

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.

NOTE:	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.

Radioactive Material	Chemical/Physical Form	Maximum Amount
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 (μCi), 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:

Radioactive Material	Chemical/Physical Form	Maximum Amount
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:

Radioactive Material	Chemical/Physical Form	Maximum Amount
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.

(*If possess sealed sources under RH-8404)

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 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 SDR 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 μCi (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 μCi (3.7 MBq) or less of beta-emitting or gamma-emitting material, or 10 μCi (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 use¹,
- 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.

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

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.**

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.

APPENDIX A

ALARA PROGRAM

I. THE ALARA PHILOSOPHY

The Rules and Regulations for Control of Sources of Ionizing Radiation, Paragraph RH-1004, “Radiation Protection Programs” requires the use, to the extent practical, of procedures and engineering controls based upon sound radiation protection principles to achieve occupational and public doses that are As Low As Reasonably Achievable (ALARA). The primary concept of the ALARA philosophy is that unnecessary exposure to radiation should be avoided, even though current occupational dose limits provide a very low risk of injury.

The objective is to reduce occupational radiation dose (both individual and collective) as far below regulatory limits as is reasonably achievable by means of good radiation protection planning and practice, as well as by a management commitment to policies that deter departures from good practices.

The three primary methods of minimizing exposure to radiation are: TIME, DISTANCE and SHIELDING. When working with sources of radiation, always minimize the TIME, maximize the DISTANCE, and make use of available SHIELDING to keep dose ALARA.

II. MANAGEMENT COMMITMENT

Management is committed to the ALARA philosophy of maintaining occupational and public radiation doses as low as reasonably achievable.

- A. All personnel using radioactive material will be made aware of our commitment to the ALARA philosophy and they will be instructed in the procedures necessary to keep their radiation dose as low as possible.
- B. The RSO will be delegated authority to ensure adherence to ALARA principles. Management will support the RSO in instances where this authority must be asserted.
- C. All reasonable modifications will be made to procedures, equipment and facilities to reduce radiation dose, unless the cost is considered to be unjustified. Management will be prepared to describe the reasons for not implementing modifications that have been recommended.

III. RADIATION SAFETY OFFICER RESPONSIBILITIES

- A. The RSO will emphasize the ALARA philosophy to workers, instruct personnel on current procedures and provide guidance on relevant changes to reduce radiation dose.
- B. The RSO will review dosimetry reports for all monitored personnel to determine if unnecessary dose is being received. The RSO will establish written investigational personnel dose limits and investigate within 30 days the cause of any personnel radiation dose greater than the established limit. If warranted, the RSO will take corrective actions to ensure that unnecessary exposures are halted and recurrence is prevented. A report of each investigation and the actions taken, if any, will be recorded and maintained for inspection purposes.

- C.** At least annually, the RSO will insure that a formal review of the radiation protection program's content and implementation, as required by Paragraph RH-1004, "Radiation Protection Programs" is performed. The review will include an evaluation of equipment, procedures, dosimetry records, inspection findings, and incidents. The RSO will assess trends in occupational exposures as an index of the program's success and determine if any modifications to the program are needed. A summary of the results of each annual review, including a description of actions proposed and taken (if any) will be documented by the RSO, discussed with management, and signed and dated by both. A report on each audit will be maintained on file for 3 years from the date of the review.
- D.** The RSO will provide written notifications of annual radiation dose to all monitored personnel as required by Paragraph RH-2804, "Notifications and Reports to Individuals", and will be available to respond to any questions regarding the dose reports.
- E.** Other typical duties of the RSO are described in Appendix C-2.

APPENDIX B

MEDICAL USE TRAINING AND EXPERIENCE

Documentation of Training and Experience to Identify Individuals on a License as Authorized User, Radiation Safety Officer, Authorized Nuclear Pharmacist, or Authorized Medical Physicist

Licensing Guidance for Using Department Form A Series of Forms

I. Experienced Authorized Users, Authorized Medical Physicists, Authorized Nuclear Pharmacists, or Radiation Safety Officer

An applicant or licensee that is adding an experienced authorized user, authorized medical physicist, authorized nuclear pharmacist, or Radiation Safety Officer to its medical use license only needs to provide evidence that the individual is listed on a medical use license issued by the Department, the U.S. Nuclear Regulatory Commission (NRC) or an Agreement State, a permit issued by a NRC master material licensee, a permit issued by a NRC or Agreement State broad scope licensee, or a permit issued by a NRC master material broad scope permittee, provided that the individual is authorized for the same types of use(s) requested in the application under review, and the individual meets the recentness of training criteria described in RH-8319. When adding an experienced authorized nuclear pharmacist to the license, the applicant also may provide evidence that the individual is listed on a Department, a NRC or Agreement State commercial nuclear pharmacy license or identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy authorized to identify authorized nuclear pharmacists. For individuals who have been previously authorized by, but not listed on, the commercial nuclear pharmacy license, medical broad scope license, or master materials license medical broad scope permit, the applicant should submit either verification of previous authorizations granted or evidence of acceptable training and experience.

II. Applications that Include Individuals for New Authorized User, Authorized Medical Physicist, Authorized Nuclear Pharmacist or Radiation Safety Officer Recognition by the Department

Applicants should submit the appropriate completed form in the Department Form A series to show that the individuals meet the correct training and experience criteria in Section 9. For the applicant's convenience, the Department Form A series is separated into six separate forms. The forms are Department Form A (RSO) for the Radiation

Safety Officer; Department Form A (AMP) for the authorized medical physicist; Department Form A (ANP) for the authorized nuclear pharmacist; Department Form A (AUD) for the authorized user of the medical uses included in RH-8500, RH-8530, and/or RH-8620; Department Form A (AUT) for the authorized user for the medical use included in RH-8550; and Department Form A (AUS) for the authorized user for the medical uses included in RH-8600 and/or RH-8630.

There are two primary training and experience routes to qualify an individual as an authorized user, authorized medical physicist, authorized nuclear pharmacist, or Radiation Safety Officer.

The first is by means of certification by a board recognized by Department and listed on the NRC website. Additional training may need to also be documented for Radiation Safety Officers, authorized medical physicists, and RH-8630 authorized users. The second route is by meeting the structured educational program, supervised work experience, and preceptor attestation requirements.

In some cases there may be additional training and experience routes for recognized authorized users, authorized nuclear pharmacists, authorized medical physicists or Radiation Safety Officers to seek additional authorizations.

III. Recentness of Training

The required training and experience, including board certification, described in Section 9 must be obtained within the 7 years preceding the date of the application, or the individual must document having had related continuing education, retraining, and experience since obtaining the required training and experience. Examples of acceptable continuing education and experience include the following:

1. Successful completion of classroom and laboratory review courses that include radiation safety practices relative to the proposed type of authorized medical use;
2. Practical and laboratory experience with patient procedures using radioactive material for the same use(s) for which the applicant is requesting authorization;
3. Practical and laboratory experience under the supervision of an Authorized User (AU) at the same or another licensed facility that is authorized for the same use(s) for which the applicant is requesting authorization; and
4. For therapy devices, experience with the therapy unit and/or comparable linear accelerator experience and completion of an in-service review of operating and emergency procedures relative to the therapy unit to be used by the applicant.

IV. General Instructions and Guidance for Filling Out Department Form A Series

If the applicant is proposing an individual for more than one type of authorization, the applicant may need to either submit multiple Department Form A series forms or fill out some sections more than once. For example, an applicant that requests a physician be authorized for RH-8530 and RH-8550 medical uses and as the RSO, needs to provide three completed Department Form A series forms, i.e., Department Form A (RSO), Department Form A (AUD) and Department Form A (AUT).

Also, if the applicant requests a physician be authorized for both high dose rate remote afterloading and gamma stereotactic radiosurgery under RH-8630, only one form, Department Form A (AUS) needs to be completed, but one part (i.e., “Supervised Work and Clinical Experience”) must be filled out twice.

If you need to identify a license and it is an Agreement State license, provide a copy of the license. If you need to identify a NRC Master Materials License permit, provide a copy of the permit. If you need to identify an individual (i.e., supervising individual or preceptor) who is authorized under a broad scope license or broad scope permit of a NRC Master Materials License, provide a copy of the permit issued by the broad scope licensee/permittee. Alternatively, you may provide a statement signed by the Radiation Safety Officer or chairperson of the Radiation Safety Committee similar to the following: “_____ (name of supervising individual or preceptor) is authorized under _____ (name of licensee/permittee) broad scope license number _____ to use _____ (materials) during _____ (time frame)”.

INTRODUCTORY INFORMATION

Name of individual

Provide the individual’s complete name so that the Department can distinguish the training and experience received from that received by others with a similar name.

NOTE: Do not include personal or private information (e.g., date of birth, social security number, home address, personal phone number) as part of your qualification documentation.

The Department requires physicians, dentists, podiatrists, and pharmacists to be licensed in the State of Arkansas to prescribe drugs in the practice of medicine, practice of dentistry, practice of podiatry, or practice of pharmacy, respectively (see definitions in RH-8100). Submit a copy of the current Arkansas license.

Requested Authorization(s)

Check all authorizations that apply and fill in the blanks as provided.

Part I. Training and Experience

There are always multiple pathways provided for each training and experience section. Select the applicable one.

Item 1. Board Certification

The applicant or licensee may use this pathway if the proposed new authorized individual is certified by a board recognized by Department (The Department recognizes Board certifications recognized by the NRC. To confirm that Department recognizes specific Board certifications, see the NRC web page <http://www.nrc.gov/materials/miau/med-use-toolkit.html>).

<p>NOTE: An individual that is board eligible will not be considered for this pathway until the individual is actually board certified. Further, individuals holding other board certifications will also not be considered for this pathway.</p>
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The applicant or licensee will need to provide a copy of the board certification and other training, experience, or clinical casework as indicated on the specific form of the Department Form A series.

All applicants under this pathway (except for RH-8620 uses) must submit a completed Part II Preceptor Attestation.

Item 2. Current Authorized Individuals Seeking Additional Authorizations

Provide the information requested for training, experience, or clinical casework as indicated on the specific form of the Department Form A series. (**Note:** This section does not include individuals who are authorized only on foreign licenses.)

All applicants under this pathway must submit a completed Part II Preceptor Attestation.

Item 3. Training and Experience for Proposed New Authorized Individuals

This pathway is used for those individuals not listed on the license as an authorized individual, who cannot meet requirements for the board certification pathway.

The proposed authorized individual is not required to receive the classroom and laboratory training, supervised work experience, or clinical casework at any one location or at one time, therefore space is provided to identify each location and date of training or experience. The date should be provided in the month/day/year format. The clock hours must be indicated for those individuals that must meet a minimum number of training and work experience hours. The specific number of hours needed for each training element will depend upon the type of approval sought.

NOTE: Classroom and Laboratory Training or Didactic Training may be provided at medical teaching/university institutions. In some cases, a course may be provided for that particular need and taught in consecutive days; in others, the period may be a semester or quarter as part of the formal curriculum. The required “structural educational programs” or “training” may be obtained in any number of settings, locations, and educational situations.

The Department expects that clinical laboratory hours credited toward meeting the requirements for classroom and laboratory training will involve training in radiation safety aspects of the medical use of radioactive material. The Department recognizes, for example, that physicians in training may not dedicate all of their clinical laboratory time specifically to the subject areas covered in these subparts and will be attending to other clinical matters involving the medical use of the material under the supervision of an AU (e.g., reviewing case histories or interpreting scans). However, those hours spent on other duties, not related to radiation safety, should not be counted toward the minimum number of hours of required classroom and laboratory training in radiation safety. This type of supervised work experience, even though not specifically required by the Department, may be counted toward the supervised work experience to obtain the required total hours of training.

Similarly, the Department recognizes that clinicians will not dedicate all of their time in training specifically to the subject areas described and will be attending to other clinical matters. The Department will broadly interpret “classroom training” to include various types of instruction received by candidates for approval, including online training, as long as the subject matter relates to radiation safety and safe handling of radioactive material.

NOTE: If the proposed new authorized individual had more than one supervisor, provide the information requested for each supervising individual.

