ARKANSAS STATE BOARD OF HEALTH

~~**Radiation Control Programs**~~

RULES 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

This Revision Effective ~~December 20, 2021~~ Xxxxxxxx XX, 2023

By the Arkansas State Board of Health

Arkansas Department of Health
Radiation Control Programs
Little Rock, Arkansas

~~**José R. Romero, MD**~~
~~**Secretary of Health**~~

Renee Mallory, RN, BSN
Interim Secretary of Health

Jennifer Dillaha, MD
Director of the Department of Health

TABLE OF CONTENTS

SECTION 1. REGISTRATION OF SOURCES OF RADIATION (Cont'd)

SECTION 2. LICENSING OF RADIOACTIVE MATERIALS

SECTION 2. LICENSING OF RADIOACTIVE MATERIALS (Cont'd)

SECTION 2. LICENSING OF RADIOACTIVE MATERIALS (Cont'd)

SECTION 3. STANDARDS FOR PROTECTION AGAINST RADIATION

SECTION 3. STANDARDS FOR PROTECTION AGAINST RADIATION (Cont'd)

SECTION 3. STANDARDS FOR PROTECTION AGAINST RADIATION (Cont'd)

SECTION 4. TRANSPORTATION OF RADIOACTIVE MATERIALS

SECTION 4. TRANSPORTATION OF RADIOACTIVE MATERIALS (Cont'd)

SECTION 5. RULES OF PRACTICE

SECTION 5. RULES OF PRACTICE (Cont'd)

SECTION 6. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

SECTION 6. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS (Cont'd)

SECTION 6. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS (Cont'd)

SECTION 7. NATURALLY OCCURRING RADIOACTIVE MATERIAL (NORM)

SECTION 7. NATURALLY OCCURRING RADIOACTIVE MATERIAL (Cont'd)

SECTION 8. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

SECTION 8. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS (Cont'd)

SECTION 8. LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS (Cont'd)

SECTION 9. USE OF RADIONUCLIDES IN THE HEALING ARTS

SECTION 9. USE OF RADIONUCLIDES IN THE HEALING ARTS (Cont'd)

SECTION 9. USE OF RADIONUCLIDES IN THE HEALING ARTS (Cont'd)

SECTION 9. USE OF RADIONUCLIDES IN THE HEALING ARTS (Cont'd)

SECTION 10. RESERVED

SECTION 11. THERAPEUTIC RADIATION MACHINES

SECTION 11. THERAPEUTIC RADIATION MACHINES (Cont'd)

SECTION 12. PHYSICAL PROTECTION OF CATEGORY 1 AND 2 QUANTITIES OF RADIOACTIVE MATERIAL

SECTION 12. PHYSICAL PROTECTION OF CATEGORY 1 AND 2 QUANTITIES OF RADIOACTIVE MATERIAL (Cont'd)

SECTION 1.
REGISTRATION OF ~~SOURCES OF~~ RADIATION MACHINE FACILITIES AND VENDOR SERVICES

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~~ Rules.

RH-4. **Communications**.

All communications concerning these ~~Regulations~~ Rules shall be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-5. **Additional Requirements**.

In addition to the requirements of this Section, all registrants are subject to the applicable provisions of other Sections of these ~~Regulations~~ Rules.

RH-6.- RH-9. Reserved.

PART B.
DEFINITIONS

RH-10. **Definitions**.

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

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.

Department - The Arkansas Department of Health.

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.

Installation - The location where one or more reportable sources of radiation are used, operated or stored.

Person -

1. Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency of this state, political subdivision of this state, any other state or political subdivision or agency thereof; and

2. Any legal successor, representative, agent, or agency of the foregoing, but not including United States Government agencies.

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

Possessing a source of radiation - Using, operating, storing, manufacturing or otherwise having control of a source of radiation in the State of Arkansas.

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.

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

RH-10. (Cont'd)

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

Registrant - Any person who is registering or who has registered with the Department pursuant to these ~~Regulations~~ Rules.

Reportable source of radiation - Any source of radiation as specified under RH-20 of these ~~Regulations~~ Rules.

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

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**.

a. Each person (registrant) having physical possession or control of a radiation machine capable of producing radiation in the state of Arkansas shall apply for registration of such machine with the Department within thirty (30) days of the date of acquisition.

b. Notwithstanding RH-21.a., each applicant for the following uses shall apply for and receive authorization from the Department prior to operation of the machine: healing arts screening; therapeutic radiation machine use pursuant to RH-10301.~~,~~ or RH-10307.~~, or;~~ other use of electronically-produced radiation to deliver therapeutic radiation dose pursuant to RH-10308.; and use of radiation therapy simulation systems.

c. A Radiation Safety Officer shall be designated on each application form. The qualifications of this individual shall be submitted for Department approval with the application.

d. Each application shall be signed by the applicant or registrant or other individual duly authorized to act for and on his behalf.

e. A prospective Authorized User physician responsible for directing the operation of therapeutic radiation machines subject to RH-10301.~~,~~ or RH-10307., or the use of electronically-produced radiation to deliver therapeutic radiation dose subject to RH-10308., as applicable, shall be designated on each ~~therapeutic radiation machine~~ application.

f. An application for registration will be approved if the Department determines that an application meets the requirements of the Act and these Rules. The registration authorizes the proposed activity in such form and containing such conditions and limitations as the Department deems appropriate or necessary to effectuate the purposes of the Act.

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. **Radiation Machine Registration Forms**.

Initial registration and subsequent notifications to the Department shall be made on forms RC FORM 200 and RC FORM 201, as applicable, and shall contain all appropriate information required by the forms. The Department may request additional information as part of the registration process.

RH-24. **Separate Installations**.

Every person who registers shall complete a separate registration form for each installation.

RH-25. **Terms and Conditions of Registrations.**

a. Each registration issued pursuant to this Section shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules and orders of the Department.

b. No registration issued under this Section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any registration 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 registered by the Department pursuant to this Section shall confine use and possession of the radiation machine registered to the locations and purposes authorized in the registration.

d. The Department may incorporate in the registration at the time of issuance, or thereafter by appropriate rule or order, such additional requirements and conditions with respect to the registrant's possession, use, and transfer of radiation machines subject to this Section as it deems appropriate or necessary in order to:

1. Protect health or to minimize danger to life or property;

RH-25.d. (Cont'd)

2. Require such reports and the keeping of such records as may be necessary or appropriate to effectuate the purposes of the Act; and

3. Prevent loss or theft of radiation machines subject to this Section.

e. The Department may request, and the registrant shall provide, additional information after the registration has been issued to enable the Department to determine whether the registration should be modified in accordance with RH-29.

RH-26. **Report of Changes**.

The registrant shall notify the Department in writing of any changes that would render the information contained in the application for registration no longer accurate, including, but not limited to, the following changes: name or mailing address of the registrant; location of the installation or an additional use location; designation of the Radiation Safety Officer; the receipt, sale, or disposal of any radiation machine; and placement or removal of a radiation machine into or out of storage. Notification of the Department is required within ten (10) days of a change, unless the change involves a machine use listed in RH-21.b. Changes regarding RH-21.b. uses must be reported in writing to the Department prior to the change being made.

RH-27. **Report of Discontinuance**.

Every registrant who permanently discontinues the use of all his radiation machines at an installation shall notify the Department in writing within ten (10) days of such action. The notice shall be signed by the registrant or other individual duly authorized to act for and on his behalf.

RH-28. **Report of Termination.**

Every registrant who permanently disposes or transfers all his radiation machines at an installation shall, within ten (10) days of such action:

1. Notify the Department in writing, signed by the registrant or other individual duly authorized to act for and on his behalf; and

2. Submit to the Department a record of the disposal of the radiation machines, if applicable; and if transferred, to whom they were transferred.

RH-29. **Modification, Suspension, and Revocation of Part C Registrations.**

a. The terms and conditions of registrations issued pursuant to Part C of this Section shall be subject to revision or modification. A registration may be suspended or revoked by reason of amendments to the Act or by reason of rules or orders issued by the Department.

b. Any registration may be revoked, suspended, or modified, in whole or in part, for any of the following:

1. Aany material false statement in the application or any statement of fact required under provisions of the Act or of these Rules~~, or because of~~ ;

2. Cconditions revealed by such application or statement of fact or any report, record, or inspection or other means ~~which~~ that would warrant the Department to refuse to grant a registration on an original application~~,~~; ~~or for~~

3. V~~v~~iolation of, or failure to observe any of, the terms and conditions of the Act, or the registration, or of any rule or order of the Department~~.~~; or

4. Existing conditions that constitute a substantial threat to public health or safety or the environment.

c. Except in cases of willful violation or those in which the public health, interest, or safety requires otherwise, no registration shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the registrant in writing, and the registrant shall have been accorded opportunity to demonstrate or achieve compliance with all lawful requirements.

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

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. **Vendor Services Registration Forms**.

Registration and changes to a registration shall be made on forms RC FORM 800 or RC FORM 801, as applicable, and shall contain all information required by the Department as indicated on the forms and accompanying instructions. The Department may request additional information as part of the registration process.

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.

RH-34. (Cont'd)

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.

f. Providing training to licensee or registrant personnel. Training outline must be submitted to the Department at the time of application. Training includes but is not limited to:

1. Safe use and handling of x-ray equipment.

2. Safe use and handling of radioactive material.

3. Safe use and handling of Naturally Occurring Radioactive Material (NORM).

4. Training provided to Radiation Safety/Protection Officer.

g. **Personnel Dosimetry Services**.

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

A. Name of exposed individual.

B. Name and address of the registrant or licensee employing the individual.

C. Amount of the exposure.

D. Monitoring year exposed.

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

RH-34.g. (Cont'd)

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

RH-35. **Assembler and/or Transfer Requirement**.

a. Any person who sells, leases, transfers, lends, disposes, assembles or installs radiation machines in this state shall notify the Department within fifteen (15) days of:

1. The name and address of persons who have received these machines;

2. The manufacturer, model and serial number of each radiation machine transferred; and

3. The date of transfer of each radiation machine.

b. In the case of diagnostic x-ray systems which contain certified components, a copy of the assembler's report prepared in compliance with requirements of the Federal diagnostic x-ray standard (21 CFR 1020.30(d)) shall be submitted to the Department within 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~~ Rules.

RH-36. **Modification, Suspension, and Revocation of Part D Registrations**.

a. The terms and conditions of registrations issued pursuant to Part D of this Section shall be subject to revision or modification. A registration may be suspended or revoked by reason of amendments to the Act, or by reason of rules or orders issued by the Department.

b. Any registration may be revoked, suspended, or modified, in whole or in part, for any of the following:

1. Aany material false statement in the application or any statement of fact required under provisions of the Act or of these Rules~~, or because of~~ ;

2. Cconditions revealed by such application or statement of fact or any report, record, or inspection or other means ~~which~~ that would warrant the Department to refuse to grant a registration on an original application~~,~~; ~~or for~~

3. V~~v~~iolation of, or failure to observe any of, the terms and conditions of the Act, or the registration, or of any rule or order of the Department~~.~~; or

4. Existing conditions that constitute a substantial threat to public health or safety or the environment.

c. Except in cases of willful violation or those in which the public health, interest, or safety requires otherwise, no registration shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the registrant in writing, and the registrant shall have been accorded opportunity to demonstrate or achieve compliance with all lawful requirements.

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

RH-37.- 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~~ Rules, "Standards for Protection Against Radiation."

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~~ Rules.

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 regulations~~, 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~~ rule, including, but not limited to, tests of:

a. Sources of radiation.

RH-54. (Cont'd)

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~~ Rules 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~~ Rules 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:

A. that the exemption of the prime contractor or subcontractor is authorized by law; and

B. 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~~ these Rules 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:

a. Comply with all applicable ~~regulations~~ rules 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 Arkansas Code 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.

In accordance with Arkansas Code Annotated §20-21-217, X-ray Registration Fees are as follows:

a. All x-ray units - $65.00 per tube, up to a maximum of $260.00.

b. Vendor services providing radiation equipment services or radiation safety services, or both - $65.00.

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~~ Rules.

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 Session of 1961, as amended.

RH-101. **Effective Date**.

The provisions of these ~~Regulations~~ Rules 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. **Purpose and Scope**.

a. Section 2, Part I of Section 3, Part J of Section 3, and Sections 7 through 9 provide for the licensing of radioactive material. Except for persons exempt as provided in Part C of Section 2 and RH-750., no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use radioactive material except as authorized in a specific or general license issued in accordance with these ~~Regulations~~ Rules.[1/]

b. In addition to the requirements of this Section, all licensees, except as otherwise noted in these ~~Regulations~~ Rules, are subject to the requirements of Section 3 and Section 4 ~~of these Regulations~~ as well as any ~~regulations~~ rules specific to the type of radioactive material or particle accelerator use. Licensees engaged in industrial radiographic operations are subject to the requirements in Part I of Section 3; licensees engaged in well logging and subsurface tracer studies are subject to the requirements in Part J of Section 3; licensees using Naturally Occurring Radioactive Material (NORM) are subject to the requirements in Section 7; licensees using irradiators are subject to the requirements in Section 8; and licensees using radionuclides in the healing arts are subject to the requirements in Section 9. Particle accelerators are licensed pursuant to Section 6, with use requirements found in Sections 6 and 11.

RH-103. ~~License~~ **Fees**.

In accordance with Act 596 of 2011, codified at Arkansas Code Annotated §20-21-217, annual fees for licensing shall be paid. Applicants shall be charged for a full calendar year regardless of the month the license is issued. Nonpayment of fees shall result in escalated enforcement action and/or revocation of license.

a. The following ~~Radioactive Material~~ Specific License Fees are based upon 15% of the U. S. Nuclear Regulatory Commission's ~~Federal~~ Fiscal Year 2012 annual fees found in 10 CFR 171.16~~.~~:

~~a. The Radioactive Material Fees are as follows:~~

CATEGORY	CODE	FEE
Academic Broad Scope	01100, 01110, 01120	$2,115~~.00~~
Academic R&D	03620	$1,215~~.00~~
Accelerator Produced Radionuclides	03210	$2,280~~.00~~
~~Consultant~~ Other Services	03225	$2,145~~.00~~
Eye Applicator (Sr-90)	02210	$1,260~~.00~~
Gamma Knife	02310	$2,625~~.00~~
Gas Chromatographs	03123	$720~~.00~~
High Dose Rate Remote Afterloader	02230	$1,260~~.00~~
Industrial Radiography	03310, 03320	$3,855~~.00~~
Instrument Calibration; Leak Testing	03221~~;~~, 03222; 03220	$720~~.00~~
In-vitro Testing	02410	$720~~.00~~
Irradiators – Activity < 10,000 Curies	03511	$2,280~~.00~~
Irradiators – Activity ≥ 10,000 Curies	03521	$20,625~~.00~~
Irradiators – Self-shielded	03510, 03520	$1,305~~.00~~
Manufacturing & Distributing	03214	$1,770~~.00~~
Measuring Systems – Analytical Devices	03122	$720~~.00~~
Measuring Systems – Fixed Gauge	03120	$720~~.00~~
Measuring Systems – Portable Gauge	03121	$720~~.00~~
Medical Broad Scope	02110	$6,810~~.00~~
Medical ~~Facility~~ Institution – No Written Directive Required	02121	$1,260~~.00~~
Medical ~~Facility~~ Institution – Written Directive Required	02120	$1,260~~.00~~
Medical Private Practice – No Written Directive Required	~~02200;~~ 02201	$1,260~~.00~~
Medical Private Practice – Written Directive Required	02200	$1260
Medical Therapy – Emerging Technologies	02240	$1,260~~.00~~

Mobile Medical Services	02220, 02231	$1,260.00
Nuclear Pharmacy	02500	$2,430.00
Veterinary	02400	$720.00
Well Logging – Including Tracers	03110; 03111; 03112	$1,500.00
Other Radioactive Material (non-NORM) Decommissioning – All Radioactive Material	99999	$5,000.00

b. Deleted. See RH-5003.

c. b. The General~~ly~~ License~~d Device~~ Registration Fees are as follows:

CATEGORY	FEE
Certain detecting, measuring, gauging, ~~and~~ or controlling devices and certain devices for producing light or an ionized atmosphere (including certain ECDs in gas chromatographs)	$720.00
~~Generally licensed gas chromatographs~~	~~$720.00~~
~~Static elimination devices~~	~~$125.00~~
~~Source material devices~~	~~$500.00~~
~~Devices containing depleted uranium~~	~~$500.00~~
~~Public safety devices containing radioactive material~~	~~$25.00~~
~~All other general license registrations other than those specified above~~	~~$300.00~~
~~Portable and fixed gauges~~	~~$1,125.00~~
Depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device	$150
In vitro clinical or laboratory testing	$25
Naturally Occurring Radioactive Material (NORM)	$500

d. c. Other fees are as follows:

CATEGORY	FEE
Naturally Occurring Radioactive Material (NORM) Specific License	$2,500.00
~~Naturally Occurring Radioactive Material (NORM) Site – General License~~	~~$500.00~~
Arkansas State Board of Health Rules ~~and Regulations~~ for Control of Sources of Ionizing Radiation	$0.00 for first hard copy $30.00 for each additional hard copy

Amendment to existing license	$50~~.00~~ per amendment

~~e.~~ d. Reciprocity fees are as follows:

CATEGORY	FEE
Consultant	$2,145~~.00~~
~~Other Radioactive Material (non-NORM)~~ Decommissioning – All Radioactive Material	$5,000~~.00~~
~~Naturally Occurring Radioactive Material (NORM)~~ Decommissioning – Naturally Occurring Radioactive Material (NORM) Only	$2,500~~.00~~
~~Gas Chromatograph, Lead Paint Analyzer~~	~~$720.00~~
Industrial Radiography~~, Field~~	$3,855~~.00~~
Mobile Medical Services	$1260
Nuclear Gauge, Gas Chromatograph, Lead Paint Analyzer, or other similar specifically licensed device	$720~~.00~~
~~Well Logging with Sealed Sources Only~~	~~$1,500.00~~
Well Logging ~~with~~ – Including Tracers ~~Studies~~	$1,500~~.00~~

RH-104. **Communications**.

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

RH-105. **Interpretations**.

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

RH-106. **Completeness and Accuracy of Information.**

a. Information provided to the Department by an applicant for a license or by a licensee or information required by statute or by the Department's ~~regulations~~ rules, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.

b. Each applicant or licensee shall notify the Department of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety or property. An applicant or licensee violates this paragraph only if the applicant or licensee fails to notify the Department of information that the applicant or licensee has identified as having a significant implication for public health and safety or property. Notification shall be provided to the Department within two (2) working days of identifying the information. This requirement is not applicable to information which is already required to be provided to the Department by other reporting or updating requirements.

RH-107. **Deliberate Misconduct**.

a. Any licensee, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee, certificate of registration holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder, or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, certificate holder, contractor or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's, or applicant's activities subject to this Section, may not:

1. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate of registration holder, or applicant to be in violation of any rule~~, regulation,~~ or order; or any term, condition, or limitation of any license issued by the Department; or

2. Deliberately submit to the Department, a licensee, certificate of registration holder, an applicant, or a licensee's, certificate holder's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Department.

b. A person who violates paragraph a.1. or a.2. of this section may be subject to enforcement action in accordance with the procedures in RH-700.

c. For purposes of paragraph a.1. of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

1. Would cause a licensee, certificate of registration holder, or applicant to be in violation of any rule~~, regulation,~~ or order; or any term, condition, or limitation, of any license issued by the Department; or

2. Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, applicant, contractor, or subcontractor.

RH-108.- RH-199. Reserved.

PART B.
DEFINITIONS

RH-200. **Definitions**.

Accelerator-produced material - Any material made radioactive by a particle accelerator.

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

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.

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

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.

Becquerel (Bq) – One becquerel is equal to one disintegration per second (dps).

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.

Byproduct material -

1. Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

2. The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution

extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

3. A. Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

B. Any material that:

i. Has been made radioactive by use of a particle accelerator; and

ii. Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

4. Any discrete source of naturally occurring radioactive material, other than source material, that:

A. The U.S. Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

B. Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

CFR - Code of Federal Regulations.

Chelating agent - Amine polycarboxylic acids (e.g., EDTA, DTPA), hydroxycarboxylic acids and polycarboxylic acids (e.g., citric acid, carbolic acid and glucinic acid).

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

Consortium - An association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the

operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.

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

1. Changes for temporary use of the land for public recreational purposes;

2. Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

3. Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

4. Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this part;

5. Excavation;

6. Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

7. Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);

8. Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or

9. Taking any other action that has no reasonable nexus to radiological health and safety.

Curie (Ci) – One curie is that amount of radioactive material which disintegrates at the rate of 37 billion atoms per second.

Custodial Agency - An agency of the government designated to act on behalf of the government owner of the disposal site.

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

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.

Department - Arkansas Department of Health.

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.

Discrete source – A radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

Disposal - The isolation of radioactive wastes from the biosphere inhabited by man and containing his food chains by emplacement in a land disposal facility.

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.

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.

Dose commitment – The total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it is assumed that from the time of intake the period of exposure to retained material will not exceed 50 years.

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.

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.

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.

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.

Hazardous waste - Those wastes designated as hazardous by Environmental Protection Agency regulations in 40 CFR Part 261.

Human use - The internal or external administration of radiation or radioactive materials to human beings.

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.

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.

Individual - Any human being.

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.

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 Section or engineered structures that provide equivalent protection to the inadvertent intruder.

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.

License - Except where otherwise specified, a license issued pursuant to these ~~Regulations~~ Rules.

Licensed material - Source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general license provided by ~~regulation~~ rule or a specific license issued by the Department.

Licensee - Any person who is licensed by the Department in accordance with these ~~Regulations~~ Rules and the Act.

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).

Lot Tolerance Percent Defective – Expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

Monitoring - Observing and making measurements to provide data to evaluate the performance and characteristics of the disposal site.

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.

Particle accelerator - Any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, ''accelerator'' is an equivalent term.

Person -

1. Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency of this state, political subdivision of this state, any other state or political subdivision or agency thereof; and

2. Any legal successor, representative, agent, or agency of the foregoing, but not including United States Government agencies.

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

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

Principal activities - Activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

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.

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.

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

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~~ Rules and the conditions of registration or of a license.

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.

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.

RH-200. (Cont'd)

Radiography - The examination of the macroscopic structure of materials by nondestructive methods utilizing sources of radiation.

Registrant - Any person who is registered with Department and is legally obligated to register with the Department pursuant to these ~~Regulations~~ Rules and the Act.

Registration - Registration with the Department in accordance with these ~~Regulations~~ Rules adopted by the Department.

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~~ Rules does not include the internal or external administration of radiation or radioactive material to human beings.

Sealed source - Radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

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

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.

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.

Source material -

1. Uranium or thorium or any combination thereof in any physical or chemical form, or

RH-200. (Cont'd)

2. Ores which contain by weight one-twentieth of one percent (0.05%) or more of uranium, thorium or any combination thereof. Source material does not include special nuclear material.

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

Special nuclear material -

1. Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the U.S. Nuclear Regulatory Commission, pursuant to the provisions of Section 51 of the Atomic Energy Act of 1954, as amended, 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.

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:

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

Stability - Structural stability.

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.

Unrefined and unprocessed ore - Ore in its natural form prior to any processing, such as grinding, roasting, beneficiating or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

RH-200. (Cont'd)

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.)

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 radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs 2., 3., and 4. of the definition of byproduct material set forth in this section.

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. **Unimportant Quantities of Source Material**.

a. Any person is exempt from this Section to the extent that such person receives, possesses, uses, owns, transfers, or delivers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than one-twentieth of one percent (0.05%) of the mixture, compound, solution, or alloy.

b. Any person is exempt from this Section 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. 1. Any person is exempt from this Section and Section 3 to the extent that such person receives, possesses, uses, or transfers:

A. Any quantities of thorium contained in:

i. Incandescent gas mantles;

ii. Vacuum tubes;

iii. Welding rods;

iv. Electric lamps for illuminating purposes, provided that each lamp does not contain more than fifty (50) milligrams of thorium;

v. Germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting, provided that each lamp does not contain more than two (2) grams of thorium;

vi. Rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these; or

vii. Personnel neutron dosimeters, provided that each dosimeter does not contain more than fifty (50) milligrams of thorium;

B. Source material contained in the following products:

i. Glazed ceramic tableware manufactured before August 27, 2013, provided that the glaze contains not more than twenty percent (20%) by weight source material;

ii. Piezoelectric ceramic containing not more than two percent (2%) by weight source material;

iii. Glassware containing not more than two percent (2%) by weight source material or, for glassware manufactured before August 27, 2013, 10 percent (10%) by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction; or

iv. Glass enamel or glass enamel frit containing not more than ten percent (10%) by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983;

C. Photographic film, negatives, and prints containing uranium or thorium;

D. 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 percent (4%) by weight and that the exemption contained in RH-300.c.1.D. shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;

E. Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles or stored or handled in connection with installation or removal of such counterweights, provided that:

i. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "**DEPLETED URANIUM**";[2/]

ii. Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement "**UNAUTHORIZED ALTERATIONS PROHIBITED**";[2/] and

iii The exemption contained in RH-300.c.1.E. 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;

F. Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

i. The shipping container is conspicuously and legibly impressed with the legend "**CAUTION - RADIOACTIVE SHIELDING - URANIUM**"; and

ii. The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of one-eighth inch (3.2 mm);

G. Thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than ten percent (10%) by weight thorium or uranium or, for lenses manufactured before August 27, 2013, 30 percent (30%) by weight of thorium; and that the exemption contained in RH-300.c.1.G. does not authorize either:

i. The shaping, grinding, or polishing of such lens or mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror; or

ii. The receipt, possession, use, or transfer of uranium or thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments;

H. Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

i. The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide); and

ii. The thorium content in the nickel-thoria alloy does not exceed four percent (4%) by weight.

2. The exemptions contained in RH-300.c.1. do not authorize the manufacture, of any of the products described.

3. No person may initially transfer for sale or distribution a product containing source material to persons exempt under RH-300.c.1., or equivalent regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State, unless authorized by a license issued under 10 CFR 40.52 to initially transfer such products for sale or distribution.

A. Persons initially distributing source material in products covered by the exemptions in RH-300.c.1. before August 27, 2013, without specific authorization may continue such distribution for 1 year beyond this date. Initial distribution may also be continued until the NRC takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than 1 year beyond this date.

B. Persons authorized to manufacture, process, or produce these materials or products containing source material by the Department or any Agreement State, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued under 10 CFR 40.52 for distribution only and are exempt from the requirements of Section 3 and RH-404.a. and b.

RH-301. **Radioactive Material Other Than Source Material**.

a. **Exempt concentrations**.

1. Except as provided in RH-301.a.3. and RH-301.a.4., any person is exempt from ~~this Section~~ the requirements for a license set forth in the Act and from these Rules to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing radioactive material in concentrations not in excess of those listed in Schedule C to Section ~~3~~2, RH-902.

2. This section shall not be deemed to authorize the import of radioactive material or products containing radioactive material.

3. A manufacturer, processor, or producer of a product or material in an Agreement State is exempt from the requirements for a license and from these ~~Regulations~~ Rules to the extent that this person transfers radioactive material contained in a product or material in concentrations not in excess of those specified in RH-902. (Schedule C to Section 2) and introduced into the product or material by a licensee holding a specific license issued by the U.S. Nuclear Regulatory Commission expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

4. 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., or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, except in accordance with a license issued by the NRC pursuant to 10 CFR 32.11.

RH-301. (Cont'd)

b. **Certain items containing radioactive material**.

1. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products, or persons who initially transfer for sale or distribution the following products containing radioactive material, any person is exempt from ~~these Regulations~~ the requirements for a license set forth in the Act and from these Rules to the extent that such person receives, possesses, uses, transfers, owns or acquires the following products:

A. Time pieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:

i. 25 millicuries of tritium per timepiece;

ii. 5 millicuries of tritium per hand;

iii. 15 millicuries of tritium per dial (bezels when used shall be considered as part of the dial);

iv. 100 microcuries of promethium-147 per watch or 200 microcuries of promethium-147 per other timepiece;

v. 20 microcuries of promethium-147 per watch hand or 40 microcuries of promethium-147 per other timepiece hand;

vi. 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);

vii. The levels of radiation from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(a). For wrist watches, 0.1 millirad per hour at ten (10) centimeters from any surface;

(b). For pocket watches, 0.1 millirad per hour at one (1) centimeter from any surface;

RH-301.b.1.A.vii. (Cont'd)

(c). For any other timepiece, 0.2 millirad per hour at ten (10) centimeters from any surface.

viii. 1 microcurie (0.037 MBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

B. i. Static elimination devices which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 μCi (18.5 MBq) of polonium-210 per device.

ii. Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 μCi (18.5 MBq) of polonium-210 per device or of a total of not more than 50 mCi (1.85 GBq) of hydrogen-3 (tritium) per device.

iii. Such devices authorized before October 23, 2012 for use under the general license then provided in RH-402.l. and equivalent regulations of the U.S. Nuclear Regulatory Commission and Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the NRC.

C. Balances of precision containing not more than one (1) millicurie of tritium per balance or not more than 0.5 millicuries of tritium per balance part manufactured before December 17, 2007.

