantity for Isotope B}} < 1$$

RH-902. Schedule C. Exempt Concentrations.

Element (atomic number)	Isotope	Column I Gas concentration Ci/ml ^{12/}	Column II Liquid and solid concentration Ci/ml ^{13/}
Antimony (51) -----	Sb 122	-----	3 X 10 ⁻⁴
	Sb 124	-----	2 X 10 ⁻⁴
	Sb 125	-----	1 X 10 ⁻³
Argon (18) -----	A 37	1 X 10 ⁻³	-----
	A 41	4 X 10 ⁻⁷	-----
Arsenic (33) -----	As 73	-----	5 X 10 ⁻³
	As 74	-----	5 X 10 ⁻⁴
	As 76	-----	2 X 10 ⁻⁴
	As 77	-----	8 X 10 ⁻⁴
Barium (56) -----	Ba 131	-----	2 X 10 ⁻³
	Ba 140	-----	3 X 10 ⁻⁴
Beryllium (4) -----	Be 7	-----	2 X 10 ⁻²
Bismuth (83) -----	Bi 206	-----	4 X 10 ⁻⁴
Bromine (35) -----	Br 82	4 X 10 ⁻⁷	3 X 10 ⁻³
Cadmium (48) -----	Cd 109	-----	2 X 10 ⁻³
	Cd 115m	-----	3 X 10 ⁻⁴
	Cd 115	-----	3 X 10 ⁻⁴
Calcium (20) -----	Ca 45	-----	9 X 10 ⁻⁵
	Ca 47	-----	5 X 10 ⁻⁴
Carbon (6) -----	C 14	1 X 10 ⁻⁶	8 X 10 ⁻³
Cerium (58) -----	Ce 141	-----	9 X 10 ⁻⁴
	Ce 143	-----	4 X 10 ⁻⁴
	Ce 144	-----	1 X 10 ⁻⁴
Cesium (55) -----	Cs 131	-----	2 X 10 ⁻²
	Cs 134m	-----	6 X 10 ⁻²
	Cs 134	-----	9 X 10 ⁻⁵
Chlorine (17) -----	Cl 38	9 X 10 ⁻⁷	4 X 10 ⁻³
Chromium (24) -----	Cr 51	-----	2 X 10 ⁻²
Cobalt (27) -----	Co 57	-----	5 X 10 ⁻³
	Co 58	-----	1 X 10 ⁻³
	Co 60	-----	5 X 10 ⁻⁴
Copper (29) -----	Cu 64	-----	3 X 10 ⁻³
Dysprosium (66) -----	Dy 165	-----	4 X 10 ⁻³
	Dy 166	-----	4 X 10 ⁻⁴
Erbium (68) -----	Er 169	-----	9 X 10 ⁻⁴
	Er 171	-----	1 X 10 ⁻³
Europium (63) -----	Eu 152	-----	6 X 10 ⁻⁴
	(T/2=9.2 hrs) Eu 155	-----	-----
Fluorine (9) -----	F 18	2 X 10 ⁻⁶	2 X 10 ⁻³
	Gadolinium (64) -----	Gd 153	8 X 10 ⁻³
Gallium (31) -----	Gd 159	-----	2 X 10 ⁻³
	Ge 72	-----	8 X 10 ⁻⁴
Germanium (32) -----	Ge 71	-----	4 X 10 ⁻⁴
			2 X 10 ⁻²

RH-902. Schedule C. Exempt Concentrations. (Continued)

Element (atomic number)	Isotope	Column I Gas concentration Ci/ml ^{12/}	Column II Liquid and solid concentration Ci/ml ^{13/}
Gold (79) -----	Au 196	-----	2 X 10 ⁻³
	Au 198	-----	5 X 10 ⁻⁴
	Au 199	-----	2 X 10 ⁻³
Hafnium (72) -----	Hf 181	-----	7 X 10 ⁻⁴
Hydrogen (1) -----	H 3	5 X 10 ⁻⁶	3 X 10 ⁻²
Indium (49) -----	In 113m	-----	1 X 10 ⁻²
	In 114m	-----	2 X 10 ⁻⁴
Iodine (53) -----	I 126	3 X 10 ⁻⁹	2 X 10 ⁻⁵
	I 131	3 X 10 ⁻⁹	2 X 10 ⁻⁵
	I 132	8 X 10 ⁻⁸	6 X 10 ⁻⁴
	I 133	1 X 10 ⁻⁸	7 X 10 ⁻⁵
	I 134	2 X 10 ⁻⁷	1 X 10 ⁻³
Iridium (77) -----	Ir 190	-----	2 X 10 ⁻³
	Ir 192	-----	4 X 10 ⁻⁴
	Ir 194	-----	3 X 10 ⁻⁴
Iron (26) -----	Fe 55	-----	8 X 10 ⁻³
	Fe 59	-----	6 X 10 ⁻⁴
Krypton (36) -----	Kr 85m	1 X 10 ⁻⁶	-----
	Kr 85	3 X 10 ⁻⁶	-----
Lanthanum (57) -----	La 140	-----	2 X 10 ⁻⁴
Lead (82) -----	Pb 203	-----	4 X 10 ⁻³
Lutetium (71) -----	Lu 177	-----	1 X 10 ⁻³
Manganese (25) -----	Mn 52	-----	3 X 10 ⁻⁴
	Mn 54	-----	1 X 10 ⁻³
	Mn 56	-----	1 X 10 ⁻³
Mercury (80) -----	Hg 197m	-----	2 X 10 ⁻³
	Hg 197	-----	3 X 10 ⁻³
	Hg 203	-----	2 X 10 ⁻⁴
Molybdenum (42) -----	Mo 99	-----	2 X 10 ⁻³
Neodymium (60) -----	Nd 147	-----	6 X 10 ⁻⁴
	Nd 149	-----	3 X 10 ⁻³
Nickel (28) -----	Ni 65	-----	1 X 10 ⁻³
Niobium (Columbium) (41)	Nb 95	-----	1 X 10 ⁻³
	Nb 97	-----	9 X 10 ⁻³
Osmium (76) -----	Os 185	-----	7 X 10 ⁻⁴
	Os 191m	-----	3 X 10 ⁻²
	Os 191	-----	2 X 10 ⁻³
	Os 193	-----	6 X 10 ⁻⁴
Palladium (46) -----	Pd 103	-----	3 X 10 ⁻³
	Pd 109	-----	9 X 10 ⁻⁴
Phosphorus (15) -----	P 32	-----	2 X 10 ⁻⁴
Platinum (78) -----	Pt 191	-----	1 X 10 ⁻³
	Pt 193m	-----	1 X 10 ⁻²
	Pt 197m	-----	1 X 10 ⁻²
	Pt 197	-----	1 X 10 ⁻³
Polonium (84) -----	Po 210	-----	7 X 10 ⁻⁶

RH-902. Schedule C. Exempt Concentrations. (Continued)

Element (atomic number)	Isotope	Column I Gas concentration Ci/ml ^{12/}	Column II Liquid and solid concentration Ci/ml ^{13/}
Potassium (19) -----	K 42	-----	3 X 10 ⁻³
Praseodymium (50) -----	Pr 142	-----	3 X 10 ⁻⁴
	Pr 143	-----	5 X 10 ⁻⁴
Promethium (61) -----	Pm 147	-----	2 X 10 ⁻³
	Pm 149	-----	4 X 10 ⁻⁴
Radium (88) -----	Ra 226	-----	1 X 10 ⁻⁷
	Ra 228	-----	3 X 10 ⁻⁷
Rhenium (75) -----	Re 183	-----	6 X 10 ⁻³
	Re 186	-----	9 X 10 ⁻⁴
	Re 188	-----	6 X 10 ⁻⁴
Rhodium (45) -----	Rh 103m	-----	1 X 10 ⁻¹
	Rh 105	-----	1 X 10 ⁻³
Rubidium (37) -----	Rb 86	-----	7 X 10 ⁻⁴
Ruthenium (44) -----	Ru 97	-----	4 X 10 ⁻³
	Ru 103	-----	8 X 10 ⁻⁴
	Ru 105	-----	1 X 10 ⁻³
	Ru 106	-----	1 X 10 ⁻⁴
Samarium (62) -----	Sm 153	-----	8 X 10 ⁻⁴
Scandium (21) -----	Sc 46	-----	4 X 10 ⁻⁴
	Sc 47	-----	9 X 10 ⁻⁴
	Sc 48	-----	3 X 10 ⁻⁴
Selenium (34) -----	Se 75	-----	3 X 10 ⁻³
Silicon (14) -----	Si 31	-----	9 X 10 ⁻³
Silver (47) -----	Ag 105	-----	1 X 10 ⁻³
	Ag 110m	-----	3 X 10 ⁻⁴
	Ag 111	-----	4 X 10 ⁻⁴
Sodium (11) -----	Na 24	-----	2 X 10 ⁻³
Strontium (38) -----	Sr 85	-----	1 X 10 ⁻³
	Sr 89	-----	1 X 10 ⁻⁴
	Sr 91	-----	7 X 10 ⁻⁴
	Sr 92	-----	7 X 10 ⁻⁴
Sulfur (16) -----	S 35	9 X 10 ⁻⁸	6 X 10 ⁻⁴
Tantalum (73) -----	Ta 182	-----	4 X 10 ⁻⁴
Technetium (43) -----	Tc 96m	-----	1 X 10 ⁻¹
	Tc 96	-----	1 X 10 ⁻³
Tellurium (52) -----	Te 125m	-----	2 X 10 ⁻³
	Te 127m	-----	6 X 10 ⁻⁴
	Te 127	-----	3 X 10 ⁻³
	Te 129m	-----	3 X 10 ⁻⁴
	Te 131m	-----	6 X 10 ⁻⁴
	Te 132	-----	3 X 10 ⁻⁴
Terbium (65) -----	Tb 160	-----	4 X 10 ⁻⁴
Thallium (81) -----	Tl 200	-----	4 X 10 ⁻³
	Tl 201	-----	3 X 10 ⁻³
	Tl 202	-----	1 X 10 ⁻³
	Tl 204	-----	1 X 10 ⁻³

RH-902. Schedule C. Exempt Concentrations. (Continued)

Element (atomic number)	Isotope	Column I Gas concentration Ci/ml ^{12/}	Column II Liquid and solid concentration Ci/ml ^{13/}
Thulium (69) -----	Tm 170	-----	5 X 10 ⁻⁴
	Tm 171	-----	5 X 10 ⁻³
Tin (50) -----	Sn 113	-----	9 X 10 ⁻⁴
	Sn 125	-----	2 X 10 ⁻⁴
Tungsten (Wolfram)(74)--	W 181	-----	4 X 10 ⁻³
	W 187	-----	7 X 10 ⁻⁴
Vanadium (23) -----	V 48	-----	3 X 10 ⁻⁴
Xenon (54) -----	Xe 131m	4 X 10 ⁻⁶	-----
	Xe 133	3 X 10 ⁻⁶	-----
	Xe 135	1 X 10 ⁻⁶	-----
Ytterbium (80) -----	Yb 175	-----	1 X 10 ⁻³
Yttrium (30) -----	Y 90	-----	2 X 10 ⁻⁴
	Y 91m	-----	3 X 10 ⁻²
	Y 91	-----	3 X 10 ⁻⁴
	Y 92	-----	6 X 10 ⁻⁴
	Y 83	-----	3 X 10 ⁻⁴
Zinc (30) -----	Zn 65	-----	1 X 10 ⁻³
	Zn 69m	-----	7 X 10 ⁻⁴
	Zn 69	-----	2 X 10 ⁻²
Zirconium (40) -----	Zr 95	-----	6 X 10 ⁻⁴
	Zr 97	-----	2 X 10 ⁻⁴
Beta and/or gamma emitting radioactive material not listed above with half- life less than 3 years		-----	1 X 10 ⁻⁶

NOTE 1: Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Schedule C, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of RH-301 where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Schedule C for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e. unity).

Example:

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} < 1$$

Schedule D.Groups of Diagnostic Uses of Radioactive Material in Humans.Group I. Uptake, dilution and excretion studies (does not include imaging or tumor localizations).

1. Chromium-51 as labeled human serum albumin for gastrointestinal protein loss studies.
2. Chromium-51 as sodium chromate for determination of red blood cell volumes and studies of red blood cell survival time.
3. Cobalt-57, Cobalt-58 or Cobalt-60 as labeled cyanocobalamin (vitamin B-12) for intestinal absorption studies.
4. Iodine-123 as sodium iodide for measurement of thyroid uptake.
5. Iodine-123 as sodium iodohippurate for renal function studies.
6. Iodine-125 as iothalamate sodium for the evaluation of glomerular filtration.
7. Iodine-131 or Iodine-125 as labeled fats or fatty acids for fat absorption studies.
8. Iodine-131 or Iodine-125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume.
9. Iodine-131 or Iodine-125 as labeled iodopyracet, sodium iodohippurate, sodium diatrizoate, diatrizoate methylglucamine, sodium diprotrizoate, sodium acetrizoate or sodium iothalamate for kidney function studies.
10. Iodine-131 or Iodine-125 as labeled rose bengal for liver function studies.
11. Iodine-131 or Iodine-125 as sodium iodide for thyroid function studies.
12. Iron-59 as chloride, citrate or sulfate for iron turnover studies.
13. Mercury-197 as chlormerodrin for kidney function studies.
14. Potassium-42 as chloride for potassium space determinations.
15. Sodium-24 as chloride for sodium space determinations.
16. Technetium-99m as pertechnetate for blood flow studies.

Group II. Imaging and tumor localizations.

1. Chromium-51 as sodium chromate for spleen imaging.
2. Fluorine-18 as fluoride for bone imaging agent to define areas of altered osteogenic activity.

3. Gallium-67 as citrate for soft tumor localization, and acute inflammatory lesions.
4. Gold-198 in colloidal form for liver imaging.
5. Indium-111 chloride as Indiclor for colorectal or ovarian imaging.
6. Indium-111 as Penetate Indium Disodium (DTPA) for cisternography.
7. Indium-111 as oxyquinoline (oxine) for radiolabeling of autologous leukocytes for detection of inflammatory processes.
8. Indium-113m as chloride for blood pool imaging including placenta localization.
9. Iodine-123 as iodide for thyroid imaging.
10. Iodine-123 as sodium iodohippurate for renal imaging and renal function; urinary tract distention.
11. Iodine-123 as iofetamine injection (Spectamine) for brain imaging and evaluation of nonlacunar stroke.
12. Iodine-125 as Sodium Iothalamate for evaluation of glomerular filtration in the diagnosis or monitoring of patient's renal disease.
13. Iodine-125 as Iodinated for blood and plasma volume determination.
14. Iodine-125 as fibrinogen for detection and monitoring of developing deep vein thrombosis.
15. Iodine-131 as colloidal (microaggregated) iodinated human serum albumin for liver imaging.
16. Iodine-131 as iodinated human serum albumin (IHSA) for brain tumor localizations and cardiac imaging.
17. Iodine-131 as iodopyracet, sodium iodohippurate, sodium diatrizoate, diatrizoate methylglucamine, sodium diprotrizoate or sodium acetrizoate for kidney imaging.
18. Iodine-131 as macroaggregated iodinated human serum albumin for lung imaging.
19. Iodine-131 as labeled rose bengal for liver imaging.
20. Iodine-131 or Iodine-125 as sodium iodide for thyroid imaging.
21. Iodine-131 as sodium iodipamide for cardiac imaging.
22. Mercury-197 as chlormerodrin for kidney and brain imaging.
23. Mercury-203 as chlormerodrin for brain imaging.
24. Phosphorus-32 as sodium phosphate for localizing ocular tumors or cerebral tumors.
25. Selenium-75 as labeled selenomethionine for pancreas imaging.
26. Strontium-85 as nitrate or chloride for bone imaging in patients with suspected or diagnosed cancer.
27. Strontium-87m as chloride for bone imaging.

28. Technetium-99m as labeled red blood cells (Ultratag) for blood pool imaging, including cardiac first pass and gated equilibrium imaging and for detection of sites of gastrointestinal bleeding.
29. Thallium-201 as chloride for myocardial perfusion imaging and parathyroid hyperactivity.
30. Xenon-127 as gas for the evaluation of pulmonary function and for imaging the lungs.
31. Xenon-133 as saline solution for diagnosis of cardiac abnormalities, cerebral blood flow studies, pulmonary function studies, muscle blood flow studies and skin blood flow.
32. Ytterbium-169 as labeled Penetate Calcium Trisodium (DTPA) for cisternography.
33. Any radioactive material in a radiopharmaceutical prepared from a reagent kit listed in RH-903, Schedule D, Group III, for a use listed in Group III.

Group III. Generators and Reagent Kits.

1. Molybdenum-99/Technetium-99m generators for the elution of Technetium-99m as pertechnetate for:
 - a. Brain imaging;
 - b. Thyroid imaging;
 - c. Salivary gland imaging;
 - d. Blood pool imaging including placenta localization;
 - e. Blood flow studies;
 - f. Direct isotope cystography;
 - g. Urinary bladder imaging for detection of vesicoureteral reflux;
 - h. Nasolacrimal imaging;
 - i. LaVeen shunt imaging;
 - j. Use with reagent kits for preparation and use of radiopharmaceuticals containing Technetium-99m as provided in Subparagraph 3 of Group III.
2. Technetium-99m as pertechnetate for use with reagent kits for preparation and use of radiopharmaceuticals containing Technetium-99m as provided in Subparagraph 3 of Group III.
3. Reagent kits for preparation of Technetium-99m labeled:
 - a. Albumin Colloid for Reticuloendothelial (RE) system imaging of liver, spleen and bone marrow;

- b. Diethylenetriamine pentaacetic acid (Sn) for brain imaging;
 - c. Diethylenetriamine pentaacetic acid (Sn) for kidney imaging and kidney function studies;
 - d. Disofenin for hepatobiliary imaging;
 - e. Distannous etidronate complex for bone imaging;
 - f. Etidronate for bone or skeletal imaging agent;
 - g. Exametazime for the detection of regional cerebral perfusion;
 - h. Gluceptate sodium for brain imaging and renal perfusion studies;
 - i. Human serum albumin for heart blood pool imaging;
 - j. Human serum albumin microspheres for lung imaging; radionuclide venography of deep vein thrombosis;
 - k. Iron-ascorbate-diethylenetriamine pentaacetic acid complex for kidney imaging;
 - l. Lidofenin for hepatobiliary imaging;
 - m. Macroaggregated human serum albumin for lung imaging; and LaVeen shunt imaging;
 - n. Mertiatide (MAG-3) for renal imaging;
 - o. Mebrofenin for hepatobiliary imaging;
 - p. Medronate sodium for bone imaging;
 - q. Oxidronate sodium for bone imaging;
 - r. Polyphosphates for bone imaging;
 - s. Pyro- and Trimetaphosphates for bone and cardiac imaging; gated cardiac blood pool imaging, gastrointestinal bleeding studies;
 - t. Succimer (DMSA) for renal imaging;
 - u. Sulfur colloid for liver, spleen and bone marrow imaging; for esophageal transit and gastrointestinal reflux studies; for gastrointestinal imaging; for LaVeen shunt imaging; for detection of pulmonary aspiration of gastric contents;
 - v. Sestamibi as myocardial imaging agent;
 - w. Teboroxime as myocardial imaging agent.
4. Strontium-85 as nitrate used as a bone imaging agent.
5. Tin-113/Indium-113m as chloride for blood pool imaging including placenta localization.
6. Yttrium-87/Strontium-87m generators for the elution of Strontium-87m.
7. Krypton-81m gas generator for the study of pulmonary ventilation.

Group IV. Prepared Radiopharmaceuticals for Certain
Therapeutic Uses That Do Not Normally Require
Hospitalization for Purposes of Radiation Safety.

1. Iodine-131 as iodide for treatment of hyperthyroidism and cardiac dysfunction.
2. Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia, bone metastases and localization of ocular tumors and cerebral tumors.
3. Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions.

Group V. Prepared Radiopharmaceuticals for Certain
Therapeutic Uses That Normally Require
Hospitalization for Purposes of Radiation Safety.

1. Gold-198 as colloid for intracavitary treatment of malignant effusions and palliative management of ascites and pleural effusion.
2. Iodine-131 as iodide for treatment of thyroid carcinoma.

RH-904. Schedule E. Limits for Broad Licenses.

