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

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By the Arkansas State Board of Health

Arkansas Department of Health
Little Rock, Arkansas

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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. - RH-9. Reserved.

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.

RH-10. (Cont'd)

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.

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 device or equipment emitting or capable of producing any radiation.

n. These Regulations - The Arkansas State Board of Health Rules and Regulations for Control of Sources of Ionizing Radiation, Section 1.

RH-11. - RH-19. Reserved.

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.

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.

RH-34. (Cont'd)

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.

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. <u>Assembler and/or Transfer Requirement.</u>

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;

RH-35. (Cont'd)

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.

RH-36.- RH-39. Reserved.

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 cm^2 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.- RH-49. Reserved.

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 sub-contract, 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.

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.-RH-69. Reserved.

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.-RH-99. Reserved.

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.

RH-105.-
RH-199. Reserved.

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

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.

RH-200. (Cont'd)

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 or 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 pre-construction 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.

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.

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 130^0 F (54.5^0 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.

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 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

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.

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.

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.)

RH-200 (Cont'd)

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.

RH-201.-
RH-299. Reserved.

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 twenty (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 labeled 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

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.

f. 1. Radioactive drug: Capsules containing carbon-14 urea for "in vivo" diagnostic use for humans. Except as provided in paragraphs RH-301.f.2. and RH-301.f.3., any person is exempt from the requirements for a license set forth in Section 5(c) of the Atomic Energy Act of 1954, as amended and from the regulations in this Section provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing one (1) microcurie (37 kBq) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

2. Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to this Section.

3. Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive specific license pursuant to RH-405.o.

RH-301. (Cont'd)

4. Nothing in this Section relieves persons from complying with applicable Food & Drug Administration (FDA), other Federal, and State requirements governing receipt, administration, and use of drugs.

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 Energy (DOE) contractor or subcontractor and any U.S. Nuclear of 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 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.

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/]

RH-306.-
RH-399. Reserved.

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 detecting, measuring, gauging or controlling of 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 device at the time of receipt and bearing a the 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, transfer or dispose of the device containing shall 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;

l. 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 such device pursuant to licensing requirements of 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.

RH-402. (Cont'd)

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 the 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 contain eradequately 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 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.[11] 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 micro-curies 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 micro-curies 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.I:

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.

h. An application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source must either:

1. Identify the source or device by manufacturer and model number as registered with the U.S. Nuclear Regulatory Commission under RH-403.i. or with an Agreement State; or

2. Contains the information identified in RH-403.i.

i. Registration of product information.

1. Any manufacturer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license may submit a request to the U.S. Nuclear Regulatory Commission (NRC) for evaluation of radiation safety information about its product and for its registration

2. The request for review must be made in duplicate and sent to the U.S. Nuclear Regulatory Commission; Division of Industrial and Medical Nuclear Safety; Medical, Academic, and Commercial Use Safety Branch; Washington, D.C. 20555.

3. The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

4. The NRC normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the NRC formulates reasonable standards and criteria with the help of the manufacturer or distributor. The NRC shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.

5. After completion of the evaluation, the Commission issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product.

RH-403. (Cont'd)

6. The person submitting the request for evaluation and registration of safety information about the product in accordance with:

   i. The statements and representations, including quality control program, contained in the request; and

   ii. The provisions of the registration certificate.

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.

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 thirty (30) 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 thirty (30) 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

   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.

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.

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 of10 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 Molybdenum-99. This testing shall be of 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 exceed15 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 ten (10%) percent 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

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 ten (10%) percent 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;

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 re-concentration 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 of10 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:

RH-405. (Cont'd)

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.

RH-405. (Cont'd)

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 exceed10 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.

l. 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

RH-405. (Cont'd)

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.I.1.B.iii or RH-405.I.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.I.2.B and RH-405.I.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.I.2.A and RH-405.I.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.I.2.B.i and RH-405.I.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.

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,

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 material,

   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.

o. Radioactive drug. Manufacture, preparation, or transfer for commercial distribution of capsules containing carbon-14 urea for "in vivo" diagnostic use for humans to persons exempt from licensing. Requirements for a license:

1. An application for a specific license to manufacture, prepare, produce, package, repackage, or transfer for commercial distribution of capsules containing carbon-14 capsules containing one (1) microcurie (37 kBq) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use, to persons exempt from licensing under RH-301.f. or the equivalent regulations of the Nuclear Regulatory Commission or of an Agreement State will be approved if:

   a. The applicant satisfies the general requirements specified in RH-404, provided that the requirements of RH-404.a.1. and a.2. do not apply to an application for a license to transfer radioactive material manufactured, prepared, processed, produced, packaged, or repackaged pursuant to license issued by the Nuclear Regulatory Commission or another Agreement State;

   b. The applicant meets the requirements under RH-405.I.1.B. of this Section;

   c. The applicant provides evidence that each capsule contains one (1) microcurie (37 kBq) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process);

   d. The carbon -14 urea is not contained in any food, beverage, cosmetic, drug (except as described in this Section) or other commodity designed for ingestion or inhalation by, or topical application to, a human being;

   e. The carbon -14 urea is in the form of a capsule, identified as radioactive, and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

   f. The applicant submits copies of prototype labels and brochures and the Department approves these labels and brochures.