D. Reserved.

E. 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 manufactured before December 17, 2007.

F. Reserved.

RH-301.b.1. (Cont'd)

G. Ionization chamber smoke detectors containing not more than one (1) microcurie (μCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

H. Electron tubes: Provided, that each tube does not contain more than one (1) of the following specified quantities of radioactive material:

i. 150 millicuries of tritium per microwave receiver protector tube or ten (10) millicuries of tritium per any electron tube;

ii. One (1) microcurie of cobalt-60;

iii. Five (5) microcuries of nickel-63;

iv. Thirty (30) microcuries of krypton-85;

v. Five (5) microcuries of cesium-137;

vi. Thirty (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 one (1) millirad per hour at one (1) centimeter from any surface when measured through seven (7) milligrams per square centimeter of absorber.[4/]

I. Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material: provided, that:

i. Each source contains no more than one exempt quantity set forth in Schedule B to Section 2; and

ii. 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 (1) or more of the exempt quantities in Schedule B, provided that the sum of each fraction shall not exceed unity.

RH-301.b.1.I. (Cont'd)

iii. For purposes of this RH-301.b.1.I., 0.05 microcurie of americium-241 is considered an exempt quantity under Schedule B.

J. Reserved.

2. Any person who desires to apply radioactive material to, or to incorporate radioactive material into, the products exempted in RH-301.b.1. above, or who desires to initially transfer for sale or distribution such products containing radioactive material, should apply for a specific license pursuant to 10 CFR 32.14, which license states that the product may be distributed by the licensee to persons exempt from RH-301.b.1.

c. Deleted.

d. **Gas and aerosol detectors containing radioactive material**.

1. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from the requirements for a license set forth in the Act and from these ~~Regulations~~ Rules to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in gas and aerosol detectors designed to protect health, safety, or property, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.26, which license authorizes the initial transfer of the product for use under RH-301.d. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by an Agreement State under comparable provisions to 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements.

2. Any person who desires to manufacture, process, or produce gas and aerosol detectors containing radioactive material, or to initially transfer such products for use under RH-301.d.1., should apply for a license under 10 CFR 32.26 and for a certificate of registration in accordance with 10 CFR 32.210 or equivalent Agreement State regulations.

RH-301. (Cont'd)

e. **Self-luminous products containing radioactive material**.

1. **Tritium, krypton-85, or promethium-147**.

Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85 or promethium-147, any person is exempt from these ~~Regulations~~ Rules 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, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.22, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements or equivalent regulations of an Agreement State. The exemption in RH-301.e. does not apply to tritium, krypton-85 or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

2. **Radium-226**.

Any person is exempt from these ~~Regulations~~ Rules to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 μCi (3.7 kBq) of radium-226 which were manufactured prior to November 30, 2007.

3. Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under RH-301.e.1., should apply for a license under 10 CFR 32.22 and for a certificate of registration in accordance with 10 CFR 32.210 or equivalent Agreement State regulations.

f. **Radioactive drug: capsules containing carbon-14 urea for "in vivo" diagnostic use for humans**.

1. Except as provided in paragraphs RH-301.f.2. and RH-301.f.3., any person is exempt from the requirements for a license and from the ~~regulations~~ rules in this Section and Section 9 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.

RH-301.f. (Cont'd)

2. Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to Section 9.

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 10 CFR 32.21.

4. Nothing in RH-301.f. relieves persons from complying with applicable Food & Drug Administration (FDA), other Federal, and State requirements governing receipt, administration, and use of drugs.

g. **Certain industrial devices.**

1. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in the Act and from these ~~Regulations~~ Rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.30, which license authorizes the initial transfer of the device for use under RH-301.g. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

2. Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material for use under RH-301.g.1., should apply for a license under 10 CFR 32.30 and for a certificate of registration in accordance with 10 CFR 32.210 or equivalent Agreement State regulations.

RH-302. **Carriers**.

Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from the ~~regulations~~ rules in this Section and Part I of Section 3, Part J of Section 3, Sections 6 through 9, and Section 12 of these ~~Regulations~~ Rules and the requirements for a license set forth in the Act to the extent that they transport or store radioactive material in the regular course of carriage for another or storage incident thereto.

RH-303. **U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors**.

Any U.S. Department of Energy (DOE) contractor or subcontractor and any U.S. Nuclear of Regulatory Commission (NRC) contractor or subcontractor of the following categories operating within this state is exempt from these ~~Regulations~~ Rules 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:

    1. that the exemption of the prime contractor or subcontractor is authorized by law; and

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

RH-304. **Specific Exemptions**.

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

RH-305. **Exempt Quantities**.

a. Except as provided in paragraphs c. through e. of this section, any person is exempt from these ~~Regulations~~ Rules 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 to Section 2.

b. Any person who possesses radioactive material received or acquired under the general license formerly provided in RH-402.a. or similar general license of the U.S. Nuclear Regulatory Commission or an Agreement State, is exempt from the requirements for a license set forth in this Section 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 to Section 2, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this section 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 section or the equivalent regulations of the U.S. Nuclear Regulatory Commission or any Agreement State.

e. No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in RH-901. (Schedule B to Section 2), except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the ~~regulations~~ rules in this Section.

RH-306.- RH-399. Reserved.

PART D.
LICENSES

RH-400. **Types of Licenses**.

Licenses for radioactive materials are of two (2) types: general and specific.

General License - provided by ~~regulation~~ rule, grants authority to a person for certain activities involving radioactive material, and is effective without the filing of an application with the Department or the issuance of a licensing document to a particular person. However, registration with the Department may be required by the particular general license.

Specific License - issued to a named person who has filed an application with the Department for the license under the provisions of these ~~Regulations~~ Rules.

RH-401. **General Licenses - Source Material**.

a. **Small quantities of source material**.

1. A general license is hereby issued authorizing commercial and industrial firms; research, educational, and medical institutions; and Federal, State, and local government agencies to receive, possess, use, and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities:

A. No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year. Persons possessing source material in excess of these limits as of March 1, 2016, may continue to possess up to 7 kg (15.4 lb) of uranium and thorium at any one time for one year beyond this date, or until the Department takes final action on a pending license amendment or application for a specific license submitted on or before March 1, 2017, for such

material; and receive up to 70 kg (154 lb) of uranium or thorium in any one calendar year until December 31, 2017, or until the Department takes final action on a pending license amendment or application for a specific license submitted on or before March 1, 2017, for such material; and

B. No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under this paragraph unless it is accounted for under the limits found in paragraph a.1.A. of this section; or

C. No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under this paragraph; or

D. No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

2. Any person who receives, possesses, uses, or transfers source material in accordance with the general license in paragraph a. of this section:

A. Is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Department in a specific license.

RH-401.a.2. (Cont'd)

B. Shall not abandon such source material. Source material may be disposed of as follows:

i. A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of this paragraph is exempt from the requirements to obtain a license under this Section to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued pursuant to these ~~Regulations~~ Rules; or

ii. In accordance with RH-1400.

C. Is subject to the provisions in RH-102., RH-104. through RH-107., RH-200., RH-409.a. through d., RH-416., Part E of Section 2., RH-600. through 603., ~~RH-416.,~~ and RH-700, RH-751., and Section 4.

D. Shall respond to written requests from the Department to provide information relating to the general license within 30 calendar days of the date of the request, or other time frame specified in the request. If the person cannot provide the requested information within the allotted time, the person shall, within that same time period, request a longer period to supply the information by providing the Department a written justification for the request;

E. Shall not export such source material except in accordance with 10 CFR Part 110.

RH-401.a. (Cont'd)

3. Any person who receives, possesses, uses, or transfers source material in accordance with paragraph a. of this section shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Department in writing about such contamination and may consult with the Department as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in RH-1216.

4. Any person who receives, possesses, uses or transfers source material in accordance with the general license granted in paragraph a. of this section is exempt from the provisions of Section 3 ~~of these Regulations~~ to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of RH-1216. and RH-1400. to the extent necessary to meet the provisions of paragraphs a.2.B. and a.3. of this section. However, this exemption does not apply to any person who also holds a specific license issued pursuant to these ~~Regulations~~ Rules.

5. No person may initially transfer or distribute source material to persons generally licensed under paragraph a.1.A. or a.1.B. of this section, or equivalent regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State, unless authorized by a specific license issued in accordance with RH-405.b.1. or equivalent provisions of the NRC or of an Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by paragraph a.1. of this section before March 1, 2016, without specific authorization may continue for one year beyond this date. Distribution may also be continued until the Department takes final action on a pending application for license or license amendment to specifically authorize distribution submitted on or before March 1, 2017.

b. **Receipt of title to source material**.

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, deliver, use, or transfer source material.

c. **Certain industrial products or devices**.

1. A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of paragraphs c.2. through c.5. of this section, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

2. The general license in paragraph c.1. of this section applies only to industrial products or devices which have been manufactured or initially transferred either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to RH-405.a.1. or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the NRC or an Agreement State.

3. A. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by paragraph c.1. of this section shall file RC FORM 513, "Registration Certificate - Use of Depleted Uranium Under General License," with the General License Registration Program, Radiation Control Section, Arkansas Department of Health. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. Persons possessing depleted uranium pursuant to the general license in paragraph c.1. of this section as of March 1, 2016, shall register the depleted uranium with the Department on or before March 1, 2017. The general licensee shall furnish on the form the following information and such other information as may be required by the form:

i. Name and address of the general licensee;

ii. A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in paragraph c.1. of this section and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

iii. Name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the general licensee in supervising the procedures identified in paragraph c.3.A.ii. of this section.

B. The general licensee possessing or using depleted uranium under the general license established by paragraph c.1. of this section shall report in writing to the Department any changes in information originally furnished by the licensee in RC FORM 513, "Registration Certificate - Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of such change.

4. A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by paragraph c.1. of this section:

A. Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

B. Shall not abandon such depleted uranium;

C. Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of Part E of Section 2 and RH-1400. In the case where the transferee receives the depleted uranium pursuant to the general license established by paragraph c.1. of this section, the transferor shall furnish the transferee a copy of paragraph c. of this section and a copy of RC FORM 513, "Registration Certificate - Use of Depleted Uranium Under General License." In the case where the transferee receives the depleted uranium pursuant to a general license of the U.S. Nuclear Regulatory Commission or an Agreement State that is equivalent to paragraph c., the transferor shall furnish the transferee a copy of paragraph c. and a copy of RC FORM 513, "Registration Certificate - Use of Depleted Uranium Under General License," accompanied by a note explaining that use of the product or device is regulated by the governing agency, the agency who has jurisdiction where the product or device will be in use, under requirements substantially the same as those in paragraph c.; and

D. Shall report in writing to the Department, within 30 days of any transfer, the name and address of the person receiving the depleted uranium pursuant to such transfer.

5. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by paragraph c.1. of this section is exempt from the requirements of Section 3~~ of these Regulations~~, except for RH-1216. and RH-1400., with respect to the depleted uranium covered by that general license.

6. The general license provided in paragraph c.1. of this section is subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-409.a.-d., RH-416., RH-600. through 603., RH-700., RH-751., and Section 4.

RH-402. **General Licenses - Radioactive Material Other Than Source Material**.

NOTE: Different general licenses are issued in this section, each of which has its own specific conditions and requirements.

a. **Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere**.

NOTE: Persons possessing radioactive material in devices under a general license in RH-402.a. before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of RH-402.a. devices in effect on January 14, 1975.

A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of RH-402.b., c. and d., radioactive material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

b. 1. The general license in RH-402.a. applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in:

A. A specific license issued under RH-405.e.; or

B. An equivalent specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State; or

C. An equivalent specific license issued by a State with provisions comparable to RH-405.e.

2. The devices must have been received from one of the specific licensees described above in RH-402.b.1. or through a transfer made under RH-402.c.9.

RH-402. (Cont'd)

c. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in RH-402.a.:

1. Shall assure that all labels affixed to the device at the time of receipt and bearing the statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;

2. 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 (6) month intervals or at such other intervals as are specified in the label; however:

A. Devices containing only krypton need not be tested for leakage of radioactive material, and

B. Devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material or ten (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;

3. Shall assure that the tests required by RH-402.c.2. and other testing, installation, servicing and removal from installation involving the radioactive materials, its shielding or containment, are performed:

A. In accordance with the instructions provided by the labels; or

B. By a person holding a specific license from the Department, the U.S. Nuclear Regulatory Commission or an Agreement State to perform such activities;

4. Shall maintain records showing compliance with the requirements of RH-402.c.2. and c.3. The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:

   A. Each record of a test for leakage or radioactive material required by RH-402.c.2. must be retained for three (3) years after the next required leak test is performed or until the sealed source is transferred or disposed of.

   B. Each record of a test of the on-off mechanism and indicator required by RH-402.c.2. must be retained for three (3) years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of.

   C. Each record that is required by RH-402.c.3. must be retained for three (3) years from the date of the recorded event or until the device is transferred or disposed of.

5. Shall immediately suspend operation of the device if there is 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 185 bequerel (0.005 microcurie) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued under RH-405.e. or the U.S. Nuclear Regulatory Commission or by an Agreement State.

   The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the Department. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for

ensuring that the premises and environs are acceptable for unrestricted use, must be furnished within thirty (30) days to:

RH-402.c.5. (Cont'd)

Arkansas Department of Health
Radiation Control Section
ATTN: General License Registration Program
4815 West Markham Street, Slot 30
Little Rock, Arkansas 72205-3867

Under these circumstances, the criteria set out in RH-1216., ''Radiological Criteria for Unrestricted Use,'' may be applicable, as determined by the Department on a case-by-case basis;

6. Shall not abandon the device containing radioactive material;

7. Shall not export the device containing radioactive material except in accordance with U.S. Nuclear Regulatory Commission Regulations outlined in Part 110, "Export and Import of Nuclear Equipment and Material";

8. A. Shall transfer or dispose of the device containing radioactive material only by export as provided by U.S. Nuclear Regulatory Commission Regulations outlined in Part 110, "Export and Import of Nuclear Equipment and Material," by transfer to another general licensee as authorized by RH-402.c.9., or to a person authorized to receive the device by a specific license issued under Section 2, or Section 2 that authorizes waste collection, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, or as otherwise approved under RH-402.c.8.C.

B. Shall, within thirty (30) days after the transfer of the device to a specific licensee or export, furnish a report to:

Arkansas Department of Health
Radiation Control Section
ATTN: General License Registration Program
4815 West Markham Street, Slot 30
Little Rock, Arkansas 72205-3867

The report must contain:

i. The identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;

RH-402.c.8.B. (Cont'd)

ii. The name, address, and license number of the person receiving the device (license number not applicable if exported); and

iii. The date of the transfer.

C. Shall obtain written Department approval before transferring the device to any other specific licensee not specifically identified in RH-402.c.8.A.; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

i. Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

ii. Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by RH-402.c.1.) so that the device is labeled in compliance with RH-1309.; however, the manufacturer, model number, and serial number must be retained;

iii. Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

iv. Reports the transfer under RH-402.c.8.B.

9. Shall transfer the device to another general licensee only if:

A. The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of RH-402.a.-e., RH-600., RH-1501., and RH-1502., and any safety documents identified in the label of the device. Within thirty (30) days of the transfer, the transferor shall report to:

Arkansas Department of Health
Radiation Control Section
ATTN: General License Registration Program
4815 West Markham Street, Slot 30
Little Rock, Arkansas 72205-3867

i. The manufacturer's (or initial transferor's) name;

ii. The model number and the serial number of the device transferred;

iii. The transferee's name and mailing address for the location of use; and

iv. The name, title, and phone number of the responsible individual identified by the transferee in accordance with RH-402.c.12. to have knowledge of and authority to take actions to ensure compliance with the appropriate ~~regulations~~ rules and requirements; or

B. The device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

10. 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~~.

11. Shall respond to written requests from the Department to provide information relating to the general license within thirty (30) calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the General License Registration Program a written justification for the request.

12. Shall appoint an individual responsible for having knowledge of the appropriate ~~regulations~~ rules and requirements and the authority for taking required actions to comply with appropriate ~~regulations~~ rules and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate ~~regulations~~ rules and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

13. A. Shall register, in accordance with RH-402.c.13.B. and C. devices containing at least ten (10) mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, one (1) mCi (37 MBq) of cobalt-60, 0.1 mCi (3.7 MBq) of radium-226, one (1) mCi (37 MBq) of nickel-63, or one (1) mCi (37 MBq) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under RH-402.c.13.C., represents a separate general licensee and requires a separate registration and fee.

B. If in possession of a device meeting the criteria of RH-402.c.13.A., shall register these devices annually with the Department and shall pay the appropriate fee. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Department. The registration information must be submitted to the Department within thirty (30) days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of RH-402.c.13.A. is subject to the bankruptcy notification requirement in RH-409.g.

C. In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Department:

i. Name and mailing address of the general licensee.

ii. Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity as indicated on label.

RH-402.c.13.C. (Cont'd)

iii. Name, title, and telephone number of the responsible person designated as a representative of the general licensee under RH-402.c.12.

iv. Address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage.

v. Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.

vi. Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

D. Persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State with respect to devices meeting the criteria in RH-402.c.13.A. are subject to registration requirements if the devices are used in areas subject to Arkansas Department of Health jurisdiction. The Department will request registration information from such licensees.

14. Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the:

Arkansas Department of Health
Radiation Control Section
Attention: General License Registration Program
4815 West Markham Street, Slot 30
Little Rock, Arkansas 72205-3867

within thirty (30) days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage.

RH-402.c. (Cont'd)

15. May not hold devices that are not in use for longer than twenty-four (24) months following the last principal activity use.

A. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by RH-402.c.2. need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use.

B. Devices kept in standby for future use are excluded from the twenty-four (24) month time limit if the Department approves a plan for future use submitted by the licensee. Licensees shall submit plans at least thirty (30) days prior to the end of the twenty-four (24) months of nonuse.

C. The general licensee shall perform quarterly physical inventories of these devices while they are in standby. Records of the quarterly physical inventories shall be maintained for inspection by the Department for five (5) years after they are made.

d. The general license in RH-402.a. does not authorize the manufacture or import of devices containing radioactive material.

e. The general license provided in RH-402.a. is subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-301.a.4., RH-409.a.-d., RH-416., Part E of Section 2, ~~RH-600., RH-602., RH-603.,~~ RH-600. through 603., RH-700., RH-751., and Section 4.

RH-402. (Cont'd)

f. **Luminous safety devices in aircraft**.

1. 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 (370 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium-147 and that each device has been manufactured, assembled, or initially transferred in accordance with the specifications contained in a specific license issued to the manufacturer, assembler, or initial transferor by the Department pursuant to RH-405.h.,or by the U.S. Nuclear Regulatory Commission or an Agreement State pursuant to equivalent requirements.

2. Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in RH-402.f.1. are exempt from the requirements of Section 3, except that they shall comply with the provisions of RH-1501. and RH-1502.

3. This general license does not authorize the manufacture, assembly, repair, import, or export 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 in paragraph f.1. of this section is subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-301.a.4., RH-409.a.-d., RH-416., Part E of Section 2, ~~RH-600., RH-602., RH-603.,~~ RH-600. through 603., RH-700., RH-751., and Section 4.

g. **Calibration and reference sources**.

1. A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance

with the provisions of paragraphs g.4. and g.5. of this section, americium-241 in the form of calibration or reference sources:

A. Any person who holds a specific license issued by the Department which authorizes receipt, possession, use, and transfer of radioactive material; and

RH-402.g.1. (Cont'd)

B. Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes receipt, possession, use, and transfer of special nuclear material.

2. A general license is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of paragraphs g.4. and g.5. of this section to any person who holds a specific license issued by the Department which authorizes receipt, possession, use, and transfer of 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 paragraphs g.4. and g.5. of this section to any person who holds a specific license issued by the Department which authorizes receipt, possession, use, and transfer of radioactive material.

4. The general licenses in paragraphs g.1. through g.3. of this section apply only to calibration or reference sources which have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued to the manufacturer or initial transferor of the sources by the Department pursuant to RH-405.i., or by the U.S. Nuclear Regulatory Commission or an Agreement State pursuant to equivalent requirements.

5. The general licenses in paragraphs g.1. through g.3. of this section are subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-301.a.4., RH-409.a.-d., RH-416., Part E of Section 2, RH-600. through RH-603., RH-700., RH-751., Section 3, and Section 4. The general license in paragraph g.2. is also subject to RH-409.g. In addition, persons who own, receive, acquire, possess, use, or transfer one (1) 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 five (5) microcuries (185 kBq) of americium-241, five (5) microcuries (185 kBq) of plutonium, or five (5) microcuries (185 kBq) of radium-226 in such sources;

RH-402.g.5. (Cont'd)

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 OR RADIUM-226]. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
(name of manufacturer or initial transferor)"

C. Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to receive the source;

D. Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

E. Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

6. These general licenses do not authorize the manufacture, import, or export of calibration or reference sources containing americium-241, plutonium, or radium-226.

RH-402. (Cont'd)

h. **Ownership of byproduct material**.

A general license is hereby issued to own byproduct material without regard to quantity. Notwithstanding any other provision of these ~~Regulations~~ Rules, a general licensee under this paragraph is not authorized to manufacture, produce, transfer, receive, possess, use, import, or export byproduct material, except as authorized in a specific license.

i. **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 (1.85 MBq) of strontium-90 and that each device has been manufactured or initially transferred in accordance with the specifications contained in a specific license issued to the manufacturer or initial transferor by the Department pursuant to RH-405.k., or by the U.S. Nuclear Regulatory Commission or an Agreement State pursuant to equivalent requirements.

2. Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in paragraph i.1. of this section:

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 from the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of RH-1400;

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.

3. This general license does not authorize the manufacture, assembly, disassembly, repair, import, or export of strontium-90 in ice detection devices.

RH-402.i. (Cont'd)

4. The general license in paragraph i.1. of this section is subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-301.a.4., RH-409.a.-d., RH-416., Part E of Section 2, ~~RH-600., RH-602., RH-603.,~~ RH-600. through 603., RH-700., RH-751., and Section 4.

j. **Products containing radium-226**.

1. A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of RH-402.j.2. through 4., radium-226 contained in the following products manufactured prior to November 30, 2007.

A. Antiquities originally intended for use by the general public. For the purposes of this subparagraph, antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

B. Intact timepieces containing greater than one (1) microcurie (0.037 MBq), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

C. Luminous items installed in air, marine, or land vehicles.

D. All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.

E. Small radium sources containing no more than one (1) microcurie (0.037 MBq) of radium-226. For the purposes

of this subparagraph,‘‘small radium sources’’ means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the U.S. Nuclear Regulatory Commission.

RH-402.j. (Cont'd)

2. Persons who acquire, receive, possess, use, or transfer radioactive material under the general license issued in RH-402.j.1. are exempt from the provisions of Section 3, and RH-600.a., b., d.-f., and RH-601., to the extent that the receipt, possession, use, or transfer of radioactive material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this Section.

3. Any person who acquires, receives, possesses, uses, or transfers radioactive material in accordance with the general license in RH-402.j.1. shall:

A. Notify the Department should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished within 30 days to:

Arkansas Department of Health
Radiation Control Section
Attention: Radioactive Materials Program
4815 West Markham Street, Slot 30
Little Rock, Arkansas 72205

B. Not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to RH-1408. or by transfer to a person authorized by a specific license to receive the radium- 226 in the product or as otherwise approved by the U.S. Nuclear Regulatory Commission or an Agreement State.

C. Not export products containing radium-226 except in accordance with 10 CFR Part 110.

RH-402.j.3. (Cont'd)

D. Dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under Section 2, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, or as otherwise approved by the U.S. Nuclear Regulatory Commission or an Agreement State.

E. Respond to written requests from the Department to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Department a written justification for the request.

4. The general license in RH-402.j.1. does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

5. The general license in RH-402.j.1. is subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-301.a.4., RH-409.a.-d., RH-416., Part E of Section 2, RH-600.c., RH-602. and 603., RH-700., RH-751., and Section 4.

k. **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.k.2., 3., 4., 5. and 6. ~~of this paragraph k.~~, the following radioactive materials in prepackaged units:

A. Carbon-14, in units not exceeding ten (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.

B. Cobalt-57, in units not exceeding ten (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.

RH-402.k.1. (Cont'd)

C. Hydrogen-3 (tritium), in units not exceeding fifty (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 ten (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 ten (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 twenty (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 ten (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.k.1. until the individual has filed RC FORM 512, "Registration Certificate - *In Vitro* Testing with Radioactive Material under General License," with the General License Registration Program, Radiation Control Section, Arkansas Department of Health and received from the Department a

RH-402.k.2. (Cont'd)

validated copy of this form with registration number assigned or until he has been authorized pursuant to RH-8013. to use radioactive material under the general license in RH-402.k. The registrant shall furnish on the above form 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.k., 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.k.1. shall comply with the following:

A. The general licensee shall not possess at any one (1) time, pursuant to the general license established by RH-402.k.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.k.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.

RH-402.k.3. (Cont'd)

E. The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in RH-402.k.1.G. as required by RH-1400.

4. The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to RH-402.k.1.:

A. Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, or any Agreement State that authorizes manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59, cobalt-57, or Mock Iodine-125 for distribution to persons generally licensed under RH-402.k.1.

B. Unless the following statement or a substantially similar statement which contains the information called for in the following 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 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 the 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 material under the general license of RH-402.k.1. shall report in writing to the Radiation Control Section, any changes in the information furnished by him in the RC FORM 512, "Registration Certificate - *In Vitro* Testing with Radioactive Material under General License." The report shall be furnished within thirty (30) days after the effective date of such change.

RH-402.k. (Cont'd)

6. Any person using radioactive material pursuant to the general license of RH-402.k.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.k.1.G. shall comply with the provisions of RH-1400., RH-1501., and RH-1502.

7. The general license in RH-402.k.1. is subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-301.a.4., RH-409.a.-d., RH-416., Part E of Section 2, RH-600. through 603., RH-700., RH-751., and Section 4.

l. Reserved.

m. **Ownership of special nuclear material**.

A general license is hereby issued to receive title to and own special nuclear material without regard to quantity. Notwithstanding any other provision of these ~~Regulations~~ Rules, a general licensee under this paragraph is not authorized to acquire, deliver, receive, possess, use, transfer, import, or export special nuclear material, except as authorized in a specific license.

n. **Incidentally produced radioactive material generated by the operation of a particle accelerator**.

A general license is hereby issued to possess radioactive material produced incidentally to the operation of a particle accelerator. The general license is subject to the applicable provisions of this Section and Section 3. A licensee shall transfer this radioactive material in accordance with Part E of this Section and Section 4. A licensee shall dispose of this radioactive material only by way of Department approved procedures. However, license complexity may require the Department to issue a specific license, instead, regarding the incidentally produced radioactive material.

RH-403. **Application for Specific Licenses**.

a. Application for specific licenses shall be filed on forms supplied by the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, 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.

RH-403. (Cont'd)

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 to Section 2 – "Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must contain either:

A. 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 rem to the thyroid; or

B. 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 RH-403.g.1.A.:

A. The radioactive material is physically separated so that only a portion could be involved in an accident;

RH-403.g.2. (Cont'd)

B. All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

C. 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;

D. The solubility of the radioactive material would reduce the dose received;

E. Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in RH-905.;

F. Operating restrictions or procedures would prevent a release fraction as large as that shown in RH-905.; or

G. Other factors appropriate for the specific facility.

3. An emergency plan for responding to a release of radioactive material submitted under RH-403.g.1.B. must include the following information:

A. **Facility description**.

A brief description of the licensee's facility and area near the site.

B. **Types of accidents**.

An identification of each type of radioactive materials accident for which protective actions may be needed.

C. **Classification of accidents**.

A system for classifying each accident as "alert" or "site area emergency."

D. **Detection of accidents**.

Identification of the means of detecting each type of accident in a timely manner.

RH-403.g.3. (Cont'd)

E. **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.

F. **Assessment of releases**.

A brief description of the methods and equipment to assess releases of radioactive materials.

G. **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.

H. **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 after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

I. **Information to be communicated**.

A brief description of the types of information regarding facility status, radioactive releases and, if necessary, recommended protective actions.

RH-403.g.3. (Cont'd)

J. **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.

K. **Safe shutdown**.

A brief description of the means of restoring the facility to a safe condition after an accident.

L. **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.

RH-403.g.3. (Cont'd)

M. **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. 1. Except as provided in paragraphs h.2., h.3., and h.4. of this section, 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:

A. Identify the source or device by manufacturer and model number as registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210, with an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to 10 CFR 32.210; or

B. Contains the information identified in 10 CFR 32.210(c).

2. For sources or devices manufactured before October 23, 2012 that are not registered with the NRC under 10 CFR 32.210 or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c), the application must include:

A. All available information identified in 10 CFR 32.210(c) concerning the source, and, if applicable, the device; and

RH-403.h.2. (Cont'd)

B. Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

3. For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR 32.210(g)(1), the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

4. If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

i. In accordance with RH-409.h., certain licensees must furnish a proposed decommissioning funding plan or a certification of financial assurance for decommissioning.

j. An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under Section 9 ~~of these regulations~~ or equivalent Agreement State requirements shall include:

1. A request for authorization for the production of PET radionuclides or evidence of an existing license issued under this Section or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

2. Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in RH-405.l.1.B.

3. Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in RH-405.l.2.B.

