

# **LICENSING GUIDE**

**INSTRUCTIONS FOR PREPARING AN APPLICATION  
FOR A RADIOACTIVE MATERIALS LICENSE AUTHORIZING  
THE  
USE OF RADIOACTIVE MATERIAL  
IN THE  
HEALING ARTS**

**February 20, 2007**

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## **INTRODUCTION**

### **A. PURPOSE OF GUIDE**

This Licensing Guide provides instructions to an applicant for preparing an application for a specific license authorizing the possession and medical use of radioactive material. It also describes the Department of Health and Human Service's criteria for evaluating a medical use license application. The Guide addresses a variety of the many radiation safety issues associated with the possession and medical use of radioactive material.

The information submitted in the application must be sufficient to demonstrate that proposed equipment, facilities, personnel, and procedures are adequate to protect the public health and safety of the citizens of Arkansas. Submission of incomplete or inadequate information will result in delays in the approval process for the license. Additional information will be requested when necessary to ensure that an adequate radiation safety program will be established and implemented. Such requests for additional information will delay completion of the application's review and may be avoided by a thorough study of the regulations and these instructions prior to submitting the application.

<b>NOTE:</b>	The Licensing Guide for the Use of Radioactive Material in Medicine is not a regulation. It serves only as guidance to assist the Applicant in completing an Application for a Radioactive Material License.
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### **B. AGREEMENT STATE**

Arkansas is an Agreement State with the U.S. Nuclear Regulatory Commission (NRC). This Agreement authorizes the State of Arkansas to assume regulatory authority over most activities involving radioactive material within the state. The exceptions are nuclear power plants and federally controlled facilities, which remain under NRC jurisdiction. The Arkansas Department of Health and Human Services (Department), Radiation Control Section, Radioactive Materials Program, regulates the possession and use of radioactive material within Arkansas.

Under authority of the Arkansas State Board of Health's, Rules and Regulations for Control of Sources of Ionizing Radiation, the Department issues licenses to users of radioactive material and performs inspections to ensure compliance with the regulations.

### **C. TYPES OF LICENSES**

The Department defines "Medical use" as "the intentional internal or external administration of radioactive material, or the radiation from radioactive material, to patients or human research subjects under the supervision of an authorized user" (RH-8100). An Authorized User is defined as "a physician, dentist, or podiatrist" who meets the training and experience requirements specified in the applicable sections of the Rules and

Regulations, Section 9, “Use of Radionuclides in the Healing Arts”, or who is identified as an authorized user on a Department or Agreement State or NRC license; on a permit issued by a NRC master material licensee or a NRC master material permittee that is authorized to permit the medical use of radioactive material; or on a permit issued by an Agreement State or NRC broad scope licensee authorized to permit the medical use of radioactive material (RH-8100).

The Department issues two types of specific licenses for the medical use of radioactive material in medical practices and facilities:

- the specific license of limited scope (see Section C.1), and
- the specific license of broad scope (see Section C.2).

Medical use includes research involving human subjects, which may occur under either limited scope or broad scope specific licenses (see Section C.3).

The Department also issues a general license pursuant to RH-402.h, under which a physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital may use radioactive material for certain *in vitro* clinical or laboratory testing. Such testing may not involve internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals (see Section C.4).

The Department usually issues a single radioactive material license to cover an entire radionuclide program. A license including teletherapy may also contain the authorization for source material (i.e., depleted uranium) used as shielding in many teletherapy units, and a license may include authorization for possession of sealed sources to be used to calibrate dose calibration devices.

The Department may issue separate licenses to individual licensees for different medical uses. However, the Department does not usually issue separate licenses to different departments in a medical facility or to individuals employed by a medical facility or with whom the medical facility has contracted. Only the facility’s management may sign the license application.

Applicants should study this License Guide, related guidance, and all applicable regulations carefully before completing Application for Radioactive Material License. The Department expects licensees to provide information on specific aspects of the proposed radiation protection program in attachments to the Application. When necessary, the Department may ask the applicant for additional information in order to gain reasonable assurance that an adequate radiation protection program has been established.

After a license is issued, the licensee must conduct its program in accordance with the following:

- Statements, representations, and procedures contained in the application and in correspondence with the Department, when incorporated into a license by reference;
- Terms and conditions of the license; and
- Department rules and regulations.

## 1. **SPECIFIC LICENSE OF LIMITED SCOPE**

The Department issues specific medical licenses of limited scope to private or group medical practices and to medical institutions. A medical institution is an organization in which more than one medical discipline is practiced. In general, individual physicians or physician groups located within a licensed medical facility (e.g., hospital) may not apply for a separate license because the rules and regulations refers to the applicant's facilities. Since a physician group does not normally have control over the facilities, the hospital remains responsible for activities conducted on its premises and must apply for the license. On specific licenses of limited scope, the authorized users are specifically listed in the license.

Radioactive material may be administered to patients on an inpatient (i.e., hospitalized) or outpatient basis. For patients to whom radioactive material is administered and who are not releasable under RH-8420, inpatient facilities are required. In general, facilities for private and group practices do not include inpatient rooms and, therefore, procedures requiring hospitalization of the patient under RH-8420 cannot be performed.

A specific license of limited scope may also be issued to an entity requesting to perform mobile medical services (RH-8425, RH-8647). A medical institution or a private or group practice may apply for authorization to use radioactive material in a mobile medical service.

## 2. **SPECIFIC LICENSE OF BROAD SCOPE**

Medical institutions that provide patient care and conduct research programs that use radionuclides for *in vitro*, animal, and medical procedures may request a specific license of broad scope in accordance with RH-406.

No medical use of radioactive material, including research involving human subjects, may be conducted without an authorization in a license from the Department as provided in the Section 9.

The criteria for the various types of broad scope licenses are found in RH-406. Generally, the Department issues specific licenses of broad scope for medical use (i.e., licenses authorizing multiple quantities and types of radioactive material for medical use under Section 9 as well as other uses) to institutions that

- (1) have experience successfully operating under a specific license of limited scope, and
- (2) are engaged in medical research and routine diagnostic and therapeutic uses radioactive material.

### **3. RESEARCH INVOLVING HUMAN SUBJECTS**

Paragraph RH-8100 defines “medical use” to include the administration of radioactive material or radiation therefrom to human research subjects. Furthermore, RH-8004 “Provisions for the protection of human research subjects,” addresses the protection of the rights of human subjects involved in research by medical use licensees. The licensee must apply for a specific amendment and receive approval for the amendment before conducting such research. Whether or not a license amendment is required, licensees must obtain informed consent from human subjects and prior review and approval of the research activities by an Institutional Review Board in accordance with the meaning of those terms under the Federal Policy. In accordance with RH-8004, research involving human subjects shall be conducted only with radioactive materials listed in the license for the uses authorized in the license.

### **4. GENERAL IN VITRO LICENSE**

In RH-402.h, “General License for Use of Radioactive Material for Certain *In Vitro* Clinical or Laboratory Testing,” the Department establishes a general license authorizing physicians, veterinarians, clinical laboratories, and hospitals to receive, acquire, possess, or use small quantities of certain radioactive material for *in vitro* clinical or laboratory tests not involving “medical use” (i.e., not involving administration to humans). If the general license alone meets the applicant’s needs, only a Department Form 102, “Registration Certificate  $\forall$  In Vitro Testing With Radioactive Material Under General License” need be filed. Medical-use licensees authorized pursuant to Section 9 do not need to file the form.

The Department limits possession to a total of 200 microcuries of photon-emitting materials listed in RH-402.h at any one time, at any one location of storage or use. The use of materials listed in RH-402.h within the inventory limits of that section is subject only to the requirements of that section and not to the requirements of Section 3, “Standards for Protection Against Radiation”, except as set forth in RH-402.h.

An applicant needing more than 200 microcuries of these materials must apply for a specific license and may request the increased inventory limit as a separate line item

on the application. This type of applicant generally requests an increased limit of 3 millicuries. If requesting an increased inventory limit, the applicant will be subject to the requirements of Section 3, “Standards for Protection Against Radiation”, including the requirements for waste disposal.

#### **D. MANAGEMENT RESPONSIBILITY**

The Department recognizes that effective implementation and management of the radiation safety program is mandatory for achieving a safe program that complies with the Rules and Regulations for Control of Sources of Ionizing Radiation.

To help insure effective management involvement in all aspects of the radiation safety program, the Department requires that a management representative sign the license application acknowledging management’s overall commitment to and responsibility for the following:

1. Radiation safety, security, and control of radioactive material.
2. Completeness and accuracy of the radiation safety program records and all information provided to the Department.
3. Knowledge about the contents of the application and the license.
4. Committing adequate resources (including personnel, time, facilities and equipment) to the radiation safety program to help insure that patients, the public, and workers are protected against radiation hazards.
5. Compliance with the Department’s Rules and Regulations for Control of Sources of Ionizing Radiation and the Licensee’s Operating and Emergency Procedures.
6. Selecting and appointing a qualified individual who has agreed in writing to serve as the Radiation Safety Officer (RSO).
7. Approval of qualified individual(s) to serve as Authorized Medical Physicists (AMPs), Authorized Nuclear Pharmacists (ANPs), and Authorized Users (AUs) for licensed activities.

#### **E. THE “AS LOW AS REASONABLY ACHIEVABLE (ALARA) CONCEPT”**

The Rules and Regulations, RH-1004, “Radiation Protection Programs”, states that “each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities” and “the licensee shall use to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

Paragraph RH-1004 also requires that licensees review the content of the radiation protection program and its implementation at least annually. The RSO is responsible for the day-to-day operation of the radiation protection program.

Appendix A, “ALARA Program” describes the required ALARA program.

## F. APPLICABLE REGULATIONS

The following portions of the Rules and Regulations for Control of Sources of Ionizing Radiation are applicable to the use of radioactive material and should be used in conjunction with these instructions:

- ◆ Section 2 “Licensing of Radioactive Materials”
- ◆ Section 3 “Standards for Protection Against Radiation”
- ◆ Section 4 “Transportation of Radioactive Materials”
- ◆ Section 5 “Rules of Practice”
- ◆ Section 9 “Use of Radionuclides in the Healing Arts”

The Department periodically amends the regulations. Notification of proposed changes will be provided as they occur in accordance with the Administrative Procedures Act of the State of Arkansas.

## G. PURPOSE OF APPENDICES

The Rules and Regulations require applicants to acquire equipment, train workers, and implement procedures that will help insure compliance. In addition to the guidance for the “Application for Radioactive Material License”, a set of Appendices are included in this Licensing Guide to assist the Applicant in the development of a radiation safety program for medical users of radioactive material. The Appendices contain information that must be submitted for review (for example, Appendix E, Leak Test of Sealed Radioactive Sources) and some Appendices contain example procedures that may be used to help meet regulatory requirements. The Applicant must develop operating and emergency procedures as part of the Radiation Safety Program and must submit the procedures with the Application for review and approval by the Department. In submitting the procedures, the Applicant is committing to following the procedures as part of the Radiation Safety Program.

Carefully read the applicable regulations, the Appendices, and the example procedures and forms to determine if the examples are appropriate for the Applicant’s proposed activities. The example procedures and forms may be used as guides for developing procedures which would then be incorporated into the Applicant’s radiation safety program and the Application for a Radioactive Material License.