<u>Radioactive Material</u>	<u>Column I Curies</u>	<u>Column II Curies</u>
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1.
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1.
Cesium-134m	100	1.
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1.
Chromium-51	100	1.
Cobalt-57	10	0.1
Cobalt-58m	100	1.
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1.
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1
Europium-152 9.2 h	10	0.1
Europium-152 13 y	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1.
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1

RH-904. Schedule E. Limits for Broad Licenses. (Continued)

<u>Radioactive Material</u>	<u>Column I Curies</u>	<u>Column II Curies</u>
Germanium-71	100	1.
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1.
Indium-113m	100	1.
Indium-114m	1	0.01
Indium-115m	100	1.
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1.
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1.
Osmium-185	1	0.01
Osmium-191m	100	1.
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1

RH-904. Schedule E. Limits for Broad Licenses. (Continued)

<u>Radioactive Material</u>	<u>Column I Curies</u>	<u>Column II Curies</u>
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1.
Platinum-193	10	0.1
Platinum-197m	100	1.
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1,000	10.
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1.
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10.
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulfur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1.
Technetium-99	1	0.01

RH-904. Schedule E. Limits for Broad Licenses. (Continued)

<u>Radioactive Material</u>	<u>Column I Curies</u>	<u>Column II Curies</u>
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1.
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10.
Xenon-133	100	1.
Xenon-135	100	1.
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1.
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01

Any radioactive material
other than alpha emitting
radioactive material,
source material or special
nuclear material not listed
above

0.1

0.001

RH-905 Schedule F Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release

<u>Radioactive Material^{15/ 16/}</u>	<u>Release Fraction</u>	<u>Quantity (Curies)</u>
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9 (20 mg)
Carbon-14 (Non CO)	.01	50,000
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Gadolinium-153	.01	5,000
Germanium-68	.01	2,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114m	.01	1,000

RH-905 Schedule F (Continued)

Radioactive Material ^{15/ 16/}	Release Fraction	Quantity (Curies)
Iridium-192	0.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000

RH-905 Schedule F (Continued)

Radioactive material	Release Fraction	Quantity (Curies)
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment, beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha ^{16/}	.0001	20
Combinations of radioactive materials listed above ^{15/}	-	-

**APPENDIX A: Criteria Relating to Use of Financial Tests
and Parent Company Guarantees for Providing Reasonable
Assurance of Funds for Decommissioning**

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This Appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee.

II. Financial Test

- A. To pass the financial test, the parent company must meet the criteria of either paragraph A.1 or A.2 of this Appendix:
1. The parent company must have:
 - i. Two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5; and
 - ii. Net working capital and tangible net worth each at least six times the current decommissioning cost estimates (or prescribed amount if a certification is used); and
 - iii. Tangible net worth of at least \$10 million; and
 - iv. Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certificate is used).

Appendix A. (Cont'd)

2. The parent company must have:
 - i. A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor's or Aaa, Aa, A, or Baa as issued by Moody's; and
 - ii. Tangible net worth at least six times the current decommissioning cost estimate (or prescribed amount if a certification is used); and
 - iii. Tangible net worth of at least \$10 million; and
 - iv. Assets located in the United States amounting to at least 90 percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if certification is used).

- B. The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test, which is derived from the independently audited, year end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure the licensee shall inform the Department within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

- C.
 1. After the initial financial test, the parent company must repeat the passage of the test within 90 days after the close of each succeeding fiscal year.
 2. If the parent company no longer meets the requirements of paragraph A of this Appendix, the licensee must send notice to the Department of intent to establish alternate financial assurance as specified in the Department's regulations. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

Appendix A. (Cont'd)

III. Parent Company Guarantee

The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

- A. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Department. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Department, as evidenced by the return receipts.
- B. If the licensee fails to provide alternate financial assurance as specified in the Department's regulations within 90 (ninety) days after receipt by the licensee and Department of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.
- C. The parent company guarantee and financial test provisions must remain in effect until the Department has terminated the license.
- D. If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the Department. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

Revision effective January 1, 1997

**APPENDIX B: Criteria Relating to Use of Financial Tests
and Self Guarantees for Providing Reasonable
Assurance of Funds for Decommissioning**

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes a financial test of Section II of Appendix B. The terms of the self-guarantee are in Section III of Appendix B. This Appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

- A. To pass the financial test, a company must meet all of the following criteria:
- i. Tangible net worth at least ten (10) times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.
 - ii. Assets located in the United States amounting to at least 90 percent (90%) of total assets or at least ten (10) times the total current decommissioning cost estimate (or prescribed amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.
 - iii. A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moodys.

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Appendix B. (Cont'd)

- B. To pass the financial test, a company must meet all of the following additional requirements:
 - i. The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.
 - ii. The company's independent certified public accountant must have compared the data used by the company in the financial test which is derived from the independently audited, yearend financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Department within 90 (ninety) days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.
 - iii. After the initial financial test, the company must repeat the passage of the test within 90 (ninety) days after the close of each succeeding fiscal year.
- C. If the licensee no longer meets the requirements of Section II.A of Appendix B, the licensee must send notice to the Department of its intent to establish alternate financial assurance as specified in the Department's Regulations within 120 days of such notice.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee obtains must provide that:

- A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Department. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Department, as evidenced by the return receipt.
- B. The licensee shall provide alternate financial assurance as specified in the Department's regulations within 90 (ninety) days following receipt by the Department of a notice of cancellation of the guarantee.

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Appendix B. (Cont'd)

- C. The guarantee and financial test provisions must remain in effect until the Department has terminated the license or until another financial assurance method acceptable to the Department has been put in effect by the licensee.

- D. The licensee will promptly forward to the Department and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

- E. If, at any time, the licensee's most recent bond issuances ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the Department within 20 (twenty) days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poor and Moodys, the licensee no longer meets the requirements of Section II.A of Appendix B.

- F. The applicant or licensee must provide to the Department a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Department, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

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FOOTNOTES FOR SECTION 2

- 1/ Attention is directed to the fact that regulation by the State of source material, byproduct material and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the State and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.
- 2/ The requirements specified in Subdivision B and C of this Subparagraph need not be met by counterweights manufactured prior to December 31, 1969; provided that such counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM," as previously required by these Regulations.
- 3/ Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity or other product containing source or byproduct material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.
- 4/ For purposes of this Subparagraph, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwaves tubes, indicator tubes, pick-up tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents.
- 5/ Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity or other product containing byproduct material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.
- 6/ Attention is directed particularly to the provisions of Section 3 of these Regulations which relate to the labeling of containers.
- 7/ Any notification of incidents referred to in those requirements shall be filed with or made to the Department.
- 8/ The New Drug provisions of the Federal Food, Drug and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.
- 9/ The model, serial number and name of manufacturer or distributor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

(Continued)

FOOTNOTES FOR SECTION 2, CONTINUED

- 10/ Deleted. Deleted when RH-405.m was deleted.
- 11/ Authority to transfer possession or control by the manufacturer, processor or producer of any equipment, device, commodity or other product containing source or byproduct material whose subsequent possession, use, transfer and disposal by all other persons are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.
- 12/ Values are given in Column 1 only for those materials normally used in gases.
- 13/ Ci/gm for solids.
- 14/ These reporting requirements do not supersede or release licensee of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499 or other state or federal reporting requirements.
- 15/ For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Schedule F exceeds one.
- 16/ Waste packaged in Type B containers does not require an emergency plan.

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END OF SECTION 2

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SECTION 3. STANDARDS FOR PROTECTION AGAINST RADIATION
(FOOTNOTES APPEAR AT THE END OF THIS SECTION)

PART A. GENERAL

- RH-1000. Authority. Act 8 of Second Extraordinary Session of 1961, as amended.
- RH-1001. Effective Date. The provisions of these Regulations shall become effective on January 1, 1963, except where another effective date is specifically noted.
- RH-1002. Purpose and Scope.
- a. These Regulations establish standards for protection against radiation hazards. Except as otherwise specifically provided, this Part applies to all licensees or registrants.
 - b. It is the purpose of the Regulations in this Part to control the receipt, possession, use, transfer, and disposal of licensed material by any licensee or registrant in such a manner that the total dose to an individual (including doses resulting from licensed and unlicensed radioactive material and from radiation sources other than background radiation) does not exceed the standards for protection against radiation prescribed in the Regulations in this Part. However, nothing in this Part shall be construed as limiting actions that may be necessary to protect health and safety.
- RH-1003. Communications. All communications concerning these Regulations should be addressed to the Division Director, Division of Radiation Control and Emergency Management, Arkansas Department of Health, 4815 West Markham, Mail Slot 30, Little Rock, Arkansas 72205-3867.

RH-1004

Radiation Protection Programs.

- a. Each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this Part. (See RH-1500 for recordkeeping requirements relating to these programs.)
- b. The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).
- c. The licensee shall periodically (at least annually) review the radiation protection program content and implementation.

PART B. DEFINITIONS

RH-1100 Definitions as used in these Regulations. Additional definitions used only in a certain Part will be found in that Part.

- a. Absorbed dose - The energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).
- b. Act - The Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.), as amended.
- c. Activity - The rate of disintegration (transformation) or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).
- d. Adult - An individual 18 or more years of age.
- e. Agreement State - Any State with which the U.S. Nuclear Regulatory Commission has entered into an effective agreement under Section 274 b. of the Atomic Energy Act of 1954 as amended (73 Stat. 689).
- f. Airborne radioactive material - Radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.
- g. Airborne radioactivity area - A room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations:
 1. In excess of the derived air concentrations (DACs) specified in Appendix G to RH-1000 through RH-2110, or
 2. To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

- h. ALARA (acronym for "as low as is reasonably achievable") - Making every reasonable effort to maintain exposures to radiation as far below the dose limits in this Part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.
- i. Annual limit on intake (ALI) - The derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 5 rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue. (ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table 1, Columns 1 and 2, of Appendix G to RH-1000 through RH-2110).
- j. Approved qualified expert - An individual who has, prior to offering health physics services, registered with and demonstrated to the satisfaction of the Department that he/she possesses the knowledge and training to measure ionizing radiation parameters, to evaluate safety techniques and to advise regarding radiation protection matters.
- k. Background radiation - Radiation from cosmic sources, naturally occurring radioactive materials, including Radon (except as a decay product of source or special nuclear material) and global fallout as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include radiation from source, byproduct, or special nuclear materials regulated by the Department.

- l. Bioassay (radiobioassay) - The determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.
- m. Byproduct material - Any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material.
- n. Class (or lung class or inhalation class) - A classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D (Days) of less than 10 days, for Class W (Weeks) from 10 to 100 days, and for Class Y (Years) of greater than 100 days.
- o. Collective dose - The sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.
- p. Committed dose equivalent ($H_{T,50}$) - The dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.
- q. Committed effective dose equivalent ($H_{E,50}$) - The sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \sum w_T H_{T,50}$).
- r. Controlled area - An area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

- s. Declared pregnant woman - A woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.
- t. Deep-dose equivalent (H_d) - (which applies to external whole-body exposure) The dose equivalent at a tissue depth of 1 cm (1000 mg/cm^2).
- u. Department - The Arkansas Department of Health or its duly authorized representatives.
- v. Department of Energy (DOE) - The Department of Energy established by the Department of Energy Organization Act (Public Law 95-91, 91 Stat. 565, 42 U.S.C. 7101 et seq.) to the extent that the DOE, or its duly authorized representatives, exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers, and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to Sections 104 (b), (c), and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, 88 Stat. 1233 at 1237, 42 U.S.C. 5814) and retransferred to the Secretary of Energy pursuant to Section 301(a) of the Department of Energy Organization Act (Public Law 95-91, 91 Stat. 565 at 577-578, 42 U.S.C. 7151).
- w. Derived air concentration (DAC) - The concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour), results in an intake of one ALI. DAC values are given in Table 1, Column 3, of Appendix G to RH-1000 through RH-2110.
- x. Derived air concentration-hour (DAC-hour) - The product of the concentration of radioactive material in air (expressed as a fraction or multiple of the derived air concentration for each radionuclide) and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 5 rems (0.05 Sv).

- y. Director - Director of the Arkansas Department of Health.
- z. Dose or radiation dose - A generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in other Paragraphs of this Section.
- aa. Dose equivalent (H_T) - The product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).
- ab. Dosimetry processor - An individual or an organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the equipment.
- ac. Effective dose equivalent (H_E) - The sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum w_T H_T$).
- ad. Embryo/fetus - The developing human organism from conception until the time of birth.
- ae. Entrance or access point - Any location through which an individual could gain access to radiation areas or to radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.
- af. Exposure - Being exposed to ionizing radiation or to radioactive material.
- ag. External dose - That portion of the dose equivalent received from radiation sources outside the body.

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- ah. Extremity - Hand, elbow, arm below the elbow, foot, knee, and leg below the knee.
- ai. Eye dose equivalent - The external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm²).
- aj. Generally applicable environmental radiation standards - Standards issued by the Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.
- ak. 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.
- al. Gray - See RH-1102. Units of Radiation Dose.
- am. High radiation area - An area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in one (1) hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.
- an. Individual - Any human being.
- ao. Individual monitoring -
 - 1. The assessment of dose equivalent by the use of devices designed to be worn by an individual;

2. The assessment of committed effective dose equivalent by bioassay (see Bioassay) or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours; or
 3. The assessment of dose equivalent by the use of survey data.
-
- ap. Individual Monitoring Devices (individual monitoring equipment) - Devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.
 - aq. Internal dose - That portion of the dose equivalent received from radioactive material taken into the body.
 - ar. License - Except where otherwise specified, means a license issued pursuant to Section 2, Section 6, or Section 7.
 - as. Licensed material - Source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general or specific license issued by the Department.
 - at. Licensee - The holder of a license.
 - au. Limits (dose limits) - The permissible upper bounds of radiation doses.
 - av. 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.

- aw. Member of the public - An individual in a controlled or unrestricted area. However, an individual is not a member of the public during any period in which the individual receives an occupational dose.

- ax. Minor - An individual less than 18 years of age.

- ay. Misadministration - The administration of:
 - 1. A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131:
 - A. Involving the wrong individual or wrong radiopharmaceutical; or
 - B. When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries.

 - 2. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:
 - A. Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or
 - B. When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

 - 3. A gamma stereotactic radiosurgery radiation dose:
 - A. Involving the wrong individual or wrong treatment site; or
 - B. When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.

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4. A teletherapy radiation dose or medical particle accelerator dose:
 - A. Involving the wrong individual, wrong mode of treatment, or wrong treatment site;
 - B. When the treatment consists of three (3) or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;
 - C. When the calculated weekly administered dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose; or
 - D. When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

5. A brachytherapy radiation dose:
 - A. Involving the wrong individual, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);
 - B. Involving a sealed source that is leaking;
 - C. When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or
 - D. When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

6. A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, both:
 - i. Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

- ii. When the dose to the individual exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ.

- az. Monitoring (radiation monitoring, radiation protection monitoring) - The measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

- ba. Nonstochastic effect - Health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect (also called a deterministic effect).

- bb. Occupational dose - The dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to radiation and/or radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include dose received from background radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the general public.

- bc. Person - Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other State or political subdivision or agency thereof and any legal successor, representative, agent or agency of the foregoing, other than the U.S. Nuclear Regulatory Commission and other federal government agencies.

- bd. Pharmacist - An individual registered by this State to compound and dispense drugs, prescriptions and poisons.

- be. Planned special exposure - An infrequent exposure to radiation, separate from and in addition to the annual dose limits.

- bf. Prescribed dosage - The quantity of radiopharmaceutical activity as documented:
 - 1. In a written directive; or
 - 2. Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for the diagnostic procedure.

- bg. 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; or
 - 3. For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.

- bh. Public dose - The dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation either within a licensee's controlled area or in unrestricted areas. It does not include occupational dose or doses received from background radiation, as a patient from medical practices, or from voluntary participation in medical research programs.

- bi. Qualified Expert - A person qualified by training and experience to calibrate a teletherapy unit and establish procedures for spot-check measurements. This person shall:
 - 1. Be certified by the American Board of Radiology in Therapeutic Radiological Physics, Radiological Physics, Roentgen-Ray and Gamma-Ray Physics or X-ray and Radium Physics; or

2. Is certified by the American Board of Medical Physics in radiation oncology physics; or
 3. Have the following minimum training and experience:
 - A. A Master's Degree or Doctorate in physics, biophysics, radiological physics, or health physics;
 - B. One year of full-time training in therapeutic radiological physics; and
 - C. One year of full-time experience in a radiotherapy facility including personal calibration and spot-check of a least one teletherapy unit.
- bj. Quality Factor (Q) - The modifying factor (listed in Tables 1 and 2 of RH-1102) that is used to derive dose equivalent from absorbed dose.
- bk. Quarter - A period of time equal to one-fourth of the year observed by the licensee (approximately 13 consecutive weeks), providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.
- bl. Rad - See RH-1102. Units of Radiation Dose.
- bm. Radiation (ionizing radiation) - Alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. Radiation, as used in this Part, does not include non-ionizing radiation, such as radio- or microwaves, or visible, infrared, or ultraviolet light.

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- bn. Radiation area - An area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in one (1) hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.
- bo. Radiation machine - Any device capable of producing radiation, but excluding devices which produce radiation only by the use of radioactive material.
- bp. Radioactive material - Any material (solid, liquid or gas) which emits radiation spontaneously including any natural radioactive material such as Radium.
- bq. Radioactivity - The transformation of unstable atomic nuclei by the emission of radiation.
- br. Recordable event - The administration of:
 - 1. A radiopharmaceutical or radiation without a written directive where a written directive is required;
 - 2. A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;
 - 3. A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131 when both:
 - A. The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage; and
 - B. The difference between the administered dosage and prescribed dosage exceeds 15 microcuries;

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4. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;
 5. A teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15 percent or more of the weekly prescribed dose; or
 6. A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.
- bs. Reference man - A hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.
- bt. Rem - See RH-1102. Units of Radiation Dose.
- bu. Respiratory protective device - An apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.
- bv. Restricted area - An area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.
- bw. Sanitary sewerage - A system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.

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- bx. Shallow-dose equivalent (H_p) (which applies to the external exposure of the skin or an extremity) - Is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of one (1) square centimeter.
- by. Sievert - See RH-1102. Units of Radiation Dose.
- bz. Site boundary - That line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.
- ca. Source material -
 - 1. Uranium or Thorium or any combination of Uranium and Thorium in any physical or chemical form; or
 - 2. Ores that contain, by weight, one-twentieth of one (1) percent (0.05 percent), or more, of Uranium, Thorium, or any combination of Uranium and Thorium. Source material does not include special nuclear material.
- cb. Source of radiation - Any radioactive material or any radiation machine.
- cc. Storage container - A device in which sealed sources are transported or stored.
- cd. Special nuclear material -
 - 1. Plutonium, Uranium-233, Uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Department, pursuant to the provisions of Section 51 of the Act, determines to be special nuclear material, but does not include source material, or
 - 2. Any material artificially enriched by any of the foregoing but does not include source material.

- ce. Stochastic effects - Health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

- cf. Survey - An evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

- cg. These Regulations - Section 3, Rules and Regulations of the State Board of Health, Standards for Protection Against Radiation.

- ch. Total Effective Dose Equivalent (TEDE) - The sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

- ci. Uncontrolled area or unrestricted area - Any area to which access is not controlled by the licensee or registrant for the purposes of protection of individuals from exposure to radiation and radioactive materials and any area used for residential quarters.

- cj. Uranium fuel cycle - The operations of milling of Uranium ore, chemical conversion of Uranium, isotopic enrichment of Uranium, fabrication of Uranium fuel, generation of electricity by a light-water-cooled nuclear power plant using Uranium fuel, and reprocessing of spent Uranium fuel to the extent that these activities directly support the production of electrical power for public use. Uranium fuel cycle does not include mining operations, operations at waste disposal sites, transportation of radioactive material in support of these operations, and the reuse of recovered non-Uranium special nuclear and byproduct materials from the cycle.

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ck. Very high radiation area - An area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in one (1) hour at one (1) meter from a radiation source or from any surface that the radiation penetrates.

Note: At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts).

cl. Week - Seven (7) consecutive days starting on Sunday.

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

ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30 ^a
Whole Body	1.00 ^b

^a 0.30 results from 0.06 for each of 5 "remainder" organs (excluding the skin and the lens of the eye) that receive the highest doses.

