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

By the Arkansas State Board of Health

Arkansas Department of Health
Little Rock, Arkansas

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Secretary of Health

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SECTION 1.
REGISTRATION OF SOURCES OF RADIATION

PART A.
GENERAL

RH-1. **Authority**.

Act 96 of 1913, Act 8 of Second Extraordinary Special Session of 1961, as Amended.

RH-2. **Effective Date**. January 1, 1963.

RH-3. **Registration Requirement**.

Every person possessing a reportable source of radiation shall register in accordance with the provisions of these Regulations.

RH-4. **Communications**.

All communications concerning these Regulations shall be addressed to the 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.

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.

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

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., RH-10307., or 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., RH-10307., or 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 material false statement in the application or any statement of fact required under provisions of the Act or of these Rules, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the Department to refuse to grant a registration on an original application, or for violation 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.

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.

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 material false statement in the application or any statement of fact required under provisions of the Act or of these Rules, or because of

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

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, "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.

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, 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 as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

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

1. Prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

2. Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the Department and the U.S. Nuclear Regulatory Commission jointly determine:

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 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 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.

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 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.[1/]

b. In addition to the requirements of this Section, all licensees, except as otherwise noted in these Regulations, are subject to the requirements of Section 3 and Section 4 of these Regulations as well as any regulations 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. Nonpayment of fees shall result in escalated enforcement action and/or revocation of license.

The following Radioactive Material 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	01120	$2,115.00
Academic R&D	03620	$1,215.00
Accelerator Produced Radionuclides	03210	$2,280.00
Consultant 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	$3,855.00
Instrument Calibration	03221; 03222	$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	$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 – No Written Directive Required	02121	$1,260.00
Medical Facility – Written Directive Required	02120	$1,260.00
Medical Private Practice	02200; 02201	$1,260.00
Medical Therapy	02240	$1,260.00
Mobile Medical Services	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		$5,000.00

RH-103. (Cont'd)

b. Deleted. See RH-5003.

c. The Generally Licensed Device Fees are as follows:

CATEGORY	FEE
Certain measuring, gauging, and controlling devices	$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

d. Other fees are as follows:

CATEGORY	FEE
Naturally Occurring Radioactive Material (NORM) 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 copy $30.00 for each additional copy
Amendment to existing license	$50.00 per amendment

e. Reciprocity fees are as follows:

CATEGORY	FEE
Naturally Occurring Radioactive Material (NORM) Decommissioning	$2,500.00
Other Radioactive Material (non-NORM) Decommissioning	$5,000.00
Radiography, Field	$3,855.00
Well Logging with Sealed Sources Only	$1,500.00
Well Logging with Tracer Studies	$1,500.00
Nuclear Gauge	$720.00
Consultant	$2,145.00
Gas Chromatograph, Lead Paint Analyzer	$720.00

RH-104. **Communications**.

Except where otherwise specified, all communications concerning these Regulations 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 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, 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 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 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.

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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.

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

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

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 and the Act.

Registration - Registration with the Department in accordance with these Regulations 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 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

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.

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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 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, 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 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.

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, any person is exempt from these Regulations 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;

(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.

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.

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 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.

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 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 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 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.

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 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 in this Section and Part I of Section 3, Part J of Section 3, Sections 6 through 9, and Section 12 of these Regulations 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 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 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 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 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, 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.

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.

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; 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., Part E of Section 2., RH-600. through 603., RH-416., and RH-700.

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.

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.

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 with respect to the depleted uranium covered by that general license.

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.

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:

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;

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 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 and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations 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.

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.

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-409., RH-416., Part E of Section 2, RH-600., RH-602., RH-603., RH-700., RH-751., and Section 4.

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-409., RH-416., Part E of Section 2, RH-600., RH-602., RH-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

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-301.a.4., RH-409., RH-416., Part E of Section 2, RH-600. through RH-603., RH-700., RH-751., Section 3, and Section 4. 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;

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.

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, 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.

4. The general license in paragraph i.1. of this section is subject to the provisions of RH-409., RH-416., Part E of Section 2, RH-600., RH-602., RH-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.

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. 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.

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.

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.

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

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.

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.

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, 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.

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.

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;

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.

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.

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.

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

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 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.

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

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;

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.

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

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.

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.

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

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 averaged over areas no larger than one (1) square centimeter	200
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

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.

2. In the event the applicant desires that the device be required to be tested at intervals longer than six (6) months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Department will consider information which includes, but is not limited to:

   A. Primary containment (source capsule);

   B. Protection of primary containment;

   C. Method of sealing containment;

   D. Containment construction materials;

   E. Form of contained radioactive material;

   F. Maximum temperature withstood during prototype test;

   G. Maximum pressure withstood during prototype tests;

   H. Maximum quantity of contained radioactive material;

   I. Radiotoxicity of contained radioactive material; and

   J. Operating experience with identical devices or similarly designed and constructed devices.

3. In the event the applicant desires that the general licensee under RH-402.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.

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.

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 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).

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.

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 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).

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.

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;

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.

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

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,

(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.

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

(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.

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.

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.

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"

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.

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**."

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;

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.

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.