**NOTE:** The information contained in this Licensing Guide was taken from the following document:

U.S. Nuclear Regulatory Commission (NRC) document, NUREG-1556, Volume 9, Revision 1, “Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Medical Use Licenses”

The information is used with permission of the NRC.

## **FILING AN APPLICATION**

### **A. GENERAL**

An application for a specific license for the medical use radioactive material must be submitted on the "Application For Radioactive Material License". Space provided on the application form is limited, so separate 8.5 x 11 inch sheets of paper should be attached. Each additional sheet submitted with the application should be identified and keyed to the item number on the Application form to which it refers.

The application must be completed in triplicate. Send two (2) copies of the completed application to:

Arkansas Department of Health  
P.O. Box 1437, Slot H-30  
Little Rock, Arkansas 72203-1437

Retain at least one copy of the submitted application form, with all attachments. When issued, the license will require that radioactive material be possessed and used in accordance with statements, representations and procedures provided in the application and the supporting documentation. Regulatory requirements specified in the Rules and Regulations for Control of Sources of Ionizing Radiation shall govern unless the statements, representations and procedures set forth in the license application and correspondence are more restrictive than the regulations.

All license applications will be available for review by the general public in the Department. If it is necessary to submit proprietary information, follow the procedure in the Rules and Regulations for Control of Sources of Ionizing Radiation, Paragraph RH-4040, "Public Record-Exceptions". Failure to follow this procedure could result in disclosure of the proprietary information to the public or substantial delays in processing the application. Employee personal information, (for example, home address, home telephone number, social security number, date of birth, radiation dose information), should not be submitted unless specifically requested by the Department.

### **B. LICENSE FEES**

The following fees are assessed:

#### License Application Fee

A non-refundable administrative fee for processing a new license application varies according to the type, nature, and size of the program of the medical use radiation and radioactive material by the licensee. A Fee Schedule is included as Enclosure 1.

Review of the application will not begin until the proper fee is received by the Department.

License Amendment Fee

A non-refundable administrative fee for processing an application to amend an existing license. The amount of license amendment fee is \$50.00 per amendment.

Review of the amendment request will not begin until the proper fee is received by the Department.

Annual Fee

An annual fee covers the Department costs for administering the radioactive materials licensing program. The annual fee for a Medical Use license is as calculated in the “License Application Fee”, above.

The Annual Fees are due January 1 of each year.

**C. OVERVIEW AND GUIDANCE**

This information is intended to provide guidance on two topics to individuals who are preparing an application for a license for the medical use of radioactive material as well as Department staff who review applications:

- Preparation of a license application using the Department’s “Application for Radioactive Material License”, and
- The Department’s criteria for evaluating a medical use license application.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

This Licensing Guide provides guidance for the following types of medical uses of radioactive material (referenced to applicable paragraphs of the Rules and Regulations, Section 9, “Use of Radionuclides in the Healing Arts):

- Use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is **not** required under RH-8307 (see RH-8500-8510);
- Use of unsealed radioactive material for imaging and localization studies for which a written directive is **not** required under RH-8307 (see RH-8530-8540);
- Use of unsealed radioactive material for which a written directive is required under RH-8307 (see RH-8550-8590);
- Use of sources for manual brachytherapy (see RH-8600-8615);
- Use of sealed sources for diagnosis (see RH-8620-8621);

- Use of a sealed source in a photon emitting remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit (see RH-8630-8660); and
- Other medical uses of radioactive material or radiation from radioactive material not specifically covered by Section 9, RH-8500 through RH-8630 (see RH-8670).

**NOTE:** “Radioactive Material” is defined in the Rules and Regulations for Control of Sources of Ionizing Radiation, Paragraph RH-200.an. as

“Any material, solid, liquid or gas which emits radiation spontaneously, including natural radioactive material such as radium.”

Accelerator-Produced (e.g., Positron Emission Tomography (PET) radionuclides) and Naturally Occurring Radioactive Material are included in this definition.

To assist license applicants, this Licensing Guide includes text boxes at the beginning of each section (shown at the beginning of paragraph C) to indicate the type of use to which the guidance pertains (identified by the pertinent section of Section 9). These boxes are intended to guide the applicant through the sections of the guidance that are relevant to the applicant's particular type of use of radioactive material. A “Y” (Yes) indicates that applicants for that type of use should review the guidance section. Some of the “Y”s have asterisks next to them. These asterisks indicate that there are conditions or limitations in that particular section of the guidance relating to the applicants who are subject to the checked section of the rule.

Applicants also should be aware that Section 9 contains general information, administrative requirements, and technical requirements that are pertinent to some or all of the types of use listed above. This Licensing Guide is intended to consolidate into one document guidance that relates to satisfying Rules and Regulations in addition to Section 9 that apply to medical use licensees, including the following:

- Provisions of Section 3, “Standards for Protection Against Radiation”
- Provisions of Section 2, “Licensing of Radioactive Materials”.

As a guidance document intended to assist a wide variety of applicants, this Guide contains a considerable amount of information about how licensees may choose to implement their programs to meet Department regulatory requirements. The information in this Guide is not intended to impose any conditions beyond those required by the Rules and Regulations. This Guide provides specific guidance on what information must be submitted in an application to satisfy Department requirements. Written procedures are required to be submitted as part of the license application.

In this document, “dose” or “radiation dose” means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE). These quantities are defined in the Rules and Regulation, Section 3, and are expressed in units of rem and its SI equivalent, the Sievert (Sv) (1 rem = 0.01 Sv). (The quantities absorbed dose and exposure, and their associated units, the rad and the roentgen, are not used in Section 3 to specify dose limits.) Furthermore, the radioactive materials commonly used in medicine emit beta and photon radiation, for which the quality factor is 1; a useful rule of thumb is an exposure of 1 roentgen is equivalent to an absorbed dose of 1 rad and dose equivalent of 1 rem.

## **CONTENTS OF AN APPLICATION**

### **1. NAME AND MAILING ADDRESS**

**Provide the legal name of the applicant’s corporation or company, including the designation “doing business as”, or other legal entity with direct control and responsibility for the use of the radioactive material and to whom the license will be issued.** A division or department within the corporate organization may not be the licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

Provide the mailing address where correspondence should be sent.

Provide the telephone number and FAX number of the corporation or company.

**NOTE:** The Department must receive prior notification in the event of change of ownership or control or any bankruptcy proceedings.

### **2. STREET ADDRESS AT WHICH RADIOACTIVE MATERIAL WILL BE USED AND/OR STORED (IF DIFFERENT FROM ITEM 1.)**

**List the physical street address, city, state, and Zip Code for each permanent facility or place where radioactive material will be used and/or stored, if other than described in Item 1. Do not list an address as a Post Office Box.**

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

**3. PERSON TO CONTACT REGARDING THIS APPLICATION**

**Identify the person who can answer questions about the application.** This is typically the proposed Radiation Safety Officer, unless the Applicant has named a different person as the contact. The Department will contact this individual if there are questions about the application.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

**4. CONTACT NUMBERS FOR CONTACT PERSON**

**Provide the telephone number and FAX number of the contact person, if different than the telephone number provided in Item 1.**

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

**5. LICENSE FEE ENCLOSED**

**Mark the appropriate choice. Provide an explanation if the License Fee is not enclosed.** Review of the application will not begin until the proper fee is received by the Department. Make all checks payable to the “Arkansas Department of Health and Human Services”.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

**6. TYPE APPLICATION**

**Mark the appropriate choice. If the application is for a renewal, identify the applicable Radioactive Materials License Number.**

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

## 7. INDIVIDUAL USERS (AUTHORIZED USERS)

### AUTHORIZED USERS

The responsibilities of the **Authorized Users** involved in medical use include the following:

- Radiation safety commensurate with use of radioactive material
- Administration of a radiation dose or dosage and how it is prescribed
- Direction of individuals under the Authorized User's supervision in the preparation of radioactive material for medical use and in the medical use of radioactive material
- Preparation of Written Directives, if required.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

Applicants must meet recentness of training requirements described in RH-8319. Authorized User applicants must have successfully completed the applicable training and experience criteria described in Section 9 within 7 years preceding the date of the application. Alternatively, applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other training pathways.

Paragraph RH-8318 provides that experienced Authorized Users who are named on a license or permit are not required to comply with the training requirements in RH-8315, RH-8316, or RH-8317 to continue performing those medical uses for which they were authorized before the effective date of changes to the regulations in RH-8318 (check the regulations to determine this date). For example, a physician who was authorized to use sodium iodine-131 for imaging and localization, involving greater than 30 microcuries (a quantity for which a written directive is required under RH-8307), would continue to be authorized for this use.

Technologists, therapists, or other personnel may use radioactive material for medical use under an Authorized User's supervision in accordance with RH-8305, "Supervision", and in compliance with applicable FDA, other Federal, and State requirements (RH-8003). Examples include FDA requirements for conduct of certain types of clinical research after submission of applications for INDs (Investigational New Drugs) and under the auspices of a Radioactive Drug Research Committee (21 CFR 361.1).

There is no Department requirement that an Authorized User must render an interpretation of a diagnostic image or results of a therapeutic procedure. The Department recognizes that the Authorized User may or may not be the physician who interprets such studies. Additionally, Department regulations do not restrict who can read and interpret diagnostic scans or the results of therapeutic procedures involving the administration of radioactive material to individuals.

**Authorized User's for Non-Medical Uses:** For *in vitro* studies, animal research, calibration of survey instruments, and other uses that do not involve the intentional exposure of humans, the list of proposed Authorized Users should include the individuals who will actually be responsible for the safe use of the radioactive material for the requested use.

An applicant should note which user will be involved with a particular use by referring to Items 11 of the application and providing information about the user's training and experience.

Authorized non-medical use or uses that do not involve the intentional exposure of humans (e.g., *in vitro* and animal research, calibration, dosimetry research) will be reviewed on a case-by-case basis.

**THE APPLICANT MUST PROVIDE THE FOLLOWING:**

- Name of the proposed Authorized User and the requested uses of the radioactive material.

**AND**

**For an individual previously identified as an Authorized User on an Agreement State or NRC Radioactive Material License or permit:**

- Previous Radioactive Material License number (if issued by the Department) or a copy of the License (if issued by an Agreement State or the NRC) or a copy of a permit issued by a NRC master material licensee, a permit issued by an Agreement State or the NRC broad scope licensee, or a permit issued by a NRC master material license broad scope permittee on which the physician, dentist, or podiatrist was specifically named as an Authorized User for the uses requested.

**For an individual qualifying under RH-8510, RH-8530, RH-8560, RH-8570, RH-8580, RH-8590, RH-8610, RH-8615, RH-8621, and/or RH-8660, who is board certified:**

- Copy of the certification(s) by a specialty board(s) whose certification process has been recognized by the Department under the above paragraphs, as applicable to the use requested.

**AND**

- For an individual seeking authorization under RH-8560 and RH-8660, description of the experience and/or training specified in RH-8560 and RH-8660 demonstrating that the proposed Authorized User is qualified for the type(s) of use for which authorization is sought.

**AND**

- If applicable, description of recent related continuing education and experience as required by RH-8319.