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

- cn. Whole body - For purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.
- co. Worker - An individual engaged in work under a license or registration issued by the Department and controlled by a licensee or registrant.
- cp. Working level (WL) - Any combination of short-lived Radon daughters (for Radon-222: Polonium-218, Lead-214, Bismuth-214, and Polonium-214; and for Radon-220: Polonium-216, Lead-212, Bismuth-212, and Polonium-212) in one liter of air that will result in the ultimate emission of 1.3×10^5 MeV of potential alpha particle energy.
- cq. Working level month (WLM) - An exposure to one working level for 170 hours (2,000 working hours per year/12 months per year = approximately 170 hours per month).
- cr. Written directive - An order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in item 6 of this definition, containing the following information:
1. For any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131: the dosage;
 2. For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;
 3. For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;
 4. For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;

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5. For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or
 6. For all other brachytherapy:
 - A. Prior to implantation: the radioisotope, number of sources, and source strengths; and
 - B. After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).
 7. For any medical particle accelerator dose: the total dose, dose per fraction, treatment site, and overall treatment period.
- cs. Year - The period of time beginning in January used to determine compliance with the provisions of this Part. The licensee may change the starting date of the year used to determine compliance by the licensee provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

RH-1101. Other Definitions. Definitions of certain other words and phrases as used in these Regulations are set forth in other Paragraphs.

RH-1102. Units of Radiation Dose.

As used in this Part, the units of radiation dose are:

- a. Exposure rate – The exposure per unit of time, such as roentgen per minute and milliroentgen per hour.
- b. Gray (Gy) – The SI unit of absorbed dose. One gray is equal to an absorbed dose of one (1) joule/kilogram (100 rads).
- c. Rad – The special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 gray).
- d. Rem – The special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert).
- e. Roentgen – The special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs/kilogram of air (See "Exposure" in RH-1100).
- f. Sievert (Sv) – The SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems).
- g. As used in this Part, the quality factors for converting absorbed dose to dose equivalent are shown in Table 1.

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TABLE RH-1102 #1

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor	Absorbed Dose Equal to a Unit Dose Equivalent ^a
	(Q)	
X-, gamma, or beta radiation	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

^a Absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.

- h. If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rems per hour or sieverts per hour, as provided in RH-1102.g of this Section, 1 rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of the Regulations in this Part, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee may use the fluence rate per unit dose equivalent or the appropriate Q value from Table 2 to convert a measured tissue dose in rads to dose equivalent in rems.

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TABLE RH-1102 #2
MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE
EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron Energy (MeV)	Quality Factor ^a (Q)	Fluence per Unit Dose Equivalent ^b (neutrons cm ⁻² rem ⁻¹)
(thermal)	2.5 x 10 ⁻⁸	2	980 x 10 ⁶
	1 x 10 ⁻⁷	2	980 x 10 ⁶
	1 x 10 ⁻⁶	2	810 x 10 ⁶
	1 x 10 ⁻⁵	2	810 x 10 ⁶
	1 x 10 ⁻⁴	2	840 x 10 ⁶
	1 x 10 ⁻³	2	980 x 10 ⁶
	1 x 10 ⁻²	2.5	1010 x 10 ⁶
	1 x 10 ⁻¹	7.5	170 x 10 ⁶
	5 x 10 ⁻¹	11	39 x 10 ⁶
	1	11	27 x 10 ⁶
	2.5	9	29 x 10 ⁶
	5	8	23 x 10 ⁶
	7	7	24 x 10 ⁶
	10	6.5	24 x 10 ⁶
	14	7.5	17 x 10 ⁶
	20	8	16 x 10 ⁶
	40	7	14 x 10 ⁶
60	5.5	16 x 10 ⁶	
1 x 10 ²	4	20 x 10 ⁶	
2 x 10 ²	3.5	19 x 10 ⁶	
3 x 10 ²	3.5	16 x 10 ⁶	
4 x 10 ²	3.5	14 x 10 ⁶	

^a Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30 cm diameter cylinder tissue-equivalent phantom.

^b Monoenergetic neutrons incident normally on a 30 cm diameter cylinder tissue-equivalent phantom.

RH-1103. Units of Radioactivity.

For the purposes of this Part, activity is expressed in the special unit of curies (Ci) or in the SI unit of becquerels (Bq), or their multiples, or disintegrations (transformations) per unit of time.

- a. One becquerel = 1 disintegration per second (s^{-1}).
- b. One curie = 3.7×10^{10} disintegrations per second = 3.7×10^{10} becquerels = 2.22×10^{12} disintegrations per minute.

RH-1104. Interpretations.

Except as specifically authorized by the Department in writing, no interpretation of the meaning of the Regulations in this Part by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized to be binding upon the Department.

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RH-1105. Implementation.

- a. The applicable Section of RH-1000 through RH-2110 must be used in lieu of requirements in the standards for protection against radiation in effect prior to January 1, 1994 that are cited in license conditions except as specified in RH-1105.c through RH-1105.e of this Section. If the requirements of this Part are more restrictive than the existing license condition, then the licensee shall comply with this Part unless exempted by RH-1105.d of this Section.
- b. Any existing license condition that is more restrictive than a requirement in RH-1000 through RH-2110 remains in force until there is a license amendment or license renewal.
- c. If a license condition exempted a licensee from a requirement in the standards for protection against radiation in effect prior to January 1, 1994, it continues to exempt a licensee from the corresponding provision of RH-1000 through RH-2110.
- d. If a license condition cites provisions in requirements in the standards for protection against radiation in effect prior to January 1, 1994 and there are no corresponding provisions in RH-1000 through RH-2110, the license condition remains in force until there is a license amendment or license renewal that modifies or removes this condition.
- e. Any existing license condition that is more restrictive than a requirement in RH-1000 through RH-2110 remains in force until there is a technical specification change, license amendment, or license renewal.
- f. If a license condition exempts a licensee from a provision of this Section in RH-1 through RH-602, it also exempts the licensee from the corresponding provision of RH-1000 through RH-2110.

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RH-1105 (Cont'd)

- g. If a license condition cites provisions in Part M and there are no corresponding provisions in RH-1000 through RH-2110, then the license condition remains in force until there is a license amendment, or license renewal that modifies or removes this condition.

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PART C. PERMISSIBLE DOSES, LEVELS, AND CONCENTRATIONS

RH-1200. Occupational Dose Limits for Adults.

- a. The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures under RH-1205, to the following dose limits.
 1. An annual limit, which is the more limiting of:
 - i. The total effective dose equivalent being equal to 5 rems (0.05 Sv), or
 - ii. The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv).
 2. The annual limits to the lens of the eye, to the skin, and to the extremities which are:
 - i. An eye dose equivalent of 15 rems (0.15 Sv), and
 - ii. A shallow-dose equivalent of 50 rems (0.50 Sv) to the skin or to each of the extremities.
- b. Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, must be subtracted from the limits for planned special exposures that the individual may receive during the current year (See RH-1205.e.1.) and during the individual's lifetime (See RH-1205.e.2.).
- c. The assigned deep-dose equivalent and shallow-dose equivalent must be for the part of the body receiving the highest exposure. The deep-dose equivalent, eye dose equivalent and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

RH-1200 (Cont'd)

- d. Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table 1 of Appendix G to RH-1000 through RH-2110 and may be used to determine the individual's dose (See RH-1500.f) and to demonstrate compliance with the occupational dose limits.
- e. In addition to the annual dose limits, the licensee shall limit the soluble Uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity (See footnote 3 of Appendix G to RH-1000 through RH-2110).
- f. The licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person (see RH-1500.d.5).

RH-1201. Compliance with Requirements for Summation of External and Internal Doses.

- a. If the licensee is required to monitor under both RH-1302.a and b, the licensee shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee is required to monitor only under RH-1302.a or only under RH-1302.b, then summation is not required to demonstrate compliance with the dose limits. The licensee may demonstrate compliance with the requirements for summation of external and internal doses by meeting one of the conditions specified in RH-1201.b and the conditions in RH-1201.c and RH-1201.d.

NOTE: The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

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- b. Intake by inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep-dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:
1. The sum of the fractions of the inhalation ALI for each radionuclide, or
 2. The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or
 3. The sum of the calculated committed effective dose equivalents to all significantly irradiated^{1/} organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit.
- c. Intake by oral ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than ten percent (10%) of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.
- d. Intake through wounds or absorption through skin. The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption.

NOTE: The intake through intact skin has been included in the calculation of DAC for Hydrogen-3 and does not need to be further evaluated.

RH-1202. Determination of External Dose From Airborne Radioactive Material.

Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep-dose equivalent, eye dose equivalent, and shallow-dose equivalent from external exposure to the radioactive cloud (See Appendix G to RH-1000 through RH-2110, footnotes 1 and 2).

NOTE: Airborne radioactivity measurements and DAC values should not be used as the primary means to assess the deep-dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep-dose equivalent to an individual should be based upon measurements using instruments or individual monitoring devices.

RH-1203. Determination of Internal Exposure.

- a. For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required under RH-1302, take suitable and timely measurements of:
 1. Concentrations of radioactive materials in air in work areas; or
 2. Quantities of radionuclides in the body; or
 3. Quantities of radionuclides excreted from the body; or
 4. Combinations of these measurements.
- b. Unless respiratory protective equipment is used, as provided in RH-1303.f.5, or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

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- c. When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior or the material in an individual is known, the licensee may:
 - 1. Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record;
 - 2. Upon prior approval of the Department, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material (e.g., aerosol size distribution or density); and
 - 3. Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of given radionuclide (See Appendix G to RH-1000 through RH-2110) to the committed effective dose equivalent.
- d. If the licensee chooses to assess intakes of Class Y material using the measurements given in RH-1203.a.2 or 3, the licensee may delay the recording and reporting of the assessments for periods up to seven (7) months, unless otherwise required by RH-1502 or RH-1503, in order to permit the licensee to make additional measurements basic to the assessments.
- e. If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours must be either:
 - 1. The sum of the ratios of the concentration to the appropriate DAC value (e.g., D, W, Y) from Appendix G to RH-1000 through RH-2110 for each radionuclide in the mixture; or
 - 2. The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

- f. If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture must be the most restrictive DAC of any radionuclide in the mixture.
- g. When a mixture of radionuclides in air exists, licensees may disregard certain radionuclides in the mixture if:
 - 1. The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in RH-1200 and in complying with the monitoring requirements in RH-1302.b.;
 - 2. The concentration of any radionuclide disregarded is less than 10 percent of its DAC; and
 - 3. The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.
- h.
 - 1. In order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 5 rems (0.05 Sv) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.
 - 2. When the ALI (and the associated DAC) is determined by the nonstochastic organ dose limit of 50 rems (0.5 Sv), the intake of radionuclides that would result in a committed effective dose equivalent of 5 rems (0.05 Sv) (the stochastic ALI) is listed in parentheses in Table 1 of Appendix G to RH-1000 through RH-2110. In this case, the licensee may, as a simplifying assumption, use the stochastic ALIs to determine committed effective dose equivalent. However, if the licensee uses the stochastic ALIs, the licensee must also demonstrate that the limits in RH-1200.a.1.i and ii. are met.

RH-1204 Reserved.

RH-1205 Planned Special Exposures.

A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in RH-1201 provided that each of the following conditions is satisfied:

- a. The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical.
- b. The licensee or registrant (and employer if the employer is not the licensee) specifically authorizes the planned special exposure, in writing, before the exposure occurs.
- c. Before a planned special exposure, the licensee or registrant ensures that the individuals involved are:
 1. Informed of the purpose of the planned operation;
 2. Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and
 3. Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.
- d. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by RH-1500.d. during the lifetime of the individual for each individual involved.
- e. Subject to RH-1200.b., the licensee or registrant does not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:
 1. The numerical values of any of the dose limits in RH-1200.a., in any year; and

RH-1205 (Cont'd)

2. Five times the annual dose limits in RH-1201.a. during the individual's lifetime.
- f. The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with RH-1500.e. and submits a written report in accordance with RH-1504.
- g. The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures is not to be considered in controlling future occupational dose of the individual under RH-1201.a. but is to be included in evaluations required by RH-1205.d. and e.

RH-1206 Occupational Dose Limits for Minors.

The annual occupational dose limits for minors are 10 percent of the annual dose limits specified for adult workers in RH-1200.

RH-1207 Dose to an Embryo/Fetus.

- a. The licensee or registrant shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). (For recordkeeping requirements, see RH-1500.g.)
- b. The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in Paragraph a of this Section.
- c. The dose to an embryo/fetus shall be taken as the sum of:
 1. The deep-dose equivalent to the declared pregnant woman; and

2. The dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.
- d. If the dose to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, by the time the woman declares the pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with Paragraph a of this Section if the additional dose to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

RH-1208 Dose Limits for Individual Members of the Public.

- a. Each licensee or registrant shall conduct operations so that:
 1. The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contribution from the licensee's disposal of radioactive material into sanitary sewerage in accordance with RH-1402; and
 2. The dose in any unrestricted area from external sources does not exceed 0.002 rem (0.02 mSv) in any one hour.
- b. If the licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.
- c. A licensee or license applicant or registrant may apply for prior Department authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). The licensee or license applicant or registrant shall include the following information in this application:
 1. Demonstration of the need for and the expected duration of operations in excess of the limit in RH-1208.a. of this Section;

RH-1208 (Cont'd)

2. The licensee's or registrant's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and
 3. The procedures to be followed to maintain the dose as low as is reasonably achievable.
- d. In addition to the requirements of this Part, a licensee subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR Part 190 shall comply with those standards.
 - e. The Department may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

RH-1209. Compliance with Dose Limits for Individual Members of the Public.

- a. The licensee or registrant shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in RH-1208.
- b. A licensee or registrant shall show compliance with the annual dose limit in RH-1208 by:
 1. Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual dose limit; or
 2. Demonstrating that:
 - i. The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table 2 of Appendix G to RH-1000 through RH-2110; and

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- ii. If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.
- c. Upon approval from the Department, the licensee may adjust the effluent concentration values in Appendix G to RH-1000 through RH-2110, Table 2, for members of the public, to take into account the actual physical and chemical characteristics of the effluents (e.g., aerosol size distribution, solubility, density, radioactive decay equilibrium, chemical form).

RH-1210. Radioactivity in Effluents to Uncontrolled Areas.

- a. A licensee shall not possess, use, or transfer licensed material so as to release to an uncontrolled area radioactive material in concentrations which exceed the limits specified in RH-2200, Appendix A, Table II of this Part, except as authorized pursuant to RH-1401 or Subparagraph b of this Paragraph. For purposes of this Paragraph, concentrations may be averaged over a period not greater than one (1) year.
- b. An application for a license or amendment may include proposed limits higher than those specified in Subparagraph a of this Paragraph. The Department will approve the proposed limits if the applicant demonstrates:
 - 1. That the applicant has made a reasonable effort to minimize the radioactivity contained in effluents to uncontrolled areas; and
 - 2. That it is not likely that radioactive material discharged in the effluent would result in the exposure of an individual to concentrations of radioactive material in air or water exceeding the limits specified in RH-2200, Appendix A, Table II of this Section.
- c. An application for high limits pursuant to Subparagraph b of this Paragraph shall include information demonstrating that the applicant has made a reasonable effort to minimize the radioactivity discharged in effluents to uncontrolled areas and shall include, as pertinent:

1. Information as to flow rates, total volume of effluent, peak concentration of each radionuclide in the effluent and concentration of each radionuclide in the effluent averaged over a period of one (1) year at the point where the effluent leaves a stack, tube, pipe, or similar conduit.
2. A description of the properties of the effluents, including:
 - A. Chemical composition;
 - B. Physical characteristics, including suspended solids content in liquid effluents and nature of gas or aerosol for air effluents;
 - C. The Hydrogen ion concentrations (pH) of liquid effluents; and
 - D. The size range of particulates in effluents released into air.
3. A description of the anticipated human occupancy in the uncontrolled area where the highest concentration of radioactive material from the effluent is expected and, in the case of a river or stream, a description of water uses downstream from the point of release of the effluent.
4. Information as to the highest concentration of each radionuclide in an uncontrolled area, including anticipated concentrations averaged over a period of one (1) year:
 - A. In air at any point of human occupancy; or
 - B. In water at points of use downstream from the point of release of the effluent.
5. The background concentration of radionuclides in the receiving river or stream prior to the release of liquid effluent.
6. A description of the environmental monitoring equipment, including sensitivity of the system and procedures and calculations to determine concentrations of radionuclides in the uncontrolled area and possible reconcentrations of radionuclides.

7. A description of the waste treatment facilities and procedures used to reduce the concentration of radionuclides in effluents prior to their release.
- d. For the purposes of this Paragraph, the concentration limits in RH-2200, Appendix A, Table II of this Section shall apply at the boundary of the controlled area. The concentration of radioactive material discharged through a stack, pipe or similar conduit may be determined with respect to the point where the material leaves the conduit. If the conduit discharges within the controlled area, the concentration at the boundary may be determined by applying appropriate factors for dilution, dispersion or decay between the point of discharge and the boundary.
- e. In addition to limiting concentrations in effluent streams, the Department may limit quantities of radioactive materials released in air or water during a specified period of time if it appears that the daily intake resulting from continuous exposure to air or water containing one-third the concentration of radioactive materials specified in RH-2200, Appendix A, Table II of this Section.
- f. The provisions of this Paragraph do not apply to disposal of radioactive material into sanitary sewerage systems, which is governed by RH-1402.
- g. Soil and vegetation limiting concentrations
 1. No licensee shall possess, receive, use, or transfer radioactive material in such a manner as to cause contamination of soil or vegetation to the extent that the contamination exceeds the following on a dry weight basis:
 - A. In unrestricted areas, the concentration limits specified in RH-2200, Appendix A, Table II, Column 2, with the units changed from $\mu\text{Ci/ml}$ to $\mu\text{Ci/gm}$; and
 - B. In restricted areas, the concentration limits specified in RH-2200, Appendix A, Table I, Column 2, with the units changed from $\mu\text{Ci/ml}$ to $\mu\text{Ci/gm}$.

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2. Where combinations of radionuclides are involved, the sum of the ratios between the concentrations present and the limits specified in RH-1203.e. shall not exceed one.
3. Notwithstanding the limits imposed by RH-1210, the concentration of Radium-226 or Radium-228 in soil averaged over any 100 square meters shall not exceed the background level by more than:
 - A. 5 pCi/gm, averaged over the first 15 cm of soil below the surface; and
 - B. 15 pCi/gm, averaged over 15 cm thick layers of soil more than 15 cm below the surface.

RH-1211. Orders Requiring Furnishing of Bioassay Services.

Where necessary or desirable in order to aid in determining the extent of an individual's exposure to concentrations of radioactive material, the Department may require a licensee to make available to the individual appropriate bioassay services and to furnish a copy of the reports of such services to the Department.

RH-1212. Leak Tests.

- a. Each sealed radioactive source possessed under the provisions of a specific license, other than Hydrogen-3 (Tritium), with a half-life greater than thirty (30) days and in any form other than gas shall be tested for leakage and/or contamination prior to initial use and at intervals specified by the license. If there is reason to suspect that a sealed source might have been damaged, it shall be tested for leakage before further use.

- b. Leak tests shall be capable of detecting the presence of 0.005 microcurie of removable contamination. Any test conducted pursuant to RH-1212 which reveals the presence of 0.005 microcurie or more of removable contamination shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with RH-501.
- c. Within five (5) days after obtaining results of the test, the licensee shall file a report with the Department describing the equipment involved, the test results, and the corrective action taken.
- d. Where sealed sources are permanently mounted in devices or equipment, tests for contamination and leakage may be made by wiping appropriate accessible surfaces and measuring these wipes for transferred contamination. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Department.

RH-1213. Surface Contamination Limits for Facilities and Equipment

- a. Prior to vacating any facility or releasing areas or equipment for unrestricted use, each licensee shall ensure that radioactive contamination has been removed to levels as low as reasonably achievable. In no case shall the licensee vacate a facility or release areas or equipment for unrestricted use until radioactive surface contamination levels are below the limits specified in RH-1213.b.

b. **ACCEPTABLE SURFACE CONTAMINATION LEVELS**

NUCLIDE ¹	AVERAGE ^{2,3,6}	MAXIMUM ^{2,4,6}	REMOVABLE ^{2,3,5,6}
U-nat, U-235, U-238, and associated decay products except Ra-226, Th-230, Ac-227, and Pa-231	5,000 dpm alpha/ 100 cm ²	15,000 dpm alpha/ 100 cm ²	1,000 dpm alpha/ 100 cm ²
Transuranics, Ra-226, Ra-228, Th-230, Th-228, Pa-231, Ac-227, I-129	100 dpm/100 cm ²	300 dpm/100 cm ²	20 dpm/100 cm ²
Th-nat, Th-232, Sr-90, Ra-223, Ra-224, U-232, I-125, I-126, I-131, I-133	1,000 dpm/100 cm ²	3,000 dpm/100 cm ²	200 dpm/100 cm ²
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	5,000 dpm beta, gamma/100 cm ²	15,000 dpm beta, gamma/100 cm ²	1,000 dpm beta, gamma/100 cm ²

(Footnotes for this table are on next page)

FOOTNOTES FOR TABLE RH-1213.b.: ACCEPTABLE SURFACE CONTAMINATION LEVELS

- ¹ 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.
- ² 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.
- ³ 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.
- ⁴ The maximum contamination level applies to an area of not more than 100 cm².
- ⁵ 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 less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.
- ⁶ The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 mrad/hr at 1 cm and 1.0 mrad/hr at 1 cm, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.