2. Nothing in this Section relieves the licensee from complying with applicable Food & Drug Administration (FDA), other Federal, and State requirements governing drugs.

p. Radioactive drug. Manufacture, preparation, or transfer for commercial distribution of capsules containing carbon-14 urea for "in vivo" diagnostic use for humans to persons exempt from licensing. Conditions of license. Each license issued under RH-405.o. is subject to the following conditions:

1. The immediate container of the capsule(s) must bear a durable, legible label which:

a. Identifies the radioisotope, the physical and chemical form, the quantity of radioactivity of each capsule at a specific date; and

b. Bears the words **"Radioactive Material".**

2. In addition to the labeling information required by RH-405.p.1, the label affixed to the immediate container, or an accompanying brochure also must:

a. State that the contents are exempt from NRC or Agreement State licensing requirements; and

b. Bear the words

"Radioactive Material. For "In Vivo" Diagnostic Use Only. This Material Is Not To Be Used For Research Involving Human Subjects and Must Not Be Introduced into Foods, Beverages, Cosmetics, or Other Drugs or Medicinals, or into Products Manufactured For Commercial Distribution. This Material May Be Disposed of in Ordinary Trash."

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.

RH-406. (Cont'd)

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 specific license authorizing receipt, acquisition, a 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 proposed uses of radioactive material of 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 engineering in; 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.

RH-407. (Cont'd)

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 assurance program, tailored to LLW disposal, developed and applied by the applicant for the determination of natural disposal site characteristics and for quality assurance during the design, construction, operation and closure of the land disposal facility and the receipt, handling and emplacement of waste.

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, wasting, slope failure, settlement of mass 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, land-sliding 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 (3) 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. 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 waste form to ensure stability but also on 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 or 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 sum of fractions rule described in the RH-407.d.6.F.

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	[1]3,500
Cm-242	[1]20,000

[1]Units 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/m^3 and Cs-137 in a concentration of 22 Ci/m^3. Since the concentrations both exceed the values in Column1, 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 20^0 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.

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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.

RH-407. (Cont'd)

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.

RH-409. (Cont'd)

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 license 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 by10^5 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 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 by10^{10} is greater than 1.) ..... $ 75,000

5. The decommissioning funding plan must also contain a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning and a signed original of the financial instrument obtained to satisfy the requirements of RH-409.h.6.

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. 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.

For commercial corporations that issue bonds, 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 as contained in Appendix B of this Section. For commercial corporations that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in Appendix C of this Section. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in Appendix D 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 or insurance used to provide financial assurance for decommissioning must contain the following conditions:

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 ninety (90) 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 thirty (30) 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.

E. When a governmental entity is assuming custody and ownership of a site, an arrangement by such governmental entity.

7. Each person licensed under Section 2 shall keep records of information important to decommissioning of the facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with RH-409.b., licensees shall transfer all records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility 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 ay 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 sixty-five (65) 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;

iv. All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate to meet the criteria for decommissioning in RH-410 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.

b. Each specific license revoked by the Department expires with the Department's final determination to revoke the license, or the expiration date stated in the determination, or as otherwise provided by Department Order.

c. 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.

d. Within sixty (60) 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 twelve (12) months of notification a decommissioning plan, if required by RH-410.f., and begin decommissioning upon approval of that plan if:

1. The license has expired pursuant to RH-410.a; or RH-410.b.;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 twenty-four (24) months; or

4. No principal activities have been conducted for a period of twenty-four (24) 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.

e. Coincident with the notification required by RH-410.c., the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to RH-409.h. in conjunction with a license issuance or renewal or as required by RH-410. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to RH-410.g.4.v.

1. Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this regulation becomes effective.

2. Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Department.

f. The Department may grant a request to extend the time periods established in RH-410.c. if the Department determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than thirty (30) days notification pursuant to RH-410.c. The schedule for decommissioning set forth in RH-410.c. may not commence until the Department has made a determination on the request.

g. 1. A decommissioning plan must be submitted if required by license conditions or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Department and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i). Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(ii). Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(iii). Procedures could result in significant greater airborne concentrations of radioactive materials than are present during operation; or

(iv). Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

2. The Department may approve an alternate schedule for submittal of a decommissioning plan required in RH-410.c. if the Department determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health an safety and is otherwise in the public interest.

3. Procedures such as those listed in RH-410.g. with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

4. The proposed decommissioning plan for the site or separate building or outdoor area must include:

   (i). A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

   (ii). A description of planned decommissioning activities;

   (iii). A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

   (iv). A description of the planned final radiation survey; and

   (v). An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

   (vi). For decommissioning plans calling for completion of decommissioning later than twenty-four (24) months after plan approval, the plan shall include a justification for the delay based on the criteria in RH-410.h.

5. The proposed decommissioning plan will be approved by the Department if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

h. 1. Except as provided in RH-410.h., licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than twenty-four (24) months following the initiation of decommissioning.