Part II. Preceptor Attestation

The Department defines the term “preceptor” in RH-8100.aa, “Definitions,” to mean “an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.” While the supervising individual for the work experience may also be the preceptor, the preceptor does not have to be the supervising individual as long as the preceptor directs or verifies the training and experience required. The preceptor must attest in writing regarding the training and experience of any individual to serve as an authorized individual and attest that the individual has satisfactorily completed the appropriate training and experience criteria and has achieved a level of competency or a level of radiation safety knowledge

sufficient to function independently. This preceptor also has to meet specific requirements.

The Department may require supervised work experience conducted under the supervision of an authorized individual in a licensed material use program. In this case, a supervisor is an individual who provides frequent direction, instruction, and direct oversight of the student as the student completes the required work experience in the use of radioactive material.

Supervision may occur at various licensed facilities, from a large teaching university hospital to a small private practice.

The Department Form A series Part II - Preceptor Attestation pages have multiple sections. The preceptor must complete an attestation of the proposed user's training, experience, and competency to function independently, as well as provide information concerning his/her own qualifications and sign the attestation. Because there are a number of different pathways to obtain the required training and experience for different authorized individuals, specific instructions are provided below for each Department Form A series form.

V. RADIATION SAFETY OFFICER - Specific Instructions and Guidance for completing Department Form A (RSO)

See Section IV. "General Instructions and Guidance for Filling out Department Form A Series" for additional clarification on providing information about an individual's status on a Department license, an Agreement State license, a medical broad scope license, or a NRC Master Materials License permit.

Part I. Training and Experience - select one of four methods below:

Item 1. Board Certification

Provide the requested information, i.e., a copy of the board certification, documentation of specific radiation safety training for all types of use on the license, and completed preceptor attestation. As indicated on the Form, additional information is needed if the board certification or radiation safety training was greater than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by a Radiation Safety Officer, an authorized medical physicist, authorized nuclear pharmacist, or authorized user who is authorized for that type of use. The applicant only has to identify the supervising individual in the table in 3.c and his/her qualifications if the source of this training was a Radiation Safety Officer, an authorized medical physicist, authorized nuclear pharmacist, or authorized user. If more than one supervising individual provided the training, identify each supervising individual by name and provide their qualifications.

Item 2. Current Radiation Safety Officer Seeking Authorization to be Recognized as a Radiation Safety Officer for the Additional Medical Use(s) Checked Above.

Provide the requested information, i.e., documentation of specific radiation safety training (complete the table in 3.c) and completed preceptor attestation in Part II. As indicated on the Form, additional information is needed if the specific radiation safety training was greater than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by a Radiation Safety Officer, an authorized medical physicist, authorized nuclear pharmacist, or authorized user who is authorized for that type of use. The applicant only has to identify the supervising individual in the table in 3.c and his/her qualifications if the source of this training was a Radiation Safety Officer, an authorized medical physicist, authorized nuclear pharmacist, or authorized user. If more than one supervising individual provided the training, identify each supervising individual by name and provide their qualifications.

Item 3. Structured Educational Program for Proposed New Radiation Safety Officer

As indicated on the form, additional information is needed if the training, supervised radiation safety experience, and specific radiation safety training was completed more than 7 years ago.

Submit a completed section 3.a.

Submit a completed section 3.b. The individual must have completed one year of full-time radiation safety experience under the supervision of a Radiation Safety Officer. This is documented in section 3.b by providing the ranges of dates for supervised radiation safety experience. If there was more than one supervising individual, identify each supervising individual by name and provide their qualifications.

Provide the requested information, i.e., documentation of specific radiation safety training for each use on the license (complete the table in 3.c). Specific radiation safety training for each type of use on the license may be supervised by a Radiation Safety Officer, an authorized medical physicist, authorized nuclear pharmacist, or authorized user who is authorized for that type of use. The applicant only has to identify the supervising individual in the table in 3.c and his/her qualifications if the source of this training was a Radiation Safety Officer, an authorized medical physicist, authorized nuclear pharmacist, or authorized user. If more than one supervising individual provided the training, identify each supervising individual by name and provide their qualifications.

Submit a completed preceptor attestation in Part II.

Item 4. Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist Identified on the Licensee’s License

Provide the requested information, i.e., the license number and documentation of specific radiation safety training for each use on the license (complete the table in 3.c). As indicated on the Form, additional information is needed if the specific radiation safety training was greater than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by a Radiation Safety Officer, an authorized medical physicist, authorized nuclear pharmacist, or authorized user who is authorized for that type of use. If more than one supervising individual provided the training, identify each supervising individual by name and provide their qualifications.

Part II. Preceptor Attestation

The Preceptor Attestation page has four sections.

- The attestation to the new proposed Radiation Safety Officer’s training or identification on the license as an authorized user, authorized medical physicist, or authorized nuclear pharmacist is in the first section.
- The attestation for the specific radiation safety training is in the second section.
- The attestation of the individual’s competency to function independently as a Radiation Safety Officer for a medical use license is in the third section.
- The fourth and final section requests specific information about the preceptor’s authorization as a Radiation Safety Officer on a medical use license in addition to the preceptor’s signature.

The preceptor for a new proposed Radiation Safety Officer must fill out all four sections of this page.

The preceptor for a Radiation Safety Officer seeking authorization to be recognized as a Radiation Safety Officer for the additional medical use(s) must fill out the second, third, and fourth sections.

VI. AUTHORIZED MEDICAL PHYSICIST - Specific Instructions and Guidance for completing Department Form A (AMP)

See Section IV. “General Instructions and Guidance for Filling out Department Form A Series” for additional clarification on providing information about an individual’s status on a Department license, an Agreement State license, a medical broad scope license, or a NRC Master Materials License permit.

Part I. Training and Experience - select one of the three methods below**Item 1. Board Certification**

Provide the requested information, i.e., a copy of the board certification, documentation of device specific training in the table in 3.c, and completed preceptor attestation. As indicated on the Form, additional information is needed if the board certification or device specific training was greater than 7 years ago.

Device specific training may be provided by the vendor, or a supervising medical physicist authorized for the requested type of use. The applicant only has to identify the supervising medical physicist in the table in 3.c and his/her qualifications if this was the source of training. If more than one supervising individual provided the training, identify each supervising individual by name and provide their qualifications.

Item 2. Current Authorized Medical Physicist Seeking Additional Uses(s) Checked Above

Provide the requested information, i.e., documentation of device specific training (complete the table in 3.c) and completed preceptor attestation in Part II. As indicated on the form, additional information is needed if the device specific training was greater than 7 years ago.

Device specific training may be provided by the vendor, or a supervising medical physicist authorized for the requested type of use. The applicant only has to identify the supervising medical physicist in the table in 3.c and his/her qualifications if this was the source of training. If more than one supervising medical physicist provided the training identify each supervising individual by name and provide their qualifications.

Item 3. Training and Experience for Proposed Authorized Medical Physicist

As indicated on the Form, additional information is needed if the degree, training and/or work experience was completed more than 7 years ago.

Submit a completed section 3.a. Submit documentation of your graduate degree, for example, a copy of your diploma or transcript from an accredited college or university.

Submit a completed section 3.b. The individual must have completed one year of full time training in medical physics and an additional year of full time work experience which cannot be concurrent. This is documented in 3.b by providing the ranges of dates for training and work experience.

If the proposed authorized medical physicist had more than one supervisor, provide the

information requested in section 3.b for each supervising individual. If the supervising individual is not an authorized medical physicist, the applicant must provide documentation that the supervising individual meets the requirements in RH-8316 and RH-8319.

Submit a completed section 3.c for each specific device for which the applicant is requesting authorization.

Device specific training may be provided by the vendor, or a supervising medical physicist authorized for the requested type of use. The applicant only has to identify the supervising medical physicist in the table in 3.c and his/her qualifications if this was the source of training. If more than one supervising medical physicist provided the training, identify each supervising individual by name and provide their qualifications.

Submit a completed preceptor attestation in Part II.

Part II. Preceptor Attestation

The Preceptor Attestation page has four sections.

- The attestation to the proposed authorized medical physicist’s training is in the first section.
- The attestation for the device specific training is in the second section.
- The attestation of the individual’s competency to function independently as an authorized medical physicist for the specific devices requested by the applicant is in the third section.
- The fourth and final section requests specific information about the preceptor’s authorizations to use licensed material in addition to the preceptor’s signature.

The preceptor for a proposed new authorized medical physicist must fill out all four sections of this page. The preceptor for an authorized medical physicist seeking additional authorizations must complete the last three sections.

VII. AUTHORIZED NUCLEAR PHARMACIST -Specific Instructions and Guidance for completing Department Form A (ANP)

See Section IV. “General Instructions and Guidance for Filling out Department Form A Series” for additional clarification on providing information about an individual’s status on a Department license, an Agreement State license, a medical broad scope license, or a NRC Master Materials License permit.

Part I. Training and Experience - select one of the two methods below

Item 1. Board Certification

Provide the requested information, i.e., a copy of the board certification and completed preceptor attestation. As indicated on the form, additional information is needed if the board certification was greater than 7 years ago.

Item 2. Structured Educational Program for a Proposed Authorized Nuclear Pharmacist

As indicated on the form, additional information is needed if the training and/or supervised practical experience was completed more than 7 years ago.

Submit completed sections 2.a and 2.b. If the proposed new nuclear pharmacist had more than one supervisor, provide the name of each supervising individual in section 2.b. Submit a completed preceptor attestation.

Part II. Preceptor Attestation

The Preceptor Attestation page has two sections. The preceptor must select either the board certification or the structured educational program when filling out the first section on this page.

The second and final section of the page requests specific information about the preceptor's authorization to use licensed material in addition to the preceptor's signature.

**VIII. RH-8500, RH-8530, AND RH-8620 AUTHORIZED USERS –
Specific Instructions and Guidance for completing Department
Form A (AUD)**

See Section IV. "General Instructions and Guidance for Filling out Department Form A Series" for additional clarification on providing information about an individual's status on a Department license, an Agreement State license, a medical broad scope license, or a NRC Master Materials License permit.

Part I. Training and Experience - select one of the three methods below

Item 1. Board Certification

Provide the requested information, i.e., a copy of the board certification and completed preceptor attestation. As indicated on the form, additional information is needed if the board certification was greater than 7 years ago.

Item 2. Current RH-8560 Authorized User Seeking Additional RH-8540 Authorization

- (a) Fill in the blank in section 2.a with the current license number on which the proposed user is listed.
- (b) Provide a description of the proposed user's experience that meets the requirements of RH-8540.b, as shown in the table in 2.b. As indicated on the form, additional information is needed if this experience was obtained more than 7 years ago.

List each supervising individual by name and include the license showing the supervising individual as an authorized user.

Item 3. Training and Experience for Proposed Authorized Users

As indicated on the form, additional information is needed if the training and/or work experience was completed more than 7 years ago.

NOTE: Providing the training and experience information required under RH-8540 will allow the individual to be authorized to use materials permitted by both RH-8500 and RH-8530.

Submit a completed section 3.a for each proposed authorized use.

Submit a completed section 3.b, except for RH-8620 uses. If the proposed user had more than one supervisor, provide the information requested in section 3.b for each supervising individual.

Submit a completed section 3.c for RH-8620 uses.

Submit a completed preceptor attestation, except for RH-8620 uses.

Part II. Preceptor Attestation

The Preceptor Attestation page has two sections.

The attestations for training and experience requirements in RH-8510 and RH-8540 are found in the first section.

The second and final section requests specific information about the preceptor's authorization(s) to use licensed material in addition to the preceptor's signature.

The preceptor must fill out both sections.

NOTE:	The attestation to the proposed user's training and competency to function independently under RH-8510 covers the use of material permitted by RH-8500 only. The attestation to the proposed user's training and competency to function independently under RH-8540 training will allow the individual to be authorized to use material permitted by both RH-8500 and RH-8530.
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IX. RH-8550 AUTHORIZED USER - Specific Instructions and Guidance for completing Department Form A (AUT)

See Section IV. "General Instructions and Guidance for Filling out Department Form A Series" for additional clarification on providing information about an individual's status on a Department license, an Agreement State license, a medical broad scope license, or a NRC Master Materials License permit.

Part I. Training and Experience - select one of the three methods below

Item 1. Board Certification

If you are a nuclear medicine physician, radiologist, or radiation oncologist with a board certification listed under RH-8550 (or on the NRC website), provide the requested information, i.e., a copy of the board certification, documentation of supervised clinical experience (complete the table in section 3.c), and completed preceptor attestation. As indicated on the form, additional information is needed if the board certification or supervised clinical experience was greater than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an authorized user.