RH-403.j. (Cont'd)

4. Information identified in RH-405.l.1.C. on the PET drugs to be noncommercially transferred to members of its consortium.

RH-404. **General Requirements for the Issuance of Specific Licenses**.

A license application will be approved if the Department determines that:

a. The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these ~~Regulations~~ Rules in such a manner as to minimize danger to public health and safety or property;

b. The applicant's proposed equipment, facilities and procedures are adequate to protect health and minimize danger to public health and safety or property;

c. The issuance of the license will not be inimical to the health and safety of the public;

d. The applicant satisfies any applicable special requirements contained in Section 2, Section 3, Sections 7 through 9, and Section 12 ~~of these Regulations~~; and

e. In the case of an application for a license to receive and possess radioactive material for the conduct of any activity which the Department determines will significantly affect the quality of the environment, the Director of the Arkansas Department of Health, or his/her designee, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made pursuant to Subpart A, "National Environmental Policy Act – Regulations Implementing Section 102(2)," of 10 CFR Part 51, has concluded, after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. Commencement of construction as defined in RH-200. may include non-construction activities if the activity has a reasonable nexus to radiological safety and security.

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

a. **Licensing of the manufacture and initial transfer of industrial products and devices containing depleted uranium**.

1. **Special requirements for issuance of specific licenses under RH-405.a.1**.

A. An application for a specific license to manufacture industrial products and devices containing depleted uranium, or to initially transfer such products or devices, for use pursuant to RH-401.c. or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, will be approved if:

i. The applicant satisfies the general requirements specified in RH-404.;

ii. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in one (1) year a radiation dose in excess of ten percent (10%) of the annual limits specified in RH-1200.a.; and

iii. The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

B. In the case of an industrial product or device whose unique benefits are questionable, the Department will approve an application for a specific license under this paragraph only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

RH-405.a.1. (Cont'd)

C. The Department may deny an applicant for a specific license under this paragraph if the end uses of the industrial product or device cannot be reasonably foreseen.

2. **Conditions of specific licenses issued pursuant to RH-405.a.1**.

Each person licensed pursuant to RH-405.a.1. shall:

A. Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

B. Label or mark each unit to:

i. Identify the manufacturer or initial transferor of the product or device and the number of the license under which the product or device was manufactured or initially transferred, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

ii. State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the NRC or of an Agreement State;

C. Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "**DEPLETED URANIUM**";

D. i. Furnish a copy of the general license contained in RH-401.c. and a copy of RC FORM 513, "Registration Certificate - Use of Depleted Uranium Under General License," to each person to whom the licensee transfers depleted uranium in a product or device for use pursuant to the general license contained in RH-401.c.; or

RH-405.a.2.D. (Cont'd)

ii. Furnish a copy of the general license contained in the NRC's or Agreement State's regulation equivalent to RH-401.c. and a copy of the NRC's or Agreement State's certificate, or alternately, furnish a copy of the general license contained in RH-401.c. and a copy of RC FORM 513, "Registration Certificate - Use of Depleted Uranium Under General License," to each person to whom the licensee transfers depleted uranium in a product or device for use pursuant to the general license of the NRC or an Agreement State. If a copy of the general license in RH-401.c. and a copy of RC FORM 513, "Registration Certificate - Use of

Depleted Uranium Under General License," are furnished to such person, they shall be accompanied by a note explaining that use of the product or device is regulated by the NRC or an Agreement State, depending on which agency has jurisdiction where the product or device will be in use, under requirements substantially the same as those in RH-401.c.;

E. i. Report to the Department all transfers of industrial products or devices to persons for use under the general license in RH-401.c. Such report shall identify each general licensee by name and address, an individual by name and title 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 of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under RH-401.c. during the reporting period, the report shall so indicate;

RH-405.a.2.E. (Cont'd)

ii. Report to the agency where the product or device will be in use, the NRC or an Agreement State, all transfers of industrial products or devices to persons for use under the general license in the NRC's or an Agreement State's regulations equivalent to RH-401.c. Such report shall identify each general licensee by name and address, an individual by name and title who may constitute a point of contact between the agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar

quarter in which such product or device is transferred to the generally licensed person. If no transfers have been made to NRC general licensees or to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the NRC or to the responsible Agreement State agency upon request of the appropriate governing agency; and

F. Keep records showing the name, address, and a point of contact for each general licensee to whom the licensee transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in RH-401.c. or equivalent regulations of the NRC or an Agreement State. The records shall be maintained for three (3) years from the date of transfer and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this paragraph.

RH-405. (Cont'd)

b. **Licensing of the initial transfer of source material for use under the "small quantities of source material" general license**.

1. **Special requirements for issuance of specific licenses under RH-405.b.1**.

An application for a specific license to initially transfer source material for use under RH-401.a., or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, will be approved if:

A. The applicant satisfies the general requirements specified in RH-404.; and

B. The applicant submits adequate information on, and the Department approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.

2. **Conditions of specific licenses issued pursuant to RH-405.b.1**.

A. Each person licensed under RH-405.b.1. shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, "**RADIOACTIVE MATERIAL**."

B. Each person licensed under RH-405.b.1. shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

C. Each person licensed under RH-405.b.1. shall provide the information specified in paragraph b.2.C. of this section to each person to whom source material is transferred for use under RH-401.a. or equivalent provisions in NRC or Agreement State regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

i. A copy of RH-401.a. and Part E of Section 2, or relevant equivalent regulations of the NRC or an Agreement State; and

RH-405.b.2.C. (Cont'd)

ii. Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

D. Each person licensed under RH-405.b.1 shall report transfers as follows:

i. File a report with the Department. The report shall include the following information:

(a). The name, address, and license number of the person who transferred the source material;

(b). For each general licensee under RH-401.a. or equivalent NRC or Agreement State provisions to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(c). The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

RH-405.b.2.D. (Cont'd)

ii. File a report with the NRC and each responsible Agreement State agency that identifies all persons, operating under provisions equivalent to RH-401.a., to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to NRC jurisdiction or to the Agreement State being reported to:

(a). The name, address, and license number of the person who transferred the source material;

(b). The name and address of the general licensee to whom source material was distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(c). The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within NRC jurisdiction or within the Agreement State, as appropriate.

iii. Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under RH-401.a. or equivalent NRC or Agreement State provisions during the current period, a report shall be submitted to the Department indicating so. If no transfers have been made to NRC general licensees or to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the NRC or to the responsible Agreement State agency upon request of the appropriate governing agency.

RH-405.b.2. (Cont'd)

E. Each person licensed under RH-405.b.1. shall maintain all information that supports the reports required by this paragraph concerning each transfer to a general licensee for a period of three (3) years after the event is included in a report to the Department, the NRC, or to an Agreement State agency.

c. – d. Reserved.

e. **Licensing of the manufacture or initial transfer of devices to persons generally licensed under RH-402.a**.

1. An application for a specific license to manufacture or initially transfer devices containing radioactive material, excluding special nuclear material, to persons generally licensed under RH-402.a. or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

   A. The applicant satisfies the general requirements of RH-404.;

   B. 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:

      i. The device can be safely operated by persons not having training in radiological protection;

      ii. Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one (1) calendar year a dose in excess of 10% of the limits specified in RH-1200.a.; and

RH-405.e.1.B. (Cont'd)

      iii. 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:

Part of body	**Dose in rem**
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15
Hands and forearms; feet and ankles; localized areas of skin	200

averaged over areas no larger than one (1) square centimeter	
Other organs	50

C. 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 of radioactivity, and date of determination of the quantity; and

RH-405.e.1.C. (Cont'd)

iii. The information called for in the following statement in the same or substantially similar form[9/]:

"**The receipt, possession, use and transfer of this device, Model _____, [10/] Serial No. _____,[10/] are subject to a general license or the equivalent and the regulations of the U.S. NRC or of 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 initial transferor)"

D. Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words "**Caution-Radioactive Material**," the radiation symbol described in RH-1303., and the name of the manufacturer or initial distributor.

E. Each device meeting the criteria of RH-402.c.13.A., bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words "**Caution-Radioactive Material**," and, if practicable, the radiation symbol described in RH-1303.

F. The device has been registered in the Sealed Source and Device Registry.

RH-405.e. (Cont'd)

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.

RH-405.e. (Cont'd)

3. In the event the applicant desires that the general licensee under RH-402.a., 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 percent (10%) of the limits specified in RH-1200.a.

4. A. If a device containing radioactive material is to be transferred for use under the general license contained in RH-402.a., each person that is licensed under RH-405.e. shall provide the information specified in paragraph e.4.A. of this section to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

i. A copy of the general license contained in RH-402.a.-e.; if paragraphs RH-402.c.2. through c.4. or RH-402.c.13. do not apply to the particular device, those paragraphs may be omitted.

ii. A copy of RH-600., RH-1501., and RH-1502.,

iii. A list of the services that can only be performed by a specific licensee;

iv. Information on acceptable disposal options including estimated costs of disposal; and

v. An indication that the Department's policy is to seek high civil penalties for improper disposal.

RH-405.e.4. (Cont'd)

B. If radioactive material is to be transferred in a device for use under an equivalent general license of the NRC or an Agreement State, each person that is licensed under RH-405.e. shall provide the information specified in paragraph e.4.B. of this section to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

i. A copy of the NRC or Agreement State's regulations equivalent to RH-402.a.-e., RH-600., RH-1501., and RH-1502. or a copy of RH-402.a.-e., RH-600., RH-1501., and RH-1502. If a copy of a non-governing agency's regulations is provided to a prospective general licensee in lieu of the governing agency's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the governing agency, the agency who has jurisdiction where the device will be in use. If certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted.

ii. A list of the services that can only be performed by a specific licensee;

iii. Information on acceptable disposal options including estimated costs of disposal; and

iv. The name or title, address, and phone number of the contact at the Department, NRC, or Agreement State from which additional information may be obtained.

RH-405.e. (Cont'd)

5. **Material transfer reports and records**.

Each person licensed under RH-405.e. to initially transfer devices to generally licensed persons shall comply with the requirements of this subparagraph.

A. The person shall report to the Radiation Control Section, Attention: General License Registration Program, all transfers of such devices to persons for use under the general license in RH-402.a. and all receipts of devices from persons licensed under RH-402.a. The report must be submitted on a quarterly basis on an NRC Form 653

entitled “Transfers of Industrial Devices Report (to General Licensees)” or in a clear and legible report containing all of the data required by the form.

i. The required information for transfers to general licensees includes:

(a). The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

(b). The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate ~~regulations~~ rules and requirements;

(c). The date of transfer;

(d). The type, model number, and serial number of the device transferred; and

(e). The quantity and type of radioactive material contained in the device.

RH-405.e.5.A. (Cont’d)

ii. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

iii. For devices received from a RH-402.a. general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of

devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

iv. If the licensee makes changes to a device possessed by a RH-402.a. general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

v. The report must cover each calendar quarter, must be filed within thirty (30) days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

vi. The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

vii. If no transfers have been made to or from persons generally licensed under RH-402.a. during the reporting period, the report must so indicate.

RH-405.e.5. (Cont'd)

B. The person shall report all transfers of devices to persons for use under a general license in a U.S. Nuclear Regulatory Commission or Agreement State's regulations that are equivalent to RH-402.a. and all receipts of devices from general licensees in the NRC or Agreement State's jurisdiction to the NRC or responsible Agreement State agency. The report must be submitted on an NRC Form 653 entitled "Transfers of Industrial Devices Report (to General Licensees)" or in a clear and legible report containing all of the data required by the form.

i. The required information for transfers to general licensees includes:

(a). The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

(b). The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate ~~regulations~~ rules and requirements;

(c). The date of transfer;

(d). The type, model number, and serial number of the device transferred; and

(e). The quantity and type of radioactive material contained in the device.

ii. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

RH-405.e.5.B. (Cont'd)

iii. For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

iv. If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report

must identify the general licensee, the device, and the changes to information on the device label.

v. The report must cover each calendar quarter, must be filed within thirty (30) days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

vi. The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

vii. If no transfers have been made to or from a U. S. Nuclear Regulatory Commission jurisdiction or to or from a particular Agreement State during the reporting period, this information shall be reported to the NRC or to the responsible Agreement State agency upon request of the appropriate governing agency.

C. The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by this subparagraph. Records required by this subparagraph must be maintained for a period of three (3) years following the date of the recorded event.

RH-405. (Cont'd)

f. **Licensing the distribution of radioactive material in exempt quantities**.

Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing radioactive material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements under RH-305., or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, may be obtained only from the NRC pursuant to 10 CFR 32.18.

g. **Licensing of the introduction of radioactive material into products in exempt concentrations**.

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., or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, except in accordance with a license issued by the NRC pursuant to 10 CFR 32.11.

h. **Licensing of the manufacture, assembly, repair, or initial transfer of luminous safety devices for use in aircraft**.

1. An application for a specific license to manufacture, assemble, repair, or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under RH-402.f., will be approved if:

A. The applicant satisfies the general requirements specified in RH-404.;

B. The applicant submits sufficient information regarding each device pertinent to evaluation of the potential radiation exposure, including:

i. Chemical and physical form and maximum quantity of tritium or promethium-147 in each device;

ii. Details of construction and design;

iii. Details of the method of binding or containing the tritium or promethium-147;

RH-405.h.1.B. (Cont'd)

iv. Procedures for and results of prototype testing to demonstrate that the tritium or promethium-147 will not be released to the environment under the most severe conditions likely to be encountered in normal use;

v. Quality assurance procedures to be followed that are sufficient to ensure compliance with RH-405.h.3.;

vi. Any additional information, including experimental studies and tests, required by the Department to facilitate a determination of the safety of the device.

C. Each device will contain no more than 10 curies of tritium or 300 millicuries of promethium-147. The levels of radiation from each device containing promethium-147 will not exceed 0.5 millirad per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber.

D. The Department determines that:

i. The method of incorporation and binding of the tritium or promethium-147 in the device is such that the tritium or promethium-147 will not be released under the most severe conditions which are likely to be encountered in normal use and handling of the device;

ii. The tritium or promethium-147 is incorporated or enclosed so as to preclude direct physical contact by any person with it;

iii. The device is so designed that it cannot easily be disassembled; and

iv. Prototypes of the device have been subjected to and have satisfactorily passed the tests required by RH-405.h.1.E.

RH-405.h.1. (Cont'd)

E. The applicant shall subject at least five prototypes of the device to tests as follows:

i. The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as temperature, moisture, absolute

pressure, water immersion, vibration, shock, and weathering.

ii. The devices are inspected for evidence of physical damage and for loss of tritium or promethium-147, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in 405.h.1.E.iii.

iii. Device designs are rejected for which the following has been detected for any unit:

(a). A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device; or

(b). Surface contamination of tritium or promethium-147 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

(c). Any other evidence of physical damage.

F. The device has been registered in the Sealed Source and Device Registry.

2. **Labeling of devices.**

A. A person licensed under RH-405.h. to manufacture, assemble, or initially transfer devices containing tritium or promethium-147 for distribution to persons generally licensed under RH-402.f. shall, except as provided in RH-405.h.2.B., affix to each device a label containing the radiation symbol prescribed by RH-1303., such other information as may be required by the Department

RH-405.h.2.A. (Cont'd)

including disposal instructions when appropriate, and the following or a substantially similar statement which contains the information called for in the following statement[9/]:

"The receipt, possession, use and transfer of this device, Model _____, [10/] Serial No. _____,[10/] containing _____ (identity and quantity of radioactive material) are subject to a general license or the equivalent and the regulations of the U.S. NRC

or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION – RADIOACTIVE MATERIAL

_____

(name of manufacturer, assembler, or initial transferor)"

B. If the Department determines that it is not feasible to affix a label to the device containing all the information called for in RH-405.h.2.A., it may waive the requirements of that paragraph and require in lieu thereof that:

i. A label be affixed to the device identifying:

(a). The manufacturer, assembler, or initial transferor; and

(b). The type of radioactive material; and

ii. A leaflet bearing the following information be enclosed in or accompany the container in which the device is shipped:

(a). The name of the manufacturer, assembler, or initial transferor,

(b). The type and quantity of radioactive material,

(c). The model number,

RH-405.h.2.B.ii. (Cont'd)

(d). A statement that the receipt, possession, use, and transfer of the device are subject to a general license or the equivalent and the regulations of the U.S. NRC or of an Agreement State, and

(e). Such other information as may be required by the Department, including disposal instructions when appropriate.

3. **Quality assurance; prohibition of transfer.**

A. Each person licensed under RH-405.h. shall visually inspect each device and shall reject any that has an observable physical defect that could adversely affect containment of the tritium or promethium-147.

B. Each person licensed under RH-405.h. shall:

i. Maintain quality assurance systems in the manufacture of the luminous safety device in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

ii. Subject inspection lots to acceptance sampling procedures, by procedures specified in RH-405.h.3.C. and in the license issued under RH-405.h., to provide at least ninety-five percent (95%) confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded.

C. The licensee shall subject each inspection lot to:

i. Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as absolute pressure and water immersion.

RH-405.h.3.C. (Cont'd)

ii. Inspection for evidence of physical damage, containment failure, or for loss of tritium or promethium-147 after each stage of testing, using methods of inspection adequate for applying the following criteria for defective:

(a). A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device;

(b). Levels of radiation in excess of 0.5 millirad (5 microgray) per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, if the device contains promethium-147; and

(c). Any other criteria specified in the license issued under RH-405.h.

D. No person licensed under RH-405.h. shall transfer to persons generally licensed under RH-402.f., or under an equivalent general license of the NRC or an Agreement State:

i. Any luminous safety device tested and found defective under any condition of a license issued under RH-405.h., or RH-405.h.3.B., unless the defective luminous safety device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

ii. Any luminous safety device contained within any lot that has been sampled and rejected as a result of the procedures in RH-405.h.3.B.ii., unless:

(a). A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under RH-405.h.; and

RH-405.h.3.D.ii. (Cont'd)

(b). Each individual sub-lot is sampled, tested, and accepted in accordance with RH-405.h.3.B.ii. and RH-405.h.3.D.ii.(a). and any other criteria that may be required as a condition of the license issued under RH-405.h.

4. **Material transfer reports.**

A. Each person licensed under RH-405.h. shall file an annual report with the Department, which must state the total quantity of tritium or promethium-147 transferred to persons generally licensed under RH-402.f. The report must identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report must cover the year ending June 30 and must be filed within thirty (30) days thereafter. If no transfers have been made to persons generally licensed under RH-402.f. during the reporting period, the report must so indicate.

B. Each person licensed under RH-405.h. shall report annually all transfers of devices to persons for use under an RH-402.f. equivalent general license of the NRC or an Agreement State to the NRC or responsible Agreement State agency. The report must state the total quantity of tritium or promethium-147 transferred, identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. If no transfers have been made to a NRC jurisdiction or to a particular Agreement State during the reporting period, this information must be reported to the NRC or to the responsible Agreement State agency upon request of the appropriate governing agency.

RH-405. (Cont'd)

i. **Licensing of the manufacture or initial transfer of calibration or reference sources containing americium-241, plutonium, or radium-226**.

1. An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241, plutonium, or radium-226 for distribution to persons generally licensed under RH-402.g. will be approved if:

A. The applicant satisfies the general requirements of RH-404.;

B. The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

i. Chemical and physical form and maximum quantity of americium 241, plutonium, or radium-226 in the source;

ii. Details of construction and design;

iii. Details of the method of incorporation and binding of the americium-241, plutonium, or radium-226 in the source;

iv. Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcuries (185 Bq) of americium-241, plutonium, or radium-226, to demonstrate that the americium-241, plutonium, or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

v. Details of quality control procedures to be followed in manufacture of the source;

vi. Description of labeling to be affixed to the source or the storage container for the source;

vii. Any additional information, including experimental studies and tests, required by the Department to facilitate a determination of the safety of the source.

RH-405.i.1. (Cont'd)

C. Each source will contain no more than 5 microcuries (185 kBq) of americium-241, plutonium, or radium-226.

D. The Department determines, with respect to any type of source containing more than 0.005 microcuries (185 Bq) of americium-241, plutonium, or radium-226, that:

i. The method of incorporation and binding of the americium-241, plutonium, or radium-226 in the

source is such that the americium-241, plutonium, or radium-226 will not be released or be removed from the source under normal conditions of use and handling of the source; and

ii. The source has been subjected to and has satisfactorily passed appropriate tests required by RH-405.i.1.E.

E. The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.005 microcuries (185 Bq) of americium-241, plutonium, or radium-226 to tests as follows:

i. The initial quantity of radioactive material deposited on each source is measured by direct counting of the source.

ii. The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241, plutonium, or radium-226, such as physical handling, moisture, and water immersion.

iii. The sources are inspected for evidence of physical damage and for loss of americium-241, plutonium, or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in RH-405.i.1.E.iv.

RH-405.i.1.E. (Cont'd)

iv. Source designs are rejected for which the following has been detected for any unit: removal of more than 0.005 microcuries (185 Bq) of americium-241, plutonium, or radium-226 from the source or any other evidence of physical damage.

2. **Labeling of devices**.

Each person licensed under RH-405.i.. shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:[9/]

"The receipt, possession, use, and transfer of this source, Model __, Serial No. __, are subject to a general license and the regulations of the United States 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 OR RADIUM-226].
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer or initial transferor"

RH-405.i. (Cont'd)

3. **Leak testing of each source**.

Each person licensed under RH-405.i. shall perform a dry wipe test upon each source containing more than 0.1 microcuries (3.7 kBq) of americium-241, plutonium, or radium-226 before transferring the source to a general licensee under RH-402.g. or under equivalent regulations of the NRC or of an Agreement State. This test shall be performed by wiping the entire radioactive surface of

the source with a filter paper with the application of moderate finger pressure. The radioactivity on the filter paper shall be measured using methods capable of detecting 0.005 microcuries (185 Bq) of americium-241, plutonium, or radium-226. If a source has been shown to be leaking or losing more than 0.005 microcuries (185 Bq) of americium-241, plutonium, or radium-226 by the methods described in RH-405.i.3., the source must be rejected and must not be transferred to a general licensee under RH-402.g., or equivalent regulations of the NRC or an Agreement State.

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.k. will be approved if:

1. The applicant satisfies the general requirements specified RH-404.; and

2. The radioactive material is to be prepared for distribution in prepackaged units of:

   A. Carbon-14 in units not exceeding 10 microcuries (370 kBq) each.

   B. Cobalt-57 in units not exceeding 10 microcuries (370 kBq) each.

   C. Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.

   D. Iodine-125 in units not exceeding 10 microcuries (370 kBq) each.

RH-405.j.2. (Cont'd)

   E. Mock Iodine-125 in units not exceeding 0.05 microcuries (1.85 kBq) of iodine-129 and 0.005 microcuries (185 Bq) of americium-241 each.

   F. Iodine-131 in units not exceeding 10 microcuries (370 kBq) each.

G. Iron-59 in units not exceeding 20 microcuries (740 kBq) each.

H. Selenium-75 in units not exceeding 10 microcuries (370 kBq) each.

3. Each prepackaged unit bears a durable, clearly visible label:

A. Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcuries (1.85 KBq) of iodine-129 and 0.005 microcuries (185 Bq) 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**."

RH-405.j. (Cont'd)

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 the 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 RH-1400.

k. **Licensing of the manufacture or initial transfer of ice detection devices containing strontium-90**.

1. An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under RH-402.i. will be approved if:

A. The applicant satisfies the general requirements of RH-404.;

B. The applicant submits sufficient information regarding each type of device pertinent to evaluation of the potential radiation exposure, including:

i. Chemical and physical form and maximum quantity of strontium-90 in the device;

RH-405.k.1.B. (Cont'd)

ii. Details of construction and design of the source of radiation and its shielding;

iii. Radiation profile of a prototype device;

iv. Procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be

removed from the device under the most severe conditions likely to be encountered in normal handling and use;

v. Details of quality control procedures to be followed in manufacture of the device;

vi. Description of labeling to be affixed to the device;

vii. Instructions for handling and installation of the device;

viii. Any additional information, including experimental studies and tests, required by the Department to facilitate a determination of the safety of the device.

C. Each device will contain no more than 50 microcuries (1.85 MBq) of strontium-90 in an insoluble form.

D. Each device will bear durable, legible labeling which includes the radiation caution symbol prescribed by RH-1303., a statement that the device contains strontium-90 and the quantity thereof, instructions for disposal and statements that the device may be possessed pursuant to a general license, that the manufacturer or civil authorities should be notified if the device is found, that removal of the labeling is prohibited and that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices.

RH-405.k.1. (Cont'd)

E. The Department determines that:

i. The method of incorporation and binding of the strontium-90 in the device is such that the strontium-90 will not be released from the device under the most severe conditions which are likely to be encountered in normal use and handling of the device;

ii. The strontium-90 is incorporated or enclosed so as to preclude direct physical contact by any individual with it and is shielded so that no individual will receive a radiation exposure to a major portion of his body in excess of 0.5 rem (5 mSv) in a year under ordinary circumstances of use;

iii. The device is so designed that it cannot be easily disassembled;

iv. Prototypes of the device have been subjected to and have satisfactorily passed the tests required by RH-405.k.1.F.

v. Quality control procedures have been established to satisfy the requirements of RH-405.k.2.

F. The applicant shall subject at least five prototypes of the device to tests as follows:

i. The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of strontium-90, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

ii. The devices are inspected for evidence of physical damage and for loss of strontium-90 after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in RH-405.k.1.F.iii.

RH-405.k.1.F. (Cont'd)

iii. Device designs are rejected for which the following has been detected for any unit:

(a). A leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device; or

(b). Surface contamination of strontium-90 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

(c). Any other evidence of physical damage.

G. The device has been registered in the Sealed Source and Device Registry.

2. **Quality assurance; prohibition of transfer.**

A. Each person licensed under RH-405.k. shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the strontium-90.

B. Each person licensed under RH-405.k. shall test each device for possible loss of strontium-90 or for contamination by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The detection on the filter paper of more than 2,200 disintegrations per minute of radioactive material per 100 square centimeters of surface wiped shall be cause for rejection of the tested device.

C. Each person licensed under RH-405.k. shall:

i. Maintain quality assurance systems in the manufacture of the ice detection device containing strontium-90 in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

RH-405.k.2.C. (Cont'd)

ii. Subject inspection lots to acceptance sampling procedures, by procedures specified in RH-405.k.2.D. and in the license issued under RH-405.k., to provide at least ninety-five percent (95%) confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded.

D. Each person licensed under RH-405.k. shall subject each inspection lot to:

i. Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could possibly affect the effective containment of strontium-90, such as absolute pressure and water immersion.

ii. Inspection for evidence of physical damage, containment failure, or for loss of strontium-90 after each stage of testing, using methods of inspection adequate to determine compliance with the following criteria for defective: A leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device and any other criteria specified in the license issued under RH-405.k.

E. No person licensed under RH-405.k. shall transfer to persons generally licensed under RH-402.i., or under an equivalent general license of the NRC or of an Agreement State:

i. Any ice detection device containing strontium-90 tested and found defective under the criteria specified in a license issued under RH-405.k., unless the defective ice detection device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

RH-405.k.2.E. (Cont'd)

ii. Any ice detection device containing strontium-90 contained within any lot that has been sampled and rejected as a result of the procedures in RH-405.k.2.C.ii., unless:

(a). A procedure for defining sub-lot size, independence, and additional testing

procedures is contained in the license issued under RH-405.k.; and

(b). Each individual sub-lot is sampled, tested, and accepted in accordance with 405.k.2.C.ii. and RH-405.k.2.E.ii.(a). and any other criteria as may be required as a condition of the license issued under RH-405.k.

l. **Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under Section 9, "Use of Radionuclides in the Healing Arts."**

1. An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to Section 9, "Use of Radionuclides in the Healing Arts," will be approved if:

A. The applicant satisfies the general requirements specified in RH-404.;

B. The applicant submits evidence that the applicant is at least one of the following:

i. Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR ~~207.20(a)~~ Subpart B;

ii. ~~Registered or licensed with a state agency~~ Permitted by the Arkansas State Board of Pharmacy as a drug manufacturer;

iii. ~~Licensed~~ Permitted as a pharmacy by ~~a State~~ the Arkansas State Board of Pharmacy;

RH-405.l.1.B. (Cont'd)

iv. Operating as a nuclear pharmacy within a Federal medical institution; or

v. A Positron Emission Tomography (PET) drug production facility ~~registered with a state agency~~

permitted by the Arkansas State Board of Pharmacy.

C. The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for safe handling and storage of the radioactive drugs by medical use licensees; and

D. The applicant ~~satisfies~~ commits to 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 radioactive drug 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 radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a ~~half-life~~ 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 radioactive drug 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.

RH-405.l. (Cont'd)

2. A licensee described by paragraph ~~RH-405.~~l.1.B.iii. or ~~RH-405.~~l.1.B.iv. of this ~~paragraph l.~~ section:

A. May prepare radioactive drugs for medical use, as defined in RH-8100., provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraph ~~RH-405.~~l.2.B. and ~~RH-405.~~l.2.D. of this ~~paragraph l.~~ section, or an individual under the supervision of an authorized nuclear pharmacist as specified in RH-8306.

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-8100.;

ii. This individual meets the requirements specified in RH-8317.b. and RH-8319. and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

iii. This individual is designated as an authorized nuclear pharmacist in accordance with paragraph ~~RH-405.~~l.2.D. of this ~~paragraph l~~ section.