2. Except as provided in RH-410.h., when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than twenty-four (24) months following the initiation of decommissioning.

i. The Department may approve a request for an alternative schedule for completion of decommissioning of the site separate building or outdoor area and license termination if appropriate, if the Department determines that the alternative is warranted by consideration of the following:

1. Whether it is technically feasible to complete decommissioning within the allotted twenty-four (24) month period;

2. Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted twenty-four (24) month period;

3. Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

4. Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclidesto decay; and

5 Other site-specific factors which the Department may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

j. As the final step in decommissioning, the licensee shall:

1. Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed ADH FORM 314 or equivalent information; and

2. Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in RH-1216, RH-1217, and/or RH-1218. The licensee shall, as appropriate:

   A. Report levels of gamma radiation in units of microroentgen (millisieverts) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of disintegrations per minute or microcuries (megabecquerels) per 100 square centimeters - removable and fixed - for surfaces, microcuries (megabecquerels) per milliliter for water, and picocuries (becquerels) per gram for solids such as soils or concrete; and

   B. Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

k. Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Department determines that:

   1. Radioactive material has been properly disposed;

   2. Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

   3. A. A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in RH-1216, RH-1217, and/or RH-1218; or

      B. Other information submitted by the licensee is sufficient that the premises are suitable for release in accordance with the criteria for decommissioning in RH-1216, RH-1217, and/or RH-1218.

   4. Records required by RH-600 have been received.

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 thirty (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 public health, interest or safety requires otherwise, no the license shall be modified, suspended or revoked unless, prior to the institution of proceedings therefore, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded 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.

RH-417.
RH-499. Reserved.

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;

RH-501. (Cont'd)

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.

RH-503.
RH-599. Reserved.

PART F.
RECORDS, REPORTS, AND INSPECTIONS

RH-600. Records.

a. Each person who receives a source of radiation pursuant to a license or registration under this Section shall keep records showing the receipt, transfer and disposal of such sources of radiation as follows:

1. The licensee or registrant shall retain record of receipt of radioactive material or a source of ionizing radiation as long as the material or source is possessed and for three (3) years following transfer or disposal of the material or source of radiation.

2. The licensee or registrant who transferred the material or source of radiation shall maintain each record of transfer for three (3) years after each transfer unless a specific requirement in another part of the regulations in this Section dictates otherwise.

3. The licensee or registrant who disposed of the material or source of radiation shall retain each record of disposal of radioactive material or source of radiation until the Department terminates each license or registration that authorizes disposal of the material or source of radiation.

b. Each licensee or registrant shall retain each record that is required by this Section for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record must be retained until the Department terminates each license or registration that authorizes the activity that is subject to the recordkeeping requirement.

c. 1. Records which must be maintained pursuant to this Section may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Department regulations. 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, 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.

2. If there is a conflict between the Department's regulations in this Section, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this Section for such records shall apply unless the Department, pursuant to RH-304, has granted a specific exemption from the record retention requirements specified in this Section.

d. Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the Department:

1. Records of disposal of licensed material made under RH-1401, RH-1402, RH-1404, RH-1405; and

2. Records required by RH-1500.c.2.D.

e. If licensed activities are transferred or assigned in accordance with RH-409.b., each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

1. Records of disposal of licensed material made under RH-1401, RH-1402, RH-1404, RH-1405; and

2. Records required by RH-1500.c.2.D.

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.

RH-603.-
RH-699. Reserved.

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 that 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-701.-
RH-749. Reserved.

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.

RH-752.-
RH-899. Reserved.

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 115m)	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.** (Cont'd)

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 (Rh 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. (Cont'd)

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.

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

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	----------	3×10^{-4}
	Sb 124	----------	2×10^{-4}
	Sb 125	----------	1×10^{-3}
Argon (18)	A 37	1×10^{-3}	--------
	A 41	4×10^{-7}	--------
Arsenic (33)	As 73	----------	5×10^{-3}
	As 74	----------	5×10^{-4}
	As 76	----------	2×10^{-4}
	As 77	----------	8×10^{-4}
Barium (56)	Ba 131	----------	2×10^{-3}
	Ba 140	----------	3×10^{-4}
Beryllium (4)	Be 7	----------	2×10^{-2}
Bismuth (83)	Bi 206	----------	4×10^{-4}
Bromine (35)	Br 82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd 109	----------	2×10^{-3}
	Cd 115m	----------	3×10^{-4}
	Cd 115	----------	3×10^{-4}
Calcium (20)	Ca 45	----------	9×10^{-5}
	Ca 47	----------	5×10^{-4}
Carbon (6)	C 14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce 141	----------	9×10^{-4}
	Ce 143	----------	4×10^{-4}
	Ce 144	----------	1×10^{-4}
Cesium (55)	Cs 131	----------	2×10^{-2}
	Cs 134m	----------	6×10^{-2}
	Cs 134	----------	9×10^{-5}
Chlorine (17)	Cl 38	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr 51	----------	2×10^{-2}
Cobalt (27)	Co 57	----------	5×10^{-3}
	Co 58	----------	1×10^{-3}
	Co 60	----------	5×10^{-4}
Copper (29)	Cu 64	----------	3×10^{-3}
Dysprosium (66)	Dy 165	----------	4×10^{-3}
	Dy 166	----------	4×10^{-4}
Erbium (68)	Er 169	----------	9×10^{-4}
	Er 171	----------	1×10^{-3}
Europium (63)	Eu 152	----------	6×10^{-4}
	(T/2=9.2 hrs)	----------	--------
	Eu 155	----------	2×10^{-3}
Fluorine (9)	F 18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd 153	----------	2×10^{-3}
	Gd 159	----------	8×10^{-4}
Gallium (31)	Ga 72	----------	4×10^{-4}
Germanium (32)	Ge 71	----------	2×10^{-2}
Gold (79)	Au 196	----------	2×10^{-3}
	Au 198	----------	5×10^{-4}
	Au 199	----------	2×10^{-3}
Hafnium (72)	Hf 181	----------	7×10^{-4}

RH-902. **Schedule C. Exempt Concentrations.** (Cont'd)