If you are a radiation oncologist whose board certification is not listed under RH-8550 (or on the NRC website), provide the requested information [i.e., a copy of the board certification listed under either RH-8600 or RH-8630 or on the NRC website; documentation of training and supervised work experience with unsealed materials requiring a written directive (complete the tables in sections 3.a and 3.b); documentation of supervised clinical experience (complete the table in section 3.c); and completed preceptor attestation]. As indicated on the form, additional information is needed if the board certification, training and supervised work experience or clinical experience was greater than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an authorized user.

Item 2. Current RH-8550, RH-8600, or RH-8630 Authorized User Seeking Additional Authorization

Submit a completed section 2.a, listing the license number and the user's current authorizations.

If you are currently authorized for a subset of clinical uses under RH-8550, submit the requested information, i.e., complete the table in section 3.c to document your new supervised clinical case experience and the completed preceptor attestation. As indicated on the form, additional information is needed if the clinical case experience was greater than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an authorized user.

If you are currently authorized under RH-8610 or RH-8660 and meet the requirements in RH-8590, submit the requested information, i.e., documentation of training and supervised work experience with unsealed materials requiring a written directive (complete the tables in sections 3.a and 3.b); documentation of supervised clinical experience (complete the table in section 3.c); and completed preceptor attestation). As indicated on the form, additional information is needed if the training and supervised work experience or clinical experience was greater than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an authorized user.

Item 3. Training and Experience for Proposed Authorized Users

As indicated on the form, additional information is needed if the degree, training and/or work experience was completed more than 7 years ago.

Submit a completed section 3.a.

Submit a completed section 3.b. List each supervising individual by name and include the license number showing the supervising individual as an authorized user.

Submit a completed section 3.c for each requested authorization. List each supervising individual by name and include the license number showing the supervising individual as an authorized user.

Submit a completed preceptor attestation in Part II.

Part II. Preceptor Attestation

The Preceptor Attestation page has five sections.

The attestations for training and experience requirements in RH-8560, RH-8570, and RH-8580 are in the first section.

The attestation for supervised clinical experience is in the second section.

The attestations for competency to function independently as an authorized user for specific uses is in the third section.

The attestation for training and experience requirements and competency to function independently for radiation oncologist meeting the requirements in RH-8590 is in the fourth section.

The fifth and final section requests specific information about the preceptor's authorization(s) to use licensed material in addition to the preceptor's signature.

There are seven possible categories of individuals seeking authorized user status under this Form. Follow the instructions for the applicable category.

The preceptor for a proposed authorized user who is a nuclear medicine physician, radiologist, or radiation oncologist with a board certification listed under RH-8560 on NRC's website must complete the first, second, third, and fifth sections of this part.

The preceptor for a proposed authorized user for all the uses listed in RH-8560.b.2, who is a radiation oncologist with a board certification that is not listed under RH-8560 (or on the NRC website) must complete the first, second, third, and fifth sections of this part.

The preceptor for a proposed authorized user for RH-8560.b.2 uses who is a radiation oncologist with a board certification listed under RH-8610 or RH-8660 (or on NRC website) must complete the fourth and fifth sections of this part.

The preceptor for an authorized user who is currently authorized for a subset of clinical uses under RH-8550 must complete the second, third, and fifth sections of this part, except for an authorized user meeting the criteria in RH-8570 seeking to meet the training and experience requirements under RH-8580.

The preceptor for an authorized user meeting the criteria in RH-8570 seeking to meet the training and experience requirements under RH-8580 must complete the first, second, third, and fifth sections of this part.

The preceptor for an authorized user currently authorized under RH-8610 or RH-8660 and meeting the requirements in RH-8590 must complete the fourth, and fifth sections of this part.

The preceptor for a proposed new authorized user must complete the first, second, third and fifth sections of this part.

X. RH-8600 and RH-8630 AUTHORIZED USER - Specific Instructions and Guidance for completing Department Form A (AUS)

See Section IV. “General Instructions and Guidance for Filling out Department Form A Series” for additional clarification on providing information about an individual’s status on a Department license, an Agreement State license, a medical broad scope license, or a NRC Master Materials License permit.

Part I. Training and Experience - select one of the three methods below

Item 1. Board Certification

Provide the requested information, i.e., a copy of the board certification, for RH-8630 uses documentation of device specific training in the table in 3.e, and for all uses a completed preceptor attestation. As indicated on the form, additional information is needed if the board certification or device specific training was greater than 7 years ago.

Device specific training may be provided by the vendor for new users, or either a supervising authorized user or authorized medical physicist authorized for the requested type of use. The applicant only has to identify the supervising authorized user or authorized medical physicist in the table in 3.e and his/her qualifications if this was the source of training. If more than one supervising individual provided the training, identify each supervising individual by name and provide their qualifications.

Item 2. Current RH-8630 Authorized User requesting Additional Authorization for RH-8630 Use(s) Checked Above

Provide the requested information, i.e., documentation of device specific training (complete the table in 3.e) and completed preceptor attestation in Part II. As indicated on the form, additional information is needed if the device specific training was greater than 7 years ago.

Device specific training may be provided by the vendor, or a supervising authorized user or authorized medical physicist authorized for the requested type of use. The applicant only has to identify the supervising authorized user or authorized medical physicist in the table in 3.e and his/her qualifications if this was the source of training. If more than one supervising individual provided the training, identify each supervising individual by name and provide their qualifications.

Item 3. Training and Experience for Proposed Authorized User

As indicated on the form, additional information is needed if the training, residency program, supervised work and clinical experience was completed more than 7 years ago.

Submit a completed section 3.a for each requested use.

Submit a completed section 3.b if applying for RH-8600 uses. However, section 3.b does not have to be completed when only applying for use of strontium-90 for ophthalmic use. If more than one supervising authorized user provided the supervised work and clinical experience identify each supervising individual by name and provide their qualifications.

Submit a completed section 3.c if only applying for use of strontium-90 for ophthalmic use. If more than one supervising authorized user provided the supervised clinical experience identify each supervising individual by name and provide their qualifications. Submit a completed section 3.d for each requested RH-8630 use. If more than one supervising authorized user provided the supervised work and clinical experience, identify each supervising individual by name and provide their qualifications.

Submit a completed section 3.e for each specific RH-8630 device for which the applicant is requesting authorization.

Device specific training may be provided by the vendor, or a supervising authorized user or authorized medical physicist authorized for the requested type of use. The applicant only has to identify the supervising authorized user or authorized medical physicist in the table in 3.e and his/her qualifications if this was the source of training. If more than one supervising individual provided the training, identify each supervising individual by name and provide their qualifications.

Submit a completed preceptor attestation in Part II.

Part II. Preceptor Attestation

The Preceptor Attestation part has five sections.

- The attestation to the training and individuals competency for RH-8600 uses or strontium 90 eye applicator use is in the first section.
- The attestation to the training for the proposed authorized user for RH-8630 uses is in the second section.
- The attestation for the RH-8630 device specific training is in the third section.
- The attestation of the individual's competency to function independently as an authorized user for the specific RH-8630 devices requested by the applicant is in the fourth section.
- The fifth and final section requests specific information about the preceptor's authorization(s) to use licensed material in addition to the preceptor's signature.

The preceptor for a RH-8600 proposed authorized user must fill out the first and fifth sections of this Part.

The preceptor for a RH-8630 proposed authorized user must fill out the second, third, fourth and fifth sections.

The preceptor for an authorized user seeking additional RH-8630 authorizations must complete the third, fourth, and fifth sections.

**AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION
[RH-8316]**

Name of Proposed Authorized Medical Physicist

- Requested Authorization(s) (check all that apply)**
- RH-8600 Ophthalmic use of strontium-90 RH-8630 Teletherapy unit(s)
 RH-8630 Remote afterloader unit(s) RH-8630 Gamma stereotactic radiosurgery unit(s)

**PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)**

*Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

- 1. Board Certification**
- a. Provide a copy of the board certification.
- b. Go to the table in 3.c. and describe training provider and dates of training for each type of use for which authorization is sought.
- c. Skip to and complete Part II Preceptor Attestation.
- 2. Current Authorized Medical Physicist Seeking Additional Authorization for use(s) checked above**
- a. Go to the table in section 3.c. to document training for new device.
- b. Skip to and complete Part II Preceptor Attestation
- 3. Education, Training, and Experience for Proposed Authorized Medical Physicist**
- a. Education: Document master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university.

Degree	Major Field
College or University	

- b. Supervised Full-Time Medical Physics Training and Work Experience in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.
- Yes. Completed 1 year of full-time training in medical physics (for areas identified below) under the supervision of _____ who meets the requirements for an Authorized Medical Physicist.

AND

- Yes. Completed 1 year of full-time work experience in medical physics (for areas identified below) under the supervision of _____ who meets the requirements for an Authorized Medical Physicist.

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Education, Training, and Experience for Proposed Authorized Medical Physicist (continued)

b. Supervised Full-Time Medical Physics Training and Work Experience (continued)

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Description of Training/ Experience	Location of Training/License or Permit Number of Training Facility/Medical Devices Used+	Dates of Training*	Dates of Work Experience*
Medical Physics			
Performing sealed source leak tests and inventories			
Performing decay corrections			
Performing full calibration and periodic spot checks of external beam treatment unit(s)			
Performing full calibration and periodic spot checks of stereotactic radiosurgery unit(s)			
Performing full calibration and periodic spot checks of remote afterloading unit(s)			
Conducting radiation surveys around external beam treatment unit(s), stereotactic radiosurgery unit(s), remote after loading unit(s)			

Supervising Individual** _____ License/Permit Number listing supervising individual as an authorized Medical Physicist _____

for the following types of use:

- Remote afterloader unit(s)
 Teletherapy unit(s)
 Gamma stereotactic radiosurgery unit(s)

+ Training and work experience must be conducted in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.

* 1 year of Full-time medical physics training and 1 year of full time work experience cannot be concurrent.

** If the supervising medical physicist is not an authorized medical physicist, the licensee must submit evidence that the supervising medical physicist meets the training and experience requirements in RH-8316 and RH-8319 for the types of use for which the individual is seeking authorization.

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Education, Training, and Experience for Proposed Authorized Medical Physicist (continued)

c. Describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Hands-on device operation			
Safety procedures for the device use			
Clinical use of the device			
Treatment planning system operation			

Supervising Individual _____ License/Permit Number listing supervising individual as an authorized Medical Physicist _____
If training is provided by Supervising Medical Physicist, (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)

for the following types of use:

- Remote afterloader unit(s)
 Teletherapy unit(s)
 Gamma stereotactic radiosurgery unit(s)

If Applicable:

Authorization Sought	Device	Training Provided By	Dates of Training
RH-8600 Ophthalmic Use of strontium-90			

d. Skip to and complete Part II Preceptor Attestation.

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section

Check one of the following:

1. **Board Certification**

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized Medical Physicist
 RH-8316.

OR

2. **Education, Training, and Experience**

I attest that _____ has satisfactorily completed the 1-year of full-time
Name of Proposed Authorized Medical Physicist
 training in medical physics and an additional year of full-time work experience as required by RH-8316.

AND

Second Section

Complete the following:

I attest that _____ has training for the types of use for which authorization
Name of Proposed Authorized Medical Physicist
 is sought that include hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system.

AND

Third Section

Complete the following:

I attest that _____ has achieved a level of competency sufficient to
Name of Proposed Authorized Medical Physicist
 function independently as an Authorized Medical Physicist for the following:

- RH-8600 Ophthalmic use of strontium-90 RH-8630 Teletherapy unit(s)
 RH-8630 Remote afterloader unit(s) RH-8630 Gamma stereotactic radiosurgery unit(s)

AND

Fourth Section

Complete the following for preceptor attestation and signature:

I meet the requirements in RH-8316, or equivalent U.S. NRC or Agreement State requirements for Authorized Medical Physicist for the following:
 RH-8600 Ophthalmic use of strontium-90 RH-8630 Teletherapy unit(s)
 RH-8630 Remote afterloader unit(s) RH-8630 Gamma stereotactic radiosurgery unit(s)

Name of Preceptor	Signature	Telephone Number	Date
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License/Permit Number/Facility Name

AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [RH-8317]

Name of Proposed Authorized Nuclear Pharmacist

PART I -- TRAINING AND EXPERIENCE *(Select one of the two methods below)*

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the nuclear pharmacy uses.