PART D. PRECAUTIONARY PROCEDURES

RH-1300. Surveys.

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

RH-1301. Personnel Monitoring.

- a. All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees or registrants to comply with RH-1302.a, with other applicable provisions of these Regulations, or with conditions specified in a license must be processed and evaluated by a dosimetry processor:

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1. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology [formerly called National Bureau of Standards], and
2. Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

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

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

- a. Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:
 1. Adults likely to receive, in one (1) year from sources external to the body, a dose in excess of 10 percent of the limits in RH-1200.a;
 2. Minors and declared pregnant women likely to receive, in one (1) year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in RH-1206 or RH-1207; and
 3. Individuals entering a high or very high radiation area.
- b. Each licensee or registrant shall monitor (See RH-1203) the occupational intake of radioactive material by and assess the committed effective dose equivalent to:
 1. Adults likely to receive, in one (1) year, an intake in excess of 10 percent of the applicable ALI(s) in Table 1, Columns 1 and 2, of Appendix G to RH-1000 through RH-2110; and

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2. Minors and declared pregnant women likely to receive, in one (1) year, a committed effective dose equivalent in excess of 0.05 rem (0.5 mSv).

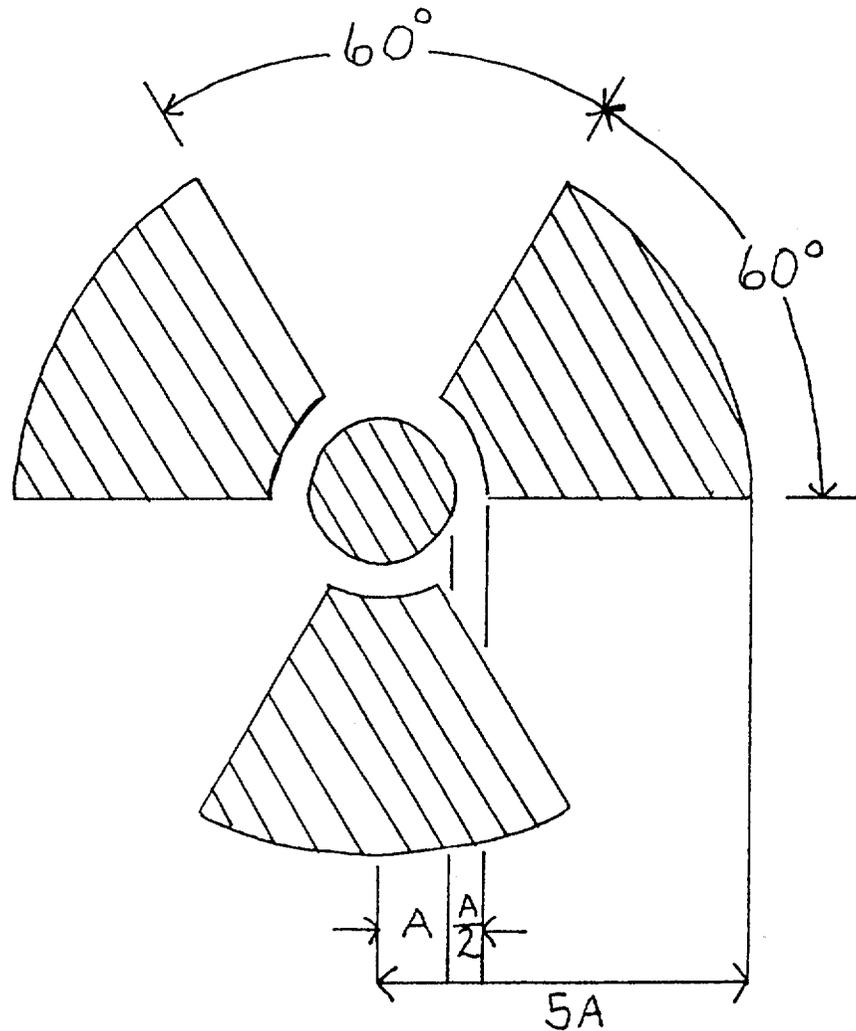
RH-1303. Caution Signs, Labels and Signals.

a. Symbol.

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

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STANDARD RADIATION SYMBOL



- b. Radiation areas. Each radiation area shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words:

CAUTION
RADIATION AREA

or

DANGER
RADIATION AREA

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4. A licensee or registrant may apply to the Department for approval of alternative methods for controlling access to high radiation areas.
5. The licensee or registrant shall establish the controls required by RH-1303.c.2 and RH-1303.c.4 of this Section in a way that does not prevent individuals from leaving a high radiation area.
6. Control is not required for each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the Department of Transportation provided that:
 - A. The packages do not remain in the area longer than three (3) days, and
 - B. The dose rate at one (1) meter from the external surface of any package does not exceed 0.01 rem (0.1 mSv) per hour.
7. Control of entrance or access to rooms or other areas in hospitals is not required solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who will take the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the limits established in this Part and to operate within the ALARA provisions of the licensee's radiation protection program.

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d. 1. Very high radiation areas.

In addition to the requirements in RH-1311, the licensee or registrant shall institute additional measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rads (5 grays) or more in one (1) hour at one (1) meter from a radiation source or any surface through which the radiation penetrates.

2. Posting of very high radiation areas.

The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words:

GRAVE DANGER, VERY HIGH RADIATION AREA

e. Very high radiation areas - irradiators.

1. Each area in which there may exist radiation levels in excess of 500 rads (5 grays) in one (1) hour at one (1) meter from a sealed radioactive source^{2/} that is used to irradiate materials must meet the following requirements.

A. Each entrance or access point must be equipped with entry control devices which:

i. Function automatically to prevent any individual from inadvertently entering the area when very high radiation levels exist;

ii. Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the sealed source, to be reduced below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (1 mSv) in one (1) hour; and

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

- ii. Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.
- D. When the shield for the stored source is a liquid, the licensee shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.
- E. Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of C and D of this Paragraph.
- F. Each area must be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source can be put into operation and in sufficient time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source from being put into operation.
- G. Each area must be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source.
- H. Each area must be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source, the radiation level from the source in the area is below that at

which it would be possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (1 mSv) in one (1) hour.

- I. The entry control devices required in RH-1303.e.1.A. must have been tested for proper functioning (See RH-1500 for recordkeeping requirements).
 - i. Testing must be conducted prior to initial operation with the source of radiation on any day (unless operations were continued uninterrupted from the previous day);
 - ii. Testing must be conducted prior to resumption of operation of the source of radiation after any unintended interruption; and
 - iii. The licensee shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.
- J. The licensee may not conduct operations, other than those necessary to place the source in safe condition or to effect repairs on controls, unless control devices are functioning properly.
- K. Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, must be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for processed materials must be equipped to detect and signal the presence of any loose radiation sources that are carried toward such an exit and to automatically prevent loose radiation sources from being carried out of the area.

2. Persons holding licenses or applicants for licenses for radiation sources that are within the purview of Part D of this Section and that will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of Part D of this Section, such as those for the automatic control of radiation levels, may apply to the Director, Division of Radiation Control and Emergency Management, for approval of the use of alternative safety measures. Any alternative safety measures must provide a degree of personnel protection at least equivalent to those specified in Part D of this Section. At least one of the alternative measures must include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such radiation sources are used.
3. The entry control devices required by RH-1303.e.1.A. and B. of this Section must be established in such a way that no individual will be prevented from leaving the area.

f. Airborne radioactivity area.

1. As used in these Regulations, "airborne radioactivity area" means:
 - A. Any room, enclosure or operating area in which airborne radioactive materials exist in concentrations in excess of the amounts specified in RH-2200, Appendix A, Table 1, Column 1; or
 - B. Any room, enclosure or operating area in which airborne radioactive material exists in concentrations which, averaged over the number of hours in any week during which individuals are in the area, exceed 25 percent of the amounts specified in RH-2200, Appendix A, Table 1, Column 1.

- i. The licensee shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health/Mine Safety and Health Administration (NIOSH/MSHA).
- ii. If the licensee wishes to use equipment that has not been tested or certified by NIOSH/MSHA, has not had certification extended by NIOSH/MSHA, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.
- iii. The licensee shall implement and maintain a respiratory protection program that includes:
 - (a). Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures;
 - (b). Surveys and bioassays, as appropriate, to evaluate actual intakes;
 - (c). Testing of respirators for operability immediately prior to each use;

- (d). Written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and recordkeeping; and
 - (e). Determination by a physician prior to initial fitting of respirators, and at least every 12 (twelve) months thereafter or periodically at a frequency determined by a physician, that the individual user is medically fit to use the respiratory protection equipment.
- iv. The licensee shall issue a written policy statement on respirator usage covering:
- (a). The use of process or other engineering controls, instead of respirators;
 - (b). The routine, nonroutine, and emergency use of respirators; and
 - (c). The periods of respirator use and relief from respirator use.
- v. The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

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- vi. The licensee shall use equipment within limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities (such as adequate skin protection) when needed.
- B. In estimating exposure of individuals to airborne radioactive materials, the licensee may make allowance for respiratory protection equipment used to limit intakes pursuant to RH-1303.f.4., provided that the following conditions, in addition to those in RH-1303.f.5.A. are satisfied:
- i. The licensee selects respiratory protection equipment that provides a protection factor (See Appendix E to RH-1000 through RH-2110) greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix G to RH-1000 through RH-2110, Table 1, Column 3. If the selection of a respiratory protection device with a protection factor greater than the peak concentration is inconsistent with the goal specified in RH-1303.f.4. of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower protection factor only if such a selection would result in keeping the total effective dose equivalent ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each

period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than estimated, the corrected value must be used; if the exposure is later found to be less than estimated, the corrected value may be used.

ii. The licensee shall obtain authorization from the Department before assigning respiratory protection factors in excess of those specified in Appendix E to RH-1000 through RH-2110. The Department may authorize a licensee to use higher protection factors on receipt of an application that:

(a). Describes the situation for which a need exists for higher protection factors; and

(b). Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

C. The licensee shall use as emergency devices only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by NIOSH/MSHA.

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

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

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

- A. Ensure that the respiratory protection program of the licensee is adequate to limit exposures of individuals to airborne radioactive materials; and
 - B. Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.
- g. Additional requirements.

1. Each area or room in which any radioactive material, other than natural uranium or thorium, is used or stored in an amount exceeding ten (10) times the quantity of radioactive material specified in RH-2300, Appendix B, shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words:

CAUTION	or	DANGER
RADIOACTIVE MATERIAL		RADIOACTIVE MATERIAL

2. Each area or room in which natural uranium or thorium is used or stored in an amount exceeding 100 times the quantity specified in RH-2300, Appendix B, shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words:

CAUTION	or	DANGER
RADIOACTIVE MATERIAL		RADIOACTIVE MATERIAL

- C. For containers that do not contain radioactive materials in concentrations greater than the applicable concentrations listed in Column 2, Table I, RH-2200, Appendix A, of this Part;
 - D. For containers when they are attended by an individual who takes the precautions necessary to prevent the exposure of any individual to radiation or radioactive materials in excess of the limits established by these Regulations in this Part;
 - E. For containers when they are in transport and packaged and labeled in accordance with regulations published by the Department of Transportation^{4/};
 - F. For containers which are accessible^{5/} only to individuals authorized to handle or use them or to work in the vicinity thereof, provided that the contents are identified to such individuals by a readily available written record; and
 - G. For manufacturing and process equipment such as piping and tanks.
- i. Each licensee shall, prior to disposal of an empty uncontaminated container to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive material.
 - j. All devices and equipment capable of producing radiation when operated shall be appropriately labeled so as to caution individuals that such devices or equipment produce radiation when operated.

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

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

- a. A room or area is not required to be posted with a caution sign because of the presence of a sealed source, provided the radiation level 12 inches from the surface of the source container or housing does not exceed 5 (five) millirems per hour.
- b. Rooms or other areas in hospitals are not required to be posted with caution signs and control of entrance or access thereto pursuant to RH-1303 is not required, because of the presence of patients containing radioactive material provided that there are personnel in attendance who will take the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established in these Regulations in this Part.
- c. Caution signs are not required to be posted in areas or rooms containing radioactive materials for periods of less than eight (8) hours provided that:
 - 1. The materials are constantly attended during such periods by an individual who shall take the precautions necessary to prevent the exposure of any individual to radiation or radioactive materials in excess of the limits established in this Part; and
 - 2. Such area or room is subject to the licensee's control.

- d. A room or other area is not required to be posted with a caution sign and control is not required for each entrance or access point to a room or other area which is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with regulations of the Department of Transportation.

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

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

RH-1306. Storage of Sources of Radiation.

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

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

- a. As used in these Regulations, Special Form means any of the following physical forms of licensed material:
 - 1. The material is in solid form having no dimension less than 0.5 millimeter or at least one dimension greater than 5 (five) millimeters; does not melt, sublime or ignite in air at a temperature of 1,000°F. (538°C), will not shatter or crumble if subjected to the percussion test described in Appendix B of this Part; and is not dissolved or converted into dispersible form to the extent of more than 0.005 percent by weight by immersion for one week in water at 68°F. (20°C) or in air at 86°F. (30°C); or
 - 2. The material is securely contained in a capsule having no dimension less than 0.5 millimeter or at least one dimension greater than 5 (five) millimeters, which will retain its contents if subjected to the tests prescribed in Appendix B of this Part; and which is constructed of materials

which do not melt, sublime or ignite in air at 1,475°F (802°C), and do not dissolve or convert into dispersible form to the extent of more than 0.005 percent by weight by immersion for one week in water at 68°F (20°C) or in air at 86°F (30°C).

- b. Procedures for picking up, receiving and opening packages. Each licensee who expects to receive a package containing quantities of radioactive material in excess of a "Type A" quantity specified in or determined by procedures described in Appendix C of this Section, shall make arrangements:
1. To receive the package when the carrier offers it for delivery; or
 2. To receive notification of the arrival of the package at the carrier's terminal and to pick up the package when the carrier offers it for delivery.
- c. Each licensee shall:
1. Monitor the external surfaces of a labeled* package for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as described in RH-3100.
 2. Monitor the external surfaces of a labeled* package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity as defined RH-3100 and RH-2700; and
 3. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

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

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- d. The licensee shall perform the monitoring required by RH-1307.c of this Section as soon as practical after receipt of the package, but not later than three (3) hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than three (3) hours from the beginning of the next working day if it is received after working hours.
- e. The licensee shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram or facsimile, the Department, if packages, other than those transported by exclusive use vehicle, are found to have:
 - 1. Removable radioactive contamination in excess of 0.001 microcurie per 100 square centimeters on the external surfaces of the package; or
 - 2. Radiation levels at the external surface of the package in excess of 200 mRem/hr or at one (1) meter from the external surface of the package in excess of 10 mRem/hr.
- f. Each licensee or registrant shall establish and maintain procedures for safely opening packages in which radioactive material is received and shall assure that such procedures are followed and that due consideration is given to special instructions for the type of package being opened.
- g. Licensees transferring special form sources in licensee-owned or licensee-operated vehicles to and from a work site are exempt from the contamination monitoring requirements of RH-1307.c of this Section, but are not exempt from the survey requirement in RH-1307.c of this Section for measuring radiation levels that is required to ensure that the source is still properly lodged in its shield.

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RH-1308. Control of Material Not in Storage.

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

PART E. WASTE DISPOSAL

RH-1400 General Requirements.

A licensee shall dispose of licensed material only:

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

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

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

- a. A description of the waste containing licensed material to be disposed of, including the physical and chemical properties important to risk evaluation, and the proposed manner and conditions of waste disposal;
- b. An analysis and evaluation of pertinent information on the nature of the environment;

- c. The nature and location of other potentially affected licensed and unlicensed facilities; and
- d. Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in this Part.

RH-1402 Disposal by Release Into Sanitary Sewerage.

- a. A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:
 - 1. The material is readily soluble (or is readily dispersible biological material) in water;
 - 2. The quantity of licensed or other radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table 3 of Appendix G to RH-1000 through RH-2101; and
 - 3. If more than one radionuclide is released, the following conditions must also be satisfied:
 - i. The licensee shall determine the fraction of the limit in Table 3 of Appendix G to RH-1000 through RH-2101 represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table 3 of Appendix G to RH-1000 through RH-2101; and
 - ii. The sum of the fractions for each radionuclide required by Paragraph a.3.i. of this Section does not exceed unity; and
 - 4. The total quantity of licensed and other radioactive material that the licensee releases into the sanitary sewerage system in a year does

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not exceed five (5) curies (185 GBq) of Hydrogen-3, one (1) curie (37 GBq) of Carbon-14, and one (1) curie (37 GBq) of all other radioactive materials combined.

- b. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material is not subject to the limitations contained in Paragraph a of this Section.

RH-1403. Disposal by Burial in Soil.

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

RH-1404. Treatment or Disposal by Incineration.

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

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RH-1405. Disposal of Specific Wastes.

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

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RH-1406. Transfer for Disposal and Manifests.

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

- a.
 1. The requirements of this Section and Appendix F and Appendix G to 10 CFR Part 20 are designed to:
 - i. Control transfers of low-level radioactive waste (LLW) by any waste generator, waste collector, or waste processor licensee, as defined in this Part, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility as defined in Section 2 of these Regulations;
 - ii. Establish a manifest tracking system; and
 - iii. Supplement existing requirements concerning transfers and recordkeeping for those wastes.
 2. Beginning March 1, 1998, all affected licensees must use Appendix G to 10 CFR Part 20. Prior to March 1, 1998, a LLW disposal facility operator or its regulatory authority may require the shipper to use Appendix F or Appendix G to 10 CFR Part 20. Licensees using Appendix F to 10 CFR Part 20 shall comply with RH-1406.b.1 of this Section. Licensees using Appendix G to 10 CFR Part 20 shall comply with RH-1406.b.2 of this Section.
- b.
 1. Each shipment of radioactive waste intended for disposal at a licensed land disposal facility must be accompanied by a shipment manifest in accordance with Section 1 of Appendix F to 10 CFR Part 20.
 2. Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G to 10 CFR Part 20.

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- c. Each shipment manifest must include a certification by the waste generator as specified in Section II of Appendix F or Appendix G to 10 CFR Part 20, as appropriate. See RH-1406.a.2 of this Section to determine the appropriate Appendix.
- d. Each person involved in the transfer for disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix F or Appendix G to 10 CFR Part 20, as appropriate. See RH-1406.a.2 of this Section to determine the appropriate appendix.

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

Nothing in this Subpart relieves the licensee from complying with other applicable Federal, State, and local regulations governing any other toxic or hazardous properties of materials that may be disposed of under this Part E.

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PART F. RECORDS, REPORTS, NOTIFICATIONS, AND TESTS

RH-1500. a. General provisions.

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

b. Records of radiation protection programs.

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

c. Records of surveys.

1. Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by RH-1300 and RH-1307. The licensee or registrant shall retain these records for three (3) years after the record is made.

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2. The licensee or registrant shall retain each of the following records until the Department terminates each pertinent license or registration requiring the record:
 - A. Records of the results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents;
 - B. Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose;
 - C. Records showing the results of air sampling, surveys, and bioassays required pursuant to RH-1303.f.5.A.iii; and
 - D. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

d. Determination of prior occupational dose.