**For an individual qualifying under RH-8510, RH-8530, RH-8560, RH-8570, RH-8580, RH-8590, RH-8610, RH-8615, RH-8621, and/or RH-8660, who is not board certified:**

- A description of the training and experience identified in the above paragraphs demonstrating that the proposed Authorized User is qualified by training and experience for the use requested.

**AND**

- For an individual seeking authorization under RH-8660, description of the training specified in RH-8660 demonstrating that the proposed Authorized User is qualified for the type(s) of use for which authorization is sought.

**AND**

- Written attestation, signed by a preceptor physician Authorized User, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an Authorized User for the medical uses authorized has been achieved.

**AND**

- If applicable, description of recent related continuing education and experience as required by RH-8319.

**Appendix B, ADHHS/Division of Health, Form A (AUT), (AUS), and/or (AUD) “Authorized User Training and Experience and Preceptor Attestation” should be used to document each Authorized User’s training and experience. Instructions for completing Form A are also contained in Appendix B.**

**NOTES:**

- The names of board certifications that have been recognized by the Department, or an Agreement State, or the NRC are posted on the NRC web page <<http://www.nrc.gov/materials/miau/med-use-toolkit.html>>.
- Licensees must notify the Department within 30 days if an Authorized User permanently discontinues his or her duties under the license or has a name change under RH-8020.
- Descriptions of training and experience will be reviewed using the criteria listed above. The Department will review the documentation to determine if the applicable criteria in the regulations are met. If the training and experience do not appear to meet the Section 9 criteria, the Department may request additional information from the applicant or may request the assistance of the Medical Advisory Committee (MAC) in evaluating such training and experience.

**Note to Reviewers:**

Licenses will reflect any limitations on use for listed Authorized Users (e.g., whether administrations in excess of 33milliCi of Iodine-131 are allowed and specific uses under RH-8630, etc.).

**AUTHORIZED NUCLEAR PHARMACIST (ANP)**

Technologists, or other personnel, may prepare radioactive material for medical use under an ANP’s supervision in accordance with RH-8306, [“Supervision”, and in compliance with applicable FDA, other Federal, and State requirements (RH-8003). (Preparation of radioactive material for medical use may also be performed under the supervision of a physician who is an Authorized User.)

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	
RH-8620	
RH-8630	
RH-8670	Y

Applicants are reminded of recentness of training requirements described in RH-8319. Specifically, Nuclear Pharmacist applicants must have successfully completed the applicable training and experience criteria described in Section 9 within 7 years preceding the date of the application. Alternatively, Nuclear Pharmacist applicants must have had related continuing education and experience since initially completing the required training and experience. This time provision applies to board certification as well as to other training pathways for meeting requirements for training and experience.

**THE APPLICANT MUST PROVIDE THE FOLLOWING:**

- Name of the proposed Authorized Nuclear Pharmacist.

**AND**

**For an individual previously identified as an Authorized Nuclear Pharmacist on an Agreement State or NRC Radioactive Material License or permit or by a commercial nuclear pharmacy that has been authorized to identify ANPs:**

- Previous Radioactive Material License number (if issued by the Department) or a copy of the license (if issued by an Agreement State or the NRC) or a copy of a permit issued by a NRC master material licensee, a permit issued by an Agreement State or a NRC broad scope licensee, or a permit issued by a NRC master material license broad scope permittee on which the individual was named an ANP or a copy of an authorization as an ANP from a commercial nuclear pharmacy that has been authorized to identify ANPs.

**For an individual qualifying under RH-8317:**

- Copy of the certification(s) of the specialty board whose certification process has been recognized under RH-8317.

**OR**

- Description of the training and experience specified in RH-8317 demonstrating that the proposed ANP is qualified by training and experience.

**AND**

- Written attestation, signed by a preceptor ANP, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved.

**AND**

- If applicable, description of recent related continuing education and experience as required by RH-8319.

**Appendix B, ADHHS/Division of Health, Form A (ANP), “Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation” should be used to document each Authorized Nuclear Pharmacist’s training and experience. Instructions for completing Form A are also contained in Appendix B.**

**NOTES:**

- The names of board certifications that have been recognized by the Department, or an Agreement State, or the NRC are posted on the NRC web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.
- Licensees must notify the Department within 30 days if an Authorized Nuclear Pharmacist permanently discontinues his or her duties under the license or has a name change under RH-8020.
- Descriptions of training and experience will be reviewed using the criteria listed above. The Department will review the documentation to determine if the applicable criteria in the regulations are met. If the training and experience do not appear to meet the criteria in Section 9, the Department may request additional information from the applicant or may request the assistance of the MAC in evaluating such training and experience.

**AUTHORIZED MEDICAL PHYSICIST (AMP)**

At some licensed medical facilities conducting radiation therapy treatments, an AMP is directly involved with the calculation and administration of the radiation dose. The American Association of Physicists in Medicine (AAPM) suggests that a medical physicist limit his or her involvement in radiation therapy to areas for which he or she has established competency.

Section 9	Applicability
RH-8500	
RH-8530	
RH-8550	
RH-8600	Y
RH-8620	
RH-8630	Y
RH-8670	Y

Applicants are reminded of recentness of training requirements described in RH-8319. Specifically, medical physicist applicants must have successfully completed the applicable training and experience criteria described in Section 9 within 7 years preceding the date of the application. Alternatively, medical physicist applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other training pathways for meeting requirements for training and experience.

**THE APPLICANT MUST PROVIDE THE FOLLOWING:**

- Name of the proposed Authorized Medical Physicist.

**AND**

**For an individual previously identified as an AMP on an Agreement State or NRC Radioactive Material License or permit:**

- Previous Radioactive Material License number (if issued by the Department) or a copy of the License (if issued by an Agreement State or the NRC) or a copy of a permit issued by a NRC master material licensee, a permit issued by an Agreement State or the NRC broad scope licensee, or a permit issued by a NRC master material license broad scope permittee on which the individual was specifically named as an Authorized Medical Physicist for the uses requested.

**For an individual qualifying under RH-8316:**

- Copy of the certification(s) of the specialty board(s) whose certification process has been recognized under RH-8316.

**AND**

- Description of the training and experience specified in RH-8316 demonstrating that the proposed AMP is qualified by training in the types of use for which he or she is requesting AMP status, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system.

**OR**

- Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in RH-8316 for the uses requested.

**AND**

- Written attestation, signed by a preceptor AMP, that the required training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved.

**AND**

- Description of the training and experience specified in RH-8316 demonstrating that the proposed AMP is qualified by training in the types of use for which the licensee seeks approval of an individual as AMP, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system.

**AND**

- If applicable, description of recent related continuing education and experience as required by RH-8319.

**Appendix B, ADHHS/Division of Health, Form A (AMP), “Authorized Medical Physicist Training and Experience and Preceptor Attestation” should be used to document each Authorized Medical Physicist’s training and experience. Instructions for completing Form A are also contained in Appendix B.**

**NOTES:**

- The names of board certifications that have been recognized by the Department, or an Agreement State, or the NRC are posted on the NRC web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.
- Licensees must notify the Department within 30 days if an Authorized Medical Physicist permanently discontinues his or her duties under the license or has a name change under RH-8020.
- Descriptions of training and experience will be reviewed using the criteria listed above. The Department will review the documentation to determine if the applicable criteria in the regulations are met. If the training and experience do not appear to meet the criteria in Section 9, the Department may request additional information from the applicant or may request the assistance of the MAC in evaluating such training and experience.

**8. TRAINING AND EXPERIENCE OF USERS**

The training and experience of Authorized Users, Authorized Nuclear Pharmacists, and Authorized Medical Physicists is addressed in Item 7. No additional information is required for Item 8.

**9. RADIATION SAFETY OFFICER**

**A. Individuals Responsible for Radiation Safety Program and their Training and Experience**

Paragraph RH-8300 provides the requirements regarding the authority and responsibilities for the radiation protection program, including those of the licensee's management and the Radiation Safety Officer (RSO) appointed by licensee management. Other personnel who have a role in the radiation protection program are Authorized Users, Authorized Medical Physicists, Authorized Nuclear Pharmacists, and members of the Licensee's Radiation Safety Committee (RSC), if the licensee is required to establish a

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

RSC. The regulations require that an applicant be qualified by training and experience to use radioactive material for the purposes requested in such a manner to protect health and safety and to minimize danger to life or property. Section 9 of the regulations provides specific criteria for acceptable training and experience for Authorized Users for medical use, Authorized Nuclear Pharmacists, Authorized Medical Physicists, and the RSO. Appendix B provides specific guidance and the format for providing training and experience information.

Applicants must insure that specific training information required by Department regulations in Section 9 is submitted. Typically, a résumé or curriculum vitae is likely to be insufficient because such documents usually do not supply all the necessary information needed by the Department to evaluate an individual's training and experience.

Licensees are responsible for their radiation protection programs and it is essential that strong management control and oversight exist to ensure that licensed activities are conducted properly. Licensee management must appoint an RSO (who agrees in writing to be responsible for implementing the radiation protection program) and must provide the RSO sufficient authority, organizational freedom, time, resources, and management prerogative to communicate with personnel and direct personnel regarding Department regulations and license provisions, including:

- identifying radiation safety problems,
- initiating, recommending, or providing corrective actions,
- stopping unsafe operations, and
- verifying the implementation of corrective actions.

Nevertheless, the licensee retains the ultimate responsibility for the conduct of licensed activities.

Medical Institution Licensees who are authorized for the use of radioactive material are required under RH-8300 to establish a Radiation Safety Committee (RSC) to oversee all uses of radioactive material authorized by the license. Membership of the committee must include an Authorized User for each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an Authorized User nor the Radiation Safety Officer. The committee may include other members the licensee considers appropriate.

Licensees may contract for medical use services, including those involving patient services. However, the licensee must not assume that by hiring a contractor to provide certain services it has satisfied all regulatory requirements or that it has transferred responsibility for the licensed program to the contractor. Licensee management must ensure that adequate mechanisms for oversight are in place to determine that the radiation protection program, including training of contractor staff, is effectively implemented by the appropriate individuals.

**Training for experienced RSO, teletherapy or medical physicist, authorized user or nuclear pharmacist; recency of training.** The Rules and Regulations, RH-8318, states that experienced individuals, who may be candidates to serve as RSO, AMP, or ANP, are not required to meet the requirements of RH-8315, RH-8316, or RH-8317, respectively, (are "grandfathered") under certain conditions, e.g., the individual is named on an Agreement State or NRC license. Authorized Users are also not required to meet the requirements in under certain conditions, e.g., if they are named on an Agreement State or NRC license. The individuals must have been named on a license or permit before the

applicable date in Section RH-8318. Regulations in RH-8319 require that the training and experience specified in Section 9 must have been obtained within 7 years preceding the date of application or the individual must have related continuing education and experience.

## **B. SPECIFIC REQUIREMENTS FOR THE RADIATION SAFETY OFFICER**

The Rules and Regulations for Control of Sources of Ionizing Radiation requires the appointment of a Radiation Safety Officer (RSO). The regulations also establish the requirements regarding the authority and responsibilities for the radiation protection program, including those of the licensee's management and the RSO appointed by licensee management. The RSO is designated by, and responsible to, management for implementing the Radiation Safety Program and the As Low As Reasonably Achievable (ALARA) Program, and for insuring compliance with applicable regulations Radioactive Material License provisions. The ALARA Program is discussed in Appendix A, "ALARA Program". Management involvement in and support of the radiation protection program is discussed throughout this Guide and specifically in Item 25, Management Control.