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

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

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);

ii. Registered or licensed with a state agency as a drug manufacturer;

iii. Licensed as a pharmacy by a State Board of Pharmacy;

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.

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 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 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.

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

   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 RH-405.l.2.B. and RH-405.l.2.D. of this paragraph l., 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 RH-405.l.2.D. of this paragraph l.

   C. The actions authorized in RH-405.l.2.A. and RH-405.l.2.B. of this paragraph l. 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.

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, no later than 30 days after the date that the licensee allows, under RH-405.1.2.B.i. and RH-405.1.2.B.iii., the individual to work as an authorized nuclear pharmacist.

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. 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.

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 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.

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;

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.

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.

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.

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

E. That the Federal or State government agency which will assume responsibility for institutional control of the disposal site is prepared to assume responsibility and ensure that the institutional requirements found necessary under RH-407.d.10.B. will be met.

c. **Performance objectives**.

1. **General requirement**.

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

2. **Protection of the general population from releases of radioactivity**.

Concentrations of radioactive material which may be released to the general environment in ground water, surface water, air, soil, plants or animals must not result in an annual dose exceeding an equivalent of 25 millirems to the whole body, 75 millirems to the thyroid and 25 millirems to any other organ of any member of the public. Reasonable effort should be made to maintain releases of radioactivity in effluents to the general environment as low as is reasonably achievable.

3. **Protection of individuals from inadvertent intrusion**.

Design, operation and closure of the land disposal facility must ensure protection of any individual inadvertently intruding into the disposal site and occupying the site or contacting the waste at any time after active institutional controls over the disposal site are removed.

4. **Protection of individuals during operations**.

Operations at the land disposal facility must be conducted in compliance with the standards for radiation protection set out in Section 3 of these Regulations, except for releases of radioactivity in effluents from the land disposal facility which shall be governed by RH-407.c.2. Every reasonable effort shall be made to maintain radiation exposures as low as is reasonably achievable.

5. **Stability of the disposal site after closure**.

The disposal facility must be sited, designed, used, operated and closed to achieve long-term stability of the disposal site and to eliminate to the extent practicable the need for ongoing active maintenance of the disposal site following closure so that only surveillance, monitoring or minor custodial care are required.

d. **Technical requirements for land disposal facilities**.

1. **Disposal site suitability for near-surface disposal**.

A. The purpose of this section is to specify the minimum characteristics a disposal site must have to be acceptable for use as a near-surface disposal facility. The primary emphasis in disposal site suitability is given to isolation of wastes (a matter having long-term impacts) and to disposal site features that ensure that the long-term performance objectives 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.

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.

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.

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.

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.

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.

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.

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.

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.

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

E. **Classification of wastes with radionuclides other than those listed in Tables 1 and 2**.

If radioactive waste does not contain any nuclides listed in either Table 1 or 2, it is Class A.

F. **The sum of the fractions rule for mixtures of radionuclides**.

For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each nuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste class is to be determined by that column.

Example: A waste contains Sr-90 in a concentration of 50 Ci/m^3 and Cs-137 in a concentration of 22 Ci/m^3. Since the concentrations both exceed the values in Column1, Table 2, they must be compared to Column 2 values. For Sr-90 fraction, 50/150 = 0.33; for Cs-137 fraction, 22/44 = 0.5; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.

G. **Determination of concentrations in wastes**.

The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste or weight of the waste if the units are expressed as nanocuries per gram.

7. **Waste characteristics**.

A. The following requirements are minimum requirements for all classes of waste and are intended to facilitate handling at the disposal site and provide protection of health and safety of personnel at the disposal site.

i. Waste must not be packaged for disposal in cardboard or fiberboard boxes.

ii. Liquid waste must be solidified or packaged in sufficient absorbent material to absorb twice the volume of the liquid.

iii. Solid waste containing liquid shall contain as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 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.

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.

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 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.

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. 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

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.

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

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).

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:

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:

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

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 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

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

(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.

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.

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.

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 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

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.

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 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 shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act or by reason of rules, regulations, and orders issued by the Department.

b. Any license or sealed source and device registration certificate may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or in any statement of fact required under provisions of the Act or of these Regulations or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means that would warrant the Department to refuse to grant a license or sealed source and device registration certificate on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act or the license or of any rule, regulation, or order of the Department.

c. Except in cases of willful violation or those in which the public health, interest, or safety requires otherwise, no license 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 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 in this Section, Part I of Section 3, Part J of Section 3, and Sections 7, 8, and 9 of these Regulations 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 each record of transfer for three (3) years after each transfer unless a specific requirement in another part of these Regulations dictates otherwise.

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 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 or license condition. If a retention period is not otherwise specified by regulation or license condition, the record must be retained until the Department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

2. If there is a conflict between the Department's regulations 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 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 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. 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

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 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

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 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.

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 or order issued thereunder. Any person who willfully violates any provision of the Act or any regulation 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.

RH-701.- RH-749. Reserved.

PART H.
RECIPROCITY

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, 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 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 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;

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 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 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 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.

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;

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 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

RH-904. **Schedule E to Section 2. Limits for Broad Licenses.** (Cont'd)

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. 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 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 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 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 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 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.

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 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. 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 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 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. 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 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 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.

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 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.