Element (atomic number)	Isotope	Column I Gas concentration Ci/ml[12]	Column II Liquid and solid concentration Ci/ml[13]
Hydrogen (1) -----	H 3	5×10^{-6}	3×10^{-2}
Indium (49) -------	In 113m	----------	1×10^{-2}
	In 114m	----------	2×10^{-4}
Iodine (53) -------	I 126	3×10^{-9}	2×10^{-5}
	I 131	3×10^{-9}	2×10^{-5}
	I 132	8×10^{-8}	6×10^{-4}
	I 133	1×10^{-8}	7×10^{-5}
	I 134	2×10^{-7}	1×10^{-3}
Iridium (77) ------	Ir 190	----------	2×10^{-3}
	Ir 192	----------	4×10^{-4}
	Ir 194	----------	3×10^{-4}
Iron (26) ---------	Fe 55	----------	8×10^{-3}
	Fe 59	----------	6×10^{-4}
Krypton (36) ----	Kr 85m	1×10^{-6}	-------
	Kr 85	3×10^{-6}	-------
Lanthanum (57)	La 140	----------	2×10^{-4}
Lead (82) -------	Pb 203	----------	4×10^{-3}
Lutetium (71) ---	Lu 177	----------	1×10^{-3}
Manganese (25)	Mn 52	----------	3×10^{-4}
	Mn 54	----------	1×10^{-3}
	Mn 56	----------	1×10^{-3}
Mercury (80) ---	Hg 197m	----------	2×10^{-3}
	Hg 197	----------	3×10^{-3}
	Hg 203	----------	2×10^{-4}
Molybdenum (42)	Mo 99	----------	2×10^{-3}
Neodymium (60)	Nd 147	----------	6×10^{-4}
	Nd 149	----------	3×10^{-3}
Nickel (28) ------	Ni 65	----------	1×10^{-3}
Niobium(Columbium)(41)	Nb 95	----------	1×10^{-3}
	Nb 97	----------	9×10^{-3}
Osmium (76) ---	Os 185	----------	7×10^{-4}
	Os 191m	----------	3×10^{-2}
	Os 191	----------	2×10^{-3}
	Os 193	----------	6×10^{-4}
Palladium (46) -	Pd 103	----------	3×10^{-3}
	Pd 109	----------	9×10^{-4}
Phosphorus (15)	P 32	----------	2×10^{-4}
Platinum (78) --	Pt 191	----------	1×10^{-3}
	Pt 193m	----------	1×10^{-2}
	Pt 197m	----------	1×10^{-2}
	Pt 197	----------	1×10^{-3}
Polonium (84) --	Po 210	----------	7×10^{-6}
Potassium (19)	K 42	----------	3×10^{-3}
Praseodymium (50) --	Pr 142	----------	3×10^{-4}
	Pr 143	----------	5×10^{-4}

RH-902. **Schedule C. Exempt Concentrations.** (Cont'd)

Element (atomic number)	Isotope	Column I Gas concentration Ci/ml[12/]	Column II Liquid and solid concentration Ci/ml[13/]
Promethium (61)	Pm 147	----------	2×10^{-3}
	Pm 149	----------	4×10^{-4}
Radium (88) ----	Ra 226	----------	1×10^{-7}
	Ra 228	----------	3×10^{-7}
Rhenium (75) --	Re 183	----------	6×10^{-3}
	Re 186	----------	9×10^{-4}
	Re 188	----------	6×10^{-4}
Rhodium (45) --	Rh 103m	----------	1×10^{-1}
	Rh 105	----------	1×10^{-3}
Rubidium (37) -	Rb 86	----------	7×10^{-4}
Ruthenium (44)	Ru 97	----------	4×10^{-3}
	Ru 103	----------	8×10^{-4}
	Ru 105	----------	1×10^{-3}
	Ru 106	----------	1×10^{-4}
Samarium (62)	Sm 153	----------	8×10^{-4}
Scandium (21)	Sc 46	----------	4×10^{-4}
	Sc 47	----------	9×10^{-4}
	Sc 48	----------	3×10^{-4}
Selenium (34) ---	Se 75	----------	3×10^{-3}
Silicon (14) ------	Si 31	----------	9×10^{-3}
Silver (47) -------	Ag 105	----------	1×10^{-3}
	Ag 110m	----------	3×10^{-4}
	Ag 111	----------	4×10^{-4}
Sodium (11) ----	Na 24	----------	2×10^{-3}
Strontium (38) -	Sr 85	----------	1×10^{-3}
	Sr 89	----------	1×10^{-4}
	Sr 91	----------	7×10^{-4}
	Sr 92	----------	7×10^{-4}
Sulfur (16) ------	S 35	9×10^{-8}	6×10^{-4}
Tantalum (73) --	Ta 182	----------	4×10^{-4}
Technetium (43)	Tc 96m	----------	1×10^{-1}
	Tc 96	----------	1×10^{-3}
Tellurium (52) --	Te 125m	----------	2×10^{-3}
	Te 127m	----------	6×10^{-4}
	Te 127	----------	3×10^{-3}
	Te 129m	----------	3×10^{-4}
	Te 131m	----------	6×10^{-4}
	Te 132	----------	3×10^{-4}
Terbium (65) ---	Tb 160	----------	4×10^{-4}
Thallium (81) ---	Tl 200	----------	4×10^{-3}
	Tl 201	----------	3×10^{-3}
	Tl 202	----------	1×10^{-3}
	Tl 204	----------	1×10^{-3}
Thulium (69) ---	Tm 170	----------	5×10^{-4}
	Tm 171	----------	5×10^{-3}
Tin (50) ---------	Sn 113	----------	9×10^{-4}
	Sn 125	----------	2×10^{-4}

RH-902. **Schedule C. Exempt Concentrations.** (Cont'd)

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

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

RH-903. 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).