C. The actions authorized in paragraphs ~~RH-405.~~l.2.A. and ~~RH-405.~~l.2.B. of this ~~paragraph l.~~ section are permitted in spite of more restrictive language in license conditions.

D. May designate a pharmacist (as defined in RH-8100.) as an authorized nuclear pharmacist if:

i. The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and

ii. The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the U.S. Nuclear Regulatory Commission.

RH-405.l.2. (Cont'd)

E. Shall provide to the Department:

i. A copy of each individual's certification by a specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission, the Department, or an Agreement State as specified in RH-8317.a. ~~with the written attestation signed by a preceptor as required by RH-8317.b.2.~~; or

ii. The Department, U.S. Nuclear Regulatory Commission, or Agreement State license, or

iii. U.S. Nuclear Regulatory Commission master materials licensee permit, or

iv. The permit issued by a licensee or U.S. Nuclear Regulatory Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or

v. Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the U.S. Nuclear Regulatory Commission; and

vi. A copy of the State ~~pharmacy licensure or registration~~ pharmacist license, no later than 30 days after the date that the licensee allows, under paragraphs ~~RH-405.~~1.2.B.i. and ~~RH-405.~~1.2.B.iii. of this section, the individual to work as an authorized nuclear pharmacist.

RH-405.l. (Cont'd)

3. A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. 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 radioactive drugs 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. A licensee shall satisfy the labeling requirements in paragraph l.1.D. of this section.

~~4~~ 5. Nothing in this paragraph l. 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**.

1. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed under Section 9, "Use of Radionuclides in the Healing Arts," for use as a calibration, transmission, or reference source or for the uses listed in RH-8600., RH-8620., RH-8630., and RH-8670. will be approved if:

A. The applicant satisfies the general requirements in RH-404.;

B. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

i. The radioactive material contained, its chemical and physical form, and amount;

ii. Details of design and construction of the source or device;

iii. 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;

iv. For devices containing radioactive material, the radiation profile of a prototype device;

v. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

vi. Procedures and standards for calibrating sources and devices;

vii. Legend and methods for labeling sources and devices as to their radioactive content;

viii. 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;

C. 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 Department has approved distribution of the (name of source or device) to persons licensed to use radioactive material identified in RH-8404., RH-8600., RH-8620., RH-8630., and RH-8670. as appropriate, and to persons who hold an equivalent license issued by the U.S. Nuclear Regulatory Commission or an Agreement State.

D. The source or device has been registered in the Sealed Source and Device Registry.

RH-405.n. (Cont'd)

2. A. 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.

B. In determining the acceptable interval for test of leakage of radioactive material, the Department will consider information that includes, but is not limited to:

i. Primary containment or source capsule;

ii. Protection of primary containment;

iii. Method of sealing containment;

iv. Containment construction materials;

v. Form of contained radioactive material;

vi. Maximum temperature withstood during prototype tests;

vii. Maximum pressure withstood during prototype tests;

viii. Maximum quantity of contained radioactive material;

ix. Radiotoxicity of contained radioactive material;

x. Operation experience with identical sources or devices or similarly designed and constructed sources or devices.

RH-406. **Special Requirements for Specific Licenses of Broad Scope**.

This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material ("broad licenses") and certain ~~regulations~~ rules governing holders of such licenses.

a. The different types of broad licenses are set forth below:

1. A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

2. A "Type B specific license of broad scope" is 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 to Section 2, 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 Schedule E to Section 2, 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 Schedule E to Section 2, 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 to Section 2, 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 Schedule E to Section 2, 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 Schedule E to Section 2, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

RH-406. (Cont'd)

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.;

2. The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

3. The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting and management review that are necessary to assure safe operations, including:

A. The establishment of a radiation safety committee composed of such persons as a radiological safety officer, a representative of management and persons trained and experienced in the safe use of radioactive materials;

B. The appointment of a radiological safety officer who is qualified by training and experience in radiation protection and who is available for advice and assistance on radiological safety matters; and

C. The establishment of appropriate administrative procedures to assure:

i. Control of procurement and use of radioactive material;

ii. Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

iii. Review, approval and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with RH-406.b.3.C.ii. prior to use of the radioactive material.

RH-406. (Cont'd)

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.; 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 RH- 406.c.2.B.ii. 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.; 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 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., Part I of Section 3, or Section 9 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.

RH-406.e. (Cont'd)

2. Each Type A specific license of broad scope issued under this section 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 section 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 section 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 paragraph 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 section 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;

RH-407.b.1.C. (Cont'd)

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 RH-407.c. and the applicable technical requirements of RH-407.d. will be met:

A. A description of the natural and demographic disposal site characteristics as determined by disposal site selection and characterization activities. The description must include geologic, geotechnical, hydrologic, meteorologic, climatologic and biotic features of disposal site and vicinity.

B. A description of the design features of the land disposal facility and the disposal units. For near-surface disposal, the description must include those design features related to infiltration of water; integrity of covers for disposal units; structural stability of backfill, waste and covers; contact of wastes with standing water; disposal site drainage; disposal site closure and stabilization; elimination to the extent practicable of long-term disposal site maintenance; inadvertent intrusion; occupational exposures; disposal site monitoring; and adequacy of the size of the buffer zone for monitoring and potential mitigative measures.

C. A description of the principal design criteria and their relationship to the performance objectives.

D. A description of the design basis natural events or phenomena and their relationship to the principal design criteria.

RH-407.b.2. (Cont'd)

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 RH-407.c.

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 RH-407.c. 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.

RH-407.b. (Cont'd)

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 RH-407.e.

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 an 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:

(a). Decontamination and/or dismantlement of surface facilities;

(b). Backfilling of excavated areas; or

(c). Stabilization of the disposal site for post-closure care.

RH-407.b.6. (Cont'd)

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 RH-407.b.6.A., the Department shall issue an amendment authorizing closure if there is reasonable assurance that the long-term performance objectives in RH-407.c. 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 in RH-407.c. 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

RH-407.b.7. (Cont'd)

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.

RH-407.c. (Cont'd)

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 in RH-407.c. 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 in RH-407.c.

D. Areas must be avoided having known natural resources which, if exploited, would result in failure to meet the performance objectives in RH-407.c.

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.

RH-407.d.1. (Cont'd)

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 in RH-407.c. 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 in RH-407.c. 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 in RH-407.c. 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 in RH-407.c. 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.

RH-407.d.2. (Cont'd)

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 in RH-407.c. 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 in RH-407.c. 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 RH-407.c.. This segregation is not necessary for Class A wastes if they meet the stability requirements in RH-407.d.7.B. of this Part.

RH-407.d.3. (Cont'd)

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 five (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.

RH-407.d.3. (Cont'd)

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 in RH-407.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.

RH-407.d. (Cont'd)

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 in RH-407.c.

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.

RH-407.d.6.A. (Cont'd)

iii. Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in RH-407.d.7.

iv. Waste that is not generally acceptable for near-surface disposal is waste for which waste form and disposal methods must be different, and in general more stringent, than those specified for Class C waste. In the absence of specific requirements in this section, proposals for disposal of this waste may be submitted to the Department for approval, pursuant to RH-407.d.9.

B. **Classification determined by long-lived radionuclides**.

If radioactive waste contains only radionuclides listed in Table 1 to RH-407., classification shall be determined as follows:

i. If the concentration does not exceed 0.1 times the value in Table 1, the waste is Class A.

ii If the concentration exceeds 0.1 times the value in Table 1 but does not exceed the value in Table 1, the waste is Class C.

iii. If the concentration exceeds the value in Table 1, the waste is not generally acceptable for near-surface disposal.

iv. For wastes containing mixtures of radionuclides listed in Table 1, the total concentration shall be

determined by the sum of fractions rule described in the RH-407.d.6.F.

RH-407.d.6.B. (Cont'd)

TABLE 1 TO RH-407.

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	100[a]
Pu-241	3500 [a]
Cm-242	20000 [a]

[a] 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 to RH-407. 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.

RH-407.d.6.C. (Cont'd)

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 TO RH-407.

Radionuclide	**Concentration (Curies per cubic meter)**		
	Col. 1	Col. 2	Col. 3
Total of all nuclides less than 5 year half-life	700	([a])	([a])
H-3	40	([a])	([a])
Co-60	700	([a])	([a])
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

[a] 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 be 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.

RH-407.d.6.D. (Cont'd)

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.

RH-407.d. (Cont'd)

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 one percent (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.7.A.vii.

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 20^0C. 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.

RH-407.d.7. (Cont'd)

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 non-dispersible waste.

i. Waste must have 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 one percent (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.

RH-407.d. (Cont'd)

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 RH-407.c.

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.

RH-407. (Cont'd)

e. **Funding for disposal site closure and stabilization**.

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

2. In order to avoid unnecessary duplication and expense, the Department will accept financial sureties that have been consolidated with earmarked financial or surety arrangements established to meet requirements of other Federal or State agencies and/or local governing bodies for such decontamination, closure and stabilization. The Department will accept this arrangement only if they are considered adequate to satisfy these requirements and that the portion of the surety which covers the closure of the disposal site is clearly identified and committed for use in accomplishing these activities.

3. The licensee's surety mechanism will be annually reviewed by the Department to assure that sufficient funds are available for completion of the closure plan, assuming that the work has to be performed by an independent contractor.

4. The amount of surety liability should change in accordance with the predicted cost of future closure and stabilization. Factors affecting closure and stabilization cost estimates include inflation; increases in the amount of disturbed land; changes in engineering plans; closure and stabilization that has already been accomplished and any other conditions affecting costs. This will yield a surety that is at least sufficient at all times to cover the costs of closure of the disposal units that are expected to be used before the next license renewal.

RH-407.e. (Cont'd)

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 (5) 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 ninety (90) days prior to the renewal date of its intention not to renew. In such a situation, the licensee must submit a replacement surety within thirty (30) days after notification of cancellation. If the licensee fails to provide a replacement surety acceptable to the Department, the site owner may collect on the original surety.

6. Proof of forfeiture must not be necessary to collect the surety so that in the event that the licensee could not provide an acceptable replacement surety within the required time, the surety shall be automatically collected prior to its expiration. The conditions described above would have to be clearly stated on any surety instrument which is not open-ended and must be agreed to by all parties. Liability under the surety mechanism must remain in effect until the closure and stabilization program has been completed and approved by the Department, and the license has been transferred to the site owner.

7. Financial surety arrangements generally acceptable to the Department include surety bonds, cash deposits, certificates of deposits, deposits of government securities, escrow accounts, irrevocable letters or lines of credit, trust funds and combinations of the above or such other types of arrangements as may be approved by the Department. However, self-insurance or any arrangement which essentially constitutes pledging the assets of the licensee will not satisfy the surety requirement for private

sector applicants since this provides no additional assurance other than that which already exists through license requirements.

RH-408. **Issuance of Specific Licenses**.

Upon a determination that an application meets the requirements of the Act and these ~~Regulations~~ Rules of the Department, the Department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate and necessary to effectuate the purposes of the Act.

RH-409. **Specific Terms and Conditions of Licenses**.

a. Each license issued pursuant to these Rules shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules and orders of the Department.

b. 1. No license issued or granted pursuant to these Rules nor any right under a license 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.

2. An application for transfer of license must include:

A. The identity, technical, and financial qualifications of the proposed transferee; and

B. Financial assurance for decommissioning information required by RH-409.h.

c. Each person licensed by the Department pursuant to these Rules shall confine his possession and use of the licensed material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to these Rules shall carry with it the right to receive, acquire, receive title to, own, possess, and use radioactive material. Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of Section 4 of these Rules.

d. The Department may incorporate, in any license issued pursuant to these Rules, at the time of issuance, or thereafter by appropriate rule 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 rules thereunder; and

3. Prevent loss or theft of licensed material.

RH-409. (Cont'd)

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 these Rules.

f. Licensees required to submit emergency plans by RH-403.g. shall follow the emergency plan approved by the Department. Proposed changes to the plan may not be implemented without prior application to and prior approval by the Department.

g. **Bankruptcy notification**.

1. Each general licensee that is required to register by RH-402.c.13., each general licensee under RH-402.g.2., and each specific licensee shall notify the Department in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (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(15)) 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;

B. The case name and number; and

C. The date of the filing of the petition.

RH-409. (Cont'd)

h. **Financial assurance and record keeping for decommissioning**.

1. A. 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 Appendix E to Section 2 shall submit a decommissioning funding plan as described in RH-409.h.5. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix E to Section 2.

B. Each holder of, or applicant for, a specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities set forth in Appendix E to Section 2 (or when a combination of isotopes is involved if R, as defined in RH-409.h.1.A., divided by 10^{12} is greater than 1) shall submit a decommissioning funding plan as described in RH-409.h.5. The decommissioning funding plan must be submitted to the Department by July 1, 2016.

C. Each applicant for a specific license authorizing the possession and use of more than 100 mCi of source material in a readily dispersible form shall submit a decommissioning funding plan as described in RH-409.h.5.

2. Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days and/or source material, in quantities specified in RH-409.h.4., shall either:

A. Submit a decommissioning funding plan as described in RH-409.h.5.; or

RH-409.h.2. (Cont'd)

B. Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by RH-409.h.4. using one of the methods described in RH-409.h.6. 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. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of RH-409.h.6. must be submitted to the Department before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the Department, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of RH-409.h.6.

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. or h.2., shall provide financial assurance for decommissioning in accordance with the criteria set forth in RH-409.h.

B. Each holder of a specific license issued before July 27, 1993, and of a type described in RH-409.h.1., 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 $1,125,000 in accordance with the criteria set forth in RH-409.h. 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. shall submit, on or before July 27, 1993, a decommissioning funding plan or a certification of financial assurance for decommissioning in accordance with the criteria set forth in RH-409.h.

RH-409.h.3. (Cont'd)

D. If, in surveys made under RH-1300.a., residual radioactivity in the facility and environment, including the subsurface, is detected at levels that would, if left uncorrected, prevent the site from meeting the RH-1216. criteria for unrestricted use, the licensee must submit a decommissioning funding plan within one year of when the survey is completed.

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

Licensees required to submit the $1,125,000 amount must do so by December 2, 2006. Licensees required to submit the $113,000 or $225,000 amount must do so by June 2, 2007. Licensees having possession limits exceeding the upper bounds of this table must base financial assurance on a decommissioning funding plan.

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities in Appendix E to Section 2 in unsealed form. (For a combination of isotopes, if R, as defined in RH-409.h.1.A., divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1) …….…… $1,125,000
Greater than 10^3 but less than or equal to 10^4 times the applicable quantities in Appendix E to Section 2 in unsealed form. (For a combination of isotopes, if R, as defined in RH-409.h.1.A., divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1) ……. $225,000

Greater than 10^{10} but less than or equal to 10^{12} times the applicable quantities in Appendix E to Section 2 in sealed sources or plated foils.
(For a combination of isotopes, if R, as defined in RH-409.h.1.A., divided by 10^{10} is greater than 1, but R divided by 10^{12} is less than or equal to 1)
…… $113,000

Greater than 10 mCi but less than or equal to 100 mCi of source material in a readily dispersible form……..…… $225,000

RH-409.h. (Cont'd)

5. A. Each decommissioning funding plan must be submitted for review and approval and must contain:

i. A detailed cost estimate for decommissioning, in an amount reflecting:

(a). The cost of an independent contractor to perform all decommissioning activities;

(b). The cost of meeting the RH-1216. criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of RH-1217., the cost estimate may be based on meeting the RH-1217. criteria;

(c). The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and

(d). An adequate contingency factor.

ii. Identification of and justification for using the key assumptions contained in the DCE;

iii. A description of the method of assuring funds for decommissioning from RH-409.h.6., including

means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

iv. A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

v. A signed original of the financial instrument obtained to satisfy the requirements of RH-409.h.6. (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

RH-409.h.5. (Cont'd)

B. At the time of license renewal and at intervals not to exceed 3 years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this can not be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

i. Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

ii. Waste inventory increasing above the amount previously estimated;

iii. Waste disposal costs increasing above the amount previously estimated;

iv. Facility modifications;

v. Changes in authorized possession limits;

vi. Actual remediation costs that exceed the previous cost estimate;

vii. Onsite disposal; and

viii. Use of a settling pond.

6. The financial instrument must include the licensee's name, license number, and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. When any of the foregoing information changes, the licensee must, within 30 days, submit financial instruments reflecting such changes. The financial instrument submitted must be a signed original or signed original duplicate, except where a copy of the signed original is specifically permitted. Financial assurance for decommissioning must be provided by one or more of the following methods:

RH-409.h.6. (Cont'd)

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 must be made into a trust account, and the trustee and the trust must be acceptable to the Department.

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, or letter 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 to Section 2.

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 to Section 2. 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 to Section 2. 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 to Section 2.

Except for an external sinking fund, a parent company guarantee or a guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of RH-409.h. A guarantee by the applicant or licensee may not be used 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:

RH-409.h.6.B. (Cont'd)

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, insurance, or other guarantee method, 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 must be in the form of a trust. If the other guarantee method is used, no surety or insurance may be combined with the external sinking fund. The

RH-409.h.6. (Cont'd)

surety, insurance, or other guarantee 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., and indicating that funds for decommissioning will be obtained when necessary.

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

7. Each person licensed under these ~~Regulations~~ Rules 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 any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

B. As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed

RH-409.h.7. (Cont'd)

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 or depleted uranium used only for shielding or as penetrators in unused munitions, a list contained in a single document and updated every two (2) years, consisting of the following:

i. All areas designated 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.h.;

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

RH-1215. through RH-1220 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.

8. In providing financial assurance under RH-409.h., each licensee must use the financial assurance funds only for decommissioning activities and each licensee must monitor the balance of funds held to account for market variations. The licensee must replenish the funds, and report such actions to the Department, as follows:

A. If, at the end of a calendar quarter, the fund balance is below the amount necessary to cover the cost of decommissioning, but is not below seventy-five percent

RH-409.h.8. (Cont'd)

(75%) of the cost, the licensee must increase the balance to cover the cost, and must do so within 30 days after the end of the calendar quarter.

B. If, at any time, the fund balance falls below seventy-five percent (75%) of the amount necessary to cover the cost of decommissioning, the licensee must increase the balance to cover the cost, and must do so within 30 days of the occurrence.

C. Within 30 days of taking the actions required by RH-409.h.8.A. or RH-409.h.8.B., the licensee must provide a written report of such actions to the Department, and state the new balance of the fund.

i. Each portable gauge licensee shall use a minimum of two (2) independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

j. Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum 99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with RH-8531. The licensee shall record the results of each test and retain each record for 3 years after

the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in RH-8531.a. at the time of generator elution, in accordance with RH-8805.

k. 1. Authorization under RH-403.j. to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

2. Each licensee authorized under RH-403.j. to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

A. Satisfy the labeling requirements in RH-405.l.1.D. for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

RH-409.k.2. (Cont'd)

B. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in RH-405.l.3.

C. A licensee that is a pharmacy authorized under RH-403.j. to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

i. An authorized nuclear pharmacist that meets the requirements in RH-405.l.2.B., or

ii. An individual under the supervision of an authorized nuclear pharmacist as specified in RH-8306.

D. A pharmacy, authorized under RH-403.j. to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to

work as an authorized nuclear pharmacist, shall meet the requirements of RH-405.l.2.E.

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

a. Except as provided in 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 on the expiration date stated in the determination, or as otherwise provided by Department Order.

RH-410. (Cont'd)

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.g., 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 Section, 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.

RH-410. (Cont'd)

e. Coincident with the notification required by RH-410.d., 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.E.

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~~ rule becomes effective July 1, 2002.

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.d. 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

before notification pursuant to RH-410.d. The schedule for decommissioning set forth in RH-410.d. 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:

A. Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

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

C. Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

RH-410.g.1. (Cont'd)

D. 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.d. 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 and safety and is otherwise in the public interest.

3. Procedures such as those listed in RH-410.g.1. 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:

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

B. A description of planned decommissioning activities;

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

D. A description of the planned final radiation survey; and

E. 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.

F. For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in RH-410.i.

RH-410.g. (Cont'd)

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.i., 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.i., 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 radionuclides to 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 that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

RH-410. (Cont'd)

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, up-to-date RC FORM 530, "Certificate of Disposition of Materials," 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 to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in RH-1216., RH-1217., and/or RH-1218.

RH-410.k. (Cont'd)

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 Licenses and Sealed Source and Device Registration Certificates**.

Applications for amendment of a license shall be filed in accordance with RH-403. and shall specify the respects in which the licensee desires his license to be

amended and the grounds for the amendment. Applications for amendment of sealed source and device registration certificates shall be filed in accordance with 10 CFR 32.210 and any other applicable provisions and shall specify the respects in which the certificate holder desires his certificate to be amended and the grounds for the amendment.

RH-413. **Department Action on Application to Renew or Amend**.

In considering an application to renew or amend a license or to amend a sealed source and device registration certificate, the Department will apply the applicable criteria set forth in RH-404., RH-405., and RH-406. and in Sections 2, 3, 4, 5, 6, 7, 8, and 9 ~~of these Regulations~~.

RH-414. Deleted. See RH-409.b.

RH-415. Reserved.

RH-416. **Modification, Suspension, and Revocation of Licenses and ~~Sealed Source and Device~~ Registration Certificates**.

a. The terms and conditions of each license and ~~sealed source and device~~ registration certificate issued under these ~~Regulations~~ Rules shall be subject to ~~amendment,~~ revision~~,~~ or modification. ~~or the~~ A license may be suspended or revoked by reason of amendments to the Act, or by reason of rules~~, regulations, and~~ or orders issued by the Department.

b. Any license or ~~sealed source and device~~ registration certificate may be revoked, suspended, or modified, in whole or in part, for any of the following:

1. A~~a~~ny material false statement in the application or any statement of fact required under provisions of the Act or of these ~~Regulations~~ Rules~~,~~; ~~or because of~~

2. C~~c~~onditions revealed by such application or statement of fact or any report, record, or inspection or other means that would warrant the Department to refuse to grant a license on an original application~~,~~; ~~or for~~

3. V~~v~~iolation 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~~.~~; or

4. Existing conditions that constitute a substantial threat to public health or safety or the environment.

c. Except in cases of willful violation or those in which the public health, interest, or safety requires otherwise, no license or ~~sealed source and device~~ registration certificate shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct that may warrant such action shall have been called to the attention of the licensee or certificate holder in writing, and the licensee or certificate holder 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. **Conditions of Transfer**.

a. Except as otherwise provided in the license and subject to the provisions of paragraphs b. and c. of this section, any licensee may transfer radioactive material, subject to acceptance by the transferee, to:

1. The Department;

2. The U.S. Department of Energy;

3. Any person exempt from these ~~Regulations~~ Rules to the extent permitted under such exemption;

4. Any person in an Agreement State, subject to the jurisdiction of that State, who has been exempted from the licensing requirements and regulations of that State, to the extent permitted under such exemption;

5. Any person in U.S. Nuclear Regulatory Commission (NRC) jurisdiction, subject to the jurisdiction of the NRC, who has been exempted from the licensing requirements and regulations of the NRC, to the extent permitted under such exemption;

6. Any person authorized to receive such material under terms of a general license or a specific license or their equivalents issued by the Department, the NRC, or an Agreement State; or

7. As otherwise authorized by the Department in writing.

b. Before transferring radioactive material to a specific licensee of the Department, the NRC, or an Agreement State, or to a general licensee who is required to register with the Department, 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.

RH-501. (Cont'd)

c. The following methods for the verification required by RH-501.b. are acceptable:

1. The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate.

2. The transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

3. For emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within ten (10) days;

4. The transferor may obtain other sources of information compiled by a reporting service from official records of the Department, the NRC, or the licensing agency of an Agreement State as to the identity of licensees and the scope and expiration dates of licenses and registrations; or

5. When none of the methods of verification in RH-501.c.1. through 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.

d. The transferor shall keep a copy of the verification documentation as a record for three (3) years.

RH-502. **Preparation and Transport**.

Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of Section 4 ~~of these Regulations~~.

RH-503.- RH-599. Reserved.

PART F.
RECORDS, REPORTS, INSPECTIONS, AND TESTS

RH-600. **Records**.

a. **Receipt, transfer, and disposal**.

Each person who receives radioactive material pursuant to a license issued pursuant to the ~~regulations~~ rules in this Section, Part I of Section 3, Part J of Section 3, and Sections 7, 8, and 9 of these ~~Regulations~~ Rules shall keep records showing the receipt, transfer, and disposal of the radioactive material as follows:

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

2. The licensee who transferred the material shall ~~maintain~~ retain each record of transfer for three (3) years after each transfer~~ unless a specific requirement in another part of these Regulations dictates otherwise.~~; however, persons in paragraph a. receiving source material shall retain each record of transfer for this material until the Department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

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

4. If radioactive material is combined or mixed with other licensed material and subsequently treated in a manner that makes direct correlation of a receipt record with a transfer, export, or disposition record impossible, the licensee may use evaluative techniques (such as first-in-first-out) to make the records that are required by this Section account for 100 percent (100%) of the material received.

b. **Record retention periods**.

1. The licensee shall retain each record that is required by the ~~regulations~~ rules in this Section, Part I of Section 3, Part J of Section 3, and Sections 7, 8, and 9 ~~of these Regulations~~ or by license condition for the period specified by the appropriate ~~regulation~~ rule or license condition. If a retention period is not

otherwise specified by ~~regulation~~ rule or license condition, the record must be retained until the Department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

RH-600.b. (Cont'd)

2. If there is a conflict between the Department's ~~regulations~~ rules in this Section, Part I of Section 3, Part J of Section 3, and Sections 7, 8, and 9 ~~of these Regulations~~, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the ~~regulations~~ rules in this Section, Part I of Section 3, Part J of Section 3, and Sections 7, 8, and 9 ~~of these Regulations~~ for such records shall apply unless the Department, pursuant to RH-304., has granted a specific exemption from the record retention requirements specified in the ~~regulations~~ rules in this Section, Part I of Section 3, Part J of Section 3, and Sections 7, 8, and 9 ~~of these Regulations~~.

c. **Record maintenance.**

Each record required by this Section, Part I of Section 3, Part J of Section 3, and Sections 7, 8, and 9 ~~of these Regulations~~ must be legible throughout the specified retention period. The record 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~~ rules. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

d. Prior to license termination, each licensee previously or currently 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., a previous RH-1403. that authorized certain burials[11/], RH-1404., RH-1405., RH-1408.; and

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

RH-600. (Cont'd)

e. If licensed activities are transferred or assigned in accordance with RH-409.b., each licensee previously or currently 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., a previous RH-1403. that authorized certain burials[11/], RH-1404., RH-1405., RH-1408.; and

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

f. Prior to license termination, each licensee shall forward the records required by RH-409.h.7. to the Department.

RH-601. **Reporting Requirements**.

a. **Immediate report**.

Each licensee shall notify the Department as soon as possible but not later than four (4) hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits. (Events may include fires, explosions, toxic gas releases, et cetera.)

b. **Twenty-four hour report**.

Each licensee shall notify the Department within twenty-four (24) hours after the discovery of any of the following events involving licensed material:

1. An unplanned contamination event that:

A. Requires access to the contamination area, by workers or the public, to be restricted for more than twenty-four (24) hours by imposing additional radiological controls or by prohibiting entry into the area;

B. Involves a quantity of material greater than five (5) times the lowest annual limit on intake specified in Appendix G to Section 3 for the material; and

RH-601.b.1. (Cont'd)

C. Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than twenty-four (24) hours to decay prior to decontamination.

2. An event in which equipment is disabled or fails to function as designed when:

A. The equipment is required by ~~regulation~~ rule or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

B. The equipment is required to be available and operable when it is disabled or fails to function; and

C. No redundant equipment is available and operable to perform the required safety function.

3. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

4. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

A. The quantity of material involved is greater than five (5) times the lowest annual limit on intake specified in Appendix G to Section 3 ~~of these Regulations~~ for the material; and

B. The damage affects the integrity of the licensed material or its container.

c. **Preparation and submission of reports**.

Reports made by licensees in response to the requirements of this section must be made as follows:

1. Licensees shall make reports required by paragraphs a. and b. of this section by telephone to the Department at 1-800-633-1735. To the extent that the information is available at the time of

RH-601.c.1. (Cont'd)

notification, the information provided in these reports must include:

A. The caller's name, title, and call back telephone number;

B. A description of the event, including date and time;

C. The exact location of the event;

D. The isotopes, quantities, and chemical and physical form of the licensed material involved; and

E. Any personnel radiation exposure data available.

2. **Written report**.

Each licensee that makes a report required by paragraph a. or b. of this section shall submit a written follow-up report within thirty (30) days of the initial report. Written reports prepared pursuant to other ~~regulations~~ rules may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the Arkansas Department of Health, Radiation Control Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867. The reports must include the following:

A. Complete information required by paragraph c.1. of this section;

B. The probable cause of the event, including all factors that contributed to the event and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

C. Corrective actions taken or planned to prevent occurrence of similar or identical events in the future and the results of any evaluations or assessments; and

D. The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

RH-602. **Inspections**.

a. Each licensee shall afford to the Department at all reasonable times opportunity to inspect radioactive material and the premises and facilities wherein such radioactive material is 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~~ Rules.