1. Board Certification

- a. Provide a copy of the board certification.
- b. Skip to and complete Part II Preceptor Attestation.

2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist

- a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of radioactive material for medical use			
Radiation biology			
Total Hours of Training:			

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION (continued)**

2. Structured Educational Program for Proposed Authorized Nuclear Pharmacist (continued)

b. Supervised Practical Experience in a Nuclear Pharmacy.

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Shipping, receiving, and performing related radiation surveys			
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides			
Calculating, assaying, and safely preparing dosages for patients or human research subjects			
Using administrative controls to avoid medical events in administration of radioactive material			
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures			
Total Hours of Experience:			
Supervising Individual			

c. Go to and complete Part II Preceptor Attestation.

**AUTHORIZED NUCLEAR PHARMACIST TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION (continued)**

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section

Check one of the following:

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized Nuclear Pharmacist

RH-8317 and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

OR

Structured Educational Program

I attest that _____ has satisfactorily completed a 700-hour structured
Name of Proposed Authorized Nuclear Pharmacist

educational program consisting of both 200 hours of classroom and laboratory training, and practical experience in nuclear pharmacy, as required by RH-8317 and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Second Section

Complete the following for preceptor attestation and signature:

I am an Authorized Nuclear Pharmacist for _____ ,
Nuclear Pharmacy or Medical Facility

License/Permit Number

Name of Preceptor	Signature	Telephone Number	Date
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**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under RH-8500, RH-8530, and RH-8620)
[RH-8510, RH-8540, and RH-8621]

Name of Proposed Authorized User

Requested Authorization(s) *(check all that apply)*

- RH-8500 Uptake, dilution, and excretion studies
- RH-8530 Imaging and localization studies
- RH-8620 Sealed sources for diagnosis (specify device _____)

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

- 1. Board Certification**
 - a. Provide a copy of the board certification.
 - b. If using only RH-8620 materials, stop here. If using RH-8500 and RH-8530 materials, skip to and complete Part II Preceptor Attestation.
- 2. Current RH-8560 Authorized User Seeking Additional RH-8540 Authorization**
 - a. Authorized user on Materials License _____ meeting RH-8560 or equivalent U.S. NRC or Agreement State requirements seeking authorization for RH-8540.
 - b. Supervised Work Experience .
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			

Total Hours of Experience:

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
------------------------	--

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check all that apply)*.

- RH-8540 RH-8560 + generator experience in RH-8540

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

 3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of radioactive material for medical use <i>(not required for RH-8621)</i>			
Radiation biology			
Total Hours of Training:			

b. Supervised Work Experience (completion of this table is not required for RH-8621).

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys			
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters			
Calculating, measuring, and safely preparing patient or human research subject dosages			

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience. (continued)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Using administrative controls to prevent a medical event involving the use of unsealed radioactive material			
Using procedures to contain spilled radioactive material safely and using proper decontamination procedures			
Administering dosages of radioactive drugs to patients or human research subjects			
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			

Total Hours of Experience:

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
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Supervisor meets the requirements below, or equivalent Agreement State requirements (*check one*).

- RH-8510
 RH-8540
 RH-8560
 RH-8560 + generator experience in RH-8540

c. For RH-8621 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

d. For RH-8620 uses only, stop here. For RH-8500 and RH-8530 uses, skip to and complete Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in RH-8621)

First Section

Check one of the following for each use requested:

For RH-8510

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

RH-8510 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RH-8500.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by RH-8510, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RH-8500.

For RH-8540

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

RH-8540 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RH-8500 and RH-8530.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User

and experience, including a minimum of 80 hours of classroom and laboratory training, required by RH-8540, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under RH-8500 and RH-8530.

Second Section

Complete the following for preceptor attestation and signature:

I meet the requirements below, or equivalent U.S. NRC or Agreement State requirements, as an authorized user for:

- RH-8510 RH-8540 RH-8560 RH-8560 + generator experience

Name of Preceptor	Signature	Telephone Number	Date
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License/Permit Number/Facility Name

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under RH-8600 and RH-8630)
[RH-8610, RH-8615, and RH-8660]

Name of Proposed Authorized User

- Requested Authorization(s)**
(check all that apply)
- RH-8600 Manual brachytherapy sources RH-8630 Teletherapy unit(s)
- RH-8600 Ophthalmic use of strontium-90 RH-8630 Gamma stereotactic radiosurgery unit(s)
- RH-8630 Remote afterloader unit(s)

PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)

*Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

- 1. Board Certification**
- a. Provide a copy of the board certification.
- b. For RH-8630, go to the table in 3.e. and describe training provider and dates of training for each type of use for which authorization is sought.
- c. Skip to and complete Part II Preceptor Attestation.
- 2. Current RH-8630 Authorized User Requesting Additional Authorization for RH-8630 Use Checked Above**
- a. Go to the table in section 3.e. to document training for new device.
- b. Skip to and complete Part II Preceptor Attestation.
- 3. Training and Experience for Proposed Authorized User**
- a. Classroom and Laboratory Training RH-8610 RH-8615 RH-8660

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			

Total Hours of Training:

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work and Clinical Experience for RH-8610. *(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)*

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys			
Checking survey meters for proper operation			
Preparing, implanting, and safely removing brachytherapy sources			
Maintaining running inventories of material on hand			
Using administrative controls to prevent a medical event involving the use of radioactive material			
Using emergency procedures to control radioactive material			

Total Hours of Work Experience

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
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Approved by:

- Residency Review Committee for Radiation Oncology of the ACGME
- Royal College of Physicians and Surgeons of Canada
- Committee on Postdoctoral Training of the American Osteopathic Association

Supervising Individual	License/Permit Number listing supervising individual as an Authorized User
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AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Experience for RH-8615

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history			
Supervising Individual		License/Permit Number listing supervising individual as an Authorized User	

d. Supervised Work and Clinical Experience for RH-8660

- Remote afterloader unit(s)
 Teletherapy unit(s)
 Gamma stereotactic radiosurgery unit(s)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Reviewing full calibration measurements and periodic spot-checks			
Preparing treatment plans and calculating treatment doses and times			
Using administrative controls to prevent a medical event involving the use of radioactive material			
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console			
Checking and using survey meters			
Selecting the proper dose and how it is to be administered			
Total Hours of Work Experience			

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

d. Supervised Work and Clinical Experience for RH-8660 (continued)

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual		License/Permit Number listing supervising individual as an Authorized User

e. For RH-8630, describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation			
Safety procedures for the device use			
Clinical use of the device			
Supervising Individual. <i>If training provided by Supervising Individual (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)</i>		License/Permit Number listing supervising individual as an Authorized User	
Authorized for the following types of use: <input type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input type="checkbox"/> Gamma stereotactic radiosurgery unit(s)			

f. Provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section

Check one of the following for each requested authorization:

For RH-8610

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

RH-8610 and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under RH-8600.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 200 hours of
Name of Proposed Authorized User

classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation oncology, as required by RH-8610, and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under RH-8600.

For RH-8615

I attest that _____ has satisfactorily completed the 24 hours of
Name of Proposed Authorized User

classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, has used strontium-90 for ophthalmic treatment of 5 individuals, as required by RH-8615 and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Second Section

RH-8660

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

RH-8660.

OR

Training and Experience

I attest that _____ has satisfactorily completed 200 hours of classroom
Name of Proposed Authorized User

and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation therapy, as required by RH-8660.

AND

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

Third Section

For RH-8660 (continued)

I attest that _____ has received training required in RH-8660 for device
Name of Proposed Authorized User
 operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.

Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

AND

Fourth Section

I attest that _____ has achieved a level of competency sufficient to
Name of Proposed Authorized User
 achieve a level of competency sufficient to function independently as an authorized user for:

Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

Fifth Section

Complete the following for preceptor attestation and signature:

- I meet the requirements in RH-8610, RH-8615, RH-8660, or equivalent U.S. NRC or Agreement State requirements, as an authorized user for:
 - RH-8600 Manual brachytherapy sources RH-8630 Teletherapy unit(s)
 - RH-8600 Ophthalmic use of strontium-90 RH-8630 Gamma stereotactic radiosurgery unit(s)
 - RH-8630 Remote afterloader unit(s)

Name of Preceptor	Signature	Telephone Number	Date
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License/Permit Number/Facility Name

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION
(for uses defined under RH-8550)
[RH-8560, RH-8570, RH-8580, and RH-8590]**

Name of Proposed Authorized User

Requested Authorization(s) *(check all that apply)*:

RH-8550 Use of unsealed radioactive material for which a written directive is required

OR

RH-8550 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

RH-8550 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)

RH-8550 Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

RH-8550 Parenteral administration of any other radionuclide for which a written directive is required

**PART I -- TRAINING AND EXPERIENCE
(Select one of the three methods below)**

Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

1. Board Certification

a. Provide a copy of the board certification.

b. For RH-8560, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience.

c. For RH-8590, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience.

d. Skip to and complete Part II Preceptor Attestation.

2. Current RH-8550, RH-8600, or RH-8630 Authorized User Seeking Additional Authorization

a. Authorized User on Materials License _____ under the requirements below or equivalent Agreement State requirements *(check all that apply)*:

RH-8560 RH-8570 RH-8580 RH-8610 RH-8660

b. If currently authorized for a subset of clinical uses under RH-8550, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

c. If currently authorized under RH-8610 or RH-8660 and requesting authorization for RH-8590, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training RH-8560 RH-8570 RH-8580 RH-8590

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of radioactive material for medical use			
Radiation biology			
Total Hours of Training:			

b. Supervised Work Experience RH-8560 RH-8570 RH-8580 RH-8590

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys			
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters			
Calculating, measuring, and safely preparing patient or human research subject dosages			
Using administrative controls to prevent a medical event involving the use of unsealed radioactive material			
Using procedures to contain spilled radioactive material safely and using proper decontamination procedures			

Total Hours of Supervised Work Experience:

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Supervising individual meets the requirements below, or equivalent Agreement State requirements (<i>check all that apply</i>)**:	
<input type="checkbox"/> RH-8560 With experience administering dosages of: <input type="checkbox"/> RH-8570 <input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> RH-8580 <input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> RH-8590 <input type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required <input type="checkbox"/> <input type="checkbox"/> Parenteral administration of any other radionuclide requiring a written directive	
** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.	

c. Supervised Clinical Case Experience

If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)			
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required			
Parenteral administration of any other radionuclide for which a written directive is required			
<hr style="width: 20%; margin-left: 0;"/> (List radionuclides)			

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Case Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Supervising individual meets the requirements below, or equivalent Agreement State requirements (<i>check all that apply</i>)**:	
<input type="checkbox"/> RH-8560 With experience administering dosages of: <input type="checkbox"/> RH-8570 <input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> RH-8580 <input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> RH-8590 <input type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required <input type="checkbox"/> <input type="checkbox"/> Parenteral administration of any other radionuclide requiring a written directive	
** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.	

d. Provide completed Part II Preceptor Attestation.

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section

Check one of the following for each requested authorization:

For RH-8560:

Board Certification

I attest that _____ has satisfactorily completed the training and experience requirements in RH-8560.
Name of Proposed Authorized User

OR

Training and Experience

I attest that _____ has satisfactorily completed the 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, as required by RH-8560.
Name of Proposed Authorized User

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

For RH-8570 (Identical Attestation Statement Regardless of Training and Experience Pathway):

I attest that _____ has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

and laboratory training, as required by RH-8570, and the supervised work and clinical case experience required in RH-8570.

For RH-8580 (Identical Attestation Statement Regardless of Training and Experience Pathway):

I attest that _____ has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

and laboratory training, as required by RH-8580, and the supervised work and clinical case experience required in RH-8580.