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

- B. All doses in excess of the limits (including doses received during accidents and emergencies) received during the lifetime of the individual.
3. In complying with the requirements of RH-1500.d.1 of this Section, a licensee or registrant may:
- A. Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual may have received during the current year;
 - B. Accept, as the record of lifetime cumulative radiation dose, an up-to-date Department Form Z, or equivalent, signed by the individual and counter-signed by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee); and
 - C. Obtain reports of the individual's dose equivalent(s) from the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee or registrant) by telephone, telegram, electronic media, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

4. The licensee or registrant shall record the exposure history, as required by RH-1500.d.1 of this Section, on Department Form Z, or other clear and legible record, of all the information required on that form.^{6/} The form or record must show each period in which the individual received occupational exposure to radiation or radioactive material and must be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing Department Form Z. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on Department Form Z indicating the periods of time for which data are not available.
5. If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:
 - A. In establishing administrative controls under RH-1200.f for the current year, that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and
 - B. That the individual is not available for planned special exposures.
6. The licensee or registrant shall retain the records on Department Form Z or equivalent until the Department terminates each pertinent license requiring this record. The licensee or registrant shall retain records used in preparing Department Form Z for three (3) years after the record is made.

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e. Records of planned special exposures.

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

f. Records of individual monitoring results.

1. Recordkeeping requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to RH-1302, and records of doses received during planned special exposures, accidents, and emergency conditions. These records²⁷ must include, when applicable:
 - A. The deep-dose equivalent to the whole body, eye dose equivalent, shallow-dose equivalent to the skin, and shallow-dose equivalent to the extremities;
 - B. The estimated intake or body burden of radionuclides (See RH-1201);

- C. The committed effective dose equivalent assigned to the intake or body burden of radionuclides;
 - D. The specific information used to calculate the committed effective dose equivalent pursuant to RH-1203.c;
 - E. The total effective dose equivalent when required by RH-1202; and
 - F. The total of the deep-dose equivalent and the committed dose to the organ receiving the highest total dose.
2. Recordkeeping frequency. The licensee or registrant shall make entries of the records specified in RH-1500.f.1 of this Section at least annually.
 3. Recordkeeping format. The licensee or registrant shall maintain the records specified in RH-1500.f.1 of this Section on Department Form Y, in accordance with the instructions for Department Form Y, or in clear and legible records containing all the information required by that form.
 4. Privacy protection. The records required under this Section should be protected from public disclosure because of their personal privacy nature.
 5. The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy shall also be kept on file, but may be maintained separately from the dose records.
 6. The licensee or registrant shall retain each required form or record until the Department terminates each pertinent license or registration requiring the record.

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g. Records of dose to individual members of the public.

1. Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public (See RH-1208).
2. The licensee or registrant shall retain the records required by RH-1500.g.1 of this Section until the Department terminates each pertinent license or registration requiring the record.

h. Records of waste disposal.

1. Each licensee or registrant shall maintain records of the disposal of licensed materials made under RH-1401, RH-1402, RH-1403, RH-1404, RH-1405, and disposal by burial in soil, including burials authorized before January 28, 1981.^g
2. The licensee or registrant shall retain the records required by RH-1500.h.1 of this Section until the Department terminates each pertinent license requiring the record.

i. Records of testing entry control devices for very high radiation areas.

1. Each licensee or registrant shall maintain records of tests made under RH-1303.e.1.I on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.
2. The licensee or registrant shall retain the records required by RH-1500.i.1 of this Section for three years after the record is made.

j. Form of records.

Each record required by this Part must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform

provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

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

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

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

B. Within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than ten (10) times the quantity specified in Appendix G to RH-1000 through RH-2110 that is still missing at this time.

2. Reports must be made as follows:

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

d. Written reports.

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

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

2. Reports must be made as follows:

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

RH-1502. Notification of Incidents.

- a. Immediate notification. Each licensee or registrant shall immediately notify the Division of Radiation Control and Emergency Management, Arkansas Department of Health, 4815 West Markham, Mail Slot 30, Little Rock, Arkansas 72205-3867, by telephone and confirming letter of any incident involving any source of radiation possessed by the licensee or registrant and which may have caused or threatens to cause:
 - 1. An individual to receive:
 - A. A total effective dose equivalent of 25 rems (0.25 Sv) or more; or

- B. An eye dose equivalent of 75 rems (0.75 Sv) or more; or
 - C. A shallow-dose equivalent to the skin or extremities of 250 rads (2.5 Gy) or more; or
2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 (twenty-four) hours, the individual could have received an intake five (5) times the occupational annual limit on intake (The provisions of this Paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.).
- b. Twenty-four hour notification. Each licensee or registrant shall within twenty-four (24) hours notify the Division of Radiation Control and Emergency Management, Arkansas Department of Health, 4815 West Markham, Mail Slot 30, Little Rock, Arkansas 72205-3867, by telephone and confirming letter of any incident involving any source of radiation possessed by the licensee or registrant and which may have caused or threatens to cause:
- 1. An individual to receive, in a period of 24 hours:
 - A. A total effective dose equivalent exceeding 5 rems (0.05 Sv); or
 - B. An eye dose equivalent exceeding 15 rems (0.15 Sv); or
 - C. A shallow-dose equivalent to the skin or extremities exceeding 50 rems (0.5 Sv); or

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

- B. Involves a quantity of material greater than five (5) times the lowest annual limit on intake specified in Appendix G to RH-1000 through RH-2110 for the material; and
 - C. Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 (twenty-four) hours to decay prior to decontamination.
2. An event in which equipment is disabled or fails to function as designed when:
- A. The equipment is required by regulation or licensee condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;
 - B. The equipment is required to be available and operable when it is disabled or fails to function; and
 - C. No redundant equipment is available and operable to perform the required safety function.
3. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.
4. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:
- A. The quantity of material involved is greater than five (5) times the lowest annual limit on intake specified in Appendix G of RH-1000 through RH-2110 of these Regulations for the material; and
 - B. The damage affects the integrity of the licensed material or its container.

- g. Preparation and submission of reports. Reports made by licensees or registrants in response to the requirements of this Section must be made as follows:
1. Licensees or registrants shall make reports required by RH-1502.a and RH-1502.b by telephone to the Department at 1-800-633-1735. To the extent that the information is available at the time of notification, the information provided in these reports must include:
 - A. The caller's name and call back telephone number;
 - B. A description of the event, including date and time;
 - C. The exact location of the event;
 - D. The isotopes, quantities, and chemical and physical form of the licensed material involved; and
 - E. Any personnel radiation exposure data available.
 2. Written report. Each licensee or registrant who makes a report required by RH-1502.a and RH-1502.b of this Section shall submit a written follow-up report within 30 (thirty) days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the Division of Radiation Control and Emergency Management; Arkansas Department of Health; 4815 West Markham Street, Mail Slot #30; Little Rock, Arkansas 72205-3867. The reports must include the following:
 - A. A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

- B. The exact location of the event;
- C. The isotopes, quantities and chemical and physical form of the licensed material involved;
- D. Date and time of the event;
- E. Corrective actions taken or planned and the results of any evaluations or assessments; and
- F. The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

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

- a. Sources of radiation;
- b. Facilities wherein sources of radiation are used or stored;
- c. Radiation detection and monitoring instruments; and
- d. Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

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

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

b. Contents of reports.

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

RH-1505. Notifications and Reports to Individuals.

- a. Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in Part N of this Section.

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

RH-1506. Vacating Premises.

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

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RH-1507. Records and Reports of Misadministrations.

- a. The licensee or registrant shall notify the Department by telephone and shall also notify the referring physician of the affected patient and the patient or a responsible relative (or guardian), unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee or registrant discovers the misadministration. If the referring physician, patient, or the patient's responsible relative (or guardian) cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or patient's responsible relative or guardian without first consulting the referring physician; however, the licensee or registrant shall not delay medical care for the patient because of this.
- b. Within 15 days after an initial misadministration report to the Department, the licensee or registrant shall report, in writing, to the Department and to the referring physician, and furnish a copy of the report to the patient or the patient's responsible relative (or guardian) if either was previously notified by the licensee or registrant under RH-1507.a. The written report must include the licensee's or registrant's name, the referring physician's name, a brief description of the event, the effect on the patient, the action taken to prevent recurrence, whether the licensee or registrant informed the patient or the patient's responsible relative (or guardian), and if not, why not. The report must not include the patient's name or other information that could lead to identification of the patient.
- c. Each licensee or registrant shall retain a record of each misadministration for ten years. The record must contain the names of all individuals involved in the event (including the physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event, the effect on the patient, and the action taken, if any, to prevent recurrence.

- d. Aside from the notification requirement, nothing in this Section affects any rights or duties of licensees or registrant and physicians in relation to each other, patients, or responsible relatives (or guardian).
- e. For a medical use misadministration:
 1. The licensee or registrant shall notify the Department by telephone no later than the next calendar day after the discovery of the misadministration.
 2. The licensee or registrant shall submit a written report to the Department within 15 days after the discovery of the misadministration. The written report must include the licensee's or registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee or registrant notified the patient, or the patient's responsible relative or guardian (This person will be subsequently referred to as "the patient" in this Section.), and if not, why not; and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient.
 3. The licensee or registrant shall notify the referring physician and also notify the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he/she will inform the patient or that, based on medical judgment, telling the patient would be harmful. The licensee or registrant is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the licensee or registrant shall notify the patient as soon as possible thereafter. The licensee or registrant may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

4. If the patient was notified, the licensee or registrant shall also furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either:
 - A. A copy of the report that was submitted to the Department; or
 - B. A brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the Department can be obtained from the licensee or registrant.
- f. Each licensee or registrant shall retain a record of each misadministration for five (5) years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient, what improvements are needed to prevent reoccurrence, and the actions taken to prevent reoccurrence.
- g. Aside from the notification requirement, nothing in this Section affects any rights or duties of licensees or registrants and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.

RH-1508. Deleted.

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RH-1509. Reports of Individual Monitoring.

- a. This Section applies to each person licensed by the Department to:
1. Possess or use radioactive material for purposes of radiography pursuant to Part I of these Regulations; or
 2. Possess or use at any time, for processing or manufacturing for distribution pursuant to Section 2 of these Regulations, radioactive material in quantities exceeding any one of the following quantities:

TABLE RH-1509.a.2.

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

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

- b. Each licensee in a category listed in RH-1509.a shall complete an annual report of the results of individual monitoring carried out by the licensee for each

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individual for whom monitoring was required by RH-1302 during that year. The licensee may include additional data for individuals for whom monitoring was provided but not required. The licensee shall use Department Form Y or electronic media containing all the information required by Department Form Y.

- c. The licensee shall complete the report required by RH-1509.b, covering the preceding year, on or before May 31 of each year. The licensee shall retain the report and submit it if requested to the Director, Division of Radiation Control and Emergency Management, Arkansas Department of Health, 4815 West Markham, Mail Slot 30, Little Rock, Arkansas 72205-3867.

RH-1510. Quality Management Program

- a. Each applicant or licensee under this Part, as applicable, shall establish and maintain a written quality management program to provide high confidence that radioactive material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific objectives:
 1. That, prior to administration, a written directive^{10/} is prepared for:
 - A. Any teletherapy radiation dose;
 - B. Any gamma stereotactic radiosurgery radiation dose;
 - C. Any brachytherapy radiation dose;
 - D. Any administration of quantities greater than 30 microcuries of either Sodium Iodine I-125 or I-131;
 - E. Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131; and
 - F. Any medical particle accelerators dose.

2. That, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;
3. That final plans of treatment and related calculations for brachytherapy, teletherapy, particle accelerator therapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;
4. That each administration is in accordance with the written directive; and
5. That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

b. The licensee shall:

1. Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:
 - A. A representative sample of patient and human research subject administrations;
 - B. All recordable events; and
 - C. All misadministrationsto verify compliance with all aspects of the quality management program. These reviews shall be conducted at intervals no greater than 12 (twelve) months;
2. Evaluate each of these reviews to determine the effectiveness of the quality management program, and if required, make modifications to meet the objectives of RH-1510.a; and
3. Retain records of each review, including the evaluations and findings of the review, in an auditable form for three (3) years.

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- c. The licensee shall evaluate and respond, within 30 days after discovery of the recordable event by:
 - 1. Assembling the relevant facts including the cause;
 - 2. Identifying what, if any, corrective action is required to prevent recurrence; and
 - 3. Retaining a record, in an auditable form, for three (3) years, of the relevant facts and what corrective action, if any, was taken.

- d. The licensee shall retain:
 - 1. Each written directive; and
 - 2. A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in RH-1510.a.1 above, in an auditable form, for three (3) years after the date of administration.

- e. The licensee may make modifications to the quality management program to increase the program's efficiency provided the programs effectiveness is not decreased. The licensee shall furnish the modification to the Department within 30 days after the modification has been made.

- f.
 - 1. Each applicant for a new license, as applicable, shall submit to the Department in accordance with RH-1510 a quality management program as part of the application for a license and implement the program upon issuance of the license by the Department.
 - 2. Each existing licensee as applicable, shall submit to the Department, in accordance with RH-1510, by January 1, 1994 a written certification that the quality management program has been implemented along with a copy of the program.

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RH-1511 Deliberate Misconduct

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

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

RH-1600. Scope.

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

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

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

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

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

where:

- s = Estimated standard deviation of the population.
 - \bar{x} = Mean value of observations in sample.
 - x_i = i^{th} observation in sample.
 - n = Number of observations in sample.
- q. Contact therapy system - An x-ray system used for therapy with the x-ray tube port placed in contact with or within 5 centimeters of the surface being treated.

- r. Control panel - That part of the x-ray control upon which are mounted the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors.
- s. Cooling curve - The graphical relationship between heat units stored and cooling time.
- t. Dead-man switch - A switch constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.
- u. Detector - See "Radiation detector".
- v. Diagnostic source assembly - The tube housing assembly with a beam-limiting device attached.
- w. Diagnostic x-ray system - An x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.
- x. Direct scattered radiation - The scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").
- y. Entrance exposure - The roentgens per unit time at the point where the center of the useful beam enters the patient.
- z. Equipment - See "X-ray equipment".
- aa. Exposure - The quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air. (The special unit of exposure is the roentgen [R]).
- ab. Field emission equipment - Equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.
- ac. Filter - Material placed in the useful beam to absorb preferentially selected radiations.
- ad. Fluoroscopic imaging assembly - A subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and

spot-film device, electrical interlocks, if any and structural material providing linkage between the image receptor and diagnostic source assembly.

- ae. Focal spot - The area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.
- af. Full beam detector - A radiation detector of such size that the total cross section of the maximum size useful beam is intercepted.
- ag. General purpose radiographic x-ray system - Any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.
- ah. Gonad shield - A protective barrier for the testes or ovaries.
- ai. Half-value layer - The thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.
- aj. Healing arts screening - The testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.
- ak. Heat unit - A unit of energy equal to the product of the peak kilovoltage, milliamperes and seconds, i.e., kVp x mA x second.
- al. HVL - See "Half-value layer".
- am. Image intensifier - A device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.
- an. Image receptor - Any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

- ao. Image receptor support - For mammographic systems, that part of the system designed to support the image receptor in a horizontal plane during a mammographic examination.
- ap. Inherent filtration - The filtration of the useful beam provided by the permanently installed components of the tube housing assembly.
- aq. Interlock - A device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.
- ar. Irradiation - The exposure of matter to ionizing radiation.
- as. Kilovolts peak - See "Peak tube potential".
- at. kV - Kilovolts.
- au. kVp - See "Peak tube potential".
- av. kWs - Kilowatt second. It is equivalent to 10^3 kV·mA·sec, i.e.,

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

- aw. Lead equivalent - The thickness of lead affording the same attenuation, under specified conditions, as the material in question.
- ax. Leakage radiation - Radiation emanating from the diagnostic or therapeutic source assembly except for:
 - 1. the useful beam, and
 - 2. radiation produced when the exposure switch or timer is not activated.
- ay. Leakage technique factors - The technique factors associated with the tube housing assembly which are used in measuring leakage radiation. They are defined as follows:
 - 1. For capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 mill coulombs, i.e., 10 milliamperere seconds or the

minimum obtainable from the unit, whichever is larger.

2. For field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.
 3. For all other equipment, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.
- az. Light field - That area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.
- ba. Line-voltage regulation - The difference between the no-load and the load line potentials expressed as a percentage of the load line potential. It is calculated using the following equation:
- Percent line-voltage regulation - $100(V_n - V_l) / V_l$
- where
- V_n = No-load line potential and
 V_l = Load line potential.
- bb. mA - Milliampere.
- bc. mAs - Milliampere second.
- bd. Maximum line current - The root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.
- be. Mobile equipment - See "X-ray equipment".
- bf. Patient - An individual subjected to healing arts examination, diagnosis or treatment.
- bg. Peak tube potential - The maximum value of the potential difference across the x-ray tube during an exposure.

- bh. Phantom - A volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.
- bi. Phototimer - A method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (See "Automatic exposure control").
- bj. PID - See "Position indicating device".
- bk. Position indicating device - A device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.
- bl. Primary dose monitoring system - A system which will monitor the useful beam during irradiation and which will terminate irradiation when pre-selected number of dose monitor units have been acquired.
- bm. Primary protective barrier - See "Protective barrier".
- bn. Protective apron - An apron made of radiation attenuating materials used to reduce radiation exposure.
- bo. Protective barrier - A barrier of radiation attenuating material(s) used to reduce radiation exposure. The types of protective barriers are as follows:
 - 1. Primary protective barrier - The material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.
 - 2. Secondary protective barrier - A barrier sufficient to attenuate the stray radiation to the required degree.
- bp. Protective glove - A glove made of radiation attenuating materials used to reduce radiation exposure.
- bq. Qualified expert - An individual who has demonstrated to the satisfaction of the Department that such individual possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques and to advise regarding radiation protection needs.

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

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

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- cn. Traceable to a national standard - A quantity or a measurement that has been compared to a NIST* (National Institute of Standards and Technology) standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.
- co. Therapeutic-type housing -
 - 1. For x-ray therapy equipment not capable of operating at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that the leakage radiation averaged over any 100 cm² area at a distance of one meter from the source does not exceed one roentgen in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential.
 - 2. For x-ray therapy equipment capable of operation at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that leakage radiation averaged over any 100 cm² area at a distance of one meter from the source does not exceed 0.1 percent of the useful beam dose rate at one meter from the source for any of its operating conditions.
- cp. Therapeutic x-ray and/or electron system - A system designed for irradiation of any part of the human body for the purpose of treatment or alleviation of symptoms of disease.
- cq. Tube - An x-ray tube, unless otherwise specified.
- cr. Tube housing assembly - The tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.
- cs. Tube rating chart - The set of curves which specify the rated limits of operation of the tube in terms of the technique factors.
- ct. Useful beam - The radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.
- cu. Variable-aperture beam-limiting device - A beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a give SID.

*formerly NBS (National Bureau of Standards)

- cv. Visible area - That portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.
- cw. Wedge filter - An added filter effecting continuous progressive attenuation on all or part of the useful beam.
- cx. X-ray control - A device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers and similar devices, which control the technique factors of an x-ray exposure.
- cy. X-ray equipment - An x-ray system, subsystem or component thereof. Types of x-ray equipment are as follows:
 - 1. Mobile x-ray equipment: X-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.
 - 2. Portable x-ray equipment: X-ray equipment designed to be hand-carried.
 - 3. Stationary x-ray equipment: X-ray equipment which is installed in a fixed location.
- cz. X-ray field - The area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.
- da. X-ray high-voltage generator - A device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices and other appropriate elements.
- db. X-ray system - An assemblage of components for the controlled production of x-rays. It includes an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

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- dc. X-ray subsystem - Any combination of two or more components of an x-ray system.
- dd. X-ray tube - Any electron tube which is designed to be used primarily for the production of x-rays.

RH-1602. General Requirements.

- a. Administrative Controls. Registrant. The registrant shall be responsible for directing the operation of the x-ray systems which have been registered with the Department. The registrant or the registrant's agent shall assure that the requirements of RH-1602.a are met in the operation of the x-ray system(s).
 - 1. An x-ray system which does not meet the provisions of these Regulations shall not be operated for diagnostic or therapeutic purposes.
 - 2. Individuals who will be operating the x-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment.
 - 3. A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel which specifies, for all examinations performed with that system, the following information:
 - A. patient's anatomical size versus technique factors to be utilized;
 - B. type and size of the film or film-screen combination to be used;
 - C. type and focal distance of the grid to be used, if any;
 - D. source to image receptor distance to be used; and
 - E. type and location of placement of gonad shielding to be used.
 - 4. Written safety procedures and rules shall be provided to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these rules.

5. Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:
 - A. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.
 - B. Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.
 - C. Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.
6. For patients who have not passed the reproductive age, gonad shielding of not less than 0.25 millimeter lead equivalent shall be used during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.
7. Individuals shall not be exposed to the useful beam except for healing arts purposes and such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:
 - A. Exposure of an individual for training, demonstration or other non-healing-arts purposes; and
 - B. Exposure of an individual for the purpose of healing arts screening except as authorized by RH-1602.a.9.