RH-603. **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. Radioactive material;

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-604.- RH-699. Reserved.

PART G.
ENFORCEMENT

RH-700. **Violations**.

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

b. **Impounding**.

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

RH-701.- RH-749. Reserved.

PART H.
RECIPROCITY AND ADDITIONAL REQUIREMENTS

RH-750. **Reciprocal Recognition of Licenses**.

a. **Licenses of Byproduct, Source, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass**.

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

A. The licensing document does not limit the activity authorized by such document to specified installations or locations;

B. The out-of-state licensee notifies the Department in writing at least three (3) 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 three (3) day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Department, obtain permission to proceed sooner;

C. The out-of-state licensee complies with all applicable ~~regulations~~ rules of the Department and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable ~~regulations~~ rules of the Department;

D. The out-of-state licensee supplies such other information as the Department may request; and

E. The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in RH-750.a.1. except by transfer to a person:

i. Specifically licensed by the Department or by the NRC to receive such material, or

ii. Exempt from the requirements for a license for such material under RH-301.a.

2. Notwithstanding the provisions of RH-750.a.1., any person who holds a specific license issued by the NRC or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in RH-401., RH-402.a., and RH-402.h. within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this State provided that:

A. ~~Such person shall file a report with the Department within 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 to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;~~ Reserved.

B. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the NRC or an Agreement State~~;~~.

C. 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.~~"

~~D. The holder of the specific license shall furnish to each general licensee to whom the licensee transfers such device or on whose premises the licensee installs such device a copy of the general license contained in RH-402.a. or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.~~

3. The Department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the NRC or an Agreement State, 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.

b. **Licenses of Naturally Occurring and Accelerator-Produced Radioactive Material**.

1. Subject to these ~~regulations~~ rules and Section 7 ~~of these regulations~~, any person who holds a specific license from a Licensing State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any calendar year provided that:

A. The licensing document does not limit the activity authorized by such document to specified installations or locations;

B. The out-of-state licensee notifies the Department in writing at least three (3) 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 three (3) day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Department, obtain permission to proceed sooner;

C. The out-of-state licensee complies with all applicable ~~regulations~~ rules of the Department and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable ~~regulations~~ rules of the Department;

D. The out-of-state licensee supplies such other information as the Department may request; and

E. The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in RH-750.b.1. except by transfer to a person:

i. Specifically licensed by the Department or by another Licensing State to receive such material, or

ii. Exempt from the requirements for a license for such material under these ~~Regulations~~ Rules.

2. Notwithstanding the provisions of RH-750.b.1., any person who holds a specific license issued by a Licensing State authorizing the holder to manufacture, transfer, install, or service a device described in RH-401., RH-402.a., and RH-402.h. within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this State provided that:

A. ~~Such person shall file a report with the Department within 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 to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;~~ Reserved.

B. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by a Licensing State~~;~~.

C. 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.~~"

~~D. The holder of the specific license shall furnish to each general licensee to whom the licensee transfers such device or on whose premises the licensee installs such device a copy of the general license contained in RH-402.a. or in equivalent regulations of the agency having jurisdiction over the manufacture and distribution of the device.~~

RH-750.b. (Cont'd)

3. The Department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by a Licensing State, 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.

c. **Recognition of Agreement State Licenses**.

1. Before radioactive materials can be used at a temporary job site within the State at any Federal facility, the jurisdictional status of the job site shall be determined. If the jurisdictional status is unknown, the Federal agency should be contacted to determine if the job site is under exclusive Federal jurisdiction.

A. In areas of exclusive Federal jurisdiction, the general license is subject to all the applicable rules, regulations, orders and fees of the NRC, and

B. Authorizations for use of radioactive materials at job sites under exclusive Federal jurisdiction shall be obtained from the NRC by either:

i. Filing a NRC Form-241 in accordance with 10 CFR 150.20(b); or

ii. By applying for a specific NRC license.

2. Before radioactive material can be used at a temporary job site in another State, authorization shall be obtained for the State if it is an Agreement State, or from the NRC for any non-Agreement State, either by filing for reciprocity or applying for a specific license.

RH-751. **Additional Requirements**.

The Department may, by rule~~, regulation~~, or order, impose upon any licensee such requirements in addition to those established in the ~~regulations~~ rules in this Section 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 to Section 2. Deleted.

RH-901. **SCHEDULE B TO SECTION 2**

EXEMPT QUANTITIES

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

RH-901. **SCHEDULE B TO SECTION 2**

EXEMPT QUANTITIES

Radioactive Material	Micro-curies	Radioactive Material	Micro-curies
Mercury-197 (Hg-197)	100	Samarium-153 (Sm-153)	100
Mercury-203 (Hg-203)	10	Scandium-46 (Sc-46)	10
Molybdenum-99 (Mo-99)	100	Scandium-47 (Sc-47)	100
Neodymium-147 (Nd-147)	100	Scandium-48 (Sc-48)	10
Neodymium-149 (Nd-149)	100	Selenium-75 (Se-75)	10
Nickel-59 (Ni-59)	100	Silicon-31 (Si-31)	100
Nickel-63 (Ni-63)	10	Silver-105 (Ag-105)	10
Nickel-65 (Ni-65)	100	Silver-110m (Ag-110m)	1
Niobium-93m (Nb-93m)	10	Silver-111 (Ag-111)	100
Niobium-95 (Nb-95)	10	Sodium-22 (Na-22)	10
Niobium-97 (Nb-97)	10	Sodium-24 (Na-24)	10
Osmium-185 (Os-185)	10	Strontium-85 (Sr-85)	10
Osmium-191m (Os-191m)	100	Strontium-89 (Sr-89)	1
Osmium-191 (Os-191)	100	Strontium-90 (Sr-90)	0.1
Osmium-193 (Os-193)	100	Strontium-91 (Sr-91)	10
Palladium-103 (Pd-103)	100	Strontium-92 (Sr-92)	10
Palladium-109 (Pd-109)	100	Sulphur-35 (S-35)	100
Phosphorus-32 (P-32)	10	Tantalum-182 (Ta-182)	10
Platinum-191 (Pt-191)	100	Technetium-96 (Tc-96)	10
Platinum-193m (Pt-193m)	100	Technetium-97m (Tc-97m)	100
Platinum-193 (Pt-193)	100	Technetium-97 (Tc-97)	100
Platinum-197m (Pt-197m)	100	Technetium-99m (Tc-99m)	100
Platinum-197 (Pt-197)	100	Technetium-99 (Tc-99)	10
Polonium-210 (Po-210)	0.1	Tellurium-125m (Te-125m)	10
Potassium-42 (K-42)	10	Tellurium-127m (Te-127m)	10
Potassium-43 (K-43)	10	Tellurium-127 (Te-127)	100
Praseodymium-142 (Pr-142)	100	Tellurium-129m (Te-129m)	10
Praseodymium-143 (Pr-143)	100	Tellurium-129 (Te-129)	100
Promethium-147 (Pm-147)	10	Tellurium-131m (Te-131m)	10
Promethium-149 (Pm-149)	10	Tellurium-132 (Te-132)	10
Rhenium-186 (Re-186)	100	Terbium-160 (Tb-160)	10
Rhenium-188 (Re-188)	100	Thallium-200 (Tl-200)	100
Rhodium-103m (Rh-103m)	100	Thallium-201 (Tl-201)	100
Rhodium-105 (Rh-105)	100	Thallium-202 (Tl-202)	100
Rubidium-81 (Rh-81)	10	Thallium-204 (Tl-204)	10
Rubidium-86 (Rb-86)	10	Thulium-170 (Tm-170)	10
Rubidium-87 (Rb-87)	10	Thulium-171 (Tm-171)	10
Ruthenium-97 (Ru-97)	100	Tin-113 (Sn-113)	10
Ruthenium-103 (Ru-103)	10	Tin-125 (Sn-125)	10
Ruthenium-105 (Ru-105)	10	Tungsten-181 (W-181)	10
Ruthenium-106 (Ru-106)	1	Tungsten-185 (W-185)	10
Samarium-151 (Sm-151)	10	Tungsten-187 (W-187)	100

RH-901. **SCHEDULE B TO SECTION 2**

EXEMPT QUANTITIES

Radioactive Material	Micro-curies	Radioactive Material	Micro-curies
Vanadium-48 (V-48)	10	Zinc-65 (Zn-65)	10
Xenon-131m (Xe-131m)	1,000	Zinc-69m (Zn-69m)	100
Xenon-133 (Xe-133)	100	Zinc-69 (Zn-69)	1,000
Xenon-135 (Xe-135)	100	Zirconium-93 (Zr-93)	10
Ytterbium-175 (Yb-175)	100	Zirconium-95 (Zr-95)	10
Yttrium-87 (Y-87)	10	Zirconium-97 (Zr-97)	10
Yttrium-88 (Y-88)	10		
Yttrium-90 (Y-90)	10	Any radioactive	
Yttrium-91 (Y-91)	10	material not listed above,	
Yttrium-92 (Y-92)	100	other than alpha emitting	
Yttrium-93 (Y-93)	100	radioactive material	0.1

RH-902.

SCHEDULE C TO SECTION 2

EXEMPT CONCENTRATIONS

Element (atomic number)	**Isotope**	Column I **Gas concentration** μCi/ml[a/]	Column II **Liquid and solid concentration** μCi/ml[b/]
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}

RH-902. **Schedule C to Section 2. Exempt Concentrations.** (Cont'd)

Element (atomic number)	**Isotope**	Column I **Gas concentration** μCi/ml[a/]	Column II **Liquid and solid concentration** μCi/ml[b/]
Gold (79)	Au-196	----------	2×10^{-3}
	Au-198	----------	5×10^{-4}
	Au-199	----------	2×10^{-3}
Hafnium (72)	Hf-181	----------	7×10^{-4}
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}

RH-902. **Schedule C to Section 2. Exempt Concentrations.** (Cont'd)

Element (atomic number)	**Isotope**	Column I **Gas concentration** μCi/ml[a/]	Column II **Liquid and solid concentration** μCi/ml[b/]
Platinum (78)	Pt-191	----------	1×10^{-3}
	Pt-193m	----------	1×10^{-2}
	Pt-197m	----------	1×10^{-2}
	Pt-197	----------	1×10^{-3}
Potassium (19)	K-42	----------	3×10^{-3}
Praseodymium (50)	Pr-142	----------	3×10^{-4}
	Pr-143	----------	5×10^{-4}
Promethium (61)	Pm-147	----------	2×10^{-3}
	Pm-149	----------	4×10^{-4}
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^{-4}
	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^{-4}
	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}

RH-902. **Schedule C to Section 2. Exempt Concentrations.** (Cont'd)

Element (atomic number)	**Isotope**	Column I **Gas concentration** μCi/ml[a/]	Column II **Liquid and solid concentration** μCi/ml[b/]
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}
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 (70)	Yb-175	----------	1×10^{-3}
Yttrium (39)	Y-90	----------	2×10^{-4}
	Y-91m	----------	3×10^{-2}
	Y-91	----------	3×10^{-4}
	Y-92	----------	6×10^{-4}
	Y-93	----------	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}

RH-902. **Schedule C to Section 2. Exempt Concentrations.** (Cont'd)

Notes :

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.

2. For purposes of RH-301.a. 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:

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

Footnotes for Schedule C to Section 2:

a/ Values are given in Column 1 only for those materials normally used as gases.

b/ μCi/gm for solids.

RH-903. Schedule D. Deleted. Refer to Section 9.

RH-904. **SCHEDULE E TO SECTION 2**

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

RH-904. **Schedule E to Section 2. Limits for Broad Licenses.** (Cont'd)

Radioactive Material	Column I (Curies)	Column II (Curies)
Europium-152 9.2 h	10	0.1
Europium-152 13 y	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
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

RH-904. **Schedule E to Section 2. Limits for Broad Licenses.** (Cont'd)

Radioactive Material	Column I (Curies)	Column II (Curies)
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1
Osmium-185	1	0.01
Osmium-191m	100	1
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
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

RH-904. **Schedule E to Section 2. Limits for Broad Licenses.** (Cont'd)

Radioactive Material	Column I (Curies)	Column II (Curies)
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulfur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1
Technetium-99	1	0.01
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

Radioactive Material	Column I (Curies)	Column II (Curies)
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 TO SECTION 2**

QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE

Radioactive material [a/] [b/]	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

Radioactive material [a/] [b/]	Release Fraction	Quantity (Curies)
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
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
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Radium-226	.001	100
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000

RH-905. **SCHEDULE F TO SECTION 2** (Cont'd)

Radioactive material [a/] [b/]	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 [b/]	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha [b/]	.0001	20
Combinations of radioactive materials listed above [a/]	----	----

Footnotes for Schedule F to Section 2:

[a/] For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Schedule F to Section 2 exceeds one.

[b/] Waste packaged in Type B containers does not require an emergency plan.

RH-906.- RH-999. Reserved.

APPENDIX A TO SECTION 2

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND PARENT COMPANY GUARANTEE FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

I. Introduction

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

II. Financial Test

A. To pass the financial test, the parent company must meet the criteria of either paragraph A.1. or A.2. of this section. For purposes of applying the Appendix A criteria, tangible net worth must be calculated to exclude all intangible assets and the net book value of the nuclear facility and site, and total net worth, which may include intangible assets, must be calculated to exclude the net book value and goodwill of the nuclear facility and site.

1. The parent company must have:

a. Two of the following three ratios: A ratio of total liabilities to total 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 (6) times the amount of decommissioning funds being assured by a parent company guarantee for the total of all nuclear facilities or parts thereof (or prescribed amount if a certification is used); and

c. Tangible net worth of at least $21 million; and

d. Assets located in the United States amounting to at least ninety percent (90%) of total assets or at least six (6) times the current decommissioning cost estimates for the total of all facilities or parts therof (or prescribed amount if a certificate is used).

Appendix A to Section 2. (Cont'd)

2. The parent company must have:

a. A current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, A, or BBB (including adjustments of + and -) as issued by Standard and Poor's or Aaa, Aa, A, or Baa (including adjustment of 1, 2, or 3) as issued by Moody's; and

b. Total net worth at least six (6) times the amount of decommissioning funds being assured by a parent company guarantee for the total of all nuclear facilities or parts thereof (or prescribed amount if a certification is used); and

c. Tangible net worth of at least $21 million; and

d. Assets located in the United States amounting to at least ninety percent (90%) of the total assets or at least six (6) times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if certification is used).

B. The parent company's independent certified public accountant must compare 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. The accountant must evaluate the parent company's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the parent company's ability to pay for decommissioning costs. The accountant must verify that a bond rating, if used to demonstrate passage of the financial test, meets the requirements of paragraph A. of this section. In connection with the auditing 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.

C. 1. After the initial financial test, the parent company must annually pass the test and provide documentation of its continued eligibility to use the parent company guarantee to the Department within ninety (90) days after the close of each succeeding fiscal year.

Appendix A to Section 2. (Cont'd)

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~~ rules. 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.

B. If the licensee fails to provide alternate financial assurance as specified in the Department's ~~regulations~~ rules 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 alternative financial assurance that meets the provisions of the Department's ~~regulations~~ rules 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, accepted in writing the parent company's alternate financial assurances, or accepted in writing the licensee's financial assurances.

D. A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the parent company guarantee agreement is submitted. 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, whose trust operations are regulated and examined by a Federal or State agency. The Department has the right to change the trustee. An acceptable trust will meet the regulatory criteria established in these ~~Regulations~~ Rules that govern the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

Appendix A to Section 2. (Cont'd)

E. The guarantor must agree that it would be subject to Department orders to make payments under the guarantee agreement.

F. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for the guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Department may:

1. Declare that the financial assurance guaranteed by the parent company guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

2. Exercise any and all of its other rights under applicable law.

G. 1. The guarantor must agree to notify the Department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States Code, or the occurrence of any other event listed in paragraph F of this section, by or against:

a. The guarantor;

b. The licensee;

c. An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

d. An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

Appendix A to Section 2. (Cont'd)

2. This notification must include:

   a. A description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the parent company guarantee for decommissioning will be transferred to the standby trust as soon as possible;

   b. If a petition of bankruptcy was filed, the identity of the bankruptcy court in which the petition for bankruptcy was filed; and

   c. The date of filing of any petitions.

APPENDIX B TO SECTION 2

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF GUARANTEE 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 the financial test of Section II of this Appendix. The terms of the self-guarantee are in Section III of this Appendix. 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 criteria set forth in this section. For purposes of applying the Appendix B criteria, tangible net worth must be calculated to exclude all intangible assets and the net book value of the nuclear facility and site, and total net worth, which may include intangible assets, must be calculated to exclude the net book value and goodwill of the nuclear facility and site. These criteria include:

1. Tangible net worth of at least $21 million, and total net worth at least ten (10) times the amount of decommissioning funds being assured by a self-guarantee for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all nuclear facilities or parts thereof (or the current amount required if certification is used).

2. Assets located in the United States amounting to at least ninety percent (90%) of total assets or at least ten (10) times the amount of decommissioning funds being assured by a self-guarantee, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all nuclear facilities or parts thereof (or the current amount required if certification is used).

3. A current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + and -) as issued by Standard and Poor's, or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

Appendix B to Section 2. (Cont'd)

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 compare the data used by the 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. The accountant must evaluate the company's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the company's ability to pay for decommissioning costs. The accountant must verify that a bond rating, if used to demonstrate passage of the financial test, meets the requirements of Section II, paragraph A. of this Appendix. In connection with the auditing 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 annually pass the test and provide documentation of its continued eligibility to use the self-guarantee to the Department 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 this Appendix, the licensee must send immediate notice to the Department of its intent to establish alternate financial assurance as specified in the Department's ~~regulations~~ rules within 120 days of such notice.

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 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.

Appendix B to Section 2. (Cont'd)

B. The licensee shall provide alternate financial assurance as specified in the Department's ~~regulations~~ rules 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. 1. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or in any category of "A3" and above by Moody's, the licensee will notify the Department in writing within twenty (20) days after publication of the change by the rating service.

2. 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 Moody's, the licensee no longer meets the requirements of Section II.A of this Appendix.

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 guaranteed by the self-guarantee agreement.

G. 1. A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the self-guarantee agreement is submitted.

Appendix B to Section 2. (Cont'd)

2. 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. The Department has the right to change the trustee. An acceptable trust will meet the regulatory criteria established in these ~~Regulations~~ Rules that govern the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

H. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for the guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Department may:

1. Declare that the financial assurance guaranteed by the self-guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

2. Exercise any and all of its other rights under applicable law.

I. The guarantor must notify the Department, in writing, immediately following the occurrence of any event listed in paragraph H. of this section, and must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be transferred to the standby trust as soon as possible.

APPENDIX C TO SECTION 2

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF GUARANTEE 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 the financial test of Section II of this Appendix. The terms of the self-guarantee are in Section III of this Appendix. 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 criteria set forth in this section. For purposes of applying the Appendix C criteria, tangible net worth must be calculated to exclude all intangible assets and the net book value of the nuclear facility and site, and total net worth, which may include intangible assets, must be calculated to exclude the net book value and goodwill of the nuclear facility and site. These criteria include:

1. Tangible net worth of at least $21 million, and total net worth of at least ten (10) times the amount of decommissioning funds being assured by a self-guarantee for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all nuclear facilities or parts thereof (or the current amount required if certification is used).

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 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 total net worth less than 1.5.

Appendix C to Section 2. (Cont'd)

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 compare the data used by the 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. The accountant must evaluate the company's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the company's ability to pay for decommissioning costs. In connection with the auditing 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.

2. After the initial financial test, the company must annually pass the test and provide documentation of its continued eligibility to use the self-guarantee to the Department 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 this Appendix, the licensee must send notice to the Department of its intent to establish alternate financial assurance as specified in the Department's ~~regulations~~ rules. 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 year-end 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.

Appendix C to Section 2. (Cont'd)

B. The licensee shall provide alternative financial assurance as specified in the Department's ~~regulations~~ rules 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) 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 fund the standby trust in the amount of the current cost estimates for decommissioning.

E. A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the self-guarantee agreement is submitted. 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. The Department will have the right to change the trustee. An acceptable trust will meet the regulatory criteria established in these ~~Regulations~~ Rules that govern the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

F. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for the guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Department may:

Appendix C to Section 2. (Cont'd)

1. Declare that the financial assurance guaranteed by the self-guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

2. Exercise any and all of its other rights under applicable law.

G. The guarantor must notify the Department, in writing, immediately following the occurrence of any event listed in paragraph F of this section, and must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be transferred to the standby trust as soon as possible.

APPENDIX D TO SECTION 2

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF GUARANTEE 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 the financial test of Section II of this Appendix. The terms of the self-guarantee are in Section III of this Appendix. 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 (including adjustments of + or -) as issued by Standard and Poor's or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

2. For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least $50 million, or 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.

Appendix D to Section 2. (Cont'd)

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 (including adjustments of + or -) as issued by Standard and Poor's or Aaa, Aa, or A (including adjustments of 1, 2 or 3) as issued by Moody's.

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 compare the data used by the licensee 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. The accountant must evaluate the licensee's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the licensee's ability to pay for decommissioning costs. The accountant must verify that a bond rating, if used to demonstrate passage of the financial test, meets the requirements of Section II of this Appendix. In connection with the auditing 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 licensee no longer passes the test.

2. After the initial financial test, the licensee must repeat passage of the test and provide documentation of its continued eligibility to use the self-guarantee to the Department 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 this Appendix, the licensee must send notice to the Department of its intent to establish alternate financial assurance as specified in the Department's ~~regulations~~ rules. 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 year-end 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 alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in the Department's ~~regulations~~ rules 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 fund the standby trust in the amount of the current cost estimates for decommissioning.

Appendix D to Section 2. (Cont'd)

E. 1. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee shall notify the Department in writing within twenty (20) days after publication of the change by the rating service.

2. If the licensee's most recent bond issuance ceases to be rated in any category of "A" and above by Standard and Poor's or in any category of "A3" and above by Moody's, the licensee no longer meets the requirements of Section II.A. of this Appendix.

F. 1. A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the self-guarantee agreement is submitted.

2. 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. The Department has the right to change the trustee. An acceptable trust will meet the regulatory criteria established in these ~~Regulations~~ Rules that govern the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

G. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Department may:

Appendix D to Section 2. (Cont'd)

1. Declare that the financial assurance guaranteed by the self-guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

2. Exercise any and all of its other rights under applicable law.

H. The guarantor must notify the Department, in writing, immediately following the occurrence of any event listed in paragraph G of this section, and must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be transferred to the standby trust as soon as possible.

APPENDIX E TO SECTION 2
QUANTITIES FOR USE WITH RH-409.h.

Material	Microcuries	Material	Microcuries
Americium-241	0.01	Gadolinium-159	100
Antimony-122	100	Gallium-72	10
Antimony-124	10	Germanium-71	100
Antimony-125	10	Gold-198	100
Arsenic-73	100	Gold-199	100
Arsenic-74	10	Hafnium-181	10
Arsenic-76	10	Holmium-166	100
Arsenic-77	100	Hydrogen-3	1,000
Barium-131	10	Indium-113m	100
Barium-133	10	Indium-114m	10
Barium-140	10	Indium-115m	100
Bismuth-210	1	Indium-115	10
Bromine-82	10	Iodine-125	1
Cadmium-109	10	Iodine-126	1
Cadmium-115m	10	Iodine-129	0.1
Cadmium-115	100	Iodine-131	1
Calcium-45	10	Iodine-132	10
Calcium-47	10	Iodine-133	1
Carbon-14	100	Iodine-134	10
Cerium-141	100	Iodine-135	10
Cerium-143	100	Iridium-192	10
Cerium-144	1	Iridium-194	100
Cesium-131	1,000	Iron-55	100
Cesium-134m	100	Iron-59	10
Cesium-134	1	Krypton-85	100
Cesium-135	10	Krypton-87	10
Cesium-136	10	Lanthanum-140	10
Cesium-137	10	Lutetium-177	100
Chlorine-36	10	Manganese-52	10
Chlorine-38	10	Manganese-54	10
Chromium-51	1,000	Manganese-56	10
Cobalt-58m	10	Mercury-197m	100
Cobalt-58	10	Mercury-197	100
Cobalt-60	1	Mercury-203	10
Copper-64	100	Molybdenum-99	100
Dysprosium-165	10	Neodymium-147	100
Dysprosium-166	100	Neodymium-149	100
Erbium-169	100	Nickel-59	100
Erbium-171	100	Nickel-63	10
Europium-152 9.2h	100	Nickel-65	100
Europium-152 13yr	1	Niobium-93m	10
Europium-154	1	Niobium-95	10
Europium-155	10	Niobium-97	10
Fluorine-18	1,000	Osmium-185	10
Gadolinium-153	10	Osmium-191m	100

Material	Microcuries	Material	Microcuries
Osmium-191	100	Technetium-99m	100
Osmium-193	100	Technetium-99	10
Palladium-103	100	Tellurium-125m	10
Palladium-109	100	Tellurium-127m	10
Phosphorus-32	10	Tellurium-127	100
Platinum-191	100	Tellurium-129m	10
Platinum-193m	100	Tellurium-129	100
Platinum-193	100	Tellurium-131m	10
Platinum-197m	100	Tellurium-132	10
Platinum-197	100	Terbium-160	10
Plutonium-239	0.01	Thallium-200	100
Polonium-210	0.1	Thallium-201	100
Potassium-42	10	Thallium-202	100
Praseodymium-142	100	Thallium-204	10
Praseodymium-143	100	Thorium (natural)[a/]	100
Promethium-147	10	Thulium-170	10
Promethium-149	10	Thulium-171	10
Radium-226	0.01	Tin-113	10
Rhenium-186	100	Tin-125	10
Rhenium-188	100	Tungsten-181	10
Rhodium-103m	100	Tungsten-185	10
Rhodium-105	100	Tungsten-187	100
Rubidium-86	10	Uranium (natural)[b/]	100
Rubidium-87	10	Uranium-233	0.01
Ruthenium-97	100	U-234 – U-235	0.01
Ruthenium-103	10	Vanadium-48	10
Ruthenium-105	10	Xenon-131m	1,000
Ruthenium-106	1	Xenon-133	100
Samarium-151	10	Xenon-135	100
Samarium-153	100	Ytterbium-175	100
Scandium-46	10	Yttrium-90	10
Scandium-47	100	Yttrium-91	10
Scandium-48	10	Yttrium-92	100
Selenium-75	10	Yttrium-93	100
Silicon-31	100	Zinc-65	10
Silver-105	10	Zinc-69m	100
Silver-110m	1	Zinc-69	1,000
Silver-111	100	Zirconium-93	10
Sodium-24	10	Zirconium-95	10
Strontium-85	10	Zirconium-97	10
Strontium-89	1		
Strontium-90	0.1	Any alpha emitting	0.01
Strontium-91	10	radionuclide not	
Strontium-92	10	listed above or	
Sulfur-35	100	mixtures of alpha	
Tantalum-182	10	emitters of unknown	
Technetium-96	10	composition	
Technetium-97m	100		
Technetium-97	100		

Material	Microcuries
Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	0.1

Note:

Where there is involved a combination of radionuclides in known amounts, the limit for the combination should be derived as follows: Determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1" (i.e., "unity").

Footnotes for Appendix E to Section 2:

a/ Based on alpha disintegration rate of Th-232, Th-230, and their daughter products.

b/ Based on alpha disintegration rate of U-238, U-234, and U-235.

FOOTNOTES TO 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 RH-300.c.1.E.i. and ii. 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~~ Rules.

3/ Deleted.

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/ Deleted.

6/ Deleted.

7/ Deleted.

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/ Sources licensed under RH-405.e., RH-105.h. or RH-405.i. prior to January 19, 1975 may bear labels authorized by the ~~regulations~~ rules in effect on January 1, 1975.

10/ The model, serial number, and the name of the manufacturer or initial transferor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

11/ A previous RH-1403. permitted certain burials of small quantities of licensed materials in soil before January 1, 1983, without specific Department authorization. As of January 1, 1983, these burials had to receive specific approval by the Department, in accordance with the revised RH-1403. Disposal by burial in soil came to be regulated under RH-1401.

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~~ Rules shall become effective on January 1, 1963, except where another effective date is specifically noted.

RH-1002. **Purpose and Scope**.

a. This Section establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Department.

b. It is the purpose of the ~~Regulations~~ Rules in this Section 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~~ rules in this Section. However, nothing in this Section shall be construed as limiting actions that may be necessary to protect health and safety.

RH-1003. **Communications**.

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

RH-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 Section. (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 exceeds 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**.

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).

Accelerator-produced material - Any material made radioactive by a particle accelerator.

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

Activity - The rate of disintegration (transformation or decay of radioactive material). The units of activity are the curie (Ci) and the becquerel (Bq).

Adult - An individual 18 or more years of age.

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

Airborne radioactive material - Radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

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 Section 3, 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.

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.

RH-1100. (Cont'd)

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 Section 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.

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 I, Columns 1 and 2, of Appendix G to Section 3).

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.

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.

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.

Becquerel (Bq) – One becquerel is equal to one disintegration per second (dps).

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.

RH-1100. (Cont'd)

Byproduct material -

1. Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

2. The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

3. A. Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

   B. Any material that:

      i. Has been made radioactive by use of a particle accelerator; and

      ii. Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

4. Any discrete source of naturally occurring radioactive material, other than source material, that:

   A. The U.S. Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

   B. Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

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.