### **Qualifications**

The Radiation Safety Officer(s) must have adequate training and experience. The training and experience requirements for the RSO are described in RH-8315 and allow for the following training pathways:

- Certification as provided in RH-8315 by a specialty board whose certification process has been recognized by an Agreement State or the NRC or, plus written attestation signed by a preceptor RSO as provided in RH-8315 and training as specified in RH-8315; or
- Completion of classroom and laboratory training (200 hours) and 1 year of full time radiation safety experience as described in RH-8315 plus written attestation signed by a preceptor RSO as provided in RH-8315 and training as specified in RH-8315 or
- Certification as provided in RH-8315 as a medical physicist under RH-8316, plus written attestation signed by a preceptor RSO as provided in RH-8315 and training as specified in RH-8315, or
- Identification as provided in RH-8315 on the licensee's license as an AU, AMP, or ANP with experience in the radiation safety aspects of similar types of radioactive material use for which the individual has RSO responsibilities, plus training as specified in RH-8315; or

### **Responsibilities**

The licensee must also establish, in writing, the authority, duties, and responsibilities of the RSO as required by RH-8300.

The RSO is responsible for day-to-day oversight of the radiation protection program. In accordance with RH-8300, the licensee must provide the RSO sufficient authority, organizational freedom, time, and resources to perform his or her duties. Additionally, the RSO must have a sufficient commitment from management to fulfill the duties and responsibilities specified in RH-8300 to ensure that radioactive materials are used in a safe manner. The Department requires that the name of the RSO be on the license, and an agreement in writing from the RSO, to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation and assumes the responsibilities of an RSO. Appendix C-1 contains a model RSO Delegation of Authority.

Usually, the RSO is a full-time employee of the licensed facility. The Department has authorized individuals who are not employed by the licensee, such as a consultant, to fill the role of RSO or to provide support to the facility RSO. In order to fulfill the duties and responsibilities, the RSO should be on site periodically to conduct meaningful, person-to-person interactions with licensee staff, commensurate with the scope of licensed activities, to satisfy requirements of RH-8300.

Some of the typical duties and responsibilities of the RSO include insuring the following:

- Unsafe activities involving radioactive material are stopped
- Radiation exposures are maintained ALARA
- Accountability and disposal of radioactive material
- Interaction with Department
- Timely and accurate reporting and maintenance of appropriate records
- Annual program audits
- Proper use and routine maintenance
- Personnel training, and
- Investigation of incidents involving radioactive material (e.g., medical events).

Appendix C-2 contains a detailed list of typical duties and responsibilities of the RSO.

Applicants are reminded of recentness of training requirements described in RH-8319. Specifically, RSO applicants must have successfully completed the applicable training and experience criteria described in Section 9 within 7 years preceding the date of the application. Alternatively, RSO applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other pathways to meeting requirements for training and experience.

**THE APPLICANT MUST PROVIDE THE FOLLOWING:**

- Name of the proposed Radiation Safety Officer.

**AND**

**For an individual previously identified as an RSO on a Commission or Agreement State license or permit:**

- Previous license number (if issued by the Department) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee that authorized the uses requested and on which the individual was named as the RSO.

**For an individual qualifying under RH-8315.a:**

- Copy of certification by a specialty board whose certification process has been recognized by the NRC or an Agreement State under RH-8315.

**AND**

- Written attestation, signed by a preceptor RSO, that the individual has the required training and experience in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.

**AND**

Description of the training and experience specified in RH-8315 demonstrating that the proposed RSO is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.

**For an individual qualifying under RH-8315.b:**

- Description of the training and experience specified in RH-8315 demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.

**AND**

- Written attestation, signed by a preceptor RSO, that the individual has the required training and experience in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.

**AND**

- Description of the training and experience specified in RH-8315 demonstrating that the proposed RSO is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.

**For an individual qualifying under RH-8315.c:**

- Copy of the certification(s) as a medical physicist by a board whose certification process has been recognized by the Department, the NRC or an Agreement State under RH-8316 and description of the experience specified in RH-8315 demonstrating that the proposed RSO is qualified by experience as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.

**AND**

- Written attestation, signed by a preceptor RSO, that the individual has the required training and experience in the radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval; has satisfactorily completed and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.

**AND**

- Description of the training and experience specified in RH-8315 demonstrating that the proposed RSO is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.

**OR**

- Copy of the licensee's license indicating that the individual is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the applicant seeks approval of an individual to serve as RSO.

**AND**

- Description of the training and experience specified in RH-8315 demonstrating that the proposed RSO is qualified by training in the radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.

**AND**

- If applicable, description of recent related continuing education and experience as required by RH-8319

**Appendix B, ADHHS/Division of Health, Form A (RSO), “Radiation Safety Officer Training and Experience and Preceptor Attestation” should be used to document the Radiation Safety Officer’s training and experience. Instructions for completing Form A are also contained in Appendix B.**

**NOTES:**

- The names of board certifications that have been recognized by the Department, or an Agreement State, or the NRC are posted on the NRC web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>.
- Licensees must notify the Department within 30 days if a Radiation Safety Officer permanently discontinues his or her duties under the license or has a name change under RH-8020.

**10. PERSONNEL TRAINING PROGRAM**

Individuals working with or in the vicinity of radioactive material must have adequate safety instructions as required by RH-2803, RH-8551, RH-8603, and RH-8633. Paragraph RH-8306 requires the Authorized Users and Authorized Nuclear Pharmacists to provide safety instruction to all personnel using radioactive material under their supervision.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

Describe the radiation safety training program for Authorized Users, Authorized Nuclear Pharmacists, Authorized Medical Physicists, the Radiation Safety Officer, their supervised employees, and for Ancillary Personnel. The training must be adequate to insure that individuals working with radioactive material, or who may be in the general vicinity where the radioactive material is used or stored, are aware of possible hazards, safety precautions, and emergency procedures that are associated with the use of the material. All individuals working with or around radioactive materials must receive safety instruction commensurate with their assigned duties. For example, a member of the housekeeping staff must be informed of the nature of the radioactive material and the meaning of the radiation symbol, and instructed not to touch the radioactive material and to remain out of the room if the door to the radioactive material storage location is open, but to notify a supervisor that the door was open. Providing minimal instruction to ancillary staff (e.g., housekeeping, security, etc.) may assist in controlling abnormal events, such as the loss of radioactive material.

In addition to the required safety instruction noted above (RH-2803, RH-8551, RH-8603, and RH-8633), the licensee must provide radiation safety instruction to personnel (e.g., nurses) caring for patients undergoing radiopharmaceutical therapy and/or implant therapy who cannot be released in accordance with RH-8420. This safety instruction should be commensurate with the duties of the personnel and include safe handling, patient control, visitor control, contamination control, waste control, and notification of the RSO and the Authorized User if the patient has a medical emergency or dies.

Paragraph RH-8306 requires that individuals working with radioactive material under the supervision of an Authorized User must receive instruction on the licensee's written radiation protection procedures, written directive procedures, and the Department's regulations and license conditions with respect to the use of radioactive material.

Also, in accordance with RH-8306, a licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an Authorized Nuclear Pharmacist or an Authorized User, as allowed by RH-8005, shall instruct supervised individuals in the preparation of radioactive material for medical use and require the individuals to follow their instructions, the licensee's written radiation protection procedures, the license conditions, and Department regulations. Paragraph RH-8306 states that a licensee that permits supervised activities, under paragraph RH-8306, is responsible for the acts and omissions of the supervised individuals.

Additional requirements for training in radiation safety for individuals involved with therapeutic treatment of patients are described in RH-8551, RH-8603, and RH-8633.

Appendix D provides a model training program that provides one way to satisfy the requirements referenced above. Appendix D, "Radiation Safety Training Program", describes the types of training programs that are required and prescribes the frequency at which each program is conducted. Appendix D may be used as the description of the Applicant's training program provided it is included with the application along with a statement of commitment to the program by the Applicant.

**Provide a detailed description of the Radiation Safety Training Program that will be implemented by the licensee to insure adequate training is provided to licensee personnel. Additionally, a copy of the radiation safety training procedure that will be used must be provided to the Department in Item 22, Operating Procedures, of the Application.**

**11. RADIOACTIVE MATERIAL**

**A. Type, Quantity, and Form of Radioactive Material**

The applicant must specifically request the radioactive material that will be used. The amount and type of information that must be submitted in the application supporting the request varies according to the type of use requested.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

**For Use Under Paragraph RH-8500 and RH-8530**

For RH-8500 and RH-8530 use, the chemical/physical form may be “Any” unsealed radioactive material permitted by RH-8500 or RH-8530, as appropriate. For RH-8500 or RH-8530 use, the total amount requested may be “As Needed”.

The following format may be used:

Radioactive Material	Chemical/Physical Form	Maximum Amount
Any radioactive material permitted by RH-8500	Any	As needed
Any radioactive material permitted by RH-8530	Any	As needed

**NOTE:**

The radioactive material authorized by RH-8500 and RH-8530 as “any radioactive material” **does not** include Positron Emission Tomography (PET) radionuclides.

The PET Radioactive Material must be specifically listed in the application along with the “Chemical/Physical Form” and the “Maximum Amount” requested.

**For Use Under Paragraph RH-8550**

For RH-8550 use, the radionuclide, chemical/physical form, and total amount requested must be specifically listed.

<b>Radioactive Material</b>	<b>Chemical/Physical Form</b>	<b>Maximum Amount</b>
Iodine-131	Sodium Iodide Capsules less than 33 milliCuries	100 milliCuries
Iodine-131	Sodium Iodide Capsules equal to or greater than 33 milliCuries	500 milliCuries
Iodine-125	Bexxar	500 milliCuries
Yttrium-90	Zevalin	500 millicuries
Strontium-90	Metastron	50 milliCuries
Samarium-153	Quadramet	200 milliCuries

**For Use Under Paragraph RH-8600, RH-8620, RH-8630, and RH-8670**

For RH-8600, RH-8620, RH-8630, and RH-8670 use, the radionuclide, the chemical/physical form (i.e., sealed source or device identified by manufacturer and model number), the total amount in microcuries ( $\mu\text{Ci}$ ), millicuries (mCi), or curies (Ci), or Becquerels (Bq), and the maximum number of sources or activity possessed at any one time must be specified. Applicants should include all possible new sources they might use, in order to minimize the need for license amendments if they change model or vendor. The following format may be used:

<b>Radioactive Material</b>	<b>Chemical/Physical Form</b>	<b>Maximum Amount</b>
I-125 (specific radiation therapy system liquid brachytherapy source)	Liquid source (Manufacturer Name, Model #XYZ)	2 curies total
Cesium 137 (i.e., specific brachytherapy radionuclide)	Sealed source or device (Manufacturer Name, Model #XYZ)	2 curies total
Gadolinium 153 (i.e., specific diagnostic sealed source radionuclide)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 500 millicuries per source and 1 curie total
Iridium 192 (i.e., specific afterloader sealed source radionuclide)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 10 curies per source and 20 curies total
Cobalt 60 (i.e., specific gamma stereotactic radiosurgery sealed source radionuclide)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 36 curies per source and 6,600 curies total

For sealed sources used in devices, an applicant may wish to request a possession limit adequate to allow for the possession of a spare source, to accommodate the total quantity of material in the licensee’s possession during replacement of the source in the device. The maximum activity for a single source or source loading may not exceed the activity specified by the manufacturer for the specific device and source combination as stated in the Sealed Source and Device Registration (SSDR) Certificate. However, an applicant may request a maximum activity for the source in the shipping container that exceeds the maximum activity allowed in the device. To request this authorization, applicants should provide certification that the source transport container is approved for the requested activity. A source that is received with a higher activity than permitted in the device must be allowed to decay to or below the licensed activity limit prior to installation in the device.