Any radioactive material in a radiopharmaceutical for uptake, dilution, or excretion studies. A licensee may use any of the material in a radiophamaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion for which the Food and Drug Administration (FDA) has a "Notice of Claimed Investigational Exemption for New Drug" (IND) or approved a "New Drug Application" (NDA).

Group II. Imaging and tumor localizations.

Any radioactive material in a diagnostic radiopharmaceutical, except aerosol or gaseous form, or any generator or reagent kit for preparation and diagnostic use for which the Food and Drug Administration (FDA) has a "Notice of Claimed Investigational Exemption for New Drug" (IND) or approved a "New Drug Application" (NDA).

Group III. Generators and Reagent Kits.

Any radioactive Material in a diagnostic radiopharmaceutical, except aerosol or gaseous form, or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive Material for which the Food and Drug Administration (FDA) has a "Notice of Claimed Investigational Exemption for "New Drug" (IND) or approved a "New Drug Application" (NDA).

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.**

Radioactive Material	Column I Curies	Column II Curies
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.
Chronmium-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.

RH-904. **Schedule E.** **Limits for Broad Licenses.** (Cont'd)

Radioactive Material	Column I Curies	Column II Curies
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
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
Mercuty-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

RH-904. **Schedule E. Limits for Broad Licenses.** (Cont'd)

Radioactive Material	Column I Curies	Column II Curies
Palladium-103	10	0.1
Palladium-109	10	0.1
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

RH-904. **Schedule E.** **Limits for Broad Licenses.** (Cont'd)

Radioactive Material	Column I Curies	Column II Curies
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1.
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1.
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Tallium-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.**

Radioactive material[15/ 16/]	Release Fraction	Quantity (Curies)
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
Iridium-192	0.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000

RH-905. **Schedule F. Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release.** (Cont'd)

Radioactive material[15/ 16/]	Release Fraction	Quantity (Curies)
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Maganese-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
Phosphors-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-6	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000

RH-905. **Schedule F. Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release.** (Cont'd)

Radioactive material[15/ 16/]	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 established 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:

a. 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

b. 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

c. Tangible net worth of at least $10 million; and

d. Assets located in the United States amounting to at least ninety (90) percent of total assets or at least six times the current decommissioning cost estimates (or prescribed amount if a certificate is used).

2. The parent company must have:

a. 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

b. Tangible net worth at least six times the current decommissioning cost estimate (or prescribed amount if a certification is used); and

c. Tangible net worth of at least $10 million; and

d. Assets located in the United States amounting to at least ninety (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 ninety (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 ninety (90) days after the end of the fiscal year for which the yearend 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.

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.

Appendix A. (Cont'd)

B. If the licensee fails to provide alternate financial assurance as specified in the Department's regulations within ninety (90) 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 trust 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.

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:

1. 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.

2. Assets located in the United States amounting to at least ninety 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.

3. 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.

B. To pass the financial test, a company must meet all of the following additional requirements:

1. The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

2. 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 ninety (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.

3. After the initial financial test, the company must repeat the passage of the test within ninety (90) 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 ninety (90) days following receipt by the Department of a notice of cancellation of the guarantee.

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 twenty (20) 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.

APPENDIX C: Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That Have no Outstanding Rated Bonds

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 C. The terms of the self-guarantee are in Section III of APPENDIX C. 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:

1. Tangible net worth greater than $10 million, or at least ten (10) times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

2. 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 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.

3. A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by net worth less than 1.5.

B. In addition, to pass the financial test, a company must meet all of the following additional requirements:

1. The company's independent certified public accountant must have compared the data used by the company in the financial test, which is required to be derived from the independently audited year end financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Department within ninety (90) days of any matters that may 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.

2. After the initial financial test, the company must repeat the passage of the test within ninety (90) days after the close of each succeeding fiscal year.

3. If the licensee no longer meets the requirements of Section II.A of APPENDIX C, the licensee must send notice to the Department of its intent to establish alternate financial assurance as specified in the Department's Regulations. The notice must be sent by certified mail, return receipt requested, within ninety (90) days after the end of the fiscal year for which the yearend financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

III. Company Self-Guarantee

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

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the Department. Cancellation may not occur until an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in the Department's regulations within ninety (90) days following receipt by the Department of a notice of cancellation of the guarantee.

Appendix C. (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 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.

APPENDIX D: Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning by Nonprofit Colleges, Universities, and Hospitals

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 applicant or licensee passes a financial test of Section II of APPENDIX D. The terms of the self-guarantee are in Section III of APPENDIX D. 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. For colleges and universities, to pass the financial test, a college or university must meet either the criteria in Paragraph II.A.1. or the criteria in Paragraph II.A.2. of this Appendix.

1. For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moodys.

2. For applicants or licensees that do not issue bonds, States of at least $50 million, at least thirty (30) times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as self-guaranteeing licensee and as parent-guarantor.

B. For hospitals, to pass the financial test, a hospital must meet either the criteria in Paragraph II.B.1. or the criteria in Paragraph II.B.2. of this Appendix.