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.

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.

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

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

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.

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

Curie (Ci) - One curie is that amount of radioactive material which disintegrates at the rate of 37 billion atoms per second.

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.

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.

RH-1100. (Cont'd)

Deep-dose equivalent (H_d) - (which applies to external whole-body exposure) The dose equivalent at a tissue depth of one (1) cm (1000 mg/cm^2).

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.

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

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).

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 I, Column 3, of Appendix G to Section 3.

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).

Director - Director of the Arkansas Department of Health.

Discrete source – A radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

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).

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.

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.

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).

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.

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

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

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.

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

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

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

RH-1100. (Cont'd)

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).

Filtering facepiece (dust mask) – A negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable strap.

Fit factor – A quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

Fit test – The use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

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.

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.

Gray - See RH-1102., "Units of Radiation Dose."

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

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.

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

Individual - Any human being.

RH-1100. (Cont'd)

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.

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.

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

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).

License - Except where otherwise specified, a license issued pursuant to these ~~Regulations~~ Rules.

Licensed material - Source material, special nuclear material, or byproduct material received, possessed, used, transferred, or disposed of under a general license provided by ~~regulation~~ rule or a specific license issued by the Department.

Licensee - The holder of a license.

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

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

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.

Member of the public - Any individual except when that individual is receiving an occupational dose.

Minor - An individual less than 18 years of age.

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.

Nationally tracked source - A sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix D of this Section. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

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.

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).

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-8420., from voluntary participation in medical research programs, or as a member of the general public.

Particle accelerator - Any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, ''accelerator'' is an equivalent term.

Person -

1. Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency of this state, political subdivision of this state, any other state or political subdivision or agency thereof; and

2. Any legal successor, representative, agent, or agency of the foregoing, but not including United States Government agencies.

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

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

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

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

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

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.

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-8420, or from voluntary participation in medical research programs.

Qualitative fit test (QLFT) - A pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

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.

Quantitative fit test (QNFT) – An assessment of the adequacy of respirator fit by numerically measuring the leakage into the respirator.

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.

Rad - See RH-1102., "Units of Radiation Dose."

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.

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.

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

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

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

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.

Rem - See RH-1102., "Units of Radiation Dose."

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 and previous burials at the site, even if

those burials were made in accordance with the provisions of Part E, "Waste Disposal."

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

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.

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.

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

Shallow-dose equivalent (H_s) - (which applies to the external exposure of the skin of the whole body or the skin of an extremity) - The dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

Sievert - See RH-1102., "Units of Radiation Dose."

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

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 percent (0.05%), or more, of uranium, thorium, or any combination of uranium and thorium. Source material does not include special nuclear material.

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

Special nuclear material -

1. Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the U.S. Nuclear Regulatory Commission, pursuant to the provisions of Section 51 of the Atomic

Energy Act of 1954, as amended, 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.

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

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.

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.

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.

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.

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

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

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.

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.

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.

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).

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 radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs 2., 3., and 4. of the definition of byproduct material set forth in this section.

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

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:

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.

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

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

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.

RH-1100. (Cont'd)

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).

Year - The period of time beginning in January used to determine compliance with the provisions of this Section. 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. Reserved.

RH-1102. **Units of Radiation Dose**.

As used in this Section, 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 X 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 Section, the quality factors for converting absorbed dose to dose equivalent are shown in Table I to RH-1102.

TABLE I TO RH-1102.
QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

Type of Radiation	**Quality Factor (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~~ rules in this Section, 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 II to RH-1102. to convert a measured tissue dose in rads to dose equivalent in rems.

RH-1102.h. (Cont'd)

TABLE II TO RH-1102.
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}).

RH-1103. (Cont'd)

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 interpretations of the meaning of the ~~regulations~~ rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-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 Section are more restrictive than the existing license condition, then the licensee shall comply with this Section 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 in RH-1000. through RH-2110.

RH-1105. (Cont'd)

g. If a license condition cites provisions in the former Part M of Section 3 (currently Appendices A, B, E-H, and J of Section 3 and Appendix A of Section 4) 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 of the whole body, and to the skin of 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 of the whole body or to skin of any extremity.

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.).

RH-1200. (Cont'd)

c. When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the Department. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous ten (10) square centimeters of skin 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 I of Appendix G to Section 3 and may be used to determine the individual's dose (See RH-1500.f.) and to demonstrate compliance with the occupational dose limits.

e. In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. (See footnote c of Appendix G to Section 3.)

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.

RH-1201. (Cont'd)

b. **Intake by inhalation**. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep-dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

1. The sum of the fractions of the inhalation ALI for each radionuclide, or

2. The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or

3. The sum of the calculated committed effective dose equivalents to all significantly irradiated[1/] organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit.

c. **Intake by oral ingestion**. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than ten percent (10%) of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.

d. **Intake through wounds or absorption through skin**. The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption.

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

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

Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep-dose equivalent, eye dose equivalent, and shallow-dose equivalent from external exposure to the radioactive cloud. (See Appendix G to Section 3, footnotes a and b.)

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

RH-1203. **Determination of Internal Exposure**.

a. For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required under RH-1302., take suitable and timely measurements of:

1. Concentrations of radioactive materials in air in work areas; or

2. Quantities of radionuclides in the body; or

3. Quantities of radionuclides excreted from the body; or

4. Combinations of these measurements.

b. Unless respiratory protective equipment is used, as provided in RH-1303.f.5., or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

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 Section 3.) 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-1504., in order to permit the licensee to make additional measurements basic to the assessments.

RH-1203. (Cont'd)

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 Section 3 for each radionuclide in the mixture; or

2. The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

f. If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture must be the most restrictive DAC of any radionuclide in the mixture.

g. When a mixture of radionuclides in air exists, licensees may disregard certain radionuclides in the mixture if:

1. The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in RH-1200. and in complying with the monitoring requirements in RH-1302.b.;

2. The concentration of any radionuclide disregarded is less than ten percent (10%) of its DAC; and

3. The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent (30%).

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.

RH-1203.h. (Cont'd)

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 I of Appendix G to Section 3.

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 limit in RH-1200.a.1.B. is 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-1200. 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.

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.

RH-1205. (Cont'd)

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 (5) times the annual dose limits in RH-1200.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-1200.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 percent (10%) of the annual dose limits specified for adult workers in RH-1200.

RH-1207. **Dose Equivalent 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.f.)

RH-1207. (Cont'd)

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-8420., 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-8420., 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. Notwithstanding RH-1208.a.1. of this section, a licensee may permit visitors to an individual who cannot be released, under RH-8420., to receive a radiation dose greater than 0.1 rem (1 mSv) if:

1. The radiation dose received does not exceed 0.5 rem (5 mSv);

2. The authorized user, as defined in Section 9, has determined before the visit that it is appropriate; and

3. Documentation shall be maintained by the licensee.

d. 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.

e. In addition to the requirements of this Section, a licensee subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR Part 190 shall comply with those standards.

f. The Department may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

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

a. The licensee or registrant shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in RH-1208.

b. A licensee or registrant shall show compliance with the annual dose limit in RH-1208. by:

1. Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual dose limit; or

2. Demonstrating that:

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 II of Appendix G to Section 3; 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 Table II of Appendix G to Section 3 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. Deleted.

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. **Testing for Leakage and/or Contamination of Sealed Sources**.

a. A licensee possessing any sealed radioactive source under the provisions of a specific license, except as specified in paragraph b. of this section, shall assure that:

1. Each sealed source is tested for leakage and/or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within the interval listed in the Sealed Source and Device Registry prior to transfer to the licensee;

2. Each sealed source that is not designed to emit alpha particles is tested for leakage and/or contamination at intervals not to exceed those listed in the Sealed Source and Device Registry;

3. Each sealed source that is designed to emit alpha particles is tested for leakage and/or contamination at intervals not to exceed three (3) months.

4. Each sealed source for which there is reason to suspect might have been damaged or might be leaking is tested for leakage and/or contamination before further use.

5. Tests for leakage and/or contamination shall be capable of detecting the presence of 0.005 microcuries (185 Bq) of radioactive material on the test sample.

6. Test samples shall be collected at the most accessible area where contamination would accumulate if the sealed source were leaking.

b. A licensee need not perform tests for leakage and/or contamination on the following sources:

1. Sealed sources containing only radioactive material with a half-life of less than 30 days;

2. Sealed sources containing only radioactive material as a gas;

3. Sealed sources containing 100 microcuries (3.7 MBq) or less of beta- and/or photon-emitting material or 10 microcuries (370 kBq) or less of alpha-emitting material;

4. Sealed sources containing only hydrogen-3;

5. Seeds of iridium-192 encased in nylon ribbon; and

RH-1212.b. (Cont'd)

6. Sealed sources, except for alpha sources, which are stored, not being used and are identified as being in storage. The licensee shall, however, test each such sealed source for leakage and/or contamination and receive the test results before any use or transfer unless it has been tested for leakage and/or contamination within the required leak test interval before the date of use or transfer. No sealed source shall be stored for a period of more than 3 years without being tested for leakage and/or contamination.

c. Tests for leakage and/or contamination, including sample collection and analysis, shall be performed by persons specifically authorized by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform such services.

d. Records of test results for leakage and/or contamination shall be made in accordance with RH-1500.j.

e. Any test conducted pursuant to RH-1212. which reveals the presence of 0.005 microcuries (185 Bq) or more of removable contamination shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with these ~~Regulations~~ Rules.

f. Reports of test results indicating a leaking sealed source shall be made to the Department in accordance with RH-1508.

RH-1213. Deleted.

RH-1214. Deleted.

RH-1215. **General Provisions and Scope – Radiological Criteria for License Termination.**

a. Any person licensed to receive, possess, own, acquire, use, process, transfer, or dispose of radioactive material is subject to RH-1215. through RH-1220.

RH-1215. (Cont'd)

b. After a site has been decommissioned and the license terminated in accordance with the criteria in RH-1215. through RH-1220., the Department will require additional cleanup only if, based on new information, it determines that the criteria in RH-1215. through RH-1220. were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

c. When calculating TEDE to the average member of the critical group, the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

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 a trust segregated from the licensee's assets and outside the licensee's administrative control, and in which the adequacy of the trust funds is to be assessed based on an assumed annual one percent (1%) real rate of return on investment;

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

3. 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 the 100 mrem/y (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; and

RH-1217.e.2. (Cont'd)

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.A.i., 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 of Section 3, 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:

RH-1218.a.4. (Cont'd)

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.

5. Has provided sufficient financial assurance in the form of a trust fund 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.

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.

RH-1219. (Cont'd)

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**.

a. 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.

b. Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in Part A of Section 3 and radiological criteria for license termination in RH-1215. through RH-1220.

RH-1221. Deleted. See RH-409.i.

RH-1222.- RH-1299. Reserved.

PART D.
PRECAUTIONARY PROCEDURES

RH-1300. **Surveys**.

a. Each licensee or registrant shall make or cause to be made, surveys of areas, including the subsurface, that:

1. May be necessary for the licensee or registrant to comply with the ~~regulations~~ rules in this Section; and

2. Are reasonable under the circumstances to evaluate:

A. The magnitude and extent of radiation levels,

B. Concentrations or quantities of residual radioactivity, and

C. The potential radiological hazards of the radiation levels and residual radioactivity detected.

b. Notwithstanding RH-1500.c.1., records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with RH-409.h.7., as applicable.

c. The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated ~~periodically~~ at intervals recommended by the manufacturer or approved by the Department for the radiation measured. However, a more frequent interval may be required in another applicable Part of these Rules.

RH-1301. **Personnel Monitoring**.

a. All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees or registrants to comply with RH-~~1302.a.~~ 1200., with other applicable provisions of these ~~Regulations~~ Rules, or with conditions specified in a license or a registration must be processed and evaluated by a dosimetry processor:

1. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology ~~[formerly called National Bureau of Standards],~~; and

RH-1301.a. (Cont'd)

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

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

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

a. Each licensee or registrant shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by:

1. Adults likely to receive, in one (1) year from sources external to the body, a dose in excess of ten percent (10%) of the limits in RH-1200.a;

2. Minors likely to receive, in one (1) year, from sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv); and

3. Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv); and

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

4. Individuals entering a high or very high radiation area.

5. Individuals working with medical fluoroscopic equipment.

A. An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to RH-1207.a., shall be located under the protective apron at the waist.

RH-1302.a.5. (Cont'd)

B. An individual monitoring device used for lens dose equivalent shall be located at the neck (collar), or an unshielded location closer to the eye, outside the protective apron. If leaded eyewear is worn, the device should be clipped to the eyewear.

C. When only 1 individual monitoring device is used to determine the effective dose equivalent for external radiation, it shall be located at the neck (collar) outside the protective apron. When a second individual monitoring device is used for the same purpose, it shall be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant woman.

b. Each licensee or registrant shall monitor, to determine compliance with RH-1203., the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

1. Adults likely to receive, in one (1) year, an intake in excess of ten percent (10%) of the applicable ALI(s) in Table I, Columns 1 and 2, of Appendix G to Section 3; and

2. Minors likely to receive, in one (1) year, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

3. Declared pregnant women likely to receive, during the entire pregnancy, a committed dose equivalent in excess of 0.1 rem (1 mSv).

RH-1303. **Caution Signs, Labels, and Signals**.

a. **Symbol**.

1. Except as otherwise authorized by the Department, symbols prescribed by this Section shall use the conventional radiation caution colors (magenta, or purple, or black, on yellow background).

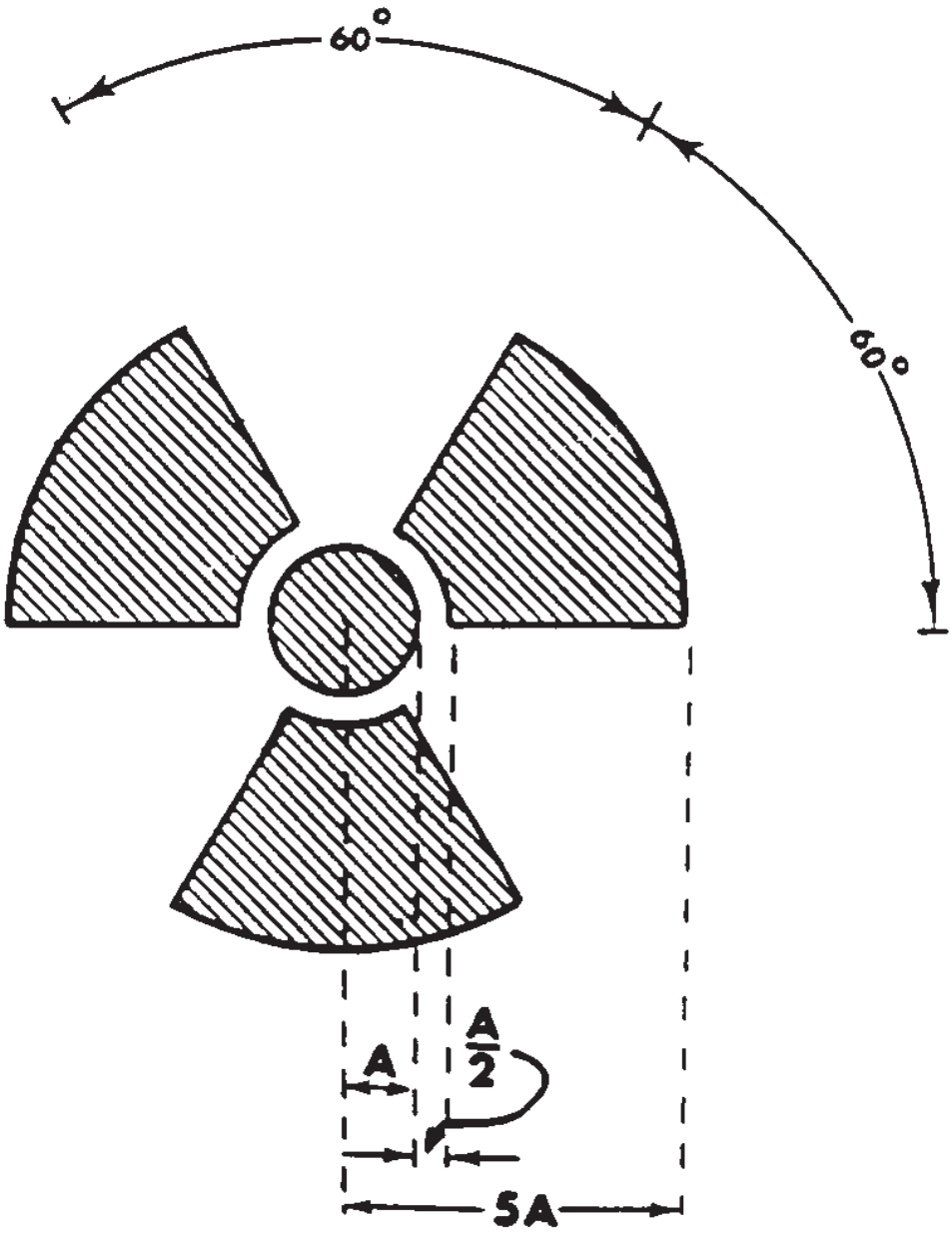
2. The symbol prescribed by this Section is the conventional three-bladed design. The cross-hatched area shall be magenta, or purple, or black and the background yellow.

RH-1303.a. (Cont'd)

3. Notwithstanding the requirements of RH-1303.a. of this section, licensees or registrants are authorized to label sources, source holders, or device components containing sources of licensed materials that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

4. In addition to the contents of signs and labels prescribed in this Section, a licensee or registrant may provide on or near such signs and labels any additional information which may be appropriate in aiding individuals to minimize exposure to radiation.

RH-1303.a. (Cont'd)



RADIATION SYMBOL

RH-1303. (Cont'd)

b. **Posting requirements**.

1. **Posting of Radiation Areas.**

The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

2. **Posting of High Radiation Areas.**

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

3. **Posting of Very High Radiation Areas.**

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

4. **Posting of Airborne Radioactivity Area.**

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

5. **Posting of Areas or Rooms in which Licensed Material is Used or Stored.**

The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding ten (10) times the quantity of such material specified in Appendix H to Section 3 with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

c. **High radiation areas**.

1. Deleted. See RH-1303.b.

2. The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

   A. A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep-dose equivalent of 0.1 rem (1 mSv) in one (1) hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates;

   B. A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

   C. Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

3. In place of the controls required by RH-1303.c.2. of this section for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

4. A licensee or registrant may apply to the Department for approval of alternative methods for controlling access to high radiation areas.

5. The licensee or registrant shall establish the controls required by RH-1303.c.2 and RH-1303.c.4 of this section in a way that does not prevent individuals from leaving a high radiation area.

6. Control is not required for each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the Department of Transportation provided that:

   A. The packages do not remain in the area longer than three (3) days; and

   B. The dose rate at one (1) meter from the external surface of any package does not exceed 0.01 rem (0.1 mSv) per hour.

7. Control of entrance or access to rooms or other areas in hospitals is not required solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who will take the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the limits established in this Section and to operate within the ALARA provisions of the licensee's radiation protection program.

d. 1. **Very high radiation areas**.

In addition to the requirements in RH-1303.c., the licensee or registrant shall institute additional measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rads (5 grays) or more in one (1) hour at one (1) meter from a radiation source or any surface through which the radiation penetrates.

2. Deleted. See RH-1303.b.

e. **Very high radiation areas - irradiators**.

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

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

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

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

iii. Prevent operation of the source if the source would produce radiation levels in the area that could result in a deep-dose equivalent to an individual in excess of 0.1 rem (1 mSv) in one (1) hour.

B. Additional control devices must be provided so that upon failure of the entry control devices to function as required by RH-1303.e.1.A. of this section:

i. The radiation level within the area, from the sealed source, is reduced below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (1 mSv) in one (1) hour; and

ii. Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity and prepared to render or summon assistance, aware of the failure of the entry control devices.

C. The licensee shall provide control devices so that, upon failure or removal of physical radiation barriers other than the source's shielded storage container:

i. The radiation level from the source is reduced below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (1 mSv) in one (1) hour; and

ii. Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

D. When the shield for the stored source is a liquid, the licensee shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

E. Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of C. and D. of this paragraph.

F. Each area must be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source can be put into operation and in sufficient time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source from being put into operation.

G. Each area must be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source.

H. Each area must be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source, the radiation level from the source in the area is below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (1 mSv) in one (1) hour.

I. The entry control devices required in RH-1303.e.1.A. must be tested for proper functioning. (See RH-1500.i. for recordkeeping requirements.)

i. Testing must be conducted prior to initial operation with the source of radiation on any day (unless operations were continued uninterrupted from the previous day);

ii. Testing must be conducted prior to resumption of operation of the source of radiation after any unintended interruption; and

iii. The licensee shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

J. The licensee may not conduct operations, other than those necessary to place the source in safe condition or to effect repairs on controls, unless control devices are functioning properly.

K. Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, must be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for processed materials must be equipped to detect and signal the presence of any loose radiation sources that are carried toward such an exit and to automatically prevent loose radiation sources from being carried out of the area.

2. Persons holding licenses or applicants for licenses for radiation sources that are within the purview of RH-1303.e.1. and that will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of RH-1303.e.1., such as those for the automatic control of radiation levels, may apply to the Radiation Control Section Chief for approval of the use of alternative safety measures. Any alternative safety measures must provide a degree of personnel protection at least equivalent to those specified in RH-1303.e.1. At least one of the alternative measures must include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such radiation sources are used.

3. The entry control devices required by RH-1303.e.1. and 2. of this section must be established in such a way that no individual will be prevented from leaving the area.

f. **Airborne radioactivity area**.

1. Deleted. Airborne radioactivity area is defined in RH-1100.

2. Deleted. See RH-1303.b.

3. **Use of process or other engineering controls**.

The licensee shall use, to the extent practical, process or other engineering controls (e.g., containment, decontamination, or ventilation) to control the concentration of radioactive material in air.

4. **Use of other controls**.

A. When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

i. Control of access;

ii. Limitation of exposure times;

iii. Use of respiratory protection equipment; or

iv. Other controls.

B. If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

5. **Use of individual respiratory protection equipment**.

A. If the licensee assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material,

i. The licensee shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health (NIOSH) except as otherwise noted in this Section.

ii. If the licensee wishes to use equipment that has not been tested or certified by NIOSH, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of this equipment, except as provided in this Section. The application must include evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use. This must be demonstrated either by licensee testing or on the basis of reliable test information.

iii. The licensee shall implement and maintain a respiratory protection program that includes:

(a). Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

(b). Surveys and bioassays, as necessary, to evaluate actual intakes;

(c). Testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use;

(d). Written procedures regarding:

(1). Monitoring, including air sampling and bioassays;

(2). Supervision and training of respirator users;

(3). Fit testing;

(4). Respirator selection;

(5). Breathing air quality;

(6). Inventory and control;

(7). Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;

(8). Recordkeeping; and

(9). Limitations on periods of respirator use and relief from respirator use;

(e). Determination by a physician that the individual user is medically fit to use respiratory protection equipment; before

(1). The initial fitting of a face sealing respirator;

(2). Before the first field use of a non-face sealing respirator; and

(3). Either every twelve (12) months thereafter, or periodically at a frequency determined by a physician.

(f). Fit testing, with fit factor greater than or equal to 10 times the APF for negative pressure devices, and a fit factor greater than or equal to 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed one (1) year. Fit testing must be performed with the facepiece operating in the negative pressure mode.

iv. The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

v. The licensee shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices, the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

vi. Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

vii. Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997 and included in the regulations of the Occupational Safety and Health Administration (29 CFR 1910.134(i)(1)(ii)(A) through (E). Grade D quality air criteria include:

(a). Oxygen content (v/v) of 19.5-23.5%;

(b). Hydrocarbon (condensed) content of five (5) milligrams per cubic meter of air or less;

(c). Carbon monoxide (CO) content of ten (10) ppm or less;

(d). Carbon dioxide content of 1,000 ppm or less; and

(e). Lack of noticeable odor.

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

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

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

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

The Department may impose restrictions in addition to those in RH-1303.f.4. and RH-1303.f.5. and Appendix E to Section 3 to:

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

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

7. **Application for use of higher assigned protection factors**.

The licensee shall obtain authorization from the Department before using assigned protection factors in excess of those specified in Appendix E to Section 3. The Department may authorize a licensee to use higher assigned protection factors on receipt of an application that:

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

B. Demonstrates that the respiratory protection equipment provides these protection factors under the proposed conditions of use.

g. Deleted. See RH-1303.b.

h. Deleted. (See RH-1309. and RH-1310.)

i. Each licensee shall, prior to disposal of an empty uncontaminated container to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive material.

j. All devices and equipment capable of producing radiation when operated shall be appropriately labeled so as to caution individuals that such devices or equipment produce radiation when operated.

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

RH-1304. **Exceptions From Posting Requirements**.

Notwithstanding the provisions of RH-1303.:

a. A room or area is not required to be posted with a caution sign because of the presence of a sealed source, provided the radiation level twelve (12) inches (30 centimeters) from the surface of the source container or housing does not exceed five (5) millirems (0.05 mSv) per hour.

b. Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs provided that the patient could be released from licensee control pursuant to RH-8420.

c. Caution signs are not required to be posted in areas or rooms containing radioactive materials for periods of less than eight (8) hours provided that:

1. The materials are constantly attended during such periods by an individual who shall take the precautions necessary to prevent the exposure of any individual to radiation or radioactive materials in excess of the limits established in this Section; and

2. Such area or room is subject to the licensee's control.

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

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

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

RH-1306. **Storage of Sources of Radiation**.

a. The licensee or registrant shall secure sources of radiation from unauthorized removal or access.

b. Sources of radiation shall not be stored in residential areas.

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

~~a. As used in these Regulations, Special Form means any of the following physical forms of licensed material:~~

~~1. The material is in solid form having no dimension less than 0.5 millimeter or at least one dimension greater than five (5) millimeters; does not melt, sublime or ignite in air at a temperature of 1,000 ^{0}F (538 ^{0}C), will not shatter or crumble if subjected to the percussion test described in Section 4; and is not dissolved or converted into dispersible form to the extent of more than 0.005 percent by weight by immersion for one week in water at 68 ^{0}F (20 ^{0}C) or in air at 86 ^{0}F (30 ^{0}C); or~~

~~2. The material is securely contained in a capsule having no dimension less than 0.5 millimeter or at least one (1) dimension greater than five (5) millimeters, which will retain its contents if subjected to the tests prescribed in Section 4; and which is constructed of materials which do not melt, sublime or ignite in air at 1,475 ^{0}F (802 ^{0}C), and do not dissolve or convert into dispersible form to the extent of more than 0.005 percent by weight by immersion for one week in water at 68 ^{0}F (20 ^{0}C) or in air at 86 ^{0}F (30 ^{0}C).~~

~~b~~ a. Each licensee who expects to receive a package containing quantities of radioactive material in excess of a "Type A" quantity ~~specified in or determined by procedures described in~~, as defined in RH-3100. and Appendix A to Section 4, shall make arrangements:

1. To receive the package when the carrier offers it for delivery; or

2. To receive notification of the arrival of the package at the carrier's terminal and to ~~pick up the package when the carrier offers it for delivery~~ take possession of the package expeditiously.

~~c~~ b. Each licensee shall:

1. Monitor the external surfaces of a labeled[4/] package for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as ~~described~~ defined in RH-3100.

2. Monitor the external surfaces of a labeled[4/] package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity as defined in RH-3100. and Appendix A to Section 4; and

RH-1307.c. (Cont'd)

3. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

~~d~~ c. The licensee shall perform the monitoring required by ~~RH-1307.c.~~ paragraph b. of this section as soon as practical after receipt of the package, but not later than three (3) hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than three (3) hours from the beginning of the next working day if it is received after working hours.

~~e~~ d. The licensee shall immediately notify the final delivery carrier and~~, by telephone and telegram, mailgram or facsimile,~~ the Department by telephone at 1-800-633-1735, when ~~if packages, other than those transported by exclusive use vehicle, are found to have~~:

1. Removable radioactive surface contamination ~~in excess of 0.001 microcurie per 100 square centimeters on the external surfaces of the package~~ exceeds the limits of RH-3503.i.; or

2. External ~~R~~radiation levels ~~at the external surface of the package in excess of 200 mRem/hr or at one (1) meter from the external surface of the package in excess of ten (10) mRem/hr~~ exceed the limits of RH-3400.

~~f~~ e. Each licensee ~~or registrant~~ shall:

1. ~~E~~establish, maintain, and ~~maintain~~ retain written procedures for safely opening packages in which radioactive material is received; and
2. ~~shall assure~~ Ensure that ~~such~~ the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

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

RH-1308. **Control of Material Not in Storage**.

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

RH-1309. **Labeling Containers**.

a. The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words:

CAUTION **DANGER**

or

RADIOACTIVE MATERIAL **RADIOACTIVE MATERIAL**

The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

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

RH-1310. **Exemptions to Labeling Requirements**.