**Calibration, Transmission, and Reference Sources**

For calibration, transmission, and reference sources covered under RH-8404, the specific sources do not need to be listed on the license as long as the licensee is authorized pursuant to RH-8005 for medical use of radioactive material.

**Shielding Material/Depleted Uranium**

Some high activity radionuclide generators used to produce radioactive material for RH-8530 and RH-8550 uses (e.g., Tc-99m generators) may include depleted uranium (i.e., uranium depleted in uranium-235 (U-235)) as shielding material. If a generator has depleted uranium shielding, an applicant must request authorization to possess depleted uranium as shielding material. Applicants receiving large therapy sources and devices also should determine if depleted uranium is used to shield the therapy sources and devices. If applicable, the applicant should request authorization to possess depleted uranium (i.e., uranium depleted in uranium-235 (U-235)) in quantities sufficient to include shielding material in both the device(s) and source containers used for source exchange and shielding for other devices. The applicant should review the manufacturer’s specifications for each device specified in the license request to determine:

- if depleted uranium is used to shield the source(s) within the device; and
- the total quantity of depleted uranium present in the device (in kilograms).

The applicant should also consult the manufacturer’s specifications or the source supplier to determine if depleted uranium is contained in shielding source containers used during source exchange, as well as the total quantity of depleted uranium in such containers (in kilograms).

The following format may be used:

<b>Radioactive Material</b>	<b>Chemical/Physical Form</b>	<b>Maximum Amount</b>
Depleted Uranium	Metal	999 kilograms

**Other Radioactive Material**

The applicant should make a separate entry for other items that need to be listed (e.g., more radioactive material for *in vitro* testing than is allowed under RH-402.h, survey meter calibration source, dosimetry system constancy check source, material for *in vitro*, animal, or human research studies). The following format may be used:

Radioactive Material	Chemical/Physical Form	Maximum Amount
Any radioactive material permitted by RH-402.h	Prepackaged kits	50 millicuries

Sources that are authorized by RH-8404, “Authorization for calibration, transmission, and reference sources”, should *not* be listed. Applicants should number each line entry consecutively, following the Section 9 radioactive material.

**Blood Irradiators:** If the use of a device to irradiate blood is anticipated, the applicant should review U.S. NRC, NUREG-1556, Vol. 5, “Program-Specific Guidance About Self-Shielded Irradiator Licensees”.

**NOTE:** When determining both individual and total quantities of radioactive material, all materials to be possessed at any one time under the license must be included [i.e., materials received awaiting use (new teletherapy or brachytherapy sources for exchange), materials in use or possessed, material used for shielding, and materials classified as waste awaiting disposal or held for decay-in-storage.

**Sealed Sources and Devices**

In accordance with RH-403.h, applicants must provide the manufacturer’s name and model number for each requested sealed source and device (except for calibration, transmission, and reference sources authorized by RH-8404). Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by NRC or an Agreement State.

Section 9	Applicability
RH-8500	
RH-8530	
RH-8550	
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

NRC or an Agreement State performs a safety evaluation of sealed sources and devices before authorizing a manufacturer to distribute the sources or devices to specific licensees. The safety evaluation is documented in an SSDR Certificate. Applicants must provide the manufacturer’s name and model number for each requested sealed source and device so that Department can verify that they have been evaluated in an SSDR Certificate or specifically approved on a radioactive material license. Applicants should include all possible new sources they might use, in order to minimize the need for license amendments if they change model or vendor. If such a review has not been conducted for the specific source/device model(s), licensees should contact the Department for guidance.

An applicant may consult with the proposed supplier or manufacturer to ensure that requested sources and devices are compatible with each other and that they conform to the SSDR designations registered with NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source-device combination that would alter the description or specifications from those indicated in the respective SSDR certificates without obtaining the Department’s prior permission in a license amendment. To ensure that sealed sources and devices are used in ways that comply with the SSDR Registry and registration certificates, applicants may wish to obtain copies of the appropriate sections of the Registry certificates and review or discuss them with the manufacturer. A copy of the SSD Registry specific registration certificates may be obtained from the manufacturer of the sealed source or device.

**B. Purpose for which Radioactive Material will be Used**

The applicant must specifically state the purpose for which the radioactive material will be used. The amount and type of information that must be submitted in the application supporting the proposed use varies according to the type of use requested. The medical use of radioactive material is generally divided into seven different types of use as shown in the following table:

RH-8500	Medical Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is Not Required
RH-8530	Medical Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required
RH-8550	Medical Use of Unsealed Radioactive Material for Which a Written Directive is Required
RH-8600	Medical Use of Sources for Manual Brachytherapy
RH-8620	Medical Use of Sealed Sources for Diagnosis
RH-8630	Medical Use of a Sealed Source(s) in a Device for Therapy-Teletherapy Unit
	Medical Use of a Sealed Source(s) in a Device for Therapy-Remote Afterloader Unit
	Medical Use of a Sealed Source(s) in a Device for Therapy-Gamma Stereotactic Radiosurgery Unit
RH-8670	Other Medical Uses of Radioactive Material or Radiation from Radioactive Material

**For Use Under Paragraph RH-8500, RH-8530, and RH-8550**

For RH-8500, RH-8530, and RH-8550 use, the applicant must define the purpose of use of the radioactive material by stating the applicable section of Section 9 (e.g., RH-8500, RH-8530) and by providing a description of the applicable modality (e.g., any uptake, dilution, and excretion procedure for which a written directive is not required).

The use of unsealed radioactive material in therapy (RH-8550) involves administering radioactive material, either orally or by injection, to treat or palliate a particular disease. The most common form of use of unsealed radioactive material for therapy is the treatment of hyperthyroidism with iodine-131 (I-131) sodium iodide. Other therapeutic procedures include, for example, ablation of thyroid cancer metastasis, treatment of malignant effusions, treatment of polycythemia vera and leukemia, palliation of bone pain in cancer patients, and radiation synovectomy for rheumatoid arthritis patients. References to particular diagnostic or treatment modalities in this section are intended to be examples and are not intended to imply that licensees are limited to these uses.

#### **For Use Under Paragraph RH-8600**

For RH-8600 use, the applicant must define the purpose of use by stating the applicable section of Section 9 (i.e., RH-8600). If a source is to be used in a device, applicants may need to define the purpose of use by describing the manufacturer's name and model number of the device. The licensee should relate the sealed sources listed in Item 11.A to the devices described in this item. In manual brachytherapy, several types of treatments are available. These may include, for example:

- Interstitial Treatment of Cancer.
- Eye Plaque Implants. (This is considered interstitial, not topical, treatment).
- Intracavitary Treatment of Cancer. (For purposes of the NRC's or an Agreement State's sealed source and device evaluation on radiation safety issues, intraluminal use is considered analogous to intracavitary use).
- Topical (Surface) Applications.

#### **For Use Under Paragraph RH-8620**

For RH-8620 use, the applicant must define the purpose of use by stating the applicable section of Section 9 (i.e., RH-8620) and describing the manufacturer's name(s) and model number(s) of devices containing sealed sources (where applicable). The licensee should correlate the sealed sources listed in Item 11.A with the devices described in this item. Typically, a licensee should use the sealed sources according to manufacturer's radiation safety and handling instructions and must use the sources as approved in the SSDR.

#### **For Use Under RH 8630**

For RH-8630 use, the applicant must define the purpose of use by stating the applicable section of Section 9 (e.g., teletherapy, remote afterloading, GSR) and describing the manufacturer's name(s) and model number(s) of the device containing a sealed source(s) (e.g., for use in a Manufacturer's Name and Unit Type, Model xxxx radiation therapy unit for the treatment of humans). The applicant should correlate the sealed source(s) listed in Item 11.A with the device described in this item. If applicable, the applicant should state that depleted uranium is used as shielding for the device and specify that an additional source is requested to be stored in its shipping container incident to source replacement.

### **For Use Under Paragraph RH-8670**

Applicants must apply for authorization to use radioactive material, or radiation therefrom, in medical applications under RH-8670 when the type of use is not covered under RH-8500 through RH-8630.

When applying for use under provisions of RH-8670, applicants should

- describe the purpose of use and submit the information required under RH-8010 (b) through (d),
- review regulatory requirements in other Paragraphs of Section 9, and use them as a guide on how to determine what should be included in an application that is required in RH-8010.

It is anticipated that many of the uses of radioactive material under the provisions of RH-8670 may involve research or product development; thus, applicants should ensure review and compliance with RH-8004, “Provisions for Research Involving Human Subjects”, and RH-8003, “FDA, other Federal, and State Requirements”. Use of radioactive material in a source or device after approval by U.S. Food and Drug Administration, e.g., under an IDE (investigational device exemption) or an IND (investigational new drug exemption), does not relieve individuals of the responsibility to obtain a license to use the radioactive material in medicine under the provisions of Section 9.

If the source for the type of use requested under RH-8670 is a sealed source, Item 11, “Sealed Sources and Devices” of this guide describes the information that must be provided at the time of application. Broad scope licensees are exempted under RH-8025 from requirements of RH-8010 (which relates to including certain information in an application about radiation safety aspects of medical use under RH-8670). However, broad scope licensees should make sure that the quantity of radioactive material needed for the proposed use is authorized on their license or apply for an increase amount, if not.

Applicants for uses under RH-8670 should contact the Department to discuss the contents of their application.

### **Non-Medical Uses**

Applicants may also describe non-medical uses (e.g., survey meter calibrations with NIST traceable brachytherapy sources) and reference the applicable radioactive material provided in response to Item 11.

## 12. LEAK TESTS

Each sealed radioactive source shall be periodically tested to determine if radioactive material is leaking from the sealed source. Additionally, leak testing of devices containing depleted uranium (DU) shielding to determine whether there is any radioactive leakage from the device is also required. Sealed sources containing radioactive material must be leak tested at intervals not to exceed 6 months and DU devices tested at interval not to exceed 12 months.

Section 9	Applicability
RH-8500	Y*
RH-8530	Y*
RH-8550	Y*
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

(\*If

possess sealed sources under RH-8404)

Licensees must perform leak testing of sealed sources, e.g., calibration, transmission, and reference sources, or brachytherapy sources in accordance with RH-8405. Appendix E provides model procedures that are one way to perform leak testing. Paragraph RH-8405 requires licensees to perform leak tests at six-month intervals or at other intervals approved by the Department, an Agreement State, or the NRC and specified in the SDDR certificate and before first use unless accompanied by a certificate indicating that the test was performed within the past 6 months. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 0.005  $\mu\text{Ci}$  (185 Bq) of radioactivity on the sample. Leak test samples shall be collected at the most accessible area where contamination would accumulate if the sealed source were leaking.