1. For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moodys.

2. For applicants or licensees that do not issue bonds, all the following tests must be met:

a. (Total Revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.

b. Long term debt divided by net fixed assets must be less than or equal to 0.67

c. (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.

d. Operating revenues must be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as self-guaranteeing licensee.

C. In addition, to pass the financial test; a licensee must meet all the following requirements:

1. The licensee's independent certified public accountant must have compared the data used by the licensee in the financial test, which is required to be derived from the independently audited yearend financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Department within ninety (90) days of any matters that may 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.

2. After the initial financial test, the licensee must repeat the passage of the test within ninety (90) days after the close of each succeeding fiscal year.

3. If the licensee no longer meets the requirements of Section I of APPENDIX D, the licensee must send notice to the Department of its intent to establish alternate financial assurance as specified in the Department's Regulations. The notice must be sent by certified mail, return receipt requested, within ninety (90) days after the end of the fiscal year for which the yearend financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

III. Self-Guarantee

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

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail, and/or return receipt requested, to the Department. Cancellation may not occur unless an alternate financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in the Department's regulations within ninety (90) days following receipt by the Department of a notice of cancellation of the guarantee.

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 applicant or licensee must provide to the Department a written guarantee (a written commitment by a corporate officer or officer of the institution) 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.

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 twenty (20) days after publication of the change by the rating service.

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.

10/ Deleted. Deleted when RH-405.m was deleted.

FOOTNOTES FOR SECTION 2 (Cont'd)

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, Pubic Law 99-499 or other state or federal reporting requirements.

15/ For combinations of radioactive materials, consideration of the need an emergency plan is required if the sum of the ratios of the quantity of for 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.

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 or registrant shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities or x-ray equipment use and sufficient to ensure compliance with the provisions of this Part. (See RH-1500 for recordkeeping requirements relating to these programs.)

b. The licensee or registrant shall use, to the extent practical, 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 or registrant shall periodically (at least annually) review the radiation protection program content and implementation.

d. To implement the ALARA requirements in RH-1004.b., and not withstanding the requirements in RH-1208, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of ten (10) mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceed this dose constraint, the licensee shall report the exceedance as provided in RH-1504 and promptly take appropriate corrective action to ensure against recurrence.

RH-1005.-RH-1099. Reserved.

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. Air-purifying Respirator - A respirator with an air purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

i. 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 or x-ray equipment use 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 x-ray equipment, nuclear energy and licensed materials in the public interest.

j. 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).

k. 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.

l. Assigned protection factor (APF) - The expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

m. Atmosphere-supplying respirator - A respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

n. 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 or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee or registrant.

o. 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.

p. 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.

q. 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.

r. 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.

s. 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.

t. 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 ($H_{E,50} = \Sigma w_T H_{T,50}$).

u. Constraint (dose constraint) - a value above which specified licensee or registrant actions are required.

v 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.

w. Critical Group - the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

x. Declared pregnant woman - A woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared woman withdraws the declaration in writing or is no longer pregnant.

y. Decommission - to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:

(1) Release of the property for unrestricted use and termination of the license; or

(2). Release of the property under restricted conditions and termination of the license.

z. 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).

aa. Demand respirator - An atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

ab. Department - The Arkansas Department of Health or its duly authorized representatives.

ac. 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).

ad. 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.

ae. 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).

af. Director - Director of the Arkansas Department of Health.

ag. Disposable respirator - A respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

ah. Distinguishable from background - the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

ai. 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.

aj. 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).

ak. 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.

al. 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 ($H_E = \Sigma\ w_T H_T$).

am. Embryo/fetus - The developing human organism from conception until the time of birth.

an. 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.

ao. Exposure - Being exposed to ionizing radiation or to radioactive material.

ap. External dose - That portion of the dose equivalent received from radiation sources outside the body.

aq. Extremity - Hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

ar. 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/cm^2).

as. 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.

at. 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.

au. Gray - See RH-1102. Units of Radiation Dose.

av. Helmet - A rigid respirator inlet covering that also provides head protection against impact and penetration.

aw. High radiation area - An area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in one (1) hour at thirty 30 centimeters from the radiation source or thirty (30) centimeters from any surface that the radiation penetrates.

ax. Hood - A respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

ay. Individual - Any human being.

az. 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.

ba. 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.

bb. Internal dose - That portion of the dose equivalent received from radioactive material taken into the body.

bc. Lens dose equivalent (LDE) - applies to 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/cm^2).

bd. License - Except where otherwise specified, means a license issued pursuant to Section 2, Section 6, or Section 7.

be. 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.

bf. Licensee - The holder of a license.

bg. Limits (dose limits) - The permissible upper bounds of radiation doses.

bh. Loose-fitting facepiece - A respiratory inlet covering that is designed to form a partial seal with the face.

bi. 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.

bj. Member of the public – Any individual except when that individual is receiving an occupational dose or unrestricted area.

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

bl. 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

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B. When both the administered dosage differs from the prescribed dosage by more than twenty (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 twenty (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 ten (10%) percent of the total prescribed dose.

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 ten (10%) percent of the total prescribed dose;

C. When the calculated weekly administered dose exceeds the weekly prescribed dose by thirty (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 twenty (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 twenty (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:

   A. Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage and;

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

bm. 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.

bn. Negative pressure respirator (tight fitting) - A respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

bo. 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).

bp. Occupational dose - The dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to 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, from any medical administration the individual has received from exposure to individuals administered radioactive material and released in accordance with RH-1214, from voluntary participation in medical research programs, or as a member of the general public.

bq. 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.