A licensee is not required to label:

a. Containers holding licensed material in quantities less than the quantities listed in Appendix H to Section 3 entitled “Quantities of Licensed Material Requiring Labeling”; or

b. Containers holding licensed material in concentrations less than those specified in Table 3 of Appendix G entitled “ALIs and DACs of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage.”

c. Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this Section; or

d. Containers when they are in transport and packaged and labeled in accordance with the regulations of the Department of Transportation.[5/]

RH-1310. (Cont'd)

e. Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record (examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells). The record must be retained as long as the containers are in use for the purpose indicated on the record; or

f. Installed manufacturing or process equipment, such as reactor components, piping, and tanks; or

g. Containers holding licensed material (other than sealed sources that are either specifically or generally licensed) at a facility licensed by the U.S. Nuclear Regulatory Commission (NRC) Part 50 (Domestic Licensing of Production and Utilization Facilities) or Part 52 (Licenses, Certifications, and Approvals for Nuclear Power Plants), not including non-power reactors, that are within an area posted under the requirements in RH-1303. if the containers are:

1. Conspicuously marked (such as by providing a system of color coding of containers) commensurate with the radiological hazard;

2. Accessible only to individuals who have sufficient instruction to minimize radiation exposure while handling or working in the vicinity of the containers; and

3. Subject to plant procedures to ensure they are appropriately labeled, as specified in RH-1309. before being removed from the posted area.

RH-1311. **Location of Individual Monitoring Devices**.

Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with RH-1302.a. wear individual monitoring devices as follows:

a. An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar);

RH-1311. (Cont'd)

b. An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman, pursuant to RH-1207.a., shall be located at the waist under any protective apron being worn by the woman;

c. An individual monitoring device used for monitoring the lens dose equivalent, to demonstrate compliance with RH-1200.a.2.A., shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye. If leaded eyewear is worn, the device should be clipped to the eyewear;

d. An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with RH-1200.a.2.B., shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

RH-1312.- RH-1399. Reserved.

PART E.
WASTE DISPOSAL

RH-1400. **General Requirements**.

A licensee shall dispose of licensed material only:

a. By transfer to an authorized recipient as provided in RH-1406. or in Section 2 ~~of these Regulations~~, or to the Department of Energy; or

b. By decay in storage; or

c. By release in effluents within the limits in RH-1208.; or

d. As authorized under RH-1401., RH-1402., RH-1404., RH-1405., or RH-1408.

e. A person must be specifically licensed to receive waste containing licensed material from other persons for:

1. Treatment prior to disposal; or

2. Treatment or disposal by incineration; or

3. Decay in storage; or

4. Storage until transferred to a storage or disposal facility authorized to receive the waste.

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

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

a. A description of the waste containing licensed material to be disposed of, including the physical and chemical properties important to risk evaluation, and the proposed manner and conditions of waste disposal;

b. An analysis and evaluation of pertinent information on the nature of the environment;

RH-1401. (Cont'd)

c. The nature and location of other potentially affected licensed and unlicensed facilities; and

d. Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in this Section.

RH-1402. **Disposal by Release Into Sanitary Sewerage**.

a. A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

1. The material is readily soluble (or is readily dispersible biological material) in water;

2. The quantity of licensed or other radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table III of Appendix G to Section 3; and

3. If more than one (1) radionuclide is released, the following conditions must also be satisfied:

A. The licensee shall determine the fraction of the limit in Table III of Appendix G to Section 3 represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table III of Appendix G to Section 3; and

B. The sum of the fractions for each radionuclide required by paragraph a.3.A. of this section does not exceed unity; and

4. The total quantity of licensed and other radioactive material that the licensee releases into the sanitary sewerage system in a year does not exceed five (5) Curies (185 GBq) of hydrogen-3, one (1) Curie (37 GBq) of carbon-14, and one (1) Curie (37 GBq) of all other radioactive materials combined.

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

RH-1403. Deleted.

RH-1404. **Treatment or Disposal by Incineration**.

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

RH-1405. **Disposal of Specific Wastes**.

a. Any licensee may dispose of the following licensed material without regard to its radioactivity:

1. 0.05 microcuries (1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

2. 0.05 microcuries (1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

b. A licensee may not dispose of tissue under paragraph a.2. of this section in a manner that would permit its use either as food for humans or as animal feed.

c. The licensee shall maintain records in accordance with RH-1500.h.

RH-1406. **Transfer for Disposal and Manifests**.

a. The requirements of this section and Appendix G to 10 CFR Part 20 are designed to:

1. Control transfers of low-level radioactive waste (LLW) by any waste generator, waste collector, or waste processor licensee, as defined in Section 2 ~~of these Regulations~~, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility as defined in Section 2 ~~of these Regulations~~;

2. Establish a manifest tracking system; and

3. Supplement existing requirements concerning transfers and recordkeeping for those wastes.

RH-1406. (Cont'd)

b. Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G to 10 CFR Part 20.

c. Each shipment manifest must include a certification by the waste generator as specified in Section II of Appendix G to 10 CFR Part 20.

d. Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix G to 10 CFR Part 20.

e. Any licensee shipping byproduct material as defined in paragraphs 3. and 4. of the definition of byproduct material set forth in RH-1100. intended for ultimate disposal at a land disposal facility licensed under RH-407. must document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G to 10 CFR Part 20.

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

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

RH-1408. **Disposal of Certain Byproduct Material**.

a. Licensed material as defined in paragraphs 3. and 4. of the definition of byproduct material set forth in RH-1100. may be disposed of in accordance with RH-407. of this chapter, even though it is not defined as low level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under RH-407., must meet the requirements of RH-1406.

RH-1408. (Cont'd)

b. A licensee may dispose of byproduct material, as defined in paragraphs 3. and 4. of the definition of byproduct material set forth in RH-1100., at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

RH-1409.- RH-1499. Reserved.

PART F.
RECORDS, REPORTS, NOTIFICATIONS, AND TESTS

RH-1500. **Records**.

a. **General provisions**.

1. Each licensee or registrant shall use the units: curie, rad, rem, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this Section.

2. In the records required by this Section, the licensee may record quantities in the International System of Units (SI) units in parentheses following each of the units specified in paragraph a.1. of this section. However, all quantities must be recorded as stated in paragraph a.1. of this section.

3. Notwithstanding the requirements of paragraph a.1. of this section, when recording information on shipment manifests, as required in RH-1406.b., information must be recorded in the International System of Units (SI) or in SI and units as specified in paragraph a.1. of this section.

4. The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this Section (e.g., total effective dose equivalent, shallow-dose equivalent, lens dose equivalent, deep-dose equivalent, committed effective dose equivalent).

b. **Records of radiation protection programs**.

1. Each licensee or registrant shall maintain records of the radiation protection program, including:

A. The provisions of the program; and

B. Audits and other reviews of program content and implementation.

2. The licensee or registrant shall retain the records required by paragraph b.1.A. of this section until the Department terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by paragraph b.1.B. of this section for three (3) years after the record is made.

c. **Records of surveys**.

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

2. The licensee or registrant shall retain each of the following records until the Department terminates each pertinent license or registration requiring the record:

A. Records of the results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents;

B. Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose;

C. Records showing the results of air sampling, surveys, and bioassays required pursuant to RH-1303.f.5.A.iii.; and

D. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

d. **Determination of prior occupational dose**.

1. For each individual who is likely to receive an annual occupational dose requiring monitoring pursuant to RH-1302., the licensee or registrant shall determine the occupational radiation dose received during the current year.

2. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

A. The internal and external doses from all previous planned special exposures; and

B. All doses in excess of the limits (including doses received during accidents and emergencies) received during the lifetime of the individual.

3. In complying with the requirements of paragraphs d.1.and d.2. of this section, a licensee or registrant may:

   A. Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual may have received during the current year;

   B. Accept, as the record of cumulative radiation dose, an up-to-date RC FORM 111, "Cumulative Occupational Dose History," or equivalent, signed by the individual and counter-signed by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee); and

   C. Obtain reports of the individual's dose equivalent(s) from the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee or registrant) by telephone, telegram, electronic media, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

4. The licensee or registrant shall record the exposure history, as required by paragraphs d.1. and d.2. of this section, on an up-to-date RC FORM 111, or other clear and legible record, including all of the information required on that form[6/]. The form or record must show each period in which the individual received occupational exposure to radiation or radioactive material and must be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing RC FORM 111, or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on RC FORM 111, or equivalent, indicating the periods of time for which data are not available.

5. If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

   A. In establishing administrative controls under RH-1200.f. for the current year, that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

   B. That the individual is not available for planned special exposures.

6. The licensee or registrant shall retain the records on RC FORM 111, or equivalent, until the Department terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing RC FORM 111, or equivalent, for three (3) years after the record is made.

e. **Records of planned special exposures**.

1. For each use of the provisions of RH-1205. for planned special exposures, the licensee or registrant shall maintain records that describe:

   A. The exceptional circumstances requiring the use of a planned special exposure;

   B. The name of the management official who authorized the planned special exposure and a copy of the signed authorization;

   C. What actions were necessary;

   D. Why the actions were necessary;

   E. How doses were maintained ALARA; and

   F. What individual and collective doses were expected to result and the doses actually received in the planned special exposure.

2. The licensee or registrant shall retain the records until the Department terminates each pertinent license or registration requiring these records.

f. **Records of individual monitoring results**.

1. **Recordkeeping requirement**.

Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to RH-1302., and records of doses received during planned special exposures, accidents, and emergency conditions. These records[7/] must include, when applicable:

A. The deep-dose equivalent to the whole body, lens dose equivalent, shallow-dose equivalent to the skin, and shallow-dose equivalent to the extremities;

B. The estimated intake of radionuclides (See RH-1201.);

C. The committed effective dose equivalent assigned to the intake of radionuclides;

D. The specific information used to calculate the committed effective dose equivalent pursuant to RH-1203.a. and RH-1203.c. and when required by RH-1302.;

E. The total effective dose equivalent when required by RH-1201.; and

F. The total of the deep-dose equivalent and the committed dose to the organ receiving the highest total dose.

2. **Recordkeeping frequency**.

The licensee or registrant shall make entries of the records specified in paragraph f.1. of this section at least annually.

3. **Recordkeeping format**.

The licensee or registrant shall maintain the records specified in paragraph f.1. of this section on an up-to-date RC FORM 110, "Occupational Dose Record for a Monitoring Period," in accordance with the instructions for RC FORM 110, or in clear and legible records containing all the information required by that form.

4. **Privacy protection**.

The records required under this section should be protected from public disclosure because of their personal privacy nature.

5. The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file but may be maintained separately from the dose records.

6. The licensee or registrant shall retain each required form or record until the Department terminates each pertinent license or registration requiring the record.

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

1. Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public (See RH-1208.).

2. The licensee or registrant shall retain the records required by paragraph g.1. of this section until the Department terminates each pertinent license or registration requiring the record.

h. **Records of waste disposal**.

1. Each licensee shall maintain records of the disposal of licensed materials made under RH-1401., RH-1402., a previous RH-1403. that authorized certain burials[8/], RH-1404., RH-1405., and RH-1408.

2. The licensee shall retain the records required by paragraph h.1. of this section until the Department terminates each pertinent license requiring the record. Requirements for disposition of these records, prior to license termination, are located in RH-600.

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

1. Each licensee or registrant shall maintain records of tests made under RH-1303.e.1.I. on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

2. The licensee or registrant shall retain the records required by paragraph i.1. of this section for three (3) years after the record is made.

j. **Records of tests for leakage and/or contamination of sealed sources.**

1. Each licensee shall maintain records of tests for leakage and/or contamination of sealed sources required by RH-1212.a. These records must include identification of the source such as manufacturer, model number, and serial number; the date the sample was collected; the date the sample was analyzed; and the measured activity of the sample in units of microcuries or becquerels.

2. The licensee shall retain the records required by paragraph j.1. of this section for three (3) years after the record is made.

k. **Records required at temporary jobsites**.

Each licensee or registrant conducting activities as described in the definition for temporary jobsite in RH-1100. shall have the following records available at the temporary jobsite for inspection by the Department:

1. Current copy of appropriate license issued by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State.

2. A copy of these ~~Regulations~~ Rules.

3. Operating and Emergency Procedures.

4. The latest instrument calibration, if applicable.

5. Survey records required pursuant to RH-1803.c. for the period of operation at the jobsite, if applicable.

6. The latest leak test record for the device(s) in use at the jobsite.

7. Daily pocket dosimeter record for the period of operation at the jobsite, if applicable.

l. Reserved.

m. Reserved.

n. 1. **Record retention periods**.

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

B. If there is a conflict between the Department's ~~regulations~~ rules in this Section, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the ~~regulations~~ rules in this Section for such records shall apply unless the Department, pursuant to RH-2000., has granted a specific exemption from the record retention requirements specified in the ~~regulations~~ rules in this Section.

RH-1500.n. (Cont'd)

2. **Record maintenance**.

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

RH-1501. **Reports of Lost, Stolen, or Missing Licensed or Registered Sources of Radiation**.

a. **Telephone reports**.

1. Each licensee or registrant shall report to the Department by telephone as follows:

A. Immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix H to Section 3 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas; or

B. Within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than ten (10) times the quantity specified in Appendix H to Section 3 that is still missing at this time.

C. Immediately after its occurrence becomes known to the registrant, a lost, stolen, or missing radiation machine.

2. Reports must be made as follows:

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

b. **Written reports**.

1. Each licensee or registrant required to make a report under paragraph a. of this section shall, within 30 days after making the telephone report, make a written report to the Department setting forth the following information:

A. A description of the licensed or registered source of radiation involved, including, for radioactive material, kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model number, serial number, and type and maximum energy of radiation emitted;

B. A description of the circumstances under which the loss or theft occurred;

C. A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved;

D. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;

E. Actions that have been taken, or will be taken, to recover the source of radiation; and

F. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

2. Reports must be made as follows:

All licensees or registrants shall make reports to the Arkansas Department of Health, Radiation Control Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

c. Subsequent to filing the written report, the licensee or registrant shall also report any additional substantive information on the loss or theft within thirty (30) days after the licensee or registrant learns of such information.

d. The licensee or registrant shall prepare any report filed with the Department pursuant to this section so that names of individuals who may have received exposure to radiation are stated in a separate and detachable part of the report.

RH-1502. **Notification of Incidents**.

a. **Immediate notification**.

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

1. An individual to receive:

   A. A total effective dose equivalent of 25 rems (0.25 Sv) or more; or

   B. A lens dose equivalent of 75 rems (0.75 Sv) or more; or

   C. A shallow-dose equivalent to the skin or extremities of 250 rads (2.5 Gy) or more; or

2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for twenty-four (24) hours, the individual could have received an intake five (5) times the occupational annual limit on intake. (The provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.)

b. **Twenty-four hour notification**.

Each licensee or registrant shall, within twenty-four (24) hours of discovery of the event, report to the Department any event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

1. An individual to receive, in a period of twenty-four (24) hours:

   A. A total effective dose equivalent exceeding five (5) rems (0.05 Sv); or

   B. A lens dose equivalent exceeding fifteen (15) rems (0.15 Sv); or

   C. A shallow-dose equivalent to the skin or extremities exceeding fifty (50) rems (0.5 Sv); or

RH-1502.b. (Cont'd)

2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for twenty-four (24) hours, the individual could have received an intake in excess of one occupational annual limit on intake. (The provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.)

c. Licensees or registrants shall make the reports required by this section by telephone to the Department at 1-800-633-1735 and by confirming letter to the Arkansas Department of Health, Radiation Control Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

d. The licensee or registrant shall prepare any report filed with the Department pursuant to this section so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable part of the report.

e. The provisions of this section do not include doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported under RH-1503.

RH-1503. **Reports of Planned Special Exposures.**

The licensee or registrant shall submit a written report to the Department within thirty (30) days following any planned special exposure conducted in accordance with RH-1205., informing the Department that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by RH-1500.e.

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

a. **Reportable events**.

In addition to the notification required by RH-1502., each licensee or registrant shall submit a written report within thirty (30) days after learning of any of the following occurrences:

1. Any incident for which notification is required by RH-1502.; or

2. Doses in excess of any of the following:

   A. The occupational dose limits for adults in RH-1200.; or

   B. The occupational dose limits for a minor in RH-1206.; or

   C. The limits for an embryo/fetus of a declared pregnant woman in RH-1207.; or

   D. The limits for an individual member of the public in RH-1208.; or

   E. Any applicable limit in the license; or

   F. The ALARA constraints for air emissions established under RH-1004.d.; or

3. Levels of radiation or concentrations of radioactive material in:

   A. A restricted area in excess of any applicable limit in the license; or

   B. An unrestricted area in excess of ten (10) times any applicable limit set forth in this Section or in the license (whether or not involving exposure of any individual in excess of the limits in RH-1208.); or

4. For licensees subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR Part 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

b. **Contents of reports**.

1. Each report required by paragraph a. of this section must describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

   A. Estimates of each individual's dose;

   B. The levels of radiation and concentrations of radioactive material involved;

RH-1504.b.1. (Cont'd)

C. The cause of the elevated exposures, dose rates, or concentrations; and

D. Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions.

2. Each report filed pursuant to paragraph a. of this section must include for each occupationally overexposed[9/] individual: the name, social security number, or other unique identifier, and date of birth. The report must be prepared so that this information is stated in a separate and detachable part of the report.

3. The licensee or registrant shall prepare any report filed with the Department pursuant to this section so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable part of the report.

c. Licensees or registrants who make reports pursuant to paragraph a. of this section shall submit the report in writing to the Arkansas Department of Health, Radiation Control Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-1505. **Notifications and Reports to Individuals**.

a. Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in Part N of this Section (RH-2804).

a. **Reports to individuals of exceeding dose limits**.

When a licensee or registrant is required pursuant to RH-1503. or RH-1504. to report to the Department any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee or registrant shall also provide the individual a report on his or her exposure data included in the report to the Department. The report must be transmitted no later than the transmittal to the Department.

RH-1506. **Notification of Intent to Vacate Premises.**

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

RH-1507. Deleted. Refer to RH-8703. and RH-8800.

RH-1508. **Reports of Leaking Sealed Sources.**

A licensee shall file a report with the Department within five (5) days if a test for leakage and/or contamination required by RH-1212. reveals the presence of 0.005 microcuries (185 Bq) or more of removable contamination. The written report must include the results of the test; the date the test results were received; identification of the source such as manufacturer, model number, and serial number; the radionuclide and its estimated activity; any equipment involved; any contamination which resulted from the leaking source; and the corrective actions taken.

RH-1509. **Reports of Individual Monitoring**.

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

1. Possess or use radioactive material for purposes of radiography pursuant to Part I of Section 3; or

RH-1509.a. (Cont'd)

2. Possess or use at any time, for processing or manufacturing for distribution pursuant to Section 2 or 9 ~~of these Regulations~~, radioactive material in quantities exceeding any one of the following quantities:

TABLE TO RH-1509.a.2.

Radionuclide	Activity[a]	
	Ci	GBq
Cesium-137	1	37
Cobalt-60	1	37
Gold-198	100	3,700
Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1,000	37,000
Promethium-147	10	370
Technetium-99m	1,000	37,000

[a] The Department may require as a license condition, or by rule~~, Regulation,~~ or order pursuant to RH-2001., reports from licensees who are licensed to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

b. Each licensee in a category listed in paragraph a. of this section shall complete an annual report of the results of individual monitoring carried out by the licensee for each individual for whom monitoring was required by RH-1302. during that year. The licensee may include additional data for individuals for whom monitoring was provided but not required. The licensee shall use an up-to-date RC FORM 110 or equivalent containing all the information required by RC FORM 110.

c. The licensee shall complete the report required by paragraph b. of this section, covering the preceding year, on or before May 31 of each year. The licensee shall retain the report and submit it, if requested, to the Arkansas Department of Health, Radiation Control Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-1510. Deleted. Refer to RH-8308., RH-8703., and RH-8800.

RH-1511. Deleted. Refer to RH-107.

RH-1512. Deleted. Refer to RH-1500.k.

RH-1513. **Reports of Transactions Involving Nationally Tracked Sources**.

Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in paragraphs a. through e. of this section for each type of transaction. See Appendix D to Section 3, "Nationally Tracked Source Thresholds."

a. Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

3. The manufacturer, model, and serial number of the source;

4. The radioactive material in the source;

5. The initial source strength in becquerels (curies) at the time of manufacture; and

6. The manufacture date of the source.

b. Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

3. The name and license number of the recipient facility and the shipping address;

4. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

5. The radioactive material in the source;

6. The initial or current source strength in becquerels (curies);

7. The date for which the source strength is reported;

8. The shipping date;

9. The estimated arrival date; and

10. For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

c. Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

3. The name, address, and license number of the person that provided the source;

4. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

5. The radioactive material in the source;

6. The initial or current source strength in becquerels (curies);

7. The date for which the source strength is reported;

8. The date of receipt; and

9. For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

d. Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

3. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

4. The radioactive material in the source;

5. The initial or current source strength in becquerels (curies);

6. The date for which the source strength is reported; and

7. The disassemble date of the source.

e. Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

3. The waste manifest number;

4. The container identification with the nationally tracked source;

5. The date of disposal; and

6. The method of disposal.

f. The reports discussed in paragraphs a. through e. of this section must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

1. The on-line National Source Tracking System;

2. Electronically using a computer-readable format;

3. By facsimile;

4. By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

5. By telephone with follow-up by facsimile or mail.

g. Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within five (5) business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by ~~regulation~~ rule. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by paragraphs a. through e. of this section. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

~~h. Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 31, 2009. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. The information may be submitted by using any of the methods identified by paragraph f.1. through f.4. of this section. The initial inventory report must include the following information:~~

~~1. The name, address, and license number of the reporting licensee;~~

~~2. The name of the individual preparing the report;~~

~~3. The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;~~

~~4. The radioactive material in the sealed source;~~

~~5. The initial or current source strength in becquerels (curies); and~~

~~6. The date for which the source strength is reported.~~

RH-1514.- RH-1519. Reserved.

RH-1520. **Tests**.

Upon instruction from the Department, each licensee and 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, including, but not limited to, tests of:

a. Sources of radiation;

b. Facilities wherein sources of radiation are used or stored;

c. Radiation detection and monitoring instruments; and

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

RH-1521.- RH-1599. Reserved.

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

RH-1600. **Scope**.

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

RH-1601. **Definitions**.

Accessible surface - The external surface of the enclosure or housing provided by the manufacturer.

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

Aluminum equivalent - The thickness of type 1100 aluminum alloy[11/] affording the same attenuation, under specified conditions, as the material in question.

Assembler - Any person engaged in the business of assembling, replacing or installing one or more components into an x-ray system or subsystem.

Attenuation block - A block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy[11/] or other materials having equivalent attenuation.

Automatic exposure control - A device which automatically controls one or more technique factors in order to obtain at a pre-selected location(s) a required quantity of radiation. (See also "Phototimer.")

Barrier - See "Protective barrier."

Beam axis - A line from the source through the centers of the x-ray fields.

Beam-limiting device - A device which provides a means to restrict the dimensions of the x-ray field.

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

Calibration - The determination of (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument or (2) the strength of a source of radiation relative to a standard.

Cephalometric device - A device intended for the radiographic visualization and measurement of the dimensions of the human head.

Certified components - Components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.

Certified system - Any x-ray system which has one or more certified component(s).

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

Coefficient of variation or "C" - The ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

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

where:

s = Estimated standard deviation of the population;

$\bar{x}$ = Mean value of observations in sample;

x_i = i^{th} observation in sample; and

n = Number of observations in sample.

Contact therapy system - An x-ray system used for therapy with the x-ray tube port placed in contact with or within five (5) centimeters of the surface being treated.

Control panel - That part of the x-ray control upon which are mounted the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors.

RH-1601. (Cont'd)

Cooling curve - The graphical relationship between heat units stored and cooling time.

Dead-man switch - A switch constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Detector - See "Radiation detector."

Diagnostic source assembly - The tube housing assembly with a beam-limiting device attached.

Diagnostic x-ray system - An x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

Direct scattered radiation - The scattered radiation which has been deviated in direction only by materials irradiated by the useful beam. (See "Scattered radiation.")

Entrance exposure - The roentgens per unit time at the point where the center of the useful beam enters the patient.

Equipment - See "X-ray equipment."

Exposure - The quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air. (The special unit of exposure is the roentgen [R]).

Field emission equipment - Equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

Filter - Material placed in the useful beam to absorb preferentially selected radiations.

Fluoroscopic imaging assembly - A subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Focal spot - The area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

Full beam detector - A radiation detector of such size that the total cross section of the maximum size useful beam is intercepted.

General purpose radiographic x-ray system - Any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

Gonad shield - A protective barrier for the testes or ovaries.

Half-value layer - The thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

Healing arts screening - The testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

Heat unit - A unit of energy equal to the product of the peak kilovoltage, milliamperes and seconds, i.e., kVp x mA x second.

HVL - See "Half-value layer."

Image intensifier - A device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

Image receptor - Any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

Image receptor support - For mammographic systems, that part of the system designed to support the image receptor in a horizontal plane during a mammographic examination.

Inherent filtration - The filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

Interlock - A device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

RH-1601. (Cont'd)

Irradiation - The exposure of matter to ionizing radiation.

Kilovolts peak - See "Peak tube potential."

kV - Kilovolts.

kVp - See "Peak tube potential."

kWs - Kilowatt second. It is equivalent to 10^3 kV·mA·sec, i.e.,

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

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

Leakage radiation - Radiation emanating from the diagnostic or therapeutic source assembly except for:

1. the useful beam, and

2. radiation produced when the exposure switch or timer is not activated.

Leakage technique factors - The technique factors associated with the tube housing assembly which are used in measuring leakage radiation. They are defined as follows:

1. For capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds or the minimum obtainable from the unit, whichever is larger.

2. For field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

3. For all other equipment, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Light field - That area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the focus of points at which the illumination is one-fourth of the maximum in the intersection.

Line-voltage regulation - The difference between the no-load and the load line potentials expressed as a percentage of the load line potential. It is calculated using the following equation:

Percent line-voltage regulation = $100(V_n-V_1)/V_1$

where:

V_n = No-load line potential; and
V_1 = Load line potential.

mA - Milliampere.

mAs - Milliampere second.

Maximum line current - The root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

Mobile equipment - See "X-ray equipment."

Patient - An individual subjected to healing arts examination, diagnosis or treatment.

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

Phantom - A volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

Phototimer - A method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated. (See "Automatic exposure control.")

PID - See "Position indicating device."

Position indicating device - A device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

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

Primary protective barrier - See "Protective barrier."

Protective apron - An apron made of radiation attenuating materials used to reduce radiation exposure.

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

1. Primary protective barrier - The material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.

2. Secondary protective barrier - A barrier sufficient to attenuate the stray radiation to the required degree.

Protective glove - A glove made of radiation attenuating materials used to reduce radiation exposure.

Qualified expert - An individual who has demonstrated to the satisfaction of the Department that such individual possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques and to advise regarding radiation protection needs.

Radiation detector - A device which in the presence of radiation provides by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Radiation therapy simulation system - A radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Radiograph - An image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

Radiograph imaging system - Any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

Rating - The operating limits as specified by the component manufacturer.

RH-1601. (Cont'd)

Recording - Producing a permanent form of an image resulting from x-ray photons (e.g., film, video tape).

Response time - The time required for an instrument system to reach 90 percent (90%) of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state mid scale reading.

Scattered radiation - Radiation that, during passage through matter, has been deviated in direction. (See "Direct scattered radiation.")

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

Secondary protective barrier - See "Protective barrier."

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

SID - See "Source-image receptor distance."

Source - The focal spot of the x-ray tube.

Source-image receptor distance - The distance from the source to the center of the input surface of the image receptor.

Spot check - A procedure which is performed to assure that a previous calibration continues to be valid.

Spot film - A radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

Spot-film device - A device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

SSD - The distance between the source and the skin of the patient.

Stationary equipment - See "X-ray equipment."

Stray radiation - The sum of leakage and scattered radiation.

RH-1601. (Cont'd)

Technique factors - The conditions of operation. They are specified as follows:

1. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs.

2. For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses.

3. For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs.

Termination of irradiation - The stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

Traceable to a national standard - A quantity or a measurement that has been compared to a NIST***** (National Institute of Standards and Technology) standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

Therapeutic-type housing -

1. For x-ray therapy equipment not capable of operating at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that the leakage radiation averaged over any 100 cm^2 area at a distance of one meter from the source does not exceed one roentgen in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential.

2. For x-ray therapy equipment capable of operation at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that leakage radiation averaged over any 100 cm^2 area at a distance of one meter from the source does not exceed 0.1 percent of the useful beam dose rate at one meter from the source for any of its operating conditions.

Therapeutic x-ray and/or electron system - A system designed for irradiation of any part of the human body for the purpose of treatment or alleviation of symptoms of disease.

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

*formerly NBS (National Bureau of Standards)

Tube housing assembly - The tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

Tube rating chart - The set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

Useful beam - The radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

Variable-aperture beam-limiting device - A beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

Visible area - That portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

Wedge filter - An added filter effecting continuous progressive attenuation on all or part of the useful beam.

X-ray control - A device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers and similar devices, which control the technique factors of an x-ray exposure.