The leak test may be performed in-house or by an individual who is licensed by the Department or an Agreement State or the NRC to perform leak tests as a service to other licensees.

The licensee does not need to leak test sources if any of the following criteria are met:

- Sources contain only radioactive material with a half-life of less than 30 days;
- Sources contain only radioactive material as a gas;
- Sources contain 100  $\mu\text{Ci}$  (3.7 MBq) or less of beta-emitting or gamma-emitting material, or 10  $\mu\text{Ci}$  (0.37 MBq) or less of alpha-emitting material;
- Sources contain Ir-192 seeds in nylon ribbon; or
- Sources are stored and not being used. The licensee, shall, however, test each such source for leakage before any use or transfer unless it has been leak-tested within 6 months before the date of use or transfer.

Appendix E, “Leak Test Procedures”, describes the requirement for leak testing and provides instructions for performing and documenting the tests.

Form E, entitled “**Leak Tests for Sealed Sources**”, requests specific information on the proposed leak test program and how it will be performed. **Complete Form E and submit it with the application. A copy of the written procedures that will be used to leak test sealed sources must be provided to the Department in Item 22, Operating Procedures, of the Application.**

### 13. **RADIATION DETECTION INSTRUMENTS**

#### A. **Radiation Survey Instruments**

All licensees shall possess calibrated radiation detection and measuring instruments that will be used for radiation protection purposes, including survey and monitoring instruments, and quantitative measuring instruments needed to monitor the adequacy of radioactive materials containments and contamination control.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

The survey instrument shall be capable of accurately measuring the radiation fields produced by the radioactive material currently in use, and must be visually checked for damage and for proper operation with a radiation source at the beginning of each day of use and at the beginning of each work shift to insure proper operation.

The following table summarizes the requirements for radiation survey instruments as specified in the referenced Paragraphs of Section 9:

RH-8501	Radiation Detection Survey Instrument	0.1-50 millirem/hr
RH-8532	Radiation Detection Survey Instrument, and Radiation Measurement Survey Instrument	0.1-50 millirem/hr 1.0-1000 millirem/hr
RH-8553	Radiation Detection Survey Instrument, and Radiation Measurement Survey Instrument	0.1-50 millirem/hr 1.0-1000 millirem/hr
RH-8607	Radiation Detection Survey Instrument, and Radiation Measurement Survey Instrument	0.1-50 millirem/hr 1.0-1000 millirem/hr
RH-8649	Radiation Detection Survey Instrument, and Radiation Measurement Survey Instrument	0.1-50 millirem/hr 1.0-1000 millirem/hr

Appendix F provides guidance regarding appropriate instrumentation to meet the requirements detailed in Section 9.

**Complete Item 13 of the Application for Radiation Survey Instruments by providing the requested information in the specified format.**

**B. Dose Calibrator and Other Equipment Used to Measure Unsealed Radioactive Material**

Paragraphs RH-8401 and RH-8403, describe requirements for the possession, use, calibration, and check of instruments (e.g., dose calibrators) used to measure patient dosages. As noted in RH-8403, the licensee shall determine and record the dosage prior to the medical use.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	
RH-8620	
RH-8630	
RH-8670	Y

Dosage measurement is required for all licensees who prepare patient dosages.

This requirement is further conditioned:

- For all photon-emitting radionuclides, the determination shall be made by direct measurement.
- For other than photon-emitting radionuclides, the determination may be made by direct measurement or a combination of radioactivity or volumetric measurement and mathematical calculations, provided by the manufacturer or preparer.

The measurement equipment may be a well ion chamber, a liquid scintillation counter, etc., as long as the instrument can be calibrated appropriately and is both accurate and reliable.

For other than unit dosages, the activity must be determined by direct measurement, by a combination of radioactivity measurement and mathematical calculation, or by a combination of volumetric measurement and mathematical calculation. However, there are inherent technical difficulties to overcome.

For beta-emitting radionuclides, these difficulties include dependence on geometry, lack of an industry standard for materials used in the manufacture of vials and syringes, and lack of a NIST-traceable standard for some radionuclides used. For instance, when determining the dosage of P-32, assays with a dose calibrator may result in inaccuracies caused by inherent variations in geometry; therefore, a volumetric measurement and mathematical calculation may be more accurate. Licensees must assay patient dosages in the same type of vial and geometry as used to determine the correct dose calibrator settings. Using different vials or syringes may result in measurement errors due, for example, to the variation of bremsstrahlung created by interaction between beta particles and the differing dosage containers. Licensees are reminded that beta emitters should be shielded using a low-atomic-numbered material to minimize the production of bremsstrahlung. When a high activity source is involved, consideration should be given to adding an outer shield made from material with a high atomic number to attenuate bremsstrahlung.

Complete Item 13 of the Application for the Dose Calibrator by Instruments by providing the requested information in the specified format.

**14. CALIBRATION OF INSTRUMENTS**

**A. Radiation Survey Instruments**

Radiation survey instruments must be calibrated (**not to exceed 12 months and after each servicing**) to insure the instrument accurately detects and measures the type of radiation used by the licensee. The instrument calibration must be performed by a Service Vendor who is licensed or registered to perform the service by the Arkansas Department of Health and Human Services, the NRC, or an Agreement State. However, the licensee may be authorized to calibrate instruments “in-house” provided certain requirements are met.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

If an applicant elects to perform radiation survey instrument calibration “in-house”, detailed, step-by-step procedures are required to be submitted for each instrument that will be calibrated. These procedures must be provided to the Department in Item 22, Operating Procedures, of the Application. Also, the radiation source(s) that will be used for calibration must be included in Item 11, Radioactive Material.

**Complete Form G-1 marking the appropriate spaces to describe how the calibration of radiation survey instruments will be performed.**

**B. Dose Calibrator and Other Equipment Used to Measure Unsealed Radioactive Material**

Equipment used to measure dosages must be calibrated in accordance with nationally recognized standards (e.g., ANSI) or the manufacturer’s instructions. The measurement equipment may be a well ion chamber, a liquid scintillation counter, etc., as long as the instrument can be calibrated appropriately and is both accurate and reliable.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	
RH-8620	
RH-8630	
RH-8670	Y

**The applicant must confirm in Appendix G, Form G-2, that the radiation detection instruments used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer’s instructions. A copy of each calibration procedure used must be provided to the Department in Items 22, Operating Procedures, of the Application.**

### C. Therapy Unit Calibration and Use

Department regulations contain requirements, including recordkeeping requirements, for verification and periodic spot-checks of source activity or output. To perform these measurements, the applicant must possess appropriately calibrated dosimetry equipment. For manual brachtherapy sources and LDR remote afterloader sources licensees may use source activity or output determined by the manufacturer provided that the manufacturer's measurements meet applicable requirements

Section 9	Applicability
RH-8500	
RH-8530	
RH-8550	
RH-8600	Y*
RH-8620	
RH-8630	Y*
RH-8670	Y*

(\*Special Requirements re: brachytherapy and LDR afterloader sources and Sr-90 sources)

Except for manual brachytherapy sources and low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer in accordance with Section 9, the applicant must possess a calibrated dosimetry system (e.g., Farmer chamber, electrometer, well-type ionization chamber) that will be used to perform calibration measurements of sealed sources to be used for patient therapy. Dosimetry systems and/or sealed sources used to calibrate the licensee's dosimetry systems must be traceable to NIST or to a laboratory accredited by AAPM, pursuant to RH-8635. The licensee must maintain records of calibrations of dosimetry equipment for the duration of the license.

The licensee's AMP must perform full calibrations of sealed sources and devices used for therapy in accordance with published protocols currently accepted by nationally recognized bodies (e.g., AAPM, ACR, ANSI). (Note: Calibration by an AMP is not required for manual brachytherapy sources, except for calculating the activity of strontium-90 sources.) The licensee's AMP must calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments.

In addition, the licensee must perform spot-check measurements of sealed sources and devices used for therapy in accordance with written procedures established by the AMP (RH-8643, RH-8644, and RH-8645). Calibration procedures described by the AAPM or any published protocol approved by a nationally recognized body, as applicable, may be used. The calibration procedures should address, in part:

- The method used to determine the exposure rate (or activity) under specific criteria (i.e., distances used for the measurement, whether the measurement is an "in air" measurement or done using a phantom configuration of the chamber with respect to the source(s) and device, scatter factors used to compute the exposure rate, etc.).

**Full calibrations shall be performed:**

- Before first medical use<sup>1</sup>,
- Whenever spot-check measurements (if required) indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for decay,
- Following replacement of the sources or reinstallation of the unit in a new location not previously described in the license,
- Following any repairs of the unit that include removal of sealed sources or major repair of the components associated with the source exposure assembly, and,
- At intervals as defined in RH-8640, RH-8641, and RH-8642.

Manual brachytherapy sources must be calibrated only initially, prior to use.

For sealed sources used in therapy, and in particular, for new types of use, licensees must select dosimetry equipment that will accurately measure the output or the activity of the source. .

**The applicant shall provide a list of the procedures required by RH-8643, RH-8644, and RH-8645, if applicable to the license application. A copy of each calibration procedure used must be provided to the Department in Item 22, Operating Procedures, of the Application**

**NOTE:** The following References are provided to assist the Applicants:

- AAPM Task Group No. 21, “A Protocol for the Determination of Absorbed Dose from High-Energy Photon and Electron Beams”,
- AAPM Task Group No. 40, “Comprehensive QA for Radiation Oncology”, AAPM Report No. 54, “Stereotactic Radiosurgery”,
- AAPM Task Group No. 56, “Code of Practice for Brachytherapy Physics”.

## 15. PERSONNEL MONITORING PROGRAM

### A. Dose to Occupationally-Exposed Individuals

Radioactive Material Licensees are required to develop a program for monitoring and assessing the radiation dose to occupationally exposed individuals. The licensee must evaluate the radiation exposure of all occupational workers (e.g., nurses, technologists) to determine if monitoring is required to demonstrate compliance with RH-1302. Licensees must consider the internal and external dose and the occupational workers' assigned duties when evaluating the need to monitor occupational radiation exposure. Review of dosimetry histories for workers previously engaged in similar duties may be helpful in assessing potential doses.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

Licensees must perform one of the following:

- Demonstrate that unmonitored individuals are not likely to receive, in 1 year, a radiation dose (including external and internal) in excess of 10 % of the allowable limits as shown in Figure 15.1.
- Monitor external and/or internal occupational radiation exposure, as required by RH-1302.

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Figure 15.1 Annual Occupational Dose Limits for Adults

Appendix H provides information that may be used to develop and implement, or revise, or amend procedures for a comprehensive personnel monitoring program to monitor and evaluate external and internal occupational radiation exposure.