Second Section

I attest that _____ has satisfactorily completed the required clinical case
Name of Proposed Authorized User

experience required in RH-8560 listed below:

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

Third Section

I attest that _____ has satisfactorily achieved a level of competency to
Name of Proposed Authorized User

function independently as an authorized user for:

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For RH-8590:

Current RH-8610 or RH-8660 authorized user:

I attest that _____ is an authorized user under RH-8610 or RH-8660

Name of Proposed Authorized User

or equivalent U.S. NRC or Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by RH-8590, and the supervised work and clinical case **experience** required by RH-8590, and has achieved a level of competency sufficient to function independently as an authorized user for:

Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

Parenteral administration of any other radionuclide for which a written directive is required

OR

Board Certification:

I attest that _____ has satisfactorily completed the board certification

Name of Proposed Authorized User

requirements of RH-8590, has satisfactorily completed the 80 hours of classroom and laboratory training required by RH-8590 and the supervised work and clinical case experience required by RH-8590, and has achieved a level of competency sufficient to function independently as an authorized user for:

Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

Parenteral administration of any other radionuclide for which a written directive is required

Fifth Section

Complete the following for preceptor attestation and signature:

I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

RH-8560 RH-8570 RH-8580 RH-8590

I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

Oral Nal-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

Oral Nal-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor	Signature	Telephone Number	Date
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License/Permit Number/Facility Name

**RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION
[RH-8315]**

Name of Proposed Radiation Safety Officer

Requested Authorization(s) *The license authorizes the following medical uses (check all that apply)*

- RH-8500 RH-8530 RH-8550 RH-8600 RH-8620 RH-8630 (remote afterloader)
 RH-8630 (teletherapy) RH-8630 (gamma stereotactic radiosurgery) RH-8670(_____)

**PART I -- TRAINING AND EXPERIENCE
(Select one of the four methods below)**

*Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

1. Board Certification

- a. Provide a copy of the board certification.
- b. Use Table 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.
- c. Skip to and complete Part II Preceptor Attestation.

OR

2. Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer for the Additional Medical Uses Checked Above

- a. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for the additional types of medical use for which recognition as RSO is sought.
- b. Skip to and complete Part II Preceptor Attestation.

OR

3. Structured Educational Program for Proposed Radiation Safety Officer

a. Classroom and Laboratory Training

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use			
Radiation biology			

Total Hours of Training:

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

b. Supervised Radiation Safety Experience

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Training/ License or Permit Number of Facility	Dates of Training*
Shipping, receiving, and performing related radiation surveys		
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides		
Securing and controlling radioactive material		
Using administrative controls to avoid mistakes in administration of radioactive material		
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures		
Using emergency procedures to control radioactive material		
Disposing of radioactive material		
Licensed Material Used (e.g., RH-8500, RH-8530, etc.)+ _____ _____ _____		

+ Choose all applicable sections of Section 9 to describe radioisotopes and quantities used: RH-8500, RH-8530, RH-8550, RH-8600, RH-8620, RH-8630 remote afterloader units, RH-8630 teletherapy units, RH-8630 gamma stereotactic radiosurgery units, RH-8670 emerging technologies (provide list of devices).

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

b. Supervised Radiation Safety Experience (continued)

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervising Individual	License/Permit Number listing supervising individual as a Radiation Safety Officer
This license authorizes the following medical uses: <input type="checkbox"/> RH-8500 <input type="checkbox"/> RH-8530 <input type="checkbox"/> RH-8550 <input type="checkbox"/> RH-8600 <input type="checkbox"/> RH-8620 <input type="checkbox"/> RH-8630 (remote afterloader) <input type="checkbox"/> RH-8630 (teletherapy) <input type="checkbox"/> RH-8630 (gamma stereotactic radiosurgery) <input type="checkbox"/> RH-8670(_____)	

c. Describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

Description of Training	Training Provided By	Dates of Training*
Radiation safety, regulatory issues, and emergency procedures for RH-8500, RH-8530, and RH-8620 uses		
Radiation safety, regulatory issues, and emergency procedures for RH-8550 uses		
Radiation safety, regulatory issues, and emergency procedures for RH-8600 uses		
Radiation safety, regulatory issues, and emergency procedures for RH-8630 - teletherapy uses		
Radiation safety, regulatory issues, and emergency procedures for RH-8630 - remote afterloader uses		
Radiation safety, regulatory issues, and emergency procedures for RH-8630 - gamma stereotactic radiosurgery uses		
Radiation safety, regulatory issues, and emergency procedures for RH-8670, specify use(s):		

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

c. Training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license (continued)

Supervising Individual <i>If training was provided by supervising RSO, AU, AMP, or ANP. (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)</i>	License/Permit Number listing supervising individual
License/Permit lists supervising individual as:	
<input type="checkbox"/> Radiation Safety Officer <input type="checkbox"/> Authorized User <input type="checkbox"/> Authorized Nuclear Pharmacist <input type="checkbox"/> Authorized Medical Physicist	
Authorized as RSO, AU, ANP, or AMP for the following medical uses:	
<input type="checkbox"/> RH-8500 <input type="checkbox"/> RH-8530 <input type="checkbox"/> RH-8550 <input type="checkbox"/> RH-8600 <input type="checkbox"/> RH-8620 <input type="checkbox"/> RH-8630 (remote afterloader) <input type="checkbox"/> RH-8630 (teletherapy) <input type="checkbox"/> RH-8630 (gamma stereotactic radiosurgery) <input type="checkbox"/> RH-8670 (_____)	

d. Skip to and complete Part II Preceptor Attestation.

OR

4. Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist identified on the licensee's license

- a. Provide license number.
- b. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.
- c. Skip to and complete Part II Preceptor Attestation.

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section

Check one of the following:

1. Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Radiation Safety Officer
 RH-8315

OR

2. Structured Educational Program for Proposed Radiation Safety Officers

I attest that _____ has satisfactorily completed a structural educational
Name of Proposed Radiation Safety Officer
 program consisting of both 200 hours of classroom and laboratory training and one year of full-time radiation safety experience as required by RH-8315.

OR

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

Check one of the following:

3. Additional Authorization as Radiation Safety Officer (under provisions of RH-8318)

I attest that _____ is an
Name of Proposed Radiation Safety Officer

Authorized User

Authorized Nuclear Pharmacist

Authorized Medical Physicist

identified on the Licensees license and has experience with the radiation safety aspects of similar type of use of byproduct material for which the individual has Radiation Safety Officer responsibilities

AND

Second Section

Complete for all *(check all that apply)*:

I attest that _____ has training in the radiation safety, regulatory issues, and
Name of Proposed Radiation Safety Officer

emergency procedures for the following types of use:

RH-8500

RH-8530

RH-8550 oral administration of less than or equal to 33 millicuries of sodium iodide I-131, for which a written directive is required

RH-8550 oral administration of greater than 33 millicuries of sodium iodide I-131

RH-8550 parenteral administration of any beta-emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

RH-8550 parenteral administration of any other radionuclide for which a written directive is required

RH-8600

RH-8620

RH-8630 remote afterloader units

RH-8630 teletherapy units

RH-8630 gamma stereotactic radiosurgery units

RH-8670 emerging technologies, including:

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

AND

**Third Section
Complete for ALL**

I attest that _____ has achieved a level of radiation safety knowledge
Name of Proposed Radiation Safety Officer
sufficient to function independently as a Radiation Safety Officer for a medical use licensee.

**Fourth Section
Complete the following for Preceptor Attestation and signature**

I am the Radiation Safety Officer for _____
Name of Facility

License/Permit Number: _____

Name of Preceptor	Signature	Telephone Number	Date

APPENDIX C-1

**RADIATION SAFETY OFFICER'S
MODEL DELEGATION OF AUTHORITY**

MEMORANDUM FOR RECORD

TO: _____, Radiation Safety Officer

FROM: _____, Chief Executive Officer

DATE: _____

SUBJECT: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation at _____. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management if staff members do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Arkansas Department of Health, Radioactive Materials Program, at any time. It is estimated that you will spend _____ hours per week performing radiation protection activities.

I accept the above responsibilities,

Signature of Chief Executive Officer

Signature of Radiation Safety Officer

Date

Date

cc: Affected Department Heads

APPENDIX C-2

DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER

Typical Duties and Responsibilities of the Radiation Safety Officer

The Radiation Safety Officer's duties and responsibilities include ensuring radiological safety and compliance with Department and U.S. Department of Transportation (DOT) regulations and the conditions of the radioactive material license. Applicants may either adopt these duties and responsibilities or develop alternative duties and responsibilities to meet the requirements of RH-8300. Typically, these duties and responsibilities include ensuring the following:

- Stopping unsafe activities involving radioactive material;
- Radiation exposures are maintained ALARA;
- Up-to-date radiation protection procedures in the daily operation of the licensee's radioactive material program are developed, distributed, and implemented;
- Possession, use, and storage of radioactive material is consistent with the limitations in the license, the regulations, the SSDR Certificate(s), and the manufacturer's recommendations and instructions;
- Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by a Department, NRC or Agreement State radioactive material license;
- Personnel training is conducted and is commensurate with the individual's duties regarding radioactive material;
- Documentation is maintained to demonstrate that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- Radioactive material is properly secured;
- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;

- Proper authorities are notified of incidents such as loss or theft of radioactive material, damage to or malfunction of sealed sources, and fire;
- Medical events and precursor events are investigated and reported to the Department, and cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Audits of the radiation protection program are performed at least annually and documented;
- If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Radioactive material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Radioactive material is disposed of properly;
- Appropriate records are maintained; and
- An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner.

APPENDIX D

RADIATION SAFETY TRAINING PROGRAM

Model Training Program

Model procedures for describing training programs appear below. These models provide examples of topics to be used for training, based on the experience, duties, and previous training of personnel attending the training. The topics chosen will depend on the purpose of the training, the audience, and the state of learning (background knowledge) of the audience. These models also may be useful to identify topics for annual refresher training.

Refresher training should include topics with which the individual is not involved frequently and requires reaffirmation. Topics for refresher training need not include review of procedures or basic knowledge that the trainee routinely uses.

Applicants may either adopt these model procedures or develop an alternative program to meet Department requirements. Guidance on requirements for training and experience for Authorized Medical Physicists and Authorized Users who engage in certain specialized practices is also included.

Model Training Program for Medical Uses of Radionuclides, Sealed Sources, and Medical Devices Containing Sealed Sources

Personnel will receive instruction before assuming duties with, or in the vicinity of, radioactive materials during annual refresher training, and whenever there is a significant change in duties, regulations, terms of the license, or type of radioactive material or therapy device used. Records of worker training will be maintained for at least 3 years. The training records will include the topic of the training, the date of the instruction or training, the name(s) of the attendee(s), and the names of the instructor(s).

Training for Individuals Involved in the Use of Radioactive Material

Training for professional staff (e.g., Authorized User, Authorized Medical Physicist, Authorized Nuclear Pharmacist, Radiation Safety Officer, nurse, dosimetrist, technologist, and therapist) may contain the following elements for those who provide or are involved in the care of patients during diagnostic or therapeutic procedures in the following topics, **commensurate with their duties**:

- Basic radiation biology, e.g., interaction of ionizing radiation with cells and tissues;
- Basic radiation protection to include concepts of time, distance, and shielding;
- Concept of maintaining exposure ALARA (RH-1004);

- Risk estimates, including comparison with other health risks;
- Posting requirements (RH-1303);
- Proper use of personnel dosimetry (when applicable);
- Access control procedures (RH-1303, RH-1308);
- Proper use of radiation shielding, if used;
- Patient release procedures (RH-8420);
- Instruction in procedures for notification of the Radiation Safety Officer and Authorized User, when responding to patient emergencies or death, to ensure that radiation protection issues are identified and addressed in a timely manner. The intent of these procedures should in no way interfere with or be in lieu of appropriate patient care (RH-2803, RH-8551, RH-8603, RH-8633);
- Occupational dose limits and their significance (RH-1200);
- Dose limits to the embryo/fetus, including instruction on declaration of pregnancy (RH-1207);
- Worker's right to be informed of occupational radiation exposure (RH-2804);
- Each individual's obligation to report unsafe conditions to the RSO (RH-2803);
- Applicable regulations, license conditions, information notices, bulletins, etc. (RH-2803);
- Where copies of the applicable regulations, the Department license, and its application are posted or made available for examination (RH-2802);
- Proper recordkeeping required by Department regulations (RH-2803);
- DOT training for the Radiation Safety Officer or a properly identified designee.
- Appropriate surveys to be conducted (RH-1300);
- Proper calibration of required survey instruments (RH-1300);
- Emergency procedures;
- Decontamination and release of facilities and equipment (RH-1220, RH-410);
- Dose to individual members of the public (RH-1208); and
- Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste management, sealed source leak testing) (RH-8306).