X-ray equipment - An x-ray system, subsystem or component thereof. Types of x-ray equipment are as follows:

1. Mobile x-ray equipment: X-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

2. Portable x-ray equipment: X-ray equipment designed to be hand-carried.

3. Stationary x-ray equipment: X-ray equipment which is installed in a fixed location.

X-ray field - The area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

RH-1601. (Cont'd)

X-ray high-voltage generator - A device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices and other appropriate elements.

X-ray system - An assemblage of components for the controlled production of x-rays. It includes an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

X-ray subsystem - Any combination of two or more components of an x-ray system.

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

RH-1602. **General Requirements**. **Administrative Controls**.

a. **Registrant**.

The registrant shall be responsible for directing the operation of the x-ray systems which have been registered with the Department. The registrant or the registrant's agent shall assure that the requirements of RH-1602.a. are met in the operation of the x-ray system(s).

1. An x-ray system which does not meet the provisions of these ~~Regulations~~ Rules shall not be operated for diagnostic or therapeutic purposes.

2. Individuals who will be operating the x-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment.

3. A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel which specifies, for all examinations performed with that system, the following information:

A. Patient's anatomical size versus technique factors to be utilized;

B. Type and size of the film or film-screen combination to be used;

C. Type and focal distance of the grid to be used, if any;

D. Source to image receptor distance to be used; and

E. Type and location of placement of gonad shielding to be used.

F. For mammography, indication of kVp/target/filter combination.

4. Written safety procedures and rules shall be provided to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these rules.

5. Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

A. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.

B. Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

C. Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.

6. New gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

7. Individuals shall not be exposed to the useful beam except for healing arts purposes and such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

   A. Exposure of an individual for training, demonstration or other non-healing-arts purposes; and

   B. Exposure of an individual for the purpose of healing arts screening except as authorized by RH-1602.a.11.

8. When a patient or film must be provided with auxiliary support during a radiation exposure:

   A. Mechanical holding devices shall be used when the technique permits.

   B. If a human holder must be utilized:

      i. Written safety procedures, as required by RH-1602.a.4., shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

      ii. The human holder shall be protected as required by RH-1602.a.5.;

      iii. No individual shall be used routinely to hold film or patients;

      iv. Such holding shall be permitted only in very unusual and rare situations;

v. In those cases where the patient must hold the film, except during intra-oral examinations, any portion of the body, other than the area of clinical interest, struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material; and

vi. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with x-ray operations and who are otherwise not shielded.

9. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. This is interpreted to include but not limited to:

A. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.

B. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

C. Portable or mobile equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary radiographic installation.

D. X-ray systems subject to RH-1604. shall not be utilized in procedures where the source to patient distance is less than thirty (30) centimeters.

i. X-ray systems shall not be utilized in procedures where the source to patient distance is less than thirty (30) centimeters, except for veterinary systems.

ii. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

(a) Be positioned properly, i.e., tube side facing the right direction, and grid centered to the central ray;

(b). If of the focused type, be of the proper focal distance for the SIDs being used.

10. All individuals who are associated with the operation of an x-ray system are subject to the requirements of RH-1200.

A. When protective clothing or devices are worn on portions of the body and a monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:

i. When an apron is worn, the monitoring device shall be worn at the collar outside of the apron.

ii. The dose to the whole body based on the maximum dose attributed to the most critical organ shall be recorded in the reports required by Part F ~~to~~ of Section 3 ~~of these Regulations~~. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.

B. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

11. **Healing arts screening**.

Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Department. When requesting such approval, that person shall submit the information as deemed necessary by the Department. If any information submitted to the Department becomes invalid or out-dated, the Department will be notified in writing within thirty (30) days.

12. **Information and maintenance record and associated information**.

The registrant shall maintain the following information for each x-ray system for inspection by the Department:

A. Maximum rating of technique factors;

B. Model and serial numbers of all certifiable components;

C. Aluminum equivalent filtration of the useful beam, including any routine variation;

D. Tube rating charts and cooling curves;

E. Records of surveys, calibrations, maintenance and modifications performed on the X-ray system(s) after July 1, 1983 with the names of persons who performed such services;

F. A scale drawing of the room in which a stationary x-ray system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:

i. The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or

ii. The type and thickness of materials or lead equivalency, of each protective barrier; and

G. A copy of all correspondence with the Department regarding that x-ray system.

13. **X-ray log**.

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

b. **General requirements for all diagnostic x-ray systems**.

In addition to other requirements of this Part, all diagnostic x-ray systems shall meet the following requirements:

1. **Warning label**.

The control panel containing the main power switch shall bear the warning statement or its equivalent, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

2. **Battery charge indicator**.

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

3. **Leakage radiation from the diagnostic source assembly**.

The leakage radiation from the diagnostic source assembly measured at a distance of one (1) meter in any direction from the source shall not exceed 100 milliroentgens in one (1) hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

4. **Radiation from components other than the diagnostic source assembly**.

The radiation emitted by a component other than the diagnostic source assembly shall not exceed two (2) milliroentgens in one (1) hour at five (5) centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than twenty (20) centimeters.

RH-1602.b. (Cont'd)

5. **Beam quality**.

A. **Half-value layer**.

i. The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I to RH-1602. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I TO RH-1602.

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

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

TABLE II TO RH-1602.

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

iii. Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

iv. For capacitor energy storage equipment, compliance with the requirements of RH-1602.b.5. shall be determined with the maximum quantity of charge per exposure.

v. The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.

B. **Filtration controls**.

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

6. **Multiple tubes**.

Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

7. **Mechanical support of tube head**.

The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

c. **Other requirements**.

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

2. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density for one (1) to two (2) when processed shall not suffer an increase in density greater than 0.1 (0.05 mammography) when exposed in the darkroom for two (2) minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

3. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

4. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

5. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.

6. Outdated x-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

7. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

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

B. The requirement may be permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

8. **Maintaining Compliance**.

Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-Ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.

9. **Locks**.

All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.

RH-1603. **Fluoroscopic X-Ray Systems**.

All fluoroscopic x-ray systems shall meet the following requirements:

a. **Limitation of useful beam**.

1. **Primary barrier**.

A. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any Source Image Distance (SID).

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

2. **Fluoroscopic beam limitation**.

A. For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than four percent (4%) of the SID.

B. For uncertified fluoroscopic systems with a spot film device, the x-ray beam with the shutter fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the maximum SID available but at no less than twenty (20) centimeters from the tabletop to the film plane distance.

C. For uncertified fluoroscopic systems without a spot film device, the requirements of RH-1603. apply.

D. **Other requirements for fluoroscopic beam limitation**:

i. Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;

ii. All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided either with stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less;

iii. If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of five (5) centimeters by five (5) centimeters or less;

iv. For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;

v. For noncircular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

3. **Spot-film beam limitation**.

Spot-film devices shall meet the following requirements:

A. Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot-film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

B. Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three percent (3%) of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed four percent (4%) of the SID;

C. It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, five (5) centimeters by five (5) centimeters;

D. The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent (2%) of the SID; and

E. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

4. **Override**.

If a means exists to override any of the automatic x-ray field size adjustments required, that means:

A. Shall be designed for use only in the event of system failure;

B. Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and

C. Shall have a clear and durable label as follows:

i. For x-ray fields.

ii. Limitation system failure.

iii. Activation of the fluoroscopic tube.

iv. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

b. **Exposure rate limits**.

1. **Entrance exposure rate allowable limits**.

A. Fluoroscopic equipment that is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of ten (10) roentgens (2.6 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

i. During recording of fluoroscopic images; or

ii. When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of five (5) roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

B. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of five (5) roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

i. During recording of fluoroscopic images; or

ii. When the mode or modes have an optional high level control, in which case the mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

C. Compliance with the requirements of RH-1603. shall be determined as follows:

i. Movable grids and compression devices shall be removed from the useful beam during the measurement;

ii. If the source is below the table, exposure rate shall be measured one (1) centimeter above the table top or cradle;

iii. If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

iv. All C-arm fluoroscopes, both stationary and mobile, shall meet the entrance exposure rate limits at 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any available SID provided that the end of the spacer assembly or beam-limiting device is not closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.

v. For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.

D. Fluoroscopic equipment which is provided with both automatic exposure rate control mode and a manual mode shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of ten (10) roentgens (2.6 mC/kg) per minute in either mode at the point where the center of the useful beam enters the patient, except:

i. During recording of fluoroscopic images; or

ii. When the mode or modes have an optional high-level control, in which case the mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of five (5) roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

E. Any fluoroscopic equipment manufactured after May 19, 1995, which can exceed five (5) roentgens (1.3 mC/kg) per minute shall be equipped with an automatic exposure rate control. All entrance exposure rate limits shall be ten (10) roentgens (2.6 mC/kg) per minute with an upper limit of 20 roentgens (5.2 mC/kg) per minute when the high level control is activated.

F. Conditions of periodic measurement of maximum entrance exposure rate are as follows:

i. The measurement shall be made under the conditions that satisfy the requirements;

ii. The kVp, mA, or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate;

iii. The x-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce either a milliamperage or kilovoltage or both to satisfy the conditions of RH-1603.

c. **Barrier transmitted radiation rate limits**.

1. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed two (2) milliroentgens (0.516 μC/kg) per hour at ten (10) centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

2. **Measuring compliance of barrier transmission**.

A. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

B. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

C. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

D. Movable grids and compression devices shall be removed from the useful beam during the measurement.

3. **Indication of potential and current**.

During fluoroscopy and cinefluorography, the kV and the mA shall be continuously indicated.

d. **Source-to-skin distance**.

The SSD shall not be less than:

1. 38 centimeters on stationary fluoroscopes installed on or after August 1, 1974;

2. 35.5 centimeters on stationary fluoroscopes which were in operation prior to August 1, 1974; 30 centimeters on all mobile fluoroscopes;

3. 20 centimeters for mobile fluoroscopes used for specific surgical application;

4. The written safety procedures must provide precautionary measures to be adhered to during the use of this device in addition to the procedures provided in RH-1603.

e. **Fluoroscopic timer**.

1. Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting.

2. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

f. **Control of scattered radiation**.

1. Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to un-attenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

2. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the un-attenuated scattered radiation emanating from above the tabletop unless that individual:

A. Is at least 120 centimeters from the center of the useful beam, or

B. The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in RH-1603.

3. The Department may grant exemptions where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Department shall not permit such exemption.

g. **Spot-film exposure reproducibility**.

Fluoroscopic systems equipped with spot-film (radiographic) mode shall meet the exposure reproducibility requirements when operating in the spot-film mode.

1. Radiation therapy simulation systems shall be exempt from all the requirements provided that:

A. Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and

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

h. **Special procedures estimated patient exposure documentation**.

1. Each facility using fluoroscopic equipment for procedures including, but not limited to:

A. Pacemaker implantation;

B. Diagnostic cardiac procedures (catheterization); and

C. Therapeutic cardiac procedures:

i. Angioplasty-balloon;

ii. Stent;

iii. Directional coronary atherectomy;

D. Radio frequency ablation;

E. Intravascular brachytherapy;

F. All neurointerventional procedures including:

i. Embolizations;

ii. Interventional radiology procedures such as:

(a). TIPS;

(b). Vascular embolizations;

(c). Stents; and

(d). Angioplasty;

G. Infusion drug procedures:

i. Complex biliary cases;

ii. Complex gastrointestinal cases; and

iii. Complex genitourinary procedures.

shall include in a log for Department review the estimated patient radiation exposure received per procedure. Estimated adult skin doses that exceed 300 rad and estimated skin doses for children (under the age of 18) that exceed 100 rad must be reviewed by the facility's radiation safety committee.

The review must document the reason why an estimated skin dose exceeded 300 rad for adults or 100 rad for children, and the reason must be documented in the committee's minutes. If a facility does not have a radiation safety committee, the facility must provide the Department, within thirty (30) days of the event, documentation stating why the patient's estimated dose exceeded 300 rad for adults or 100 rad for children.

i. **Equipment operation**.

1. All imaging formed by the use of fluoroscopic x-ray systems shall be directly viewed and interpreted by a licensed practitioner of the healing arts.

2. Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

3. Facilities that use fluoroscopic x-ray systems shall maintain a record of cumulative fluoroscopic exposure time used and the number of spot films for each examination. This record shall indicate patient identification, type of examination, date of examination, and operator's name.

j. **Periodic measurements**.

1. Periodic measurement of entrance exposure rate shall be performed by a qualified expert for both typical and maximum values as follows:

A. Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate.

B. Results of these measurements shall be available where any fluoroscopist may have ready access to such results while using the fluoroscope. The measurement results shall be stated in coulombs per kilogram or mR/hr and include the technique factors used in measurements. The date the measurements were performed shall also be included in the results.

C. Conditions of periodic measurement of typical entrance exposure rate are as follows:

i. The measurement shall be made under the conditions that satisfy the requirements;

ii. The kVp, mA, and/or other selectable parameters shall be adjusted to those settings typical of clinical use on a 23 cm thick abdominal patient;

iii. The x-ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliamperage and/or kilovoltage to satisfy the conditions.

RH-1603.j.1. (Cont'd)

D. Conditions of periodic measurement of maximum entrance exposure rate are as follows:

i. The measurements shall be made under the conditions that satisfy the requirements;

ii. The kVp, mA and/or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate;

iii. The x-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum entrance exposure rate of the system.

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

a. **Beam limitation**.

1. The useful beam shall be limited to the area of clinical interest. This shall be considered met if a positive beam-limiting device meeting manufacturer's specifications has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge.)

2. **General purpose stationary and mobile x-ray systems and veterinarian systems (other than portable) installed after July 1, 1998**.

A. Only x-ray systems provided with means for independent stepless adjustment of at least two (2) dimensions of the x-ray field shall be used.

B. A method shall be provided for visually defining the perimeter of the x-ray field.

i. Illuminance shall be greater than 7.5 foot-candles or 80.3 LUX at 100 centimeters or maximum SID whichever is less.

ii. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

iii. The Department may grant an exemption on non-certified x-ray provided the registrant makes a written application for such exemption and in that application demonstrates it is impractical to comply and the purpose will be met by other methods.

3. **Additional requirements for stationary general purpose x-ray systems**.

In addition to the requirements for stationary general purpose x-ray systems, both certified and non-certified systems shall also meet the following requirements:

A. Method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within two percent (2%) of the SID, and to indicate the SID to within two percent (2%);

B. The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

C. Indication of field size dimensions and SIDs shall be specified in inches or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent (2%) of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

4. Reserved.

5. **X-ray systems designed for one (1) image receptor size**.

Radiographic equipment designed for only one (1) image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

6. **Other x-ray systems and veterinary systems installed prior to July 1, 1998, and all portable veterinary x-ray systems**.

A. Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent (2%) of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

B. Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.

C. Alignment requirements may be met with either:

i. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

ii. A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

b. **Radiation exposure control devices**.

1. **Timers**.

A. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action.

B. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "**zero**" or "**off**" position if either position is provided. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "**zero**."

2. **X-ray control**. **Manual exposure control**.

A. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for exposure of one-half second or less, or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

B. Each x-ray control shall be located in such a way as to meet the following requirements:

i. Stationary x-ray systems (except dental, podiatry and veterinary units) shall be required to have the x-ray exposure switch permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure and so that the operator can view the patient while making any exposures;

ii. Mobile and portable x-ray systems which are:

(a.) Used for greater than one (1) week in the same location, i.e., a room or suite; or

(b). Used for greater than one (1) hour and less than one (1) week at the same location, i.e., a room or suite; or

(c). In a clinical setting for routine extremities only, or where moving the x-ray system from room to room is impractical;

(d). Shall meet the requirement of the above paragraph RH-1604.b.2.B.i., or one of the following must be met.

(1). Equipment installed or relocated after January 1, 2006 is placed at least nine (9) feet (2.7 meters) from the tube housing assembly.

(2). Equipment installed before January 1, 2006 is placed at least six (6) feet (1.8 meters) from the tube housing assembly.

C. Written procedures must instruct the operator to remain in the protected area during the entire exposure.

iii. (a). Stationary podiatric systems installed or relocated after January 1, 2006, which do not meet the above requirements, shall be provided with a nine (9) foot exposure button cord which allows the operator to remain behind a protective barrier during the entire exposure.

(b). Stationary podiatric systems installed before January 1, 2006, which do not meet the above requirements, shall be provided with a six (6) foot exposure button which allows the operator to remain behind a protective barrier during the entire exposure.

(c). If the protective barrier is moveable, written procedures must be on-file at the facility, which dictate that the operator will remain behind the barrier during the entire exposure.

C. The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

3. **Automatic exposure controls**.

When an automatic exposure control is provided:

A. Indication shall be made on the control panel when this mode of operation is selected;

B. If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two (2) pulses;

C. The minimum exposure time for all equipment shall be equal to or less than one-sixtieth second or a time interval required to deliver five (5) mAs, whichever is greater;

D. Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

E. A visible signal shall indicate when an exposure has been terminated, and manual resetting shall be required before further automatically timed exposures can be made.

4. **Reproducibility**.

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

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

5. **Exposure duration (timer) linearity**.

For systems having independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of C $kg^{-1}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) < 0.1\ (X_1 + X_2)$$

where X_1 and X_2 are the average C $kg^{-1}s^{-1}$ (mR/s) values.

c. **Source-to-skin distance**.

All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than thirty (30) centimeters except for veterinary systems.

d. **Exposure reproducibility**.

When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement applies to clinically used techniques.

e. **Radiation from capacitor energy storage equipment in standby status**.

Radiation emitted from the x-ray tube when the system is fully charged and the exposure switch or timer is not activated shall not exceed a rate of two (2) milliroentgens (0.516 μC/kg) per hour at five (5) centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

f. **Accuracy**.

Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed ten percent (10%) of the indicated value for kVp and twenty percent (20%) for time mA/mAs linearity.

g. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of forty percent (40%) to one hundred percent (100%) of the maximum rated:

1. **Equipment having independent selection of x-ray tube current (mA)**.

The average ratios (X_1) of exposure to the indicated milliampere-seconds product (C $kg^{-1}mAs^{-1}$ (or mR/mAs)) obtained at any two (2) consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 < 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two (2) consecutive tube current settings, or at two settings differing by no more than a factor of two (2) where the tube current selection is continuous.

2. **Equipment having a combined x-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector**.

The average ratios (X_1) of exposure to the indicated milliampere-seconds product, in units of mR/mAs (or C $kg^{-1}mAs^{-1}$), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 < 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two (2) consecutive mAs selector settings, or at two (2) settings differing by no more than a factor of two (2) where the mAs selector provides continuous selection.

3. **Measuring compliance**.

Determination of compliance shall be based on ten (10) exposures taken within a time period of one (1) hour, at each of the two (2) settings. These two (2) settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

h. **Additional requirements applicable to certified systems only**.

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

i. **Beam limitation for stationary and mobile general purpose x-ray systems**.

1. There shall be provided a means of stepless adjustment of the x-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than five (5) centimeters by five (5) centimeters.

2. When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 foot-candles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

3. The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than four (4) in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than three (3) in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination three (3) millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination three (3) millimeters from the edge of the light field away from the center of the field.

4. Compliance shall be determined with a measuring instrument aperture of one (1) millimeter in diameter.

j. **Beam limitation and alignment on stationary general purpose x-ray systems equipped with Positive Beam Limitation (PBL)**.

If PBL is being used, the following requirements shall be met:

1. PBL shall prevent the production of x-rays when:

A. Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimensions by more than three percent (3%) of the SID; or

B. The sum of the length and width differences, without regard to sign exceeds four percent (4%) of the SID;

C. Compliance shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than five (5) seconds after insertion of the image receptor;

RH-1604.j.1. (Cont'd)

D. The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than five (5) centimeters by five (5) centimeters;

E. The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function, then any change of image receptor size or SID must cause the automatic return.

2. **Beam limitation for portable x-ray systems**.

Beam limitation for portable x-ray systems shall meet the beam limitation requirements.

3. **Tube stands for portable x-ray systems**.

A tube stand or other mechanical support shall be used for portable x-ray systems, so that the x-ray tube housing assembly need not be handheld during exposures.

k. Systems used in a clinical (non-surgical) setting shall be restricted to one room within a location or suite which meets the requirements.

RH-1605. Reserved.

RH-1606. **Intraoral Dental Radiographic Systems**.

The requirements for general x-ray tubes apply to the intraoral dental machines.

a. **Source-to-skin distance**.

X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:

1. 18 centimeters if operable above 50 kVp, or

2. 10 centimeters if not operable above 50 kVp.

b. **Beam limitation**.

Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:

1. If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than seven (7) centimeters; and

2. If the minimum SSD is less than 18 centimeters, the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than six (6) centimeters.

3. The position indicating device shall be shielded and open-ended. The shielding shall be equivalent to the requirements.

c. **Exposure control**. **Exposure initiation**.

A. Means shall be provided to initiate the radiation exposure by deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and

B. It shall not be possible to make an exposure when the timer is set to a "**zero**" or "**off**" position if either position is provided.

d. **Exposure indication**.

Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated except in x-ray systems that cannot be altered to meet this requirement.

e. **Exposure termination**.

1. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

A. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "**zero**."

B. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (½) second or less.

2. **Exposure duration (timer) linearity**.

For systems having independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of C $kg^{-1}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) < 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values.

3. Each x-ray exposure switch shall be located in such a way as to meet the following requirements:

A. Stationary x-ray systems shall be required to have the x-ray exposure switch located in a protected area or have an exposure switch cord of sufficient length to permit the operator to activate the unit while in a protected area, e.g., corridor outside the operatory. The procedures must instruct the operator to remain in the protected area during the entire exposure.

B. Mobile and portable x-ray systems which are:

i. Used for greater than one (1) week in the same location, i.e., a room or suite, shall meet the other requirements.

ii. Used for greater than one (1) hour and less than one (1) week at the same location, i.e., a room or suite, shall meet the requirements of the above paragraph or be provided with a 6.5 foot (1.98 meters) high protective barrier or means to allow the operator to be at least nine (9) feet (2.7 meters) from the tube housing assembly while making exposure if the equipment has been installed or relocated after January 1, 2006.

For equipment installed before January 1, 2006, there must exist a means to allow the operator to be at least six (6) feet (1.8 meters) from the tube housing assembly while making exposure.

4. **Reproducibility**.

When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

f. **mA/mS linearity**.

The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of forty percent (40%) to one hundred percent (100%) of the maximum rated:

1. Equipment having independent selection of x-ray tube current (mA). The average ratios (X_1) of exposure to the indicated milliampere-seconds product, in units of C $kg^{-1}mAs^{-1}$ (or mR/mAs), obtained at any two (2) consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$(X_1 - X_2) < 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two (2) consecutive tube current settings, or at two settings differing by no more than a factor of two (2) where the tube current selection is continuous.

2. Equipment having a combined x-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_1) of exposure to the indicated milliampere-seconds product, in units of C $kg^{-1}mAs^{-1}$ (or mR/mAs), obtained at any two (2) consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$(X_1 - X_2) < 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two (2) mAs selector settings, or at two (2) settings differing by no more than a factor of two (2) where the mAs selector provides continuous selection.

3. **Measuring compliance**.

Determination of compliance shall be based on ten (10) exposures taken within a time period of one (1) hour, at each of the two (2) settings. These two (2) settings may include any two (2) focal spot sizes except where one (1) is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

g. **Accuracy**.

Deviation of technique factors from indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed ten percent (10%).

h. **kVp limitations**.

Dental x-ray machine with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

i. **Administrative controls**.

1. Patient and film holding devices shall be used when the techniques permit.

2. The tube housing and the Patient Imaging Device (PID) shall not be hand-held during an exposure.

RH-1606.i. (Cont'd)

3. The x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements.

4. Dental fluoroscopy without image intensification shall not be used.

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

RH-1607.- 1608. Deleted. See Section 11, "Therapeutic Radiation Machines."

RH-1609. **Veterinary Medicine**.

a. **Equipment**.

1. The protective tube housing shall be equivalent to general x-ray tube.

2. Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

3. The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

b. **Operator protection**.

All wall, ceiling, and floor areas shall be equivalent or provided with applicable protective barriers. Stationary, mobile or portable x-ray systems shall be provided with either a two (2) meter (6.5 feet) high protective barrier for operator protections during exposures, or shall be provided with means to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during exposures if the equipment has been installed or relocated after January 1, 2006.

For equipment installed before January 1, 2006, there must exist a means to allow the operator to be at least six (6) feet (1.8 meters) from the tube housing assembly during exposures.

RH-1609. (Cont'd)

c. **Operating procedures**.

1. No individual other than the operator shall be in the x-ray room while exposures are being made unless such individual's assistance is required, and

2. The operator shall stand behind the protective barrier of nine (9) feet from the useful beam and the animal during radiographic exposures, or

3. When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and shall be so positioned that no part of the holder's body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

RH-1610. **Mammography Systems**.

a. **Definitions**.

Accreditation body or body - An entity that has been approved by FDA accredit mammography facilities.

Action limits or action levels - The minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action must be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

Air kerma - Kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For x-rays with energies less than 300 kiloelectronvolts (keV), 1 Gy = 100 rad. In air, 1 Gy of absorbed dose is delivered by 114 roentgens (R) of exposure.

Breast implant - A prosthetic device implanted in the breast.

Calendar quarter - Any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31.

Category I - Medical educational activities that have been designated as Category I by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society, or an equivalent organization.

Certificate - The certificate described in the "Mammography Quality Standards Act," Subchapter I to Title 21 of the Code of Federal Regulations, paragraph (a) of Section 900.11.

Certification - The process of approval of a facility by FDA to provide mammography services.

Clinical image - A mammogram.

Consumer - An individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).

Continuing education unit or continuing education credit - One (1) contact hour of training.

Contact hour - An hour of training received through direct instruction.

Diagnostic Mammography - A problem solving radiographic procedure of higher intensity than screening mammography provided to women who are suspected to have breast pathology. Patients are usually referred for analyses of palpable abnormalities or for further evaluation of mammographically detected abnormalities. All images are immediately reviewed by the physicians interpreting the study, and additional views are obtained as needed. Physical examinations of the breast by the interpreting physician to correlate the radiologic findings is often performed as part of the study.

Direct instruction - Face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or the administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

Direct Supervision of Interpreting Physicians - During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records.

Direct Supervision of Radiologic Technologists - During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

Established operating level - The value of a particular quality assurance parameter that has been established as an acceptable normal level by the facility's quality assurance program.

Facility - A hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: operation of equipment to produce a mammogram, processing of the mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for the interpretation. This term does not include a facility of the Department of Veterans Affairs.

FDA - The Food and Drug Administration.

First allowable time - The earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body. The "first allowable time" may vary with the certifying body.

Interim regulations - The regulations entitled "Requirements for Accrediting Bodies of Mammography Facilities" (58 FR 67558-67565), published by FDA on December 21, 1993, and amended on September 30, 1994 (59 FR 49808-49813). These regulations established the standards that had to be met by mammography facilities in order to lawfully operate between October 1, 1994, and April 28, 1999.

Interpreting physician - A licensed physician who interprets mammograms and who meets the requirements set forth in the "Mammography Quality Standards Act," Subchapter I to Title 21 of the Code of Federal Regulations, paragraph (a)(1) of Section 900.12.

Kerma - The sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

Laterality -The designation of either the right or left breast.

Lead interpreting physician - The interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements in 21 CFR Part 16 and the "Mammography Quality Standards Act," Subchapter I to 21 CFR, paragraphs (d) through (f) of Section 900.12. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.

Mammogram - A radiographic image produced through mammography.

Mammographic modality - A technology, within the scope of 42 U.S.C. 263b, for radiography of the breast. Examples are screen-film mammography and digital mammography.

Mammography - Radiography of the breast, but for the purposes of this part, does not include: radiography of the breast performed during invasive interventions for localization or biopsy procedures; or radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA's investigational device exemption regulations.

Mammography equipment evaluation - An onsite assessment of mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards set forth in the "Mammography Quality Standards Act," Subchapter I to Title 21 of the Code of Federal Regulations, paragraphs (b) and (e) of Section 900.12.

Mammography medical outcomes audit - A systematic collection of mammography results and the comparison of those results with outcomes data.

Mammography unit or units - An assemblage of components for the production of x-rays for use during mammography, including, at a minimum: an x-ray generator, and x-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.

Mean optical density - The average of the optical densities measured using phantom thickness of two (2), four (4), and six (6) centimeters with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

Medical physicist - A person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications for a medical physicist set forth in the "Mammography Quality Standards Act," Subchapter I to Title 21 of the Code of Federal Regulations, paragraph (a)(3) of Section 900.12.

MQSA - The Mammography Quality Standards Act.

Multi-reading – Two (2) or more physicians, at least one (1) of whom is an interpreting physician, interpreting the same mammogram.

Patient - Any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.

Phantom - A test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

Phantom image - A radiographic image of a phantom.

Physical science - Physics, chemistry, radiation science (including medical physics and health physics), and engineering.

Positive mammogram - A mammogram that has an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy."

Provisional certificate - The provisional certificate described in 21 CFR Section 900.11(b)(2).

Qualified instructor - An individual whose training and experience adequately prepares him or her to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of 21 CFR Section 900.12(a) would be considered qualified instructors in their respective areas of mammography. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the regulations of this part include, but are not limited to, instructors in a post-high school training institution and manufacturer's representatives.

Quality control technologist - An individual meeting the requirements of 21 CFR Section 900.12(a)(2) who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.