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

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

bt. Positive pressure respirator - a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

bu. Powered air-purifying respirator (PAPR) - an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

bv. 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.

bw. 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.

bx. Pressure demand respirator - a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

by. Public dose - The dose received by a member of the public from exposure to radiation or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee or registrant. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with RH-1214, or from voluntary participation in medical research programs.

bz. 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 (1) teletherapy unit.

ca Quantitative fit test (QNFT) - an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

cb. 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

cc. 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.

cd. Rad - See RH-1102. Units of Radiation Dose.

ce. 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.

cf. 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

cg. Radiation machine - Any device capable of producing radiation, but excluding devices which produce radiation only by the use of radioactive material

ch. Radioactive material - Any material (solid, liquid or gas) which emits radiation spontaneously including any natural radioactive material such as Radium.

ci. Radioactivity - The transformation of unstable atomic nuclei by the emission of radiation.

cj. 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 ten (10%) percent of the prescribed dosage; and

   B. The difference between the administered dosage and prescribed dosage exceeds 15 microcuries;

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 ten (10%) percent of the prescribed dose.

ck. 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.

cl. Rem - See RH-1102. Units of Radiation Dose.

cm. Residual radioactivity - radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but, excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site even if those burials were made in accordance with the provision of Section 3. Part E. Waste Disposal.

cn. Respiratory protective device - An apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.

co. 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.

cp. 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.

cq. Self-contained breathing apparatus (SCBA) - an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

cr. Shallow-dose equivalent (H_s) (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.

cs. Sievert - See RH-1102. Units of Radiation Dose.

ct. Site boundary - That line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

cu. 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.

cv. Source of radiation - Any radioactive material or any radiation machine.

cw. 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.

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cx. Storage container - A device in which sealed sources are transported or stored.

cy. 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.

cz. Supplied-air respirator (SAR) or airline respirator - an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

da. 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.

db. Temporary jobsite - a location to which radioactive materials or x-ray equipment have been dispatched to perform one (1) or more of the following service operations:

1. Moisture/density measurements;

2. Level measurements;

3. Any portable devices containing radioactive materials; and/or

4. Consulting services included, but not limited to:

A. Calibration of instruments;

B. Repair of devices or sources;

C. Sealed source installation and/or exchange;

D. Decommissioning of sealed sources.

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

dd. Tight-fitting facepiece - a respiratory inlet covering that forms a complete seal with the face.

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

df. 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.

dg. 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.

dh. User seal check (fit check) - an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure, irritant smoke check, or isoamyl acetate check.

di. Very high radiation area - An area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 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).**

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

dk. 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 equivalent, the values of w_T are dose:

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.

dl. Whole body - For purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

dm. Worker - An individual engaged in work under a license or registration issued by the Department and controlled by a licensee or registrant.

dn. 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.

do. 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).

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dp. 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;

5. For high-dose-rate remote after loading 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.

dq. 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.

TABLE RH-1102 #1

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION Factor	Quality (Q)	Absorbed Dose Equal to a Unit Dose Equivalent[a]
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.

RH-1102. (Cont'd)

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)	2.5×10^{-8}	2	980×10^{6}
	1×10^{-7}	2	980×10^{6}
	1×10^{-6}	2	810×10^{6}
	1×10^{-5}	2	810×10^{6}
	1×10^{-4}	2	840×10^{6}
	1×10^{-3}	2	980×10^{6}
	1×10^{-2}	2.5	1010×10^{6}
	1×10^{-1}	7.5	170×10^{6}
	5×10^{-1}	11	39×10^{6}
	1	11	27×10^{6}
	2.5	9	29×10^{6}
	5	8	23×10^{6}
	7	7	24×10^{6}
	10	6.5	24×10^{6}
	14	7.5	17×10^{6}
	20	8	16×10^{6}
	40	7	14×10^{6}
	60	5.5	16×10^{6}
	1×10^{2}	4	20×10^{6}
	2×10^{2}	3.5	19×10^{6}
	3×10^{2}	3.5	16×10^{6}
	4×10^{2}	3.5	14×10^{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.

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.

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.

RH-1106 - RH-1199. Reserved

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:

A. The total effective dose equivalent being equal to 5 rems (0.05 Sv), or

B. 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:

A. An lens dose equivalent of 15 rems (0.15 Sv), and

B. 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, lens 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.

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.

RH-1200. (Cont'd)

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.

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.

RH-1201. (Cont'd)

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.

RH-1203. (Cont'd)

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.

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.

RH-1203. (Cont'd)

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 ten (10%) percent of its DAC; and

3. The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed thirty (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 dose estimated to result from the planned special exposure are unavailable or impractical.

RH-1205. (Cont'd)

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

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 thirty (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 ten (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 equivalent to the 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 equivalent to the embryo/fetus is the sum of:

1. The deep-dose equivalent to the declared pregnant woman; and

2. The dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

d. If the dose equivalent 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 RH-1207.a., 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 or registered operation does not exceed 0.1 rem (1 millisievert) in a year, exclusive of the dose contribution from the background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with RH-1214, from voluntary participation in medical research program, and from 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, exclusive of the dose contributions from patients administered radioactive material and released in accordance with RH-1214, does not exceed 0.002 rem (0.02 millisievert) in any one hour.