Training for the Staff Directly Involved in Administration to or Care of Patients Administered Byproduct Material for Which A Written Directive Is Required (Including Greater than 30 microCuries of I-131), or Therapeutic Treatment Planning

In addition to the topics identified above, the following topics may be included in instruction for staff involved in the therapy treatment of patients (e.g., nursing, Radiation Safety Officer, Authorized Medical Physicist, Authorized User, and dosimetrist) in the following topics, **commensurate with their duties:**

- Leak testing of sealed sources (RH-8405);
- Emergency procedures (including emergency response drills) (RH-8551, RH-8603, RH-8633);
- Operating instructions (RH-8306, RH-8633);
- Computerized treatment planning system (RH-8648);
- Dosimetry protocol (RH-8635);
- Detailed pretreatment quality assurance checks (RH-8306, RH-8633);
- Safe handling (when applicable) of the patient's dishes, linens, excretions (saliva, urine, feces), and surgical dressings that are potentially contaminated or that may contain radioactive sources (RH-8551, RH-8603);
- Patient control procedures (RH-8551, RH-8603, RH-8633);
- Visitor control procedures, such as visitors' stay times and safe lines in radiation control areas (patient's room) (RH-8551, RH-8603, RH-8633);
- Licensee's Written Directive Procedures, to ensure that each administration is in accordance with the WD, patient identity is verified, and where applicable, attention is paid to correct positioning of sources and applicators to ensure that treatment is to the correct site (or, for GSR, correct positioning of the helmet) (RH-8308);
- Proper use of safety devices and shielding to include safe handling and shielding of dislodged sources (or, in the case of remote afterloaders, disconnected sources) (RH-8603, RH-8633);
- Size and appearance of different types of sources and applicators (RH-8603, RH-8633);
- Previous incidents, events, and/or accidents; and
- For remote afterloaders, teletherapy units, and GSR units; initial training provided by the device manufacturer or by individuals certified by the device manufacturer that is device model-specific and includes:
 - Design, use, and function of the device, including safety systems and interpretation of various error codes and conditions, displays, indicators, and alarms;

- Hands-on training in actual operation of the device under the direct supervision of an experienced user including “dry runs” (using dummy sources) of routine patient set-up and treatment and implementation of the licensee’s emergency procedures;
- A method of determining each trainee’s competency to use the device for each type of proposed use, such as practical examinations.

Additional Training for Authorized Medical Physicists

Applicants for licenses to include Authorized Medical Physicists who plan to engage in certain tasks requiring special training should ensure that the Authorized Medical Physicists is trained in the activities specific to the different types of uses listed in RH-8316.

Note, for example, that additional training is necessary for Authorized Medical Physicists planning tasks such as remote afterloader therapy, teletherapy, GSR therapy, the use of the treatment planning system that applicants contemplate using, as well as calculation of activity of Sr-90 sources used for ophthalmic treatments (RH-8605). Medical physicists must also have training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system, as required in RH-8316.

Additional Training for Authorized Users of Radioactive Materials for Which a Written Directive Is Required

Applicants for licenses should carefully consider the type of radiation therapy that is contemplated. In addition to the training and experience requirements of RH-8560, RH-8580, RH-8610, RH-8615, and RH-8660, attention should be focused on the additional training and experience necessary for treatment planning and quality control system, and clinical procedures. Refer to the training and experience requirements associated with specialized uses discussed in RH-8560, RH-8610, RH-8615, and RH-8660 of Section 9.

Training for Ancillary Staff

Ancillary staff includes personnel engaged in janitorial and/housekeeping duties, dietary, laboratory, security and life-safety services, and other non-radiation workers. Ancillary staff will receive hazard awareness training to insure these individuals understand the possible hazards, safety precautions, and emergency procedures related to the use and storage of radioactive material. The training will include instruction commensurate with potential radiological health protection problems present in the work place. Alternatively, prohibitions on entry into controlled or restricted areas may be applied to ancillary personnel unless escorted by trained personnel. Topics of instruction may include the following:

- Storage, transfer, or use of radiation and/or radioactive material (RH-2803);
- Potential biological effects associated with exposure to radiation and/or radioactive material, precautions or procedures to minimize exposure, and the purposes and

functions of protective devices (e.g., basic radiation protection concepts of time, distance, and shielding) (RH-2803);

- The applicable provisions of Department regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material (e.g., posting and labeling of radioactive material) (RH-2803);
- Responsibility to report promptly to the licensee any condition that may lead to or cause a violation of Department regulations and license conditions or unnecessary exposure to radiation and/or radioactive material (e.g., notification of the RSO regarding radiation protection issues) (RH-2803);
- Appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material (RH-2803);
- Radiation exposure reports that workers may request, as per RH-2804 (RH-2803).

APPENDIX E

LEAK TEST OF SEALED RADIOACTIVE SOURCES

Each sealed radioactive source and each exposure or storage device using depleted uranium shielding must be tested at regular intervals to ensure that the radioactive material is secure and is not leaking contamination. Leak test requirements are specified in the Rules and Regulation for Control of Sources of Ionizing Radiation, Paragraph RH-1212 and Paragraph RH-8403.

Leak tests may be performed by the Licensee or by a Service Vendor who is licensed by the Department or an Agreement State or the NRC to perform leak tests as a service to radioactive material licensees. The Licensee must develop and use Leak Test Procedures which describe how the test will be performed, analyzed, and evaluated by one of the following methods:

- Leak tests performed by the Licensee using “in-house” test materials, radiological counting instrumentation, and data evaluation recording, or,
- Leak tests performed by the Licensee using vendor-supplied leak test kits with analytical and data evaluation services performed by an approved vendor, or,
- Service Vendor performs all leak tests, analysis, and evaluation.

Leak test procedures must be submitted to the Department as part of the license application and must be approved by the Department prior to performing the tests. Information that is required to be included in the procedures is dependent upon how the Licensee intends to perform the test.

Complete Form E (attached to this Appendix) describing the manner in which the required leak test will be performed and submit the Form with the Application. Specific Leak Test procedures must be included in Item 22 “Operating Procedures” of this Application.

Key Points That Must Be Considered for the Leak Test Procedures

A. Leak Test Frequency.

Sealed sources shall be leak tested at least every 6 months, unless otherwise specified in the Radioactive Material License. Exposure or storage devices using depleted uranium shielding shall be tested for leakage at intervals not to exceed 12 months.

B. Leak Test Kit

Only leak test kits provided by licensed vendors may be used to sample (smear) sealed sources and depleted uranium shielding.

C. Taking the Leak Test Sample

Leak test samples shall be taken only by the Radiation Safety Officer, or authorized designee, wearing their assigned personnel monitoring dosimeters. Leak test samples shall be taken in accordance with the written instructions provided by the supplier of the leak test kit and the sealed source or exposure device manufacturer.

D. Leak Test Sample Analysis

Leak Test kit sample analysis will be performed only by vendors specifically licensed by the Department, the NRC, or other Agreement State to provide the service.

E. Leak Test Records

If a test indicates a sealed source is leaking, the source and exposure device will be removed from service and the Department will be notified by a written report on the leaking source within 5 days. The report will be submitted to Arkansas Department of Health and Human Services, P.O. Box 1437, Slot H-30, Little Rock, Arkansas, 72203-1437. The report will describe the equipment involved, the test results, and the corrective actions taken (i.e., device removed from service until repaired; radiation surveys conducted to determine presence of contamination; decontamination as necessary).

Leak test records shall be maintained on file for inspection purposes and shall be retained for at least 3 years following the date the record was created. The records will include the following information:

- Each source's manufacturer name, model, and serial number
- The identity of each sealed source radionuclide and its estimated activity, expressed in millicuries
- Each radiographic device using depleted uranium shielding manufacturer's name, model number, and serial number
- The measured activity of each leak test sample, in microcuries
- The date the sample was collected.

Appendix E

Form E

LEAK TESTS FOR SEALED SOURCES

Please provide the requested information by checking the appropriate items. The completed Form E is a commitment by the Applicant to perform the leak test as indicated. This information will be incorporated into the Radioactive Material License as a Special License Condition.

SEALED RADIOACTIVE SOURCES WILL BE LEAK TESTED AS INDICATED:

_____ **1. Leak tests will be performed by the Licensee**

- a. Frequency of leak test _____
- b. Operating Procedure Number _____
- c. Title of individual performing the leak test _____

_____ **2. Leak tests will be performed by the applicant using a commercial leak test kit:**

- a. Frequency of leak test _____
- b. Manufacturer of kit _____
- c. Model number of kit _____
- d. Name of company to perform assay of leak test samples _____
- e. Arkansas Vendor Registration Number _____
- f. Manufacturer's instruction will be followed in the use of the leak test kit _____
- g. Operating Procedure Number _____
- h. Title of individual performing the leak test _____

_____ **3. Leak tests will be performed by a consultant or a commercial firm:**

- a. Frequency of leak test _____
- b. Name of Company _____
- c. Address _____
- d. License Number _____
- e. Arkansas Vendor Registration Number _____
- f. Operating Procedure Number _____
- g. Title of individual performing the leak test _____

**EXPOSURE OR STORAGE DEVICES USING DEPLETED URANIUM SHIELDING
WILL BE LEAK TESTED AS INDICATED**

_____ **1. Leak tests will be performed by the Licensee**

- a. Frequency of leak test _____
- b. Operating Procedure Number _____
- c. Title of individual performing the leak test _____

_____ **2. Leak tests will be performed by the applicant using a commercial leak test kit:**

- a. Frequency of leak test _____
- b. Manufacturer of kit _____
- c. Model number of kit _____
- d. Name of company to perform assay of leak test
samples _____
- e. Arkansas Vendor Registration Number _____
- f. Manufacturer's instruction will be followed in the use of the leak
test kit _____
- g. Operating Procedure Number _____
- h. Title of individual performing the leak test _____

_____ **3. Leak tests will be performed by a consultant or a commercial firm:**

- a. Frequency of leak test _____
- b. Name of Company _____
- c. Address _____
- d. License Number _____
- e. Arkansas Vendor Registration Number _____
- f. Operating Procedure Number _____
- g. Title of individual performing the leak test _____

APPENDIX F

RADIATION DETECTION INSTRUMENTS

Licensees shall possess radiation detection instruments to measure radiation levels, radioactive contamination, and radioactivity, as applicable. Instruments used for quantitative radiation measurements must be calibrated for the radiation to be measured. The instruments must be available for use at all times when radioactive material is in use. The licensee must possess survey instruments sufficiently sensitive to measure the type and energy of radiation used, including survey instruments used to locate low energy or low activity seeds (e.g., I-125, Pd-103) if they become dislodged in/from the patient in the operating room or patient's room.

General Information for Radiation Monitoring Instrument Specifications

- Low-energy beta emitters, such as carbon-14 and sulfur-35, are difficult to detect with Geiger-Mueller (GM) probes. The detection efficiency generally is about 2% for low-energy beta emitters. The proper surveying method (e.g., speed and height above surface) is important to perform adequate surveys. Additionally, wipes must be taken and counted with a liquid scintillation counter to verify potential contamination.
- Medium- to high-energy beta emitters, such as P-32 and Ca-45, can be detected with a pancake GM. The efficiency ranges from 15% to 40%, depending on the beta energy.
- Low-energy gamma emitters, such as I-125, can be detected with a sodium iodide (NaI) probe or a thin window GM probe (pancake or thin end-window). If the sodium iodide probe possesses a thin window and thin crystal, the detection efficiency is approximately 20%. If a pancake or thin end-window GM probe is used, the detection efficiency is significantly lower and care should be taken to ensure that the GM probe is capable of detecting the trigger levels.
- Medium- to high-energy gamma emitters, such as I-131, can be detected with either GM or sodium iodide probes, depending on the required sensitivity. In general, the sensitivity of GM probes is much lower than for sodium iodide probes.
- The following table (except for items marked with an asterisk (*), extracted from "The Health Physics & Radiological Health Handbook", Revised Edition, 1992, may be helpful in selecting instruments:

Table F.1 Typical Survey Instruments			
Portable Instruments Used for Contamination and Ambient Radiation Surveys			
Detectors	Radiation	Energy Range	Efficiency
Exposure Rate Meters	Gamma, X-ray	mR-R	N/A
Count Rate Meters			
GM	Alpha	All energies (dependent on window thickness)	Moderate
	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate

Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples			
Detectors	Radiation	Energy Range	Efficiency
Liquid Scintillation Counter*	Alpha	All energies	High
	Beta	All energies	High
	Gamma		Moderate
Gamma Counter (NaI)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

APPENDIX G

CALIBRATION OF RADIATION DETECTION INSTRUMENTS

RADIATION SURVEY INSTRUMENTS

Radiation survey instruments must be calibrated at intervals not to exceed twelve months and after each maintenance or servicing of the instrument, except for battery changes. The calibration must be sensitive enough to insure the instrument detects radiation emitted from the radioactive material possessed and used by the licensee and must meet all survey requirements identified in the Rules and Regulation for Control of Sources of Ionizing Radiation, Paragraph RH-1300 and Paragraph RH-8402. The survey instrument must be calibrated on all required scale readings up to 1000 millirem per hour with a radiation source.