**The Applicant must describe the proposed personnel monitoring program by completing Appendix H-1, Form H-1, “Personnel Monitoring Program” and submit the completed Form with the application. A copy of the written procedures for the personnel monitoring program must be provided to the Department in Item 22, Operating Procedures, of the Application.**

**B. Dose to Members of the Public**

Radioactive Material Licensees are required to insure that no member of the public receives a radiation dose from sources under the control of the Licensee that exceeds the dose amounts referenced in the Rules and Regulations for Control of Sources of Ionizing Radiation, Paragraph RH-1208, “Dose Limits for Individual Members of the Public”.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

Radiation Dose to Members of the Public are not to exceed:

- (1.) **Total Effective Dose Equivalent: 100 millirem per year**
- (2.) **Dose in any unrestricted area: 2 millirem in any one hour**

Paragraph RH-1100 defines “Member of the public” as

“any individual except when that individual is receiving an occupational dose”.

Members of the public include persons who are not radiation workers. This includes workers who live, work, or may be near locations where radioactive material is used or stored and employees whose assigned duties do not include the use of radioactive materials and who work in the vicinity where it is used or stored.

Paragraph RH-1209, “Compliance with Dose Limits for Individual Members of the Public” requires that the Licensee demonstrate compliance with the annual dose limit.

Appendix I contains additional guidance that may be used to develop and implement a procedure to determine and document the radiation dose to members of the public.

**The Applicant must submit with the application a copy of the Procedure that will be used to perform the annual assessment to demonstrate compliance with RH-1208. A copy of the written procedures must be provided to the Department in Item 22, Operating Procedures, of the Application.**

## 16. FACILITIES AND EQUIPMENT

Facilities and equipment must be adequate to protect health and minimize danger to life or property. Applicants are required by RH-404, RH-8010, and RH-8013 to provide information about the design and construction of facilities and safety equipment. Applications will be approved if, among other things, “the applicant’s proposed equipment and facilities are adequate to protect health and minimize danger to life or property.” Facility and equipment requirements depend on the scope of the applicant’s operations, including, for example:

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

- Planned use of the radioactive material,
- Types of radioactive emissions, or
- Quantity and form of radioactive materials possessed.

Applicants should focus particularly on operations using large quantities of radioactive materials; preparation steps involving liquids, gases, and volatile radioactive materials; and the use of alpha-emitters, high-energy photon-emitters, and high-energy beta-emitters.

Appendix J contains guidance that may be used to provide the necessary information to adequately describe the facilities and equipment. Detailed information regarding the areas in the facility which are used for the receipt, storage awaiting use, medical use, and storage awaiting disposal must be submitted for review. Patient housing facilities for patients undergoing treatment must also be thoroughly described.

### **The Applicant must provide the following information.**

In addition to written description of the facilities, the Applicant must provide the additional following information:

- Facility drawings should be to scale, and indicate the scale used.
- Location, room numbers, and principal use of each room or area where radioactive material is prepared, used or stored, as provided above.
- Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms; indicate whether the room is a restricted or unrestricted area as defined in RH-1100; and
- Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including the dimensions of any portable shield, if one is used; source storage safe, etc.).

In addition to the above, for teletherapy and GSR facilities, applicants must provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation. For manual brachytherapy facilities, provide a description of the emergency response equipment. For teletherapy, GSR, and remote afterloader facilities, provide a description of the following:

- Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room;
- Area radiation monitoring equipment;
- Viewing and intercom systems (except for LDR units);
- Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) are in the treatment room;
- Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and
- Emergency response equipment.

Licensees are required by RH-8011 to obtain a license amendment before adding to or changing an area of use identified in the application or on the license.

**A copy of the written procedures identifying, designating, controlling, operating, and using, radioactive material in the facilities and equipment must be provided to the Department in Item 22, Operating Procedures, of the Application.**

## **17. RADIATION SURVEY PROGRAM**

The Radiation Protection Program that Radioactive Material Licensees are required to develop, document, and implement in accordance with RH-1004 must include provisions for routine and special radiation surveys. Surveys are evaluations of radiological conditions and potential hazards. (The requirement for a Radiation Protection Program is discussed in Item 22 of this Application). The requirement to perform radiation surveys by medical licensees is specified in RH-8408. These surveys may be measurements (e.g., radiation levels measured with radiation survey instrument or results of wipe tests for contamination), calculations, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess radiological conditions. Licensees must perform surveys to:

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

- Insure that radioactive material is used, transported, and stored in such a way that doses to members of the public do not exceed 100 millirem/year (1 mSv /year) and that the dose in any unrestricted area will not exceed 2 mrem (0.02 mSv) in any 1 hour from licensed operations;
- Insure that radioactive material is used, transported, and stored in such a way that occupational doses to individuals will not exceed the limits specified in RH-1200;
- Control and maintain constant surveillance over radioactive material that is not in storage and to secure radioactive material from unauthorized access or removal;
- Insure that radioactive material is used, transported, and stored in such a way that the air emissions do not exceed the constraint value in RH-1004.

Appendix K contains additional information and guidance that may be used to develop/revise the radiation survey program and to document the program requirements in written operating procedures.

**Complete Item 17 of the Application by providing a list (by Title and Number) of each specific radiation survey procedure that will be used. A copy of each radiation survey procedure must be provided to the Department in Items 22 and 23, Operating and Emergency Procedures, of the Application.**

**18. ORDERING, RECEIVING, OPENING, AND SHIPPING PACKAGES CONTAINING RADIOACTIVE MATERIAL**

Radioactive material may only be possessed and used in accordance with a Radioactive Material License issued the Department. The types and quantities of radioactive material that are allowed are specified in the license and no other licensable type or quantity of radioactive material may be possessed and used. Additionally, licensees must ensure that packages are secured and radiation exposure from packages is minimized.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

Radioactive materials must be tracked from “cradle to grave” to insure accountability, identify when radioactive material could be lost, stolen, or misplaced, and insure that possession limits listed on the license are not exceeded.

Licensees must maintain accountability of radioactive material and must perform the following:

- Secure radioactive material
- Maintain records of receipt, transfer, and disposal of radioactive material
- Conduct physical inventories at required frequencies to account for radioactive material.

The receipt and opening of packages containing radioactive material must be performed in accordance with the RH-1307. Licensees must establish, maintain, and retain written procedures for safely opening packages to ensure that the monitoring requirements of RH-1307 are met and that radiation exposure to personnel coming near or in contact with the packages containing radioactive material is ALARA.

Appendix L “Ordering, Receiving and Opening and Shipping Packages Containing Radioactive Material”, provides additional information on each of these topics that may be used for the development/revision of operating procedures.

**Complete Item 18 of the Application by providing the name and title of the individual responsible for ordering radioactive material and by providing a list (by Title and Number) of specific procedures that will be used for ordering, receiving, opening and shipping packages containing radioactive material. A copy of each procedure must be provided to the Department in Item 22, Operating Procedures, of the Application.**

## 19. WASTE DISPOSAL

Radioactive material must be disposed of in accordance with Paragraph RH-1400. The Radiation Protection Program that licensees are required to develop, document, and implement in accordance with RH-1004 must include provisions for waste disposal of radioactive material. The disposal of radioactive material performed by the licensee shall be prescribed and documented in written procedures. Appendix M contains additional information and guidance for developing/revising operating procedures for waste disposal and it also contains model procedures that represent a way to provide for decay-in-storage and generator or the return of other radioactive material to the supplier. Radioactive material must be disposed of in accordance with Department requirements by:

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

- Transfer to an authorized recipient
- Decay-in-storage
- Release in effluents within the limits in RH-1210
- As authorized under RH-1402 through RH-1405.

**Complete Item 19 of the Application by providing a list (by Title and Number) of each specific procedure that will be used in the disposal or transfer of radioactive material. A copy of each procedure must be provided to the Department in Item 22, Operating Procedures, of the Application.**

## 20. CONTROL AND SECURITY OF RADIOACTIVE MATERIAL

Paragraph RH-1306 requires sources of radiation be secure from “unauthorized removal or access”. Radioactive material licensed for use at medical facilities must be controlled and secured to prevent individuals from entering areas where radioactive material is being used, and to prevent the unauthorized removal of the radioactive material from the facility.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y
RH-8670	Y

### Increased Controls

The Department, in cooperation with the U.S. Nuclear Regulatory Commission and other Agreement States, has implemented increased controls (ICs) for Radioactive Material Licensees that possess radioactive material in quantities of concern. These IC requirements for licensees are contained in Appendix N, “Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern”. The ICs must be implemented in addition to the currently mandated requirements of RH-1306.

**Applicants must review Appendix N and provide a statement in the Application confirming that either the IC requirements are not applicable to this license, or, all requirements described in the Appendix N have been implemented.** However, as appropriate, the statement may also contain the following information:

- a. Department Notification
  - (1.) If the Licensee is unable to comply with any of the requirements in Appendix N
  - (2.) If compliance with any of the requirements is unnecessary because of specific circumstances of the Licensee, or
  - (3.) If implementation of any of the requirements would cause the Licensee to be in violation of the provisions of any regulation or the license.

The notification shall provide detailed justification for seeking relief from or variation of any specific requirement.

- b. Adverse Impact

If it is considered that implementation of any of the requirements detailed in Appendix N would adversely impact the safe operation of the facility, the Application must contain notification of the Department of the following:

- Specific description of the adverse safety impact,
- Technical basis for the determination that the requirement would have an adverse safety impact, and

- Either a proposal for achieving the same objectives specified in the Appendix N requirement in question, or a schedule for modifying the facility to address the adverse safety condition.

If neither approach is appropriate, the response must be referenced to paragraph 1, above, to identify the condition as a requirement with which you cannot comply, supported with attendant justifications required in paragraph 1, above.

c. Schedule

If the ICs are required but have been not implemented and are not operational at the time of submitting the Application, provide a schedule and a commitment to follow the schedule for completion of each requirement detailed in Appendix N. The implementation of the ICs will be inspected immediately following the issuance of the Radioactive Material License.

d. **This portion of the Application shall be marked as "Withhold from Public Disclosure Under RH-4040."**

**21. TRANSPORTATION**

Applicants who will prepare for shipment, ship, or transport radioactive materials, including radioactive waste, must develop, implement, and maintain safety programs for the transport of radioactive material to ensure compliance with Department and DOT regulations.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

Most packages of radioactive material for medical use contain quantities of radioactive material that require use of Type A packages. Additionally, many packages shipped by medical licensees (e.g., unused radiopharmaceutical dosages) frequently meet the “Limited Quantity” criteria described in 49 CFR 173.421 and are therefore excepted from certain DOT requirements, provided certain other less restrictive requirements are met (e.g., activity in the package is less than the limited quantity and the radiation level on the surface of the package does not exceed 0.5 mrem per hour (0.005 mSv per hour)).

The general license in RH-3302, “General license: NRC-approved package,” provides the authorization used by most licensees to transport, or to deliver to a carrier for transport, radioactive material in a package for which a license, certificate of compliance, or other approval has been issued by NRC. This general license is subject to certain conditions. Paragraph RH-3202 sets forth the requirements for transportation of radioactive material. Paragraph RH-3300 exempts any physician licensed by a state to dispense drugs in the practice of medicine, who is also licensed under Section 9 or the equivalent Agreement State regulations from the requirements in RH-3202. This exemption applies to transport by the physician of radioactive material for use in the practice of medicine.