RH-1208. (Cont'd)

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;

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

RH-1209. (Cont'd)

2. Demonstrating that:

A. The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table 2 of Appendix G to RH-1000 through RH-2110; and

B. 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 Subparagraph a of this Paragraph. The Department will in 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.

RH-1210. (Cont'd)

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 the extent that the contamination exceeds the to 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 µCi/ml to µCi/gm; and

B. In restricted areas, the concentration limits specified in RH-2200, Appendix A, Table I, Column 2, with the units changed from µCi/ml to µCi/gm.

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

RH-1210. (Cont'd)

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 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 cm^2.

[5] The amount of removable radioactive material per 100 cm^2 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.

RH-1214. Release of Individuals Containing Radiopharmaceuticals or Permanent Implants.

a. The licensee may authorize the release from its control of any individual who has been administered Iodine 131 as Sodium Iodide if the total patient concentration has been determined to be to be thirty (30) millicuries or less.

b. The licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals with the exception of Iodine 131 as Sodium Iodide as referenced in RH-1214.a. or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (5 millisieverts).

NOTE: **U.S. Nuclear Regulatory Commission Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem five (5) millisieverts.**

c. The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 0.1 rem (one (1) millisieverts). If the dose to a breast-feeding infant or child could exceed 0.1 rem (one (1) millisieverts) assuming there were no interruption of breast-feeding, the instructions shall also include:

1. Guidance on the interruption or discontinuation of breast-feeding; and

2. Information on the consequences of failure to follow the guidance.

d. The licensee shall maintain a record of the basis for authorizing the release of an individual, for three (3) years after the date of release, if the total effective dose equivalent is calculated by:

1. Using the retained activity rather than the activity administered;

2. Using an occupancy factor less than 0.25 at one (1) meter;

3. Using the biological or effective half-life; or

4. Considering the shielding by tissue.

RH-1214. (Cont'd)

e. The licensee shall maintain a record, for three (3) years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 0.5 rem (five (5) millisieverts).

RH-1215. Reserved.

RH-1216. Radiological Criteria for Unrestricted Use.

A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

RH-1217. Criteria for License Termination Under Restricted Conditions.

A site will be considered acceptable for license termination under restricted conditions if:

a. The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of RH-1217 would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;

b. The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) per year;

c. The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

1. Funds placed into an account segregated from the licensee's assets and outside the licensee's administrative control as described in RH-409.h.6.A.;

2. Surety method, insurance, or other guarantee method as described in RH-409.h.6.B.;

3. A statement of intent in the case of State or local Government licensees, as described in RH-409.h.6.D. or;

4. When a government entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

d. The licensee has submitted a decommissioning plan or License Termination Plan (LTP) to the Department indicating the licensee's intent to decommission in accordance with RH-410.d. and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.

1. Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

A. Whether provisions for institutional controls proposed by the licensee:

i. Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) TEDE per year;

ii. Will be enforceable; and

iii. Will not impose undue burdens on the local community or other affected parties.

B. Whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

2. In seeking advice on the issues identified in RH-1217.d.1., the licensee shall provide for:

   A. Participation by representatives of a broad cross section of community interest who may be affected by the decommissioning:

   B. An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

   C. A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

e. Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either:

   1. 100 mrem (1mSv) per year; or

   2. 500 mrem (1mSv) per year provided the licensee

      A. Demonstrates that further reductions in residual radioactivity necessary to comply with the100 mrem/yr (1mSv/y) value of RH-1217.e.1. are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

      B. Makes provisions for durable institutional controls;

      C. Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every five (5) years to assure that the institutional controls remain in place as necessary to meet the criteria of RH-1217.b. and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in RH-1217.c.

RH-1218. Alternate Criteria for License Termination.

a. The Department may terminate a license using alternate criteria greater than the dose criterion of RH-1216, RH-1217.b., and RH-1217.d.1.i.A, if the licensee:

1. Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 100 mrem/y (1 mSv/y) limit of Part C (RH-1208 and RH-1209), by submitting an analysis of possible sources of exposure;

2. Has employed to the extent practical restrictions on site use according to the provisions of RH-1217 in minimizing exposures at the site; and

3. Reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal.

4. Has submitted a decommissioning plan or License Termination Plan (LTP) to the Department indicating the licensee's intent to decommission in accordance with RH-410.d. and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTP how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

A. Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

B. An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

C. A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

RH-1218. (Cont'd)

b. The use of alternate criteria to terminate a license requires the approval of the Department after consideration of the Department's staff recommendations that will address any comments provided by the U.S. Environmental Protection Agency, any other State Governmental organization, and any public comments submitted pursuant to RH-1219.

RH-1219. Public Notification and Public Participation.

Upon the receipt of an LTP or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to RH-1217 or RH-1218, or whenever the Department deems such notice to be in the public interest, the Department shall:

a. Notify and solicit comments from:

1. Local and State government organizations in the vicinity of the site and any Indian Nation or any other indigenous people that have treaty of statutory rights that could be affected by the decommissioning; and

2. The Environmental Protection Agency (EPA) for cases where the licensee proposes to release a site pursuant to RH-1218.

b. Publish a notice in a forum, such as local newspapers, letters to State or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

RH-1220. Minimization of Contamination.

Applicants for licenses, other than renewals, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

RH-1221.
RH-1299. Reserved.