8. When a patient or film must be provided with auxiliary support during a radiation exposure:
 - A. Mechanical holding devices shall be used when the technique permits.
 - B. If a human holder must be utilized:
 - i. Written safety procedures, as required by RH-1602.a.4 shall indicate the requirements for selecting a holder and the procedure the holder shall follow;
 - ii. The human holder shall be protected as required by RH-1602.a.5;
 - iii. No individual shall be used routinely to hold film or patients;
 - iv. Such holding shall be permitted only in very unusual and rare situations;
 - v. In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body, other than the area of clinical interest, struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material; and
9. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. This is interpreted to include but not limited to:
 - A. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.
 - B. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.
 - C. Portable or mobile equipment shall be used only for examinations where it is impractical

- to transfer the patient(s) to a stationary radiographic installation.
- D. X-ray systems subject to RH-1604 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.
10. All individuals who are associated with the operation of an x-ray system are subject to the requirements of RH-1200.
- A. When protective clothing or devices are worn on portions of the body and a monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:
- i. When an apron is worn, the monitoring device shall be worn at the collar outside of the apron.
 - ii. The dose to the whole body based on the maximum dose attributed to the most critical organ shall be recorded in the reports required by Part F of these Regulations. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.
- B. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.
11. Health arts screening. Any person proposing to conduct a health arts screening program shall not initiate such a program without prior approval of the Department. When requesting such approval, that person shall submit the information as deemed necessary by the Department. If any information submitted to the Department becomes invalid or outdated, the Department will be notified in writing within thirty (30) days.
12. Information and maintenance record and associated information. The registrant shall maintain the following information for each x-ray system for inspection by the Department:

- A. Maximum rating of technique factors;
 - B. Model and serial numbers of all certifiable components;
 - C. Aluminum equivalent filtration of the useful beam, including any routine variation;
 - D. Tube rating charts and cooling curves;
 - E. Records of surveys, calibrations, maintenance and modifications performed on the X-ray system(s) after July 1, 1983 with the names of persons who performed such services;
 - F. A scale drawing of the room in which a stationary x-ray system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:
 - i. The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or
 - ii. The type and thickness of materials or lead equivalency, of each protective barrier; and
 - G. A copy of all correspondence with the Department regarding that x-ray system.
13. X-ray log. Each facility shall maintain an x-ray log containing the patient I.D., the type of examinations and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.
- b. General Requirements for All Diagnostic X-Ray Systems. In addition to other requirements of this Part, all diagnostic x-ray systems shall meet the following requirements:

1. Warning label. The control panel containing the main power switch shall bear the warning statement or its equivalent, legible and accessible to view: **"WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."**
2. Battery charge indicator. On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.
3. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one (1) meter in any direction from the source shall not exceed 100 milliroentgens in one (1) hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
4. Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens in one (1) hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
5. Beam quality.
 - A. Half-value layer.
 - i. The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I

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

- ii. The requirements of RH-1602.b.5.A.1 will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table II.

TABLE II

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

- iii. Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.
 - iv. For capacitor energy storage equipment, compliance with the requirements of RH-1602.b.5 shall be determined with the maximum quantity of charge per exposure.
 - v. The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.
- B. Filtration controls. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by RH-1602.b.5.A.i or ii is in the useful beam for the given kVp which has been selected.
6. Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.
7. Mechanical support of tube head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

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

- a. Limitation of Useful Beam.
 - 1. Primary barrier.
 - A. The fluoroscopic imaging assembly shall be provided with a primary protective barrier

which intercepts the entire cross section of the useful beam at any SID.

- B. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

2. X-ray field.

- A. The x-ray field produced by non-image intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size for both fluoroscopic procedures and spot filming procedures. In addition:

- i. Means shall be provided for stepless adjustment of the field size;
- ii. The minimum field size at the greatest SID shall be equal to or less than five centimeters by five centimeters; and
- iii. For equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

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

- B. For image-intensified fluoroscopic equipment, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent of the SID. The sum of the excess length and the excess width shall be no greater than four percent of the SID. This requirement applies to field size for both fluoroscopic and spot filming procedures. In addition:

- i. Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979 and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;
 - ii. The minimum field size at the greatest SID shall be equal to or less than five centimeters by five centimeters;
 - iii. All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of five by five centimeters or less;
 - iv. For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; and
 - v. Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular x-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.
- C. Spot-film devices which are certified components shall meet the following additional requirements:

- i. Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;
 - ii. It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to or less than, five centimeters by five centimeters;
 - iii. The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent of the SID; and
 - iv. For spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance with RH-1603.a.2.A and B shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.
- b. Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording

serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

c. Exposure Rate Limits.

1. Entrance exposure rate allowable limits.

- A. The exposure measured at the point where the center of the useful beam enters the patient shall not exceed 10 roentgens per minute, except during recording of fluoroscopic images or when provided with optional high level control.
- B. When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient unless the high level control is activated.
 - i. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator.
 - ii. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.
- C. In addition to the other requirements of RH-1603, certified equipment which does not incorporate an automatic exposure control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of beam enters the patient except during recording of fluoroscopic images or when provided with an optional high level control.
- D. Compliance with the requirements of RH-1603.c shall be determined as follows:

- i. Movable grids and compression devices shall be removed from the useful beam during the measurement.
 - ii. If the source is below the table, exposure rate shall be measured or referenced to a point 1 centimeter above the tabletop or cradle.
 - iii. If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.
 - iv. In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.
2. Barrier transmission radiation rate limits.
- A. For non-image intensified fluoroscopes, the exposure rate due to transmission through the viewing screen shall not exceed 50 milliroentgens per hour;
 - B. For image intensified fluoroscopes, the exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with the radiation from the image intensifier shall not exceed 2 milliroentgens per hour at 18 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.
 - C. For certified image intensified fluoroscopic systems, the exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with the radiation from the image intensifier, shall not exceed 2 milliroentgens per hour at 10 centimeters from any accessible

surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

D. Measuring compliance of barrier transmission.

- i. For non-image intensified fluoroscopes, the exposure rate shall be determined with the screen positioned 35 centimeters from the panel or tabletop with no attenuation block in the beam.
- ii. For image intensified fluoroscopes:
 - (a). The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
 - (b). If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.
 - (c). If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.
 - (d). Movable grids and compression devices shall be removed from the useful beam during the measurement.

- (e). The attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.
- d. Indication of Potential and Current. During fluoroscopy and cinefluorography, the kV and the mA shall be continuously indicated.
- e. Source-Skin Distance. The source to skin distance shall not be less than:
 - 1. 38 centimeters on stationary fluoroscopes installed after July 1, 1974;
 - 2. 30.5 centimeters on stationary fluoroscopes which are in operation prior to July 1, 1975;
 - 3. 30.5 centimeters on all mobile fluoroscopes; and
 - 4. 20 centimeters for image intensified fluoroscopes used for specific surgical application. The users' operating manual must provide precautionary measures to be adhered to during the use of this device.
- f. Fluoroscopic Timer.
 - 1. Means shall be provided to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.
 - 2. At the completion of any preset cumulative on-time either:
 - A. The fluoroscopic tube output will be terminated; or
 - B. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

- g. Mobile Fluoroscopes. In addition to the other requirements of RH-1603, mobile fluoroscopes shall provide intensified imaging.
- h. Control of Scattered Radiation.
 - 1. Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.
 - 2. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual;
 - A. Is at least 120 centimeters from the center of the useful beam, or
 - B. The radiation has passed through not less than 0.25 millimeter lead equivalent material (e.g., drapes, Bucky-slot cover, sliding or folding panel or self-supporting curtains) in addition to any lead equivalency provided by the protective apron referred to in RH-1602.a.5.
 - 3. Exceptions to RH-1603.h.2 may be made in some special procedures where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Department shall not permit such exception.
- i. Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of RH-1603.a, c.2 and f provided that:
 - A. Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and

- B. Such systems as do not meet the requirements of RH-1603.f are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

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

- a. Beam Limitation and Alignment. The useful beam shall be limited to the area of clinical interest.
 - 1. The size of the x-ray beam projected by fixed aperture cones and collimators shall not exceed the dimensions of the image receptor by more than two (2) inches for a source to image receptor distance of seventy-two (72) inches or one (1) inch for a source to film distance of forty (40) inches or less.
 - 2. For systems with variable aperture beam limiting devices, means shall be provided for visually defining the perimeter of the x-ray field.
 - A. The beam-limiting device for stationary general purpose x-ray systems shall numerically indicate the field size in the plane of the image receptor to which it is adjusted.
 - B. Indication of field size dimensions and SID's shall be specified in inches and/or centimeters and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 (two) percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.
 - C. The total misalignment of the edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

3. For stationary general purpose x-ray systems, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor and to align the center of the image receptor to within two percent of the source to image receptor distance.
 4. The Department may grant an exemption on noncertified x-ray systems to RH-1604.a.2.B provided the registrant makes a written application for such exemption and in that application:
 - A. demonstrates it is impractical to comply with RH-1604.a.2.B; and
 - B. the purpose of RH-1604.a.2.B will be met by other methods.
 5. Systems designed for or provided with special attachments for mammography. Radiographic systems designed only for mammography and general purpose radiographic systems, when special attachments for mammography are in service, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID. This requirement can be met with a system which performs as prescribed in RH 1604.f.8. When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in RH-1604.f.8.c.i and ii shall be the maximum SID for which the beam-limiting device or aperture is designed. In addition, each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.
- b. Radiation Exposure Control Devices.
1. Technique indicators.
 - A. The technique factors to be used during an exposure shall be indicated before the

exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated.

- B. The requirement of RH-1604.b.1.A may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.
2. Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.
3. X-ray control.
- A. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:
 - i. Exposure of one-half second or less, or
 - ii. During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.
 - B. Each x-ray control shall be located in such a way as to meet the following requirements:
 - i. For stationary x-ray systems:
 - (a). The operator's station at the control shall be behind a protective barrier. The exposure switch shall be of the dead-man type and shall be so arranged that it cannot be conveniently operated outside a

shielded area. Exposure switches for "spot film" devices used in conjunction with fluoroscopes are exempted from this shielding requirement.

- (b). A window of lead-equivalent glass equal to that required by the adjacent barrier or a mirror system, shall be provided and it shall be large enough and so placed that the operator can see the patient during the exposure without having to leave the protected area.
- ii. For mobile and portable x-ray systems:
- (a). The exposure switch shall be of the dead-man type and shall be so arranged that the operator can stand at least six (6) feet from the patient and well away from the useful beam.
 - (b). Used for greater than one (1) week in the same location, i.e., a room or suite, shall meet the requirements of RH-1604.b.3.B. i.(a).
 - (c). Used for greater than one hour and less than one week at the same location, i.e., a room or suite, shall meet the requirement of RH-1604.b.3.B. ii.(b) or be provided with a 6.5 feet [1.98 m] high protective barrier which is placed at least six (6) feet [1.83 m] from the tube housing assembly and at least six (6) feet [1.83 m] from the patient; or
- iii. For all x-ray systems, the x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal

audible to the operator shall indicate that the exposure has terminated.

4. Automatic exposure controls.

When an automatic exposure control is provided:

- A. Indication shall be made on the control panel when this mode of operation is selected;
- B. If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two (2) pulses;
- C. The minimum exposure time for all equipment other than that specified in RH-1604.b.4.B shall be equal to or less than one-sixtieth second or a time interval required to deliver 5 mAs, whichever is greater;
- D. Either the product of peak x-ray tube potential, current and exposure time shall be limited to not more than 60 kW per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except when the x-ray tube potential is less than 50 kVp in which case the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and
- E. A visible signal shall indicate when an exposure has been terminated at the limits required by RH-1604.b.3.D and manual resetting shall be required before further automatically timed exposures can be made.

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

$$T \geq 5(T_{max} - T_{min}).$$

- c. Source-to-Skin Distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to not less than 30 centimeters.
- d. Exposure Reproducibility. The exposure reproducibility shall meet the following requirements:

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

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

- e. Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.
- f. Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).
 - 1. Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.
 - 2. Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, for any fixed x-ray tube potential within the range of 40 percent to 100 percent

of the maximum rating, the average ratios of exposure to the indicated milliamperere-seconds product, i.e., mR/mAs, obtained at any two (2) consecutive tube current settings shall not differ by more than 0.10 times their sum,

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

where \bar{X}_1 and \bar{X}_2 are the average mR/mAs values obtained at each of two (2) consecutive tube current settings.

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

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

- D. The following requirements shall apply to stationary general purpose x-ray systems which contain a tube housing assembly, an x-ray control and for those systems so equipped, a table, all of which are certified components:
- i. Means shall be provided for positive beam limitation which will, at the SID for which the device is designed, either cause automatic adjustment of the x-ray field in the plane of the image receptor to the image receptor size within five (5) seconds after insertion of the image receptor or, if adjustment is accomplished automatically in a time interval greater than five (5) seconds or is manual, will prevent production of x-rays until such adjustment is completed. For the SID at which the device is not intended to operate, the device shall prevent the production of x-rays.
 - ii. The x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, shall be such that neither the length nor the width of the x-ray field differs from that of the image receptor by greater than three percent of the SID and that the sum of the length and width differences without regard to sign (+/-) be no greater than four percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.
 - iii. The radiographic system shall be capable of operation, at the discretion of the operator, such that the field size at the image receptor can be adjusted to a size smaller than the image receptor. The minimum field size at a distance of 100 centimeters shall be equal to or less than five centimeters by five centimeters.

Return to positive beam limitation as specified in RH-1604.f.6.D.i and ii shall occur upon a change in image receptor.

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

- B. Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent of the SID.
 - C. RH-1604.f.8.A and B may be met with a system that meets the requirements for a general purpose x-ray system as specified in RH-1604.a or, when alignment means are also provided, may be met with either:
 - i. An assortment of removable, fixed aperture, beam-limiting devices sufficient to meet the requirement for combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or
 - ii. A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.
9. Timers. Termination of exposures shall cause automatic resetting of the timer to its initial setting or to "zero."

RH-1605. Reserved.

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

a. Equipment.

- 1. Diaphragms, cones or position indicating devices shall be used for collimating the useful beam and shall provide the same degree of protection as the

housing. The diameter of the useful beam at the end of the position indicating device shall not be more than three (3) inches.

2. A cone, spacer frame or position indicating device shall provide a source-to-skin distance of not less than seven (7) inches with equipment above 50 kVp or four (4) inches with equipment operating at 50 kVp or below.
3. The exposure control switch shall be of the dead-man type.
4. Each installation shall be provided with a protective barrier for the operator or shall be so arranged that the operator can stand at least six feet from the patient and well away from the useful beam.
5. The tube head shall remain stationary when placed in exposure position.
6. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half second or less.
7. Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.
8. Exposure reproducibility.

The exposure reproducibility shall meet the following requirements:

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

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

9. The x-ray control shall provide a signal audible to the operator to indicate that the exposure has terminated.
10. In addition to the requirements of RH-1602.c.5, all intraoral dental radiographic systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent filtration permanently installed in the useful beam.

b. Additional Requirements Applicable to Certified Systems Only.

Only diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

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

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

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

3. Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.

4. Timers. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero."
 5. Field limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:
 - A. If the minimum SSD is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters.
 - B. If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters.
 - C. An open ended, shielded PID shall be used. The shielding shall be equivalent to the requirements of RH-1602.b.4.
 6. Source-to-skin distance. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance, i.e., SSD, to not less than:
 - A. 18 centimeters if operable above 50 kVp; or
 - B. 10 centimeters if not operable above 50 kVp.
- c. Operating Procedures.
1. Neither the dentist nor his/her assistant shall be permitted to hold patients or films during exposure; neither shall any individual be regularly used for this service.
 2. During each exposure, the operator shall stand at least six (6) feet from the patient or behind a protective barrier.
 3. Only the patient shall be in the useful beam.
 4. Neither the tube housing nor the position indicating device shall be hand-held during exposure.

5. Intraoral fluoroscopic mirrors shall not be used in dental examinations.
6. The x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of RH-1606.b.5.
7. Dental fluoroscopy without image intensification shall not be used.
8. Structural shielding. Dental rooms containing x-ray machines shall be provided with such primary barriers and/or secondary barriers as are necessary to assure compliance with RH-1200.

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

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

a. Equipment Requirements.

1. Leakage radiation. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified at the distance specified for the classification of the x-ray system.
 - A. Contact therapy systems. Leakage radiation shall not exceed 100 milliroentgens per hour at 5 centimeters from the surface of the tube housing assembly.
 - B. 0-150 kVp systems. Systems which are manufactured or installed prior to the July 1, 1983 date shall have a leakage radiation which does not exceed 1 roentgen in one hour at 1 (one) meter from the source.
 - C. 0-150 kVp systems. Systems which are manufactured on or after July 1, 1983 shall have a leakage radiation which does not exceed 100 milliroentgens in one (1) hour at 1 (one) meter from the source.

- D. 151 to 999 kVp systems. The leakage radiation shall not exceed 1 (one) roentgen in one hour at 1 (one) meter from the source except systems that operate in excess of 500 kVp may have a leakage radiation at 1 (one) meter from the source equivalent to the exposure within one hour of the useful beam at 1 (one) meter from the source multiplied by a factor of 0.001.
2. Permanent beam limiting devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or higher degree of protection as required by the tube housing assembly.
3. Removable and adjustable beam limiting devices.
- A. Removable beam limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than 1 percent of the original x-ray beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.
- B. Adjustable beam limiting devices installed after July 1, 1983 shall meet the requirements of RH-1607.a.3.A.
- C. Adjustable beam limiting devices installed before July 1, 1983 shall, for the portion of the x-ray beam to be blocked by these devices, transmit not more than 5 percent of the original x-ray beam at the maximum kilovoltage and maximum treatment filter.
4. Filter system. The filter system shall be so designed that:
- A. Filters can not be accidentally displaced from the useful beam at any possible tube orientation;

- B. Each filter is marked as to its material of construction and its thickness or wedge angle for wedge filters; and
- C. It shall be possible for the operator to determine the presence or absence of each filter and the orientation of each wedge filter in the useful beam when the operator is at the control panel, either by display at the control panel or by direct observation.
- D. The radiation at 5 centimeters from the filter insertion slot opening does not exceed 30 roentgens per hour under any operating conditions.

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5. Tube immobilization. The tube housing assembly shall be capable of being immobilized during stationary treatments.
6. Focal spot marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within 5 millimeters and such marking shall be readily accessible for use during calibration procedures.
7. Beam block. Contact therapy tube housing assemblies shall have a removable shield of at least 0.5 millimeter lead equivalence at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.
8. Beam monitor system. Systems of greater than 150 kVp manufactured after July 1, 1983 shall be provided with a beam monitor system which:
 - A. Shall include a transmission detector which is a full beam detector and which is placed on the patient side of any fixed added filters other than a wedge filter;
 - B. Shall have the detector interlocked to prevent incorrect positioning in the useful beam;
 - C. Shall not allow irradiation until a preselected value of exposure (i.e. roentgens, rads/unit time, etc.) has been made at the treatment control panel;
 - D. Shall independently terminate irradiation when the preselected exposure has been reached;
 - E. Shall be so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined;
 - F. Shall have a display at the control panel from which the dose at the reference point in the treatment volume can be calculated;

- G. Shall have a control panel display which maintains the reading until intentionally reset to zero; and
- H. Shall have a control panel display which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.

9. Timer.

- A. A timer shall be provided which has a display at the treatment control panel. The timer shall be graduated in minutes and fraction of minutes. The timer shall have a pre-set timer selector and an elapsed time indicator.
- B. The timer shall be a cumulative timer which activates with the radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to cycle the pre-set time selector through zero time.
- C. The timer shall terminate irradiation when a preselected time has elapsed if any dose monitoring system present has not previously terminated irradiation.
- D. The timer shall permit accurate pre-setting and determination of exposure times as short as one (1) second.
- E. The timer shall not permit an exposure if set at zero.
- F. The timer shall comply with the provisions of RH-1607.a.13 where applicable.
- G. The timer shall not activate until the shutter is opened when patient irradiation is controlled by a shutter mechanism.