- A. Calibration of survey instruments shall be performed using radioactive material (electronic calibration is not acceptable):
1. The calibration source activity or dose rates at specified distances shall be traceable to a standard certified to within ± 5 percent accuracy to a primary radiation standard such as those maintained by the U.S. National Institute for Standards and Technology (NIST).
 2. The calibration source shall approximate a point source.
 3. For linear scale instruments, each scale of the instrument shall be calibrated on at least two points located at approximately 1/3 and 2/3 of full scale; for logarithmic scale instruments, each scale shall be calibrated at midrange for each decade and at two points on at least one decade; and for digital instruments at three points between 2 and 1000 millirem per hour.
 4. For dose rate instruments, the instrument shall be calibrated so that an accuracy within plus or minus 20 percent of the calibration source can be demonstrated at each point.
 5. The date of calibration shall be conspicuously noted on the instrument.
- B. Records of radiation survey instrument calibration shall be maintained on file for inspection purposes and shall be retained for at least 3 years following the date the record was created.
- C. Radiation survey instruments shall be checked for operability to verify the instrument is working properly. The Licensee shall check each radiation survey instrument with a dedicated check source before each use.

If any reading with the same geometry is not within 20 percent of the reading obtained immediately after calibration, the instrument should be recalibrated.

**RADIATION DETECTION INSTRUMENTS TO MEASURE DOSAGES OF 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.

The Applicant must confirm on Form G-2 that the radiation detection instruments used to measure dosages of unsealed radioactive material will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

Appendix G

Form G-1

CALIBRATION OF RADIATION SURVEY INSTRUMENTS

Please provide the requested information by checking the appropriate items or completing the information in the space provided. The completed Form G-1 is a commitment by the Applicant to perform the radiation survey instrument calibration as indicated.

RADIATION SURVEY INSTRUMENTS WILL BE CALIBRATED AS INDICATED

_____ 1. Survey instruments will be calibrated at intervals not to exceed twelve months and following each maintenance and repair activity, except battery change.

_____ 2. Calibration will be performed as follows:

- a. For linear scale instruments, each scale of the instrument shall be calibrated on at least two points located at approximately 1/3 and 2/3 of full scale
- b. For logarithmic scale instruments, each scale shall be calibrated at midrange for each decade and at two points on at least one decade
- c. For digital instruments at three points between 2 and 1000 millirem per hour.

3. Radiation survey instrument calibration will be performed by:

_____ a. **SERVICE VENDOR OR INSTRUMENT MANUFACTURER**

Name of Company _____

Address of Company _____

Arkansas Vendor Registration Number _____

Licensee Operating Procedure Number _____

_____ **b. CONSULTANT**

Name of Company_____

Address of Company_____

Arkansas Vendor Registration Number_____

Licensee Operating Procedure Number_____

_____ **c. LICENSEE (Applicant)**

(1.) Calibration Source

Radioactive Material_____

Activity (millicuries)_____

Manufacturer's Name_____

Source Model Number_____

Traceability to Primary Standard_____

Accuracy_____

Title Of Individual Performing

Calibration_____

(2.) Calibration procedures, including radiation safety procedures are included in Item 22:

YES_____ **Operating Procedure Number**_____

NO _____ **(Explain)**_____

Appendix G

Form G-2

CALIBRATION OF RADIATION DETECTION INSTRUMENTS
TO
MEASURE UNSEALED RADIOACTIVE MATERIAL

This confirms that radiation detection instruments used to measure dosages of unsealed radioactive material will be calibrated in accordance with nationally recognized standards or the instrument’s manufacturer’s calibration instructions. The completed Form G-2 is a commitment by the Applicant to perform the radiation detection instrument calibration as indicated.

A copy of each calibration procedure is included in Item 22, Operating Procedures of the Application.

Operating Procedure Numbers: _____

CONFIRMATION

(Printed Name)

(Signature)

(Title)

(Date)

APPENDIX H

PERSONNEL MONITORING

I. PERSONNEL MONITORING PROGRAM FOR OCCUPATIONAL DOSE

This Appendix provides information that may be used to develop and implement, or revise, or amend a personnel monitoring program to correctly measure radiation dose to occupationally-exposed workers. Further, it contains specific information relating to an external occupational dose program and cites references for developing an internal occupational dose program. Applicants may use this information to establish an occupational dose program to meet the requirements of RH-1302 and other requirements of Section 3 of the Rules and Regulations for Control of Sources of Ionizing Radiation. This information includes guidance as well as discussion of regulatory requirements that are to be reflected in the elements of personnel monitoring program.

“Dosimetry” is a broad term commonly applied to the use of monitoring devices, bioassay, and other methods to measure or otherwise quantify radiation doses to individuals. The licensee must control occupational doses and provide individuals with monitoring devices in accordance with the requirements of RH-1302. Paragraph RH-1200 provides the occupational dose limits for adults and RH-1302 states, in part, that adults likely to receive in one year a dose in excess of 10 percent of those dose limits must be provided with dosimetry.

Definitions of relevant terms such as Total Effective Dose Equivalent (TEDE), deep-dose equivalent (DDE), and committed effective dose equivalent (CEDE) can be found in RH-1100, “Definitions”. In addition, if monitoring is required pursuant to RH-1302, each licensee shall maintain records of doses received (RH-1509) and individuals must be informed on at least an annual basis of their doses (see RH-2804).

If an individual is likely to receive more than 10% of the annual dose limits, the Department requires the licensee to monitor the dose, to maintain records of the dose, and, on at least an annual basis, to inform the worker of the dose.

The As Low As Reasonably Achievable (ALARA) Program

The Rules and Regulations, Paragraph RH-1004 states that

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

Additionally, RH-1004 requires that licensees periodically review the content of the radiation protection program and its implementation.

EXTERNAL DOSE

Radiation Dose Limits

It is necessary to assess radiation doses to workers to demonstrate compliance with regulatory limits on radiation dose and to help demonstrate that doses are maintained at ALARA levels. Providing for the safe use of radioactive materials and radiation is a management responsibility. It is imperative that management recognize the importance of radiation monitoring in the overall requirements for radiation protection.

There are three dose limits included in RH-1200 that apply to external exposure:

- Deep dose to the whole body 5 rem or (0.05 Sv),
- Shallow dose to the skin or extremities 50 rem or (0.5 Sv), and
- Dose to the lens of the eye 15 rem or (0.15 Sv).

According to the definitions in RH-1100, the deep dose equivalent (DDE) to the whole body is considered to be at a tissue depth of 1 cm (1000 mg/cm²), shallow dose equivalent to the skin or extremities at 0.007 cm (7 mg/cm²), and eye dose equivalent at 0.3 cm (300 mg/cm²). In evaluating the eye dose equivalent, it is acceptable to take credit for the shielding provided by protective lenses.

Paragraph RH-1302 requires the use of individual monitoring devices for the following:

- Adults likely to receive, in one year, from sources external to the body, a dose in excess of 10 percent of the occupational dose limits in RH-1200. Monitoring devices are accordingly required for adults with an annual dose in excess of
 - 0.5 rem (0.005 Sv) DDE
 - 1.5 rem (0.015 Sv) eye dose equivalent
 - 5 rem (0.05 Sv) shallow dose equivalent to the skin
 - 5 rem (0.05 Sv) shallow dose equivalent to any extremity.
- Minors who are likely to receive an annual dose in excess of
 - 0.1 rem (1.0 mSv) DDE
 - 0.15 rem (1.5 mSv) eye dose equivalent
 - 0.5 rem (5 mSv) shallow dose equivalent to the skin
 - 0.5 rem (5 mSv) shallow dose equivalent to any extremity.

- Declared pregnant women likely to receive an annual dose in excess of 0.1 rem (1.0 mSv) DDE during the entire pregnancy.
- Individuals entering a high or a very high radiation area.

To demonstrate that monitoring of occupational exposure is not necessary for a group of radiation workers, it must be documented that doses will not exceed 10% of the applicable limits. In this case, the Department does not require licensees to monitor radiation doses for this class of worker.

The following methods may be used to demonstrate that doses are expected to be within 10% of regulatory limits:

- **Prior Experience:** Review of radiation dose histories for workers in a specific work area show that they are not likely to receive a dose in excess of 10% of the limits;
- **Area Surveys:** Demonstrate through the conduct of appropriate radiation surveys (e.g., using a survey meter or area thermoluminescent dosimeters (TLDs)) in the work area, combined with estimates of occupancy rates and calculations, that doses to workers are not likely to exceed 10% of the limits (personnel exposures associated with reasonable “accident” scenarios must also be evaluated);
- The licensee performs a reasonable calculation based upon source strength, distance, shielding, and time spent in the work area, that shows that workers are not likely to receive a dose in excess of 10% of the limits.

Radiation Dose Monitoring

External dose is determined by using individual radiation monitoring devices, such as **Film Badges, Optically Stimulated Luminescence Dosimeters (OSLD), and Thermoluminescent Dosimeters (TLDs)**. These devices must be evaluated by a processor that is National Voluntary Laboratory Accreditation Program (NVLAP)-approved, as required by RH-1301.

If external dose monitoring is necessary, the applicant must describe the type of personnel dosimetry, specifically, film badges, OSLs, or TLDs, that personnel will use. If occupational workers handle radioactive material, the licensee must evaluate the need to provide extremity radiation monitors, which are required if workers are likely to receive a dose in excess of 5 rem (0.05 Sv) shallow dose equivalent (SDE), in addition to whole-body badges.

- Applicants must ensure that the personnel dosimetry program contains provisions that personnel monitoring devices be worn so that the part of the body likely to receive the greatest dose will be monitored. The device for monitoring the whole body dose, eye dose, skin dose, or extremity dose shall be placed near the location expected to receive the highest dose during the year (RH-1201.c). When the whole

body is exposed fairly uniformly, the individual monitoring device is typically worn on the front of the upper torso.

- If the radiation dose is highly non-uniform, causing a specific part of the whole body (head, trunk, arms above the elbow, or legs above the knees) to receive a substantially higher dose than the rest of the whole body, the individual monitoring device shall be placed near that part of the whole body expected to receive the highest dose. For example, if the dose rate to the head is expected to be higher than the dose rate to the trunk of the body, a monitoring device shall be located on or close to the head.
- If, after the dose is received, the licensee somehow learns that the maximum dose to a part of the whole body, eye, skin, or extremity was substantially higher than the dose measured by the individual monitoring device, an evaluation shall be conducted to estimate the actual maximum dose.

Because evaluation of dose is an important part of the radiation protection program, it is critical that users return dosimeters on time. Licensees should be vigorous in their effort to recover any missing dosimeters. Delays in processing a dosimeter can result in the loss of the stored information.

Some licensees use self-reading dosimeters in lieu of processed dosimetry. This is acceptable if the regulatory requirements are met. See American National Standards Institute (ANSI) N322, "Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters", for more information. If pocket dosimeters are used to monitor personnel exposures, applicants should state the useful range of the dosimeters, along with the procedures and frequency for their calibration.

When evaluating external dose from xenon gas, the licensee may take credit for the reduction of dose resulting from the use of xenon traps. Additionally, periodic checks of the trap effluent may be used to ensure proper operation of the xenon trap. Licensees may vent xenon gas directly to the atmosphere as long as the effluent concentration is within Rules and Regulations, Section 3 limits and is specifically addressed in the Operating Procedures.