Some medical use licensees (e.g., teletherapy or gamma stereotactic radiosurgery) may need to ship radioactive material in Type B packages. Paragraphs RH-3301-RH-3303 set forth the Type B package requirements for transporting or delivering the package to a carrier for transport. Contact the Department for special licensing guidance for using Type B packages.

Also, some medical use licensees that ship radioactive material have chosen to transfer possession of radioactive materials to a manufacturer (or service licensee) with a Department, NRC or Agreement State license, who then acts as the shipper. The manufacturer (or Service Vendor/licensee), who is subject to the provisions of RH-3302 or RH-3303, as appropriate, then becomes responsible for proper packaging of the radioactive materials and compliance with Department and DOT regulations. Licensees who do this must ensure that the manufacturer (or Service Vendor/licensee):

- Is authorized to possess the radioactive material (copy of appropriate Radioactive Material License on file with manufacturer (or Service Vendor/licensee))
- Actually takes possession of the licensed material under its license.

Licensees should also ensure that the manufacturer (or Service Vendor/licensee) is authorized to possess the material at temporary job sites (e.g., the licensee's facilities).

Appendix O lists major DOT regulations that apply to medical licensees.

**Complete Item 21 of the Application by confirming in the following in writing:**

- **Appropriate Department and U.S. DOT regulations will be followed when transporting or preparing a package containing radioactive material for shipment.**
- **The Radiation Safety Officer, or specific designee, will be provided training as required by U.S. DOT, 49 CFR 172, Subpart H, before shipments of radioactive material are made.**

**Also, provide a list (Title and Number) of each specific procedure that will be used in the transportation of radioactive material. A copy of each procedure must be provided to the Department in Item 22, Operating Procedures, of the Application.**

## 22. OPERATING PROCEDURES

### A. Radiation Safety Program

Licensees who are authorized to use radioactive material for medical uses are required to develop, implement, and maintain a comprehensive radiation safety program in accordance with RH-1004 and RH-8300. The program must be commensurate with the scope and extent of activities proposed for the use of radioactive materials in medicine, and must describe how safe operations, ALARA radiation dose, and regulatory compliance will be achieved through training, procedures, and equipment. The program must be sufficient to ensure compliance with the provisions of the Rules and Regulations, Section 3, “Standards for Protection Against Radiation”.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

The licensee is responsible for the conduct of all licensed activities and the acts and omissions of individuals handling radioactive material. Paragraph RH-409 provides that the Department may incorporate into radioactive material licenses, at the time of issuance or thereafter, additional requirements and conditions that it deems appropriate or necessary to, in part, protect health or to minimize danger to life and property. Paragraph RH-8300 describes the licensee management’s authorities and responsibilities for the radiation protection program. Paragraph RH-8301 sets forth four circumstances in which the licensee may revise its radiation protection program without the Department’s approval. For example, no Department approval is required when the revision does not require a license amendment under RH-8011.

Applicants/licensees must abide by all applicable regulations, develop, implement, and maintain procedures when required, and/or provide requested information about the proposed radiation protection program during the licensing process.

**A written description of the Radiation Safety Program must be submitted to the Department. Appendix P contains topics that must be included in the Radiation Safety Program.**

### B. Operating Procedures

Radioactive material must be used and maintained in accordance with the Radioactive Material License, the Rules and Regulations for Control of Sources of Ionizing Radiation, and as appropriate, the manufacturer’s instructions for use. In order to minimize radiation doses to licensee personnel and members of the public, the Applicant must adopt operating procedures and practices that comply with and reflect the As Low As is Reasonably Achievable (ALARA) philosophy in all phases of radioactive material use and operations.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

The RSO is responsible for assuring that the radioactive material is used as required by the Operating Procedures and in a manner that is ALARA. The RSO is also responsible for completing certain radiation protection administrative functions that are required by the Rules and Regulations, such as insuring annual radiation protection program review is performed or insuring that periodically-required leak testing of sealed sources is performed. These functions must also be addressed in the operating or equivalent procedures.

Appendix P includes a listing of operating procedure topics that, as a minimum, must be addressed in the Operating Procedures.

**Complete Item 22 of the Application by submitting a copy of the Radiation Safety Program and by providing a list (Title and Number) of each specific Operating Procedure that will be used. A copy of each Operating Procedure must be provided to the Department, as specifically requested in other Paragraphs of this Licensing Guide.**

**23. EMERGENCY PROCEDURES**

Emergency procedures must be developed and implemented to manage an emergency, or abnormal event, involving radioactive material or devices containing radioactive material (e.g., remote afterloader unit). An example of an emergency is the radioactive source has failed to return to the safe position in the device, or a major spill of radioactive material. Since it is not possible to specify all possible situations that would constitute an emergency, general emergency procedures are acceptable. The procedures must describe the licensee’s actions to minimize radiation dose during and after an event. Additional procedures and instructions such as posting the restricted area, maintaining surveillance of the area, and notifying the Radiation Safety Officer and the Department must also be included.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

Appendix Q, “Emergency Procedures” contains guidance on the topics that must be included in the emergency procedures. The Appendix also contains some example emergency procedures that may be used by the Applicant to prepare procedures to guide the emergency response to various emergencies or events involving radioactive material

**Complete Item 23 of the Application by providing a list (Title and Number) of each specific Emergency Procedure that will be used when responding to an event. A copy of each Emergency Procedure must be provided to the Department.**

## 24. ADMINISTRATIVE PROCEDURES

The Licensee is responsible for documenting, recording, and maintaining records of radiation safety activities, as well as informing/notifying employees of matters pertaining to radiation safety, as specified in the Rules and Regulations for Control of Sources of Ionizing Radiation.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

Appendix R, “Administrative Requirements” provides a summary listing of personnel, recordkeeping, and reporting requirements in the Rules and Regulations which must be included in the Radiation Safety Program and Operating Procedures.

**Complete Item 24 of the Application by providing a list (Title and Number) of each specific Administrative Procedure that will be used in the Radiation Safety Program. A copy of each Administrative Procedure must be provided to the Department.**

## 25. MANAGEMENT CONTROL

**Licensee management is responsible for insuring that the Radiation Safety Program and the ALARA Program are implemented and maintained.**

**Management** refers to “the Chief Executive Officer or other individual having the authority to **manage, direct, or administer the licensee’s activities** or that person’s delegate or delegates” (see RH-8100).

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

Management involvement in and support of the Radiation Safety Program is critical to the success of the program (see RH-8300).

Management must give the Radiation Safety Officer the necessary authority and responsibility and must provide the necessary resources to implement the Radiation Safety Program and must appropriately support his actions. The Radiation Safety Officer must be afforded the necessary time in the work period to perform the assigned duties of the Radiation Safety Officer.

To ensure adequate management involvement in accordance with RH-8010 and RH-8300, a management representative (i.e., Chief Executive Officer or delegate) must sign the submitted application acknowledging management commitments to and responsibility for the following:

- Radiation protection, security, and control of radioactive materials, and compliance with regulations;

- Completeness and accuracy of the radiation protection records and all information provided to Department;
- Knowledge about the contents of the license application;
- Compliance with current Department and United States Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures;
- Provision of adequate financial and other resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that patients, the public, and workers are protected from radiation hazards;
- Appointment of a qualified individual who has agreed in writing to work as the RSO;
- Approval of qualified individual(s) to serve as Authorized Medical Physicists (AMPs), Authorized Nuclear Pharmacists (ANPs), and Authorized Users (AUs) for licensed activities.

**Submit a corporate organizational chart showing to whom the Radiation Safety Officer reports radiation safety issues. Confirm that Management has granted the Radiation Safety Officer the necessary authority and responsibility for implementing the Radiation Safety Program, including the authority to stop potentially unsafe work involving radioactive material and that the Radiation Safety Officer has accepted this authority and responsibility. This confirmation may be provided by submitting a completed and signed "Delegation of Authority" Memorandum included in Appendix C-1.**

**Confirm that the annual review of the Radiation Safety Program, as required by the Rules and Regulations for Control of Sources of Ionizing Radiation, Paragraph RH-1004, "Radiation Protection Programs" will be performed and documented. Appendix S, "Radiation Safety Program Review" contains an example annual program review that is specific to medical use of radioactive material. The example review in Appendix S is acceptable to the Department. It should be noted that not all areas included in the example review may be applicable to every medical use licensee. Also, please confirm that the report of the findings of the review will be reviewed and approved by Senior Management.**

## 26. CERTIFICATE

The Application for a Radioactive Material License and the Radioactive Material License are legal documents. License applications and all correspondence must be signed by individuals who are authorized to make legally binding statements or act on behalf of the Applicant. This individual is the Certifying Official.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

**NOTE:** Each item of this application to which you commit will be reviewed during your program compliance inspections. You should be able to provide documentation to demonstrate compliance with the rules and regulations and the license.

**NOTE:** Please identify all other individuals in the Applicant's organization who may be authorized to sign documents for the Applicant/Licensee.

## IV. LICENSE AMENDMENTS

Licensees are required to conduct operations in accordance with applicable regulations and the statements, representations and procedures contained in the license application and supporting documents.

As required by RH-8011, the license must be amended if any changes are planned. **Submittal of an amendment request does not allow immediate implementation of proposed changes.**

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

Until the license has been amended to reflect approval of the change(s), the licensee must comply with the original terms and conditions of the license. Applications for license amendments may be filed in letter form. The request must be dated and signed by a certifying official, must identify the license by name and number, must be submitted in duplicate, and must clearly describe the nature of the changes, additions or deletions requested. References to previously submitted documents must be specific and identify the applicable information by date, page and paragraph. The Licensee must maintain a copy of the submitted and referenced documentation on file for inspection.

**NOTE:** To prevent the potential for identity theft, never submit documentation that lists individuals' social security numbers or birth dates.

**NOTE:** An Amendment fee of \$50 must accompany the amendment request. Processing of the amendment will not begin until the fee is received.

## V. LICENSE RENEWAL

A Radioactive Material License remains in effect for a specific period of time, typically five to seven years, unless some other action has been taken by the Department or the licensee. The expiration date is stated on the cover page of the Radioactive Material License or by subsequent license amendment. The Licensee is responsible for completing and sending an Application For Radioactive Material License to the Department prior to the expiration date of the license.

Section 9	Applicability
RH-8500	Y
RH-8530	Y
RH-8550	Y
RH-8600	Y
RH-8620	Y
RH-8630	Y
RH-8670	Y

An application for license renewal must be received by the Department at least 30 days prior to the expiration date. This filing will ensure that the license does not expire until final action has been taken on the application, as addressed in the Rules and Regulations for Control of Sources of Ionizing Radiation, Paragraph RH-411, "Renewal of Licenses". If the application is received less than 30 days before the expiration date, the facility or individual may be without a valid license when the license expires. Renewal applications must be filed using the Department's Application For Radioactive Material License.

Renewals require submittal of an entirely new application, completed as if it were an application for a new license, with complete and up-to-date information about the Applicant's radiation protection program, demonstrating compliance with all licensing and regulatory requirements in effect at the time of renewal. Renewal applications should be submitted without reference to documentation and information submitted previously.

## VI. LICENSE TERMINATION

Prior to license termination, the Licensee must properly dispose of all licensed radioactive material. A request to terminate the Radioactive Material License may be filed in letter form to the Department prior to the expiration date of the license.