10. Control panel functions. The control panel, in addition to the displays required in other provision of RH-1607, shall have:

- A. An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;
 - B. An indication of whether x-rays are being produced;
 - C. Means for indicating kV and x-ray tube current;
 - D. The means for terminating an exposure at any time;
 - E. A locking device which will prevent unauthorized use of the x-ray system; and
 - F. For x-ray equipment manufactured after July 1, 1983, a positive display of specific filter(s) in the beam.
11. Multiple tubes. When a control panel may energize more than one x-ray tube:
- A. It shall be possible to activate only one x-ray tube during any time interval;
 - B. There shall be an indication at the control panel identifying which x-ray tube is energized; and
 - C. There shall be an indication at the tube housing assembly when that tube is energized.
12. Source-to-patient distance. There shall be means of determining the source-to-patient distance to within 1 centimeter.
13. Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five (5) seconds, the entire useful beam shall be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition,
- A. After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel; and

- B. An indication of shutter position shall appear at the control panel.
14. Low filtration x-ray tubes. Each x-ray system equipped with a beryllium or other low-filtration window shall be clearly labelled as such upon the tube housing assembly and at the control panel.
- b. Facility Design Requirements for Systems Capable of Operating Above 50 kVp. In addition to shielding adequate to meet requirements of Section 2 and Section 3, the treatment room shall meet the following design requirements:
- 1. Warning lights. Treatment rooms to which access is possible through more than one entrance shall be provided with warning lights, in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "on".
 - 2. Voice communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel; however, where excessive noise levels make aural communication impractical, other methods of communication shall be used.
 - 3. Viewing systems. Windows, mirrors or closed-circuit television or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel. When the primary viewing system is by electronic means (e.g., television), an alternate viewing system shall be available for use in the event of electronic failure.
 - 4. Additional requirements for x-ray systems capable of operation above 150 kVp.
 - A. All protective barriers shall be fixed except for entrance doors or beam interceptors.
 - B. The control panel shall be outside the treatment room;

- C. All doors of the treatment room shall be electrically connected to the control panel such that x-ray production cannot occur unless all doors are closed;
- D. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.
- E. When any door is opened while the x-ray tube is activated, the exposure at a distance of 1 (one) meter from the source shall be reduced to less than 100 milliroentgens per hour within one (1) second.
- F. After the radiation output of the x-ray tube has been affected by the opening of any door referred to in RH-1607.b.4.C, it shall be possible to restore the x-ray system to full operation only upon:
 - i. closing the door; and subsequently,
 - ii. reinitiating the exposure at the control panel.

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

1. Surveys.

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

- C. The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable regulations and shall cite all items of noncompliance.

2. Calibrations.

- A. The calibration of an x-ray system shall be performed at intervals not to exceed one (1) year and after any change or replacement of components which could cause a change in the radiation output.
- B. The calibration of the radiation output of the x-ray system shall be performed by or under the direction of a qualified expert who is physically present at the facility during such calibration.
- C. Calibration of the radiation output of an x-ray system shall be performed with a calibrated instrument. The calibration of such instrument shall be directly traceable to a national standard. The instrument shall have been calibrated within the preceding two (2) years.
- D. The calibrations made pursuant to RH-1607.c.2 shall be such that the dose at a reference point in soft tissue can be calculated to within ± 5 percent.
- E. The calibration of the x-ray system shall include, but not be limited to, the following determinations:
 - i. Verification that the x-ray system is operating in compliance with the design specifications;
 - ii. The exposure rates for each combination of field size technique factors, filter and treatment distance used;
 - iii. The degree of congruence between the radiation field and the field indicated by the localizing device if such device is present; and

- iv. An evaluation of the uniformity of the radiation field symmetry for the field sizes used and any dependence upon tube housing assembly orientation.
 - F. Records of calibration performed pursuant to RH-1607.c.2 shall be maintained by the registrant for five (5) years after completion of the calibration.
 - G. A copy of the most recent x-ray system calibration shall be available for use by the operator at the control panel.
3. Spot checks. Spot checks shall be performed on x-ray systems capable of operation at greater than 150 kVp. Such spot checks shall meet the following requirements:
- A. The spot check procedures shall be in writing and shall have been developed by a qualified expert. A copy shall be submitted to the Department prior to its implementation.
 - B. If a qualified expert does not perform the spot-check measurement, the results of the spot-check measurements shall be reviewed by a qualified expert within fifteen (15) days.
 - C. The measurements taken during the spot checks shall demonstrate the degree of consistency of the operating characteristics which can affect the radiation output of the x-ray system.
 - D. The spot check procedure shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration specified in RH-1607.c.2.
 - E. The cause for a parameter exceeding a tolerance set by the qualified expert shall be investigated and corrected before the system is used for patient irradiation.

- F. The procedure shall also note conditions which shall require that the system be recalibrated in accordance with RH-1607.c.2.
- G. Records of spot check measurements performed pursuant to RH-1607.c.3 shall be maintained by the registrant for two (2) years following such measurement.
- H. Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of RH-1607.c.2 or which has been intercompared with a system meeting those requirements within the previous year.

4. Operation procedures.

- A. Therapeutic x-ray systems shall not be left unattended unless the system is secured pursuant to RH-1607.a.10.E.
- B. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.
- C. The tube housing assembly shall not be held by an individual during exposures unless the system is designed to require such holding and the peak tube potential of the system does not exceed 50 kVp. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 mm lead equivalency at 100 kVp.
- D. No individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of RH-1200. No individual other than the patient shall be in the treatment room during exposures when the kVp exceeds 150.
- E. The x-ray system shall not be used in the administration of radiation therapy unless the requirements of RH-1607.c.2 and RH-1507.c.3.D have been met.

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

a. Definitions. In addition to the definitions provided in RH-1601, the following definitions shall be applicable to RH-1608.

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

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

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

b. Requirements for Equipment.

1. Leakage radiation inside patient area

A. New equipment shall meet the following requirements:

- i. For all operating conditions, the dose in rads (grays) due to leakage radiation, including x-rays, electrons and

neutrons, at any point in a circular plane of 2 meters radius centered on a perpendicular to the central axis of the beam at the normal treatment distance and outside the maximum useful beam, shall not exceed 0.1 percent of the maximum dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to but not exceeding 200 square centimeters.

- ii. For each system the licensee shall determine or obtain from the manufacturer, the leakage radiation existing at the positions specified in RH-1608.b.1.A.1 for specified operating conditions. Records on leakage radiation shall be maintained at the installation for inspection by the Department.

B. Existing equipment shall meet the following requirements:

- i. The leakage radiation, excluding neutrons, at any point in the area specified by RH-1608.b.1.A.1 where such area intercepts the central axis of the beam 1 meter from the virtual source, shall not exceed 0.1 percent of the maximum dose in rads of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in RH-1608.b.1.A.i.
- ii. For each system, the licensee shall determine, or obtain from the manufacturer, the leakage radiation existing

at the positions specified in RH-1608.b.1.B.i for specified operating conditions. Records on radiation leakage shall be maintained at the installation for inspection by the Department.

2. Leakage radiation outside the patient area.

A. The dose equivalent in rem due to leakage radiation, except in the area specified in RH-1608.b.1.A.i, when measured at any point 1 meter from the path of the charged particle, before the charged particle strikes the target or window, shall not exceed 0.1 percent for x-ray leakage nor 0.5 percent for neutron leakage of the maximum dose equivalent in rem of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in RH-1608.b.1.A.i.

B. The licensee shall determine or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in RH-1608.b.2.A for specified operating conditions. Measurements, excluding neutrons, shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified. Neutron measurements shall be averaged over an area up to but not exceeding 200 square centimeters.

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

4. Filters.

- A. If the absorbed dose rate information required by RH-1608.b.16 related exclusively to operation with a field flattening or beam scattering filter in place, such filter shall be removable only by the use of tools.
- B. In systems which utilize a system of wedge filters, interchangeable field flattening or interchangeable beam scattering filters:
 - i. Irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;
 - ii. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
 - iii. An indication of the wedge filter orientation with respect to the treatment field shall be provided at the control panel, by direct observation or by electronic means, when wedge filters are used;
 - iv. A display shall be provided at the treatment control panel showing the filter(s) in use;
 - v. Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.
 - vi. An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.

5. Beam quality. The licensee shall determine or obtain from the manufacturer, data sufficient to assure that the following beam quality requirements are met:
- A. The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam 10 centimeters greater than the practical range of the electrons shall not exceed the values stated in Table III. Linear interpolation shall be used for values not stated.

TABLE III

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

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

irradiation, shall not exceed the limits stated in Table IV. Linear interpolation shall be used for values not stated.

TABLE IV

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

- D. Compliance with RH-1608.b.5.C shall be determined by:
- i. Measurements made within a phantom using an instrument which will allow extrapolation to the surface absorbed dose;
 - ii. Use of a phantom whose size and placement meet the requirements of RH-1608.b.5.B;
 - iii. Removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam flattening filters; and
 - iv. The largest field size available which does not exceed 15 centimeters by 15 centimeters.
- E. The licensee shall determine or obtain from the manufacturer the maximum percentage absorbed dose in the useful beam due to neutrons, excluding stray neutron radiation, for specified operating conditions.

6. Beam monitors. All therapy systems shall be provided with radiation detectors in the radiation head.
 - A. New equipment shall be provided with at least two radiation detectors. The detectors shall be incorporated into two monitoring systems arranged either as a primary/primary combination or as a primary/secondary combination.
 - B. Existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated into a primary system.
 - C. The detectors and system into which the detector is incorporated shall meet the following requirements:
 - i. Each primary system shall have a detector which is a transmission detector and a full beam detector and which is placed on the patient side of any fixed added filters other than a wedge filter.
 - ii. The detectors shall be removable only with tools and shall be interlocked to prevent incorrect positioning.
 - iii. Each detector shall be capable of independently monitoring and controlling the useful beam.
 - iv. Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.
 - v. For new equipment the design of the dose monitoring systems of RH-1608.b.6.C.iv shall assure that the malfunctioning of one system shall not affect the correct functioning of the second system. In addition:
 - (a). The failure of any element which may be common to both systems shall terminate the useful beam.

- (b). The failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation.
- vi. Each dose monitoring system shall have a legible display at the treatment control panel. Each display shall:
 - (a). Maintain a reading until intentionally reset to zero;
 - (b). Have only one scale and no scale multiplying factors in new equipment; and
 - (c). Utilize a design such that increasing dose is displayed by increasing numbers and shall also be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined under all normal conditions of use or foreseeable failures.
- vii. In the event of power failure, the dose monitoring information required in RH-1608.b.6.C.vi displayed at the control panel at the time of failure shall be retrievable in at least one system for a twenty (20) minute period of time.

7. Beam symmetry.

- A. In new equipment inherently capable of producing useful beams with asymmetry exceeding 5 percent, at least four (4) different parts of the radiation beam shall be monitored before the beam passes through the beam limiting device and facilities shall be provided so that if the difference in dose rate between any two of these different parts exceeds 5 percent an indication of this condition is made at the control panel and so that if the difference

in dose rates between any two (2) of these different parts exceeds 20 percent the irradiation is terminated.

- B. Beam symmetry requirements of RH-1608.a.7.A shall be met if the user can demonstrate to the satisfaction of the Department that adequate fail-safe protection against the beam asymmetry is incorporated into the inherent design of the accelerator.
- C. On existing equipment where the Department has determined that beam symmetry is inadequate, the use of an automatic beam asymmetry warning system may be required.

8. Selection and display of dose monitor units.

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

9. Termination of irradiation by the dose monitoring system.

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

- B. Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.
 - C. If original design of the equipment included a second dose monitoring system, that system shall be capable of terminating irradiation when not more than 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.
 - D. For new equipment a second dose monitoring system shall be present. That system shall be capable of terminating irradiation when not more than 10% or 25 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitor system.
 - E. For new equipment an indicator on the control panel shall show which dose monitoring system has terminated irradiation.
10. Interruption switches. It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption the equipment shall go to termination condition.
11. Termination switches. It shall be possible to terminate irradiation and equipment movements or go from an interruption condition to termination condition, at any time from the operator's position at the treatment control panel.
12. Timer.
- A. A timer shall be provided which has a display at the treatment control panel. The timer shall be graduated in minutes and

decimals of minutes. The timer shall have a pre-set time selector and an elapsed time indicator.

- B. The timer shall be a cumulative timer which switches on and off with the radiation and retains its reading after irradiation is interrupted or terminated. It shall be necessary to zero and subsequently reset the elapsed time indicator and the pre-set time selector after irradiation is terminated before irradiation shall again be possible.
 - C. The timer shall terminate irradiation with a pre-selected time has elapsed if the dose monitoring systems fail to do so.
13. Selection of radiation type. Equipment capable of both X-ray therapy and electron therapy shall meet the following requirements:
- A. Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.
 - B. An interlock system shall be provided to insure that the equipment can emit only the radiation type which has been selected.
 - C. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
 - D. An interlock system shall be provided to prevent irradiation with x-rays when electron applicators are fitted and irradiation with electrons when accessories specific for x-ray therapy are fitted.
 - E. The radiation type selected shall be displayed at the treatment control panel before and during irradiation.
14. Selection of energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

- A. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.
 - B. An interlock system shall be provided to insure that the equipment can emit only the energy of radiation which has been selected.
 - C. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
 - D. The energy selected shall be displayed at the treatment control panel before and during irradiation.
 - E. For new equipment, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the x-ray target or electron window deviates by more than $\pm 20\%$ or ± 3 MeV, whichever is smaller, from the selected nominal energy.
15. Selection of stationary beam therapy or moving beam therapy. Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:
- A. Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.
 - B. An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected.
 - C. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
 - D. An interlock system shall be provided to terminate irradiation if the movement stops during moving beam therapy.

- E. The mode of operation shall be displayed at the treatment control panel.
 - F. For new equipment, an interlock system shall be provided to terminate irradiation if:
 - i. Movement of the gantry occurs during stationary beam therapy; or
 - ii. Movement of the gantry stops during moving beam therapy unless such stoppage is a preplanned function.
 - G. Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.
 - i. For new equipment, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of arc differs by more than 20 percent from the selected value.
 - ii. For new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than 5 percent from the value calculated from the absorbed dose per unit angle relationship.
 - H. Where the dose monitor system terminates the irradiation in arc therapy, the termination of irradiation shall be as required by RH-1608.b.9.
16. Absorbed dose rate. For new equipment, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated.^{12/} In addition:
- A. The quotient of the number of dose monitor units by time shall be displayed at the treatment control panel.
 - B. If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice

the maximum value specified by the manufacturer's anticipated dose rate for any machine parameters utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation will be terminated shall be a record maintained by the licensee.

17. Location of focal spot and beam orientation. The licensee shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:
 - A. The x-ray target or the virtual source of x-rays.
 - B. The electron window or the scattering foil.
 - C. All possible orientations of the useful beam.
18. System checking facilities. Capabilities shall be provided so that all radiation safety interlocks can be checked. When pre-selection of any of the operating conditions requires action in the treatment room and/or at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.
19. Shadow trays shall be designed such that the skin entrance dose due to electrons produced within the shadow tray are minimized.
- c. Facility and Shielding Requirements. In addition to Section 3, the following design requirements shall apply:
 1. Except for entrance doors or beam interceptors, all the required barriers shall be fixed barriers.
 2. The treatment control panel shall be located outside the treatment room.
 3. Windows, mirrors, close-circuit television, or other equivalent viewing systems shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. When the viewing system

is by electronic means (e.g., television), an alternate viewing system shall be provided for use in the event of failure of the primary system.

4. Provision shall be made for two-way aural communication between the patient and the operator at the treatment control panel. However, where excessive noise levels makes aural communications impractical, other methods of communications shall be used.
5. Treatment rooms to which access is possible through more than one entrance shall be provided with warning lights, which will indicate when the useful beam is "on" in a readily observable position near the outside of all access doors.
6. Interlocks shall be provided such that all entrance doors shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall be possible to restore the machine to operation only by closing the door and reinitiating exposure by manual action at the control panel.
7.
 - A. A licensee shall install in each treatment room a permanent radiation monitor capable of continuously monitoring beam status.
 - B. Each radiation monitor must be capable of providing visible notice of a therapy unit malfunction that results in failure to terminate the useful beam. The visible indicator of high radiation levels must be observable by an individual entering the treatment room.
 - C. Each radiation monitor must be equipped with an emergency power supply separate from the power supply to the therapy unit. This emergency power supply may be a battery system.
 - D. Each radiation monitor must be checked for proper operation each day before the therapy unit is used for treatment of patients.

- E. A licensee shall maintain a record of the check required by Paragraph D of this Section for two (2) years. The record must include the date of the check, notation that the monitor indicates when the useful beam is "off" and "on" and the initials of the individual who performed the check.
 - F. If a radiation monitor is inoperable for any reason, the licensee shall require any individual entering the treatment room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the unit that may result in failure to terminate the useful beam. The instrument or dosimeter must be checked for proper operation at the beginning of each day of use.
 - G. A licensee shall promptly repair or replace the radiation monitor if it is inoperable.
- d. Surveys, Calibrations, Spot Checks, and Operating Procedures.
- 1. Survey.
 - A. All new facilities and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified expert. Such surveys shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
 - B. The licensee shall obtain a written report of the survey from the qualified expert and a copy of the report shall be transmitted by the licensee to the Department within thirty (30) days of receipt of the report.
 - C. The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable regulations and shall cite the Section violated.

2. Calibrations.

- A. The full calibration of systems subject to RH-1608 shall be performed in accordance with an established calibration protocol^{19/} before the system is first used for irradiation of a patient and thereafter at time intervals which do not exceed 12 months and after any change which might significantly alter the calibration, spatial distribution or other characteristics of the therapy beam.
- B. The full calibration shall be performed under the direct supervision of a qualified expert.
- C. Calibration of the dose equivalent of the therapy beam shall be performed with a dosimeter system:
 - i. Having a calibration factor for Cobalt-60 gamma rays traceable to a national standard;
 - ii. Which has been calibrated within the previous two years and after any servicing that may have affected its calibration;
 - iii. Which has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system; and
 - iv. Which has had constancy checks performed on the system as specified by a radiological physicist.
- D. Calibrations made pursuant to RH-1608.d.2 shall be such that the dose at a reference point in soft tissue can be calculated with ± 5 percent.
- E. The calibration of the therapy beam shall include but not be limited to the following determinations:

- i. Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, the side light and back-pointer alignment with the isocenter, when applicable, variation in the axis of rotation for the table, gantry and jaw system and beam flatness and symmetry at specified depths.
 - ii. The absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam.
 - iii. The congruence between the radiation field and the field indicated by the localizing device.
 - iv. The uniformity of the radiation field and its dependency upon the direction of the useful beam.
 - v. The calibration determinations above shall be provided in sufficient detail such that the absorbed dose to tissue in the useful beam may be calculated to within ± 5 percent.
 - vi. Verification of depth-dose data and isodose curves applicable to the specific machine continue to be valid or are updated to existing machine conditions.
 - vii. Verification of the applicability of transmission factors of all accessories such as wedges, shadow trays, compensators; and their effects on electron buildup.
- F. Records of the calibration performed pursuant to RH-1608.d.2.A shall be maintained by the licensee for five (5) years after completion of the calibration.

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

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

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

- G. Where a system has built-in devices which provide a self-check of any parameter during irradiation, the spot check procedures shall require that the parameter be independently verified at specific time intervals.
- H. The reasons for spot checks which are erratic or inconsistent with calibration data shall be promptly investigated and corrected before the system is used for patient irradiation.
- I. Whenever a spot check indicates a significant change, as specified in the qualified expert's spot check procedures, in the operating characteristics of a system, the system shall be recalibrated as required in RH-1608.d.2.
- J. Records of spot-check measurements performed pursuant to RH-1608.d.3 shall be maintained by the licensee for a period of two (2) years.
- K. Where a spot check involves a radiation measurement, such measurement shall be obtained using an instrument satisfying the requirements of RH-1608.d.2.C or which has been intercompared with an instrument meeting those requirements within the previous year.

4. Operating procedures.

- A. No individual other than the patient shall be in the treatment room during treatment of a patient.
- B. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.
- C. The system shall not be used in the administration radiation therapy unless RH-1608.d.1, 2 and 3 have been met.

RH-1609. Veterinary Medicine Radiographic Installations.

a. Equipment.

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

b. Operating procedures.

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

available. If the animal must be held by an individual, the individuals shall be protected with appropriate shielding devices, such as protective gloves and apron, with a lead equivalent of not less than 0.5 millimeter and they shall be so positioned that no part of the body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

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RH-1610. Mammography Systems

a. Definitions

1. Screening Mammography - Radiographic procedure provided to a woman, who has no signs or symptoms of breast cancer, for the purpose of early detection of breast cancer. The procedure entails two views of each breast and includes a physician's interpretation of the results of the procedure.
2. Diagnostic Mammography - A problem solving radiographic procedure of higher intensity than screening mammography provided to women who are suspected to have breast pathology. Patients are usually referred for analyses of palpable abnormalities or for further evaluation of mammographically detected abnormalities. All images are immediately reviewed by the physicians interpreting the study and additional views are obtained as needed. Physical examinations of the breast by the interpreting physician to correlate the radiologic findings is often performed as part of the study.

b. Accreditation

1. All facilities performing screening or diagnostic mammography shall be accredited every three (3) years by the Arkansas Department of Health or the American College of Radiology. Such accreditation shall be by standards developed by the Food and Drug Administration in accordance with the Mammography Quality Standards Act (MQSA) of 1992.
2. No mammography shall be performed in an unaccredited facility after January 1, 1990. The owners of any unaccredited facility wherein mammography is performed after January 1, 1990 shall be subject to a civil penalty imposed by the Arkansas Department of Health in an amount not to exceed one hundred dollars (\$100) for each day the facility operates without accreditation by the Department.

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c. Quality Standards

1. Personnel

The following requirements apply to personnel involved in any aspect of mammography, including production, processing, and interpretation of mammograms and related quality assurance activities.

- A. Interpreting Physicians. Interpreting Physicians shall meet the minimum requirements of 21 CFR Part 900.12(a)(1) of the Food and Drug Administration.
- B. Radiological Technologist. Radiological Technologists shall meet the minimum requirements of 21 CFR Part 900.12.(a)(2) of the Food and Drug Administration.
- C. Mammography Imaging Medical Physicist. All Mammography Imaging Medical Physicists conducting surveys of mammography facilities and providing oversight of the facility's quality assurance program under MQSA shall meet the following requirements as well as the requirements for continuing qualification.

1. Initial qualifications. All Mammography Imaging Medical Physicists shall:

- (a) Be State approved by the Division of Radiation Control and Emergency Management, Arkansas Department of Health as qualified and/or be certified by the American Board of Radiological Physics/Diagnostic Radiological Physics, the American Board of Medical Physicists in Diagnostic Imaging Physics, or the Canadian College of Physicists in Medicine as a Fellow in Diagnostic Radiological Physics, or any other body approved by the Food and Drug Administration to certify Medical Physicists; or

- (b). Have a master's or higher degree in a science from a college or university accredited by one of the regional accreditation bodies of the Commission on Higher Education with not less than 30 (thirty) semester hours or equivalent of college level physics and/or radiation science, have two (2) years of experience in conducting performance evaluations of mammography facilities and 20 (twenty) hours of documented specialized training in conducting performance evaluations of mammography facilities. Complete surveys of five (5) mammography units shall be equal to one (1) year of experience. Two (2) or more years of training while pursuing a master's or higher degree in medical physics may be accepted in lieu of one (1) year of experience. After January 1, 1996, the experience shall be acquired under the direct supervision of a Mammography Imaging Medical Physicist who meets the requirements of RH-1610.c.1.C.1.
- (c). Prior to October 27, 1997, shall have a bachelor's degree in a physical science from a college or university accredited by one of the regional accreditation bodies of the Commission on Higher Education with not less than 15 (fifteen) semester hours or equivalent college level physics and/or radiation sciences and five (5) years of experience

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in conducting performance evaluations of mammography facilities. The individual shall have surveyed at least five (5) mammography units in each of the five (5) years and have at least 40 (forty) hours of documented specialized training in conducting performance evaluations of mammography facilities to comply with the requirements of MQSA.

ii. Continuing qualifications.

Continuing education. After the third anniversary of completion of the requirements of RH-1610.c.1.C.i, the individual shall have taught or completed at least 15 (fifteen) continuing education units in mammographic imaging over the three (3) previous years. This shall include training, if available, appropriate to each mammographic modality evaluated by the Mammography Imaging Medical Physicist during the surveys or oversights of quality assurance programs for which they are responsible.

iii. All facility survey reports must be signed by a Mammography Imaging Medical Physicist who meets the qualification requirements of RH-1610.c.1.C.i.

iv. A Mammography Imaging Medical Physicist who signs a facility survey report must have been present in that facility during the survey.

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v. Mammography Imaging Medical Physicists who fail to maintain the required continuing qualifications stated in RH-1610.c.1.C.ii shall re-establish their qualifications before independently surveying another facility. To re-establish their qualifications, Mammography Imaging Medical Physicists who fail to meet the continuing:

(a). Education requirement of RH-1610.c.1.C.ii must obtain a sufficient number of continuing education units to bring their total up to the required 15 (fifteen) in the previous three (3) years.

(b). Experience requirement of RH-1610.c.1.C.i must obtain experience by surveying one mammography unit for each year of not meeting the continuing experience requirements under the supervision of a Mammography Imaging Medical Physicist who meets the qualifications stated in RH-1610.c.1.C.i. After five (5) years of not meeting the continuing experience requirements, the Mammography Imaging Medical Physicist must requalify under RH-1610.c.1.C.i.

2. Obtaining and preserving records. All reasonable efforts must be made to obtain any of the beneficiary's previous mammogram records, including original images and films, copies of written reports prepared by interpreting physicians, and other relevant information pertinent to previous mammograms that might be available from others, for comparison with the

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current mammogram records. Records of previous mammograms obtained and of current and subsequent mammograms performed must be properly preserved and made available to other qualified physicians or others that submit a written request authorized by the beneficiary.

3. Equipment. The equipment used to perform mammography should be specifically designed for mammography and must meet the following standards:
 - A. Equipment design. The equipment should be specifically designed for mammography and identified by the manufacturer as designed only for mammography.
 - B. Food and Drug Administration (FDA) Standards. Certified equipment must meet the FDA performance standards for diagnostic x-ray systems and their major components at 21 CFR 1020.30 and FDA's standards for radiographic equipment at 21 CFR 1020.31.
 - C. Image receptor systems. The image receptor systems and all their individual components should be designed appropriately for mammography.
 - D. Focal spot size. The measured focal spot size of the x-ray tube should not exceed 0.7 mm.
 - E. Devices to immobilize and compress the breast. Devices parallel to the imaging plane should be available to immobilize and compress the breast.

- F. Control panel indicators. The equipment must have a control panel that includes a device (usually a milliammeter) or means for an audible signal to give positive indication of the production of x-rays whenever the x-ray tube is energized. The control panel must include appropriate indicators (labeled control settings of meters that show the physical factors such as kilovoltage potential [kVp], milliamperere seconds [mAs], exposure time, or whether timing is automatic) used for exposure.
4. Safety standards. Mammograms must be conducted using equipment and operating procedures free of unnecessary hazards and providing minimum radiation exposure to patients, personnel, and other persons in the immediate environment.
- A. Safety precautions. Proper safety precautions must be maintained. This includes adequate shielding for patients, personnel, and facilities. The equipment must be operable only from a shielded position.
 - B. Exposure badges. Personnel operating the equipment must be monitored in accordance with RH-1301.
 - C. Equipment inspection. Periodic inspection of equipment and shielding must be made by a staff or consultant medical physicist or by a physicist approved by an appropriate State or local government agency as meeting the qualification requirements of RH-1610. Identified hazards must be promptly corrected.
 - D. Protection against electrical hazards. All equipment must be shockproof and grounded.

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5. Quality assurance. The supplier must have an ongoing equipment quality assurance program specific to mammography imagery, and covering all components of the x-ray system, from the x-ray generator to the image developer, to ensure consistently high-quality images with minimum patient exposure. The supplier must conduct a general review of the program at least annually, and have available the services of a person qualified to furnish diagnostic x-ray physics who under the direction of the physician described in RH-1610.c.1.C.1 is responsible for establishing and conducting the program.

A. Responsibility for the quality assurance program. The person furnishing diagnostic x-ray physics support has the overall responsibility for establishing and conducting the ongoing equipment quality assurance program. That individual's specific duties must include:

- i. Conducting or training others to conduct equipment performance monitoring functions;
- ii. Analyzing the monitoring results to determine if there are any problems requiring correction; and
- iii. Carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventive maintenance.

B. Calibration of equipment. All variable parameters of the equipment must be calibrated:

- i. When the equipment is installed;
- ii. After any major changes or replacement of parts;
- iii. At least annually during use; and
- iv. When quality assurance tests indicate that calibration is needed.

- C. Performance monitoring. The facility must routinely monitor the performance of the mammography system. |
- i. At a minimum, the parameters that must be monitored are: |
- (a). Processor performance (through sensitometric-densitometric means); |
 - (b). Half value layer; |
 - (c). Output reproducibility and linearity; |
 - (d). Automatic exposure control reproducibility, kVp response, and thickness response; |
 - (e). Adequacy of film storage (both before use and after exposure if processing does not occur immediately); |
 - (f). Availability and use of technique charts that must include an indication of the kV-target-filter combination to be used with each image receptor; |
 - (g). Darkroom integrity; |
 - (h). Image quality (using a testing device called a "phantom", which simulates the composition of the breast and indicators of disease conditions, allowing objective analysis of clinic image quality); and |
 - (i). Dose. |

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- ii. The equipment must be monitored as follows:
 - (a). Processor performance and the use of a kV-target-filter combination appropriate to the image receptor should be monitored daily, before patient irradiation.
 - (b). Image quality must be monitored with a phantom every time the unit is moved, altered in any major way including the replacement of parts, and at least monthly between movements or alterations.
 - (c). The frequency of monitoring all other parameters must be proportional to the expected variability of each parameter, but monitoring must be conducted at least annually.

D. Evaluation of monitoring results.
Monitoring must be evaluated on a regular basis.

- i. Standards of image quality giving acceptable ranges of values for each of the parameters tested should be established to aid in the evaluation. The standards of image quality related to dose should include a requirement that the mean glandular dose for one craniocaudal view of a 4.5 cm compressed breast (50 percent adipose/50 percent glandular) should not exceed 100, 300, and 400 mRad (millirad) for film/screen units without grids, film/screen units with grids, and xerography units, respectively.

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- ii. The monitoring results must be compared routinely to the standards of image quality. If the results fall outside the acceptable range, the test must be repeated. If the results continue to be unacceptable, the source of the problem must be identified and corrected before further examinations are conducted.

- E. Retake analysis program. A program to analyze retakes must be established as a further aid in detecting and correcting problems affecting image quality or exposure.

- F. Responsible personnel. Responsibility for each standard, from monitoring through the annual review, must be assigned to qualified personnel. These assignments must be documented in the supplier's records.

6. Standards For Diagnostic Mammography. |

Facilities who wish to be accredited for diagnostic mammography shall, in addition to meeting all of the requirements for mammography also:

- A. Have the interpreting physician as defined in RH-1610.c.1.A present during all diagnostic mammography for direct supervision of the exam and film interpretation. |
- B. Have mammography systems with cone down compression and magnification capabilities, to enhance film interpretation.

7. Applications and Fees. |

Applications for accreditation or renewal shall be made on forms supplied by the Department. Evidence of compliance with all of the requirements for performing screening and/or diagnostic mammography and the accreditation fee must be included with the application. |

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

- RH-1700. a. General Provisions. The provisions of this Part apply to all licensees who use sealed sources in medicine and veterinary medicine and are in addition to, and not in substitution for, other applicable provisions of these Regulations set out in Sections 1 and 2.
- b. Definitions. As used in this Part, the following definitions apply:

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

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

RH-1701. Interstitial, Intracavitary and Superficial Applications.

- a. Accountability, Storage and Transit.
1. Except as otherwise specifically authorized by the Department, each licensee shall provide accountability of sealed sources and shall keep a permanent record of the issue and return of all sealed sources.
 2. When not in use, sealed sources and applicators containing sealed sources shall be kept in a protective enclosure of such material and wall thickness as may be necessary to assure compliance with the provisions of RH-1200 and RH-1203.
 3. Each licensee shall conduct a physical inventory at intervals not to exceed six (6) months to account for all sources and devices received and possessed. Records of the inventories shall be maintained for inspection by the Department and shall include the quantities and kinds of radioactive material, location of sources and devices and the date of the inventory.
 4. Each licensee shall follow the radiation safety and handling instructions approved by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State, and furnished by the manufacturer on the label attached to the source,

device or permanent container thereof, or in the leaflet or brochure which accompanies the source or device, and maintain such instruction in a legible and conveniently available form.

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

b. Testing Sealed Sources for Leakage and Contamination.

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

within five (5) days of the test with the Department describing the equipment involved, the tests results and the corrective action taken.

c. Radiation Surveys.

1. The maximum radiation level at a distance of one (1) meter from the patient in whom brachytherapy sources have been inserted shall be determined by measurement or calculation. This radiation level shall be documented and maintained for inspection by the Department.
2. The radiation levels in the patient's room and the surrounding area shall be determined, recorded and maintained for inspection by the Department.
3. The licensee shall assure that patients treated with temporary brachytherapy implants remain hospitalized until a source count and radiation survey of the patient confirm that all implants have been removed.

d. Signs and Records.

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

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- D. The precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted under Part C.

RH-1702. Teletherapy.

a. Equipment.

1. The housing shall be so constructed that at one meter from the source, the maximum exposure rate does not exceed 10 milliroentgens per hour when the beam control mechanism is in the "off" position. The average exposure rate measured at a representative number of points about the housing, each one meter from the source, shall not exceed 2 milliroentgens per hour.
2. For teletherapy equipment installed after the effective date of these Regulations, the leakage radiation measured at one meter from the source when the beam control mechanism is in the "on" position shall not exceed the larger of 1 roentgen per hour or 0.1 percent of the useful beam exposure rate.
3. Adjustable or removable beam-defining diaphragms, shall allow transmission of not more than five percent of the useful beam.
4. The beam control mechanism shall be of a positive design capable of acting in any position of the housing. In addition to an automatic closing device, the mechanism shall be designed so that it can be manually returned to the "off" position with a minimum risk of exposure.
5. The closing device shall be so designed as to return automatically to the "off" position in the event of any breakdown or interruption of the activating force and shall stay in the "off" position until activated from the control panel.
6. When any door to the treatment room is opened, the beam control mechanism shall automatically and rapidly restore the unit to the "off" position and cause it to remain there until the unit is reactivated from the control panel.

7. The equipment shall be provided with a locking device to prevent unauthorized use.
 8. There shall be at the housing and at the control panel a warning device that plainly indicates whether the beam is "on" or "off".
 9. The control panel shall be provided with a timer that automatically terminates the exposure after a pre-set time.
 10. Provision shall be made to permit continuous audible and visual observation of patients during irradiation.
- b. Shielding.
1. Primary protective barriers, as defined in RH-1601.bo.1, shall be provided for any area that the useful beam may strike when using the largest possible diaphragm opening. Such barriers should extend at least one foot beyond the useful beam for any possible orientation.
 2. Secondary protective barriers, as defined in RH-1601.bo.2, shall be provided for all occupied areas exposed to leakage and scattered radiation.
- c. Testing for Leakage and Contamination. Teletherapy sources shall be tested for leakage and contamination in accordance with the procedures described in RH-1701.b except that the leak tests shall be capable of detecting 0.05 microcuries of removable contamination and a source shall be considered to be leaking if the test reveals the presence of 0.05 microcuries or more of removable contamination. Tests of leakage may be made by wiping accessible surfaces of the housing port or collimator while the source is in the "off" position and measuring these wipes for transferred contamination.
- d. Operation. No individual shall be in the treatment room during irradiation unless that individual is the patient. Mechanical restraining or supporting devices shall be used for positioning the patient, if necessary.

- e. Requirement to Perform Full Calibration Measurements of Teletherapy Units.
1. Any licensee authorized under RH-405.d to use teletherapy units for treating humans shall cause full calibration measurements to be performed on each teletherapy unit:
 - A. Prior to the first use of the unit for treating humans;
 - B. Prior to treating humans:
 - i. Whenever spot-check measurements indicate that the output value differs by more than 5 percent from the value obtained at the last full calibration corrected mathematically for physical decay;
 - ii. Following replacement of the radiation source or following reinstallation of the teletherapy unit in a new location;
 - iii. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly.
 - C. At intervals not exceeding one year.
 2. Full calibration measurements required by RH-1702.c.1 of this Section shall include determination of:
 - A. The exposure rate or dose rate to an accuracy with ± 3 percent for the range of field sizes and for the range of distances (or for the axis distance) used in radiation therapy;
 - B. The congruence between the radiation field and the field indicated by the light beam localizing device;
 - C. The uniformity of the radiation field and its dependence upon the orientation of the useful beam;
 - D. Timer accuracy; and

- E. The accuracy of all distance measuring devices used for treating humans.
 3. Full calibration measurements shall be made in accordance with the procedures approved by the Department.
 4. The exposure rate or dose rate values determined in RH-1702.e.2.A shall be corrected mathematically for physical decay for intervals not exceeding one month.
 5. Full calibration measurements required by RH-1702.e of this Section and physical decay corrections required by RH-1702.e.4 shall be performed by an expert qualified by training and experience in accordance with RH-1702.h.
- f. Requirement to Perform Periodic Spot-Check Measurements of Teletherapy Units.
1. Any licensee authorized under RH-405.d to use teletherapy units for treating humans shall cause spot-check measurements to be performed on each teletherapy unit at intervals not exceeding one month.
 2. Spot-check measurements required by RH-1702.f.1 shall include determination of:
 - A. Timer accuracy;
 - B. The congruence between the radiation field and the field indicated by the light beam localizing device;
 - C. The accuracy of all distance measuring devices used for treating humans;
 - D. The exposure rate, dose rate or a quantity related in a known manner to these rates for one typical set of operating conditions; and
 - E. The difference between the measurement made in RH-1702.f.2.D and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

3. Spot-check measurements required by RH-1702.f.1 shall be performed in accordance with procedures established by an expert qualified by training and experience in accordance with RH-1702.h. (A qualified expert need not actually perform the spot-check measurements.) If a qualified expert does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a qualified expert within fifteen (15) days.

g. Requirement to Calibrate Instruments Used for Full Calibration and Spot-Check Measurements.

1. Full calibration required by RH-1702.e shall be performed using a dosimetry system that satisfies one of the two following conditions:
 - A. The system must have been calibrated by the National Institute of Standards and Technology [formerly called National Bureau of Standards] or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two (2) years and after any servicing that may have affected system calibration; or
 - B. The system must have been calibrated by the National Institute of Standards and Technology [formerly called National Bureau of Standards] or by a calibration laboratory accredited by the AAPM within the previous four (4) years; 18 to 30 months after that calibration, the system must have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating Cobalt-60 teletherapy units, the licensee shall use a teletherapy

unit with a Cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating Cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a Cesium-137 source.

2. Spot-check measurements required by RH-1702.f shall be performed using a dosimetry system that has been calibrated in accordance with RH-1702.g.1. Alternatively, a dosimetry system used solely for spot-check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with RH-1702.g.1. This alternative calibration method shall have been performed within the previous one (1) year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.

h. Qualified Expert.

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

- i. Records. The licensee shall maintain, for inspection by the Department, records of the measurements, tests, corrective actions and instrument calibrations made

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under the provisions of RH-1702.e through g and records of the licensee's evaluation of the qualified expert's training and experience made under RH-1702.h.

1. Records of:
 - A. Full calibration measurements under RH-1702.e and;
 - B. Calibration of the instruments used to make these measurements under RH-1702.g, shall be preserved for five (5) years after completion of the full calibration.
2. Records of:
 - A. Spot-check measurements and corrective action under RH-1702 and;
 - B. Calibration of instruments used to make spot-check measurements under RH-1702.g shall be preserved for two (2) years after completion of the spot-check measurements and corrective actions.
3. Records of the licensee's evaluation of the qualified expert's training and experience under RH-1702.h shall be preserved for five (5) years after the qualified expert's last performance of a full calibration on the licensee's teletherapy unit.

j. Radiation Monitoring Device.

1. A licensee shall install in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.
2. Each radiation monitor must be capable of providing visible notice of teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels must be observable by an individual entering the teletherapy room.
3. Each radiation monitor must be equipped with an emergency power supply separate from the power

supply to the teletherapy unit. This emergency power supply may be a battery system.

4. Each radiation monitor must be checked for proper operation each day before the teletherapy unit is used for treatment of patients.
5. A licensee shall maintain a record of the check required by RH-1702.j.4 of this Section for two (2) years. The record must include the date of the check, notation that the monitor indicates when the source is and is not exposed and the initials of the individual who performed the check.
6. If a radiation monitor is inoperable for any reason, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter must be checked for proper operation at the beginning of each day of use.
7. A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

k. Five-Year Inspection.

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

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