When evaluating dose from aerosols, licensees may take credit for the reduction of dose resulting from the use of aerosol traps. Licensees may vent aerosols directly to the atmosphere as long as the effluent concentration is within Rules and Regulations, Section 3 limits and is specifically addressed in the Operating Procedures.

Declared Pregnancy and Dose to Embryo/Fetus

The Rules and Regulations, Paragraph RH-1207 states that the licensee shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman. If the pregnancy is declared in writing and includes the worker's estimated date of conception, the dose equivalent to an embryo/fetus shall be taken as the sum of:

- The deep dose equivalent to the declared pregnant woman; and
- The dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

NOTE: The following references are provided:

- Methods for calculating the radiation dose to the embryo/fetus can be found in Regulatory Guide 8.36, "Radiation Dose To the Embryo/Fetus".
- NUREG/CR-5631, PNL-7445, Rev. 2, "Contribution of Maternal Radionuclide Burdens to Prenatal Radiation Doses" (1996).

Records of External Radiation Dose Monitoring

In order to demonstrate compliance with occupational dose limits of RH-1200, the Rules and Regulations include specific requirements for documenting, maintaining, and retaining the results of personnel radiation dose monitoring. The requirements are summarized in Section III of this Appendix.

INTERNAL DOSE

Radioactive Material Licensees are required to monitor occupational intake of radioactive material and assess the resulting dose if it appears likely that personnel will receive greater than 10% of the **annual limit on intake (ALI)** from intakes in 1 year (RH-1302). Section 3 of the Rules and Regulations provides terms and definitions for radionuclide intakes by means of inhalation and ingestion, i.e., **derived air concentration (DAC)** and **ALI**.

It may be necessary to assess the intake of radioactivity for occupationally exposed individuals in accordance with RH-1203 and RH-1302. If internal dose assessment is necessary, the Applicant shall measure the following:

- Concentrations of radioactive material in air in work areas; or
- Quantities of radionuclides in the body; or
- Quantities of radionuclides excreted from the body; or
- Combinations of these measurements.

The Applicant must describe in the Operating Procedures the criteria used to determine the type of bioassay and the frequencies at which bioassay (both *in vivo* and *in vitro*) will be performed to evaluate intakes. The criteria also must describe how tables of investigational levels are derived, including the methodology used by the evaluated internal dose assessments, i.e., the empirical models used to interpret the raw bioassay data. The bioassay procedures should provide for baseline, routine, emergency, and follow-up bioassays. If a commercial bioassay service will be used, the applicant must ensure that the service is licensed by the Department, the NRC, or an Agreement State, or provide another alternative for the Department to review.

The DAC for each class of radionuclide is the concentration of airborne radioactivity in $\mu\text{Ci/ml}$ that, if an occupational worker were to be continuously exposed to for 2,000 hours (1 year), would result in either a CEDE of 5 rem (0.05 Sv) to the whole body or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue, with no consideration for the contribution of external dose. The ALI and DAC for each radionuclide in a specific chemical form are listed in RH-2792, Appendix G.

For each class of each radionuclide, there are two ALIs, one for ingestion and one for inhalation. The ALI is the quantity of radioactive material that, if taken into the body of an adult worker by the corresponding route, would result in a committed effective dose equivalent of 5 rem (0.05 Sv) or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue, again, with no consideration for the contribution of external dose.

The total effective dose equivalent concept makes it possible to combine both the internal and external doses in assessing the overall risk to the health of an individual. The RH-2792 ALI and DAC numbers reflect the doses to all principal organs that are irradiated. The ALI and DAC were derived by multiplying a unit intake by the appropriate organ weighting factors (W_T), for the organs specifically targeted by the radionuclide compound, and then summing the organ-weighted doses to obtain a whole body risk-weighted “effective dose”. In accordance with RH-2792, Appendix G, when an ALI is defined by the stochastic dose limit, this value alone is given. When the ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses.

The types and quantities of radioactive material used at most medical facilities do not provide a reasonable possibility for an internal intake by workers. However, uses such as preparing radioiodine capsules from liquid solutions, and opening and dispensing radioiodine from vials containing milliCurie quantities require particular caution. To

monitor internal exposures from such operations, a routine bioassay program to periodically monitor workers should be established.

If a licensee determines that a program for performing thyroid uptake bioassay measurements is necessary, a program should be established. The program should include:

- Adequate equipment to perform bioassay measurements,
- Procedures for calibrating the equipment, including factors necessary to convert counts per minute into microCuries or Becquerel units,
- Technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue),
- Interval between bioassays,
- Action levels, and
- Actions to be taken at those levels.

For guidance on developing bioassay programs and determination of internal occupational dose and summation of occupational dose that is acceptable to the Department, refer to the following NRC technical documents:

- Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program" dated July 1993,
- Regulatory Guide 8.34, "Monitoring Criteria and Methods to Calculate Occupational Radiation Doses, dated July 1992, and
- NUREG-1400, "Air Sampling in the Workplace," dated September 1993.

Records of Internal Radiation Dose Monitoring

Records of measurement data, calculations of intakes, and methods for calculating dose must be maintained as required by RH-1509. In order to demonstrate compliance with occupational dose limits of RH-1200, the Rules and Regulations include specific requirements for documenting, maintaining, and retaining the results of personnel radiation dose monitoring. The requirements are summarized in Section III of this Appendix.

SUMMATION OF EXTERNAL AND INTERNAL DOSES

If the licensee is required to monitor both the external and internal doses under RH-1302, the licensee is required to demonstrate compliance with the occupational dose limits of RH-1200 by summing the external and internal doses.

III. PERSONNEL MONITORING RECORDS REQUIREMENTS

Records of Prior Occupational Dose

Prior to assigning a personnel monitoring device to a worker the worker's occupational radiation dose received during the current year will be determined. In addition, every reasonable effort must be made to obtain the individual's records indicating the individual's cumulative occupational radiation dose. If a worker is unable to provide the information, records from their previous employer will be obtained. Prior occupational dose records shall include all of the information required by the Rules and Regulations for Control of Sources of Ionizing Radiation, Paragraph RH-2826, "Cumulative Occupational Exposure History", Department Form Z, or an equivalent form.

Records of Individual Monitoring Results

Records of doses received by each monitored worker will be maintained as long as the institution's radioactive material license remains in effect. Dosimetry records will be kept in accordance with the Rules and Regulations for Control of Sources of Ionizing Radiation, Paragraph RH-2804, "Notifications and Reports to Individuals" on Department Form Y, Paragraph RH-2825, or an equivalent form, and will contain all of the information required by Paragraph RH-2804. These records shall be updated annually.

Annual Reports to Monitored Individuals

Each worker assigned a personnel monitoring badge will receive a written annual dose report describing the past year's monitoring results, as required by the Rules and Regulations for Control of Sources of Ionizing Radiation, Paragraph RH-2804, "Notifications and Reports to Individuals". Records documenting that the reports have been furnished to monitored workers will be maintained for at least 3 years.

Termination Reports to Monitored Individuals

Within 30 days of termination of employment, or within 30 days after the individual's exposure has been determined, whichever is later, each monitored worker will receive a written report summarizing the individual's occupational radiation dose, as required by Rules and Regulations for Control of Sources of Ionizing Radiation, Paragraph RH-2804, "Notifications and Reports to Individuals". Records documenting that the reports have been furnished to monitored workers will be maintained for at least 3 years.

Records for Declared Pregnancies

The fetal dose will be closely monitored so as not to exceed 500 millirem. Recordkeeping requirements specified in the Rules and Regulations for Control of Sources of Ionizing Radiation, Paragraph RH-1207, "Dose to an Embryo/Fetus" and RH-1500.f.5., "Records of Individual Monitoring Results", will be met.

Occupational Dose Limits for Minors

Minors will not exceed an annual occupational dose of 500 millirem. Recordkeeping requirements specified in Rules and Regulations for Control of Sources of Ionizing Radiation, Paragraph RH-1206, “Occupational Dose Limits for Minors” and Paragraph RH-2804, “Notifications and Reports to Individuals”, will be met.

Worker Overexposure Reports

When a report of an individual’s exposure is sent to the Arkansas Department of Health as required by Rules and Regulations for Control of Sources of Ionizing Radiation, Paragraph RH-1505, “Notifications and Reports to Individuals”, the exposed individual will also be notified no later than when the report is sent out.

**Appendix H
Form H**

PERSONNEL MONITORING PROGRAM

Describe the proposed personnel radiation dose monitoring program by marking the appropriate boxes or providing the requested information. Submit the completed Form with the Application

EXTERNAL DOSE MONITORING

1. **Personnel Monitoring Device to be Used:**
 Film OSLD TLD
2. **Radiation Detected:**
 Beta Gamma
3. **Type Monitoring:**
 Whole Body Extremity
4. **Frequency of exchange:**
 Monthly Bi-Monthly Quarterly
5. **Supplier of Personnel Monitoring Service:** _____
Arkansas Vendor Registration Number: _____
6. **External Dose Monitoring NOT Required.**
Explain: _____

INTERNAL DOSE MONITORING

1. **Type of Internal Dose Monitoring to be Performed:**

2. **Supplier of Internal Dose Monitoring Service:** _____
Arkansas Vendor Registration Number: _____
3. **Internal Dose Monitoring NOT Required.**
Explain: _____

APPENDIX I

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".

These limits 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-1209, "Compliance with Dose Limits for Individual Members of the Public" requires that the Licensee demonstrate compliance with the annual dose limit. Compliance may be demonstrated by performing and documenting surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas. Also, for areas adjacent to facilities where radioactive material is used or stored, calculations or a combination of calculations and measurements (e.g., using an environmental TLD) are often used to demonstrate compliance.

Licensees must perform the following:

- Insure that radioactive material will be used, transported, and stored in such a way that members of the public will not receive more than 100 mrem (1 mSv) in 1 year, and the dose in any unrestricted area will not exceed 2 mrem (0.02 mSv) in any one hour from licensed operations.
- Insure air emissions of radioactive materials to the environment will not result in exposures to individual members of the public in excess of 10 mrem (0.1 mSv) (TEDE) in one year from these emissions.
- Control and maintain constant surveillance of radioactive material that is not in storage and secure stored licensed material from unauthorized access, removal, or use.

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. Public dose is controlled, in part, by ensuring that radioactive material is secure (e.g., located in a locked area) to prevent unauthorized access or

use by individuals coming into the area. Some medical use devices containing radioactive material are usually restricted by controlling access to the keys needed to operate the devices and/or to keys to the locked storage area. Only Authorized Users and personnel using radioactive material under their supervision should have access to these keys.

Typical unrestricted areas may include offices, shops, laboratories, areas outside buildings, property, and nonradioactive equipment storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials; however, the licensee may control access to these areas for other reasons, such as security.

The definition of “public dose” in RH-1100 does not include doses received due to exposure to patients released in accordance with RH-8420. The provisions of RH-1208 should not be applied to radiation received by a member of the general public from patients released under RH-8420. If a patient is released pursuant to RH-8420, licensees are not required to limit the radiation dose to members of the public (e.g., visitor in a waiting room) from a patient to 2mrem (0.02mSv) in any one hour. Patient waiting rooms need only be controlled for those patients not meeting the release criteria in RH-8420.

Paragraph RH-1208.c. allows licensees to permit visitors to a patient who cannot be released under RH-8420 to receive a dose greater than 0.1 rem (1 mSv) provided the dose does not exceed 0.5 rem (5 mSv) and the authorized user has determined before the visit that it is appropriate.

In assessing adequacy of facilities to control public dose, licensees should consider the design factors discussed under “Facility Diagram” in Application Item 16 and may find confirmatory surveys to be useful in assuring compliance with RH-1208 and RH-1209.

The licensee must control emissions of radioactive material to air such that the individual member of the public likely to receive the highest total effective dose equivalent (TEDE) does not exceed the constraint level of 10 mrem (0.10 mSv) per year, specified in RH-1004, from those emissions. If exceeded, the licensee must report this in accordance with RH-1504, and take prompt actions to ensure against recurrence.

APPENDIX J

FACILITIES AND EQUIPMENT

Applicants must completely describe the proposed facilities and equipment as required by RH-8010. The facility diagram, as shown in Figure 16.1, should include the room or rooms and adjacent areas where radioactive material is prepared, used, administered, and stored at a level of detail that is sufficient to demonstrate that the facilities and equipment are adequate to protect health and minimize danger to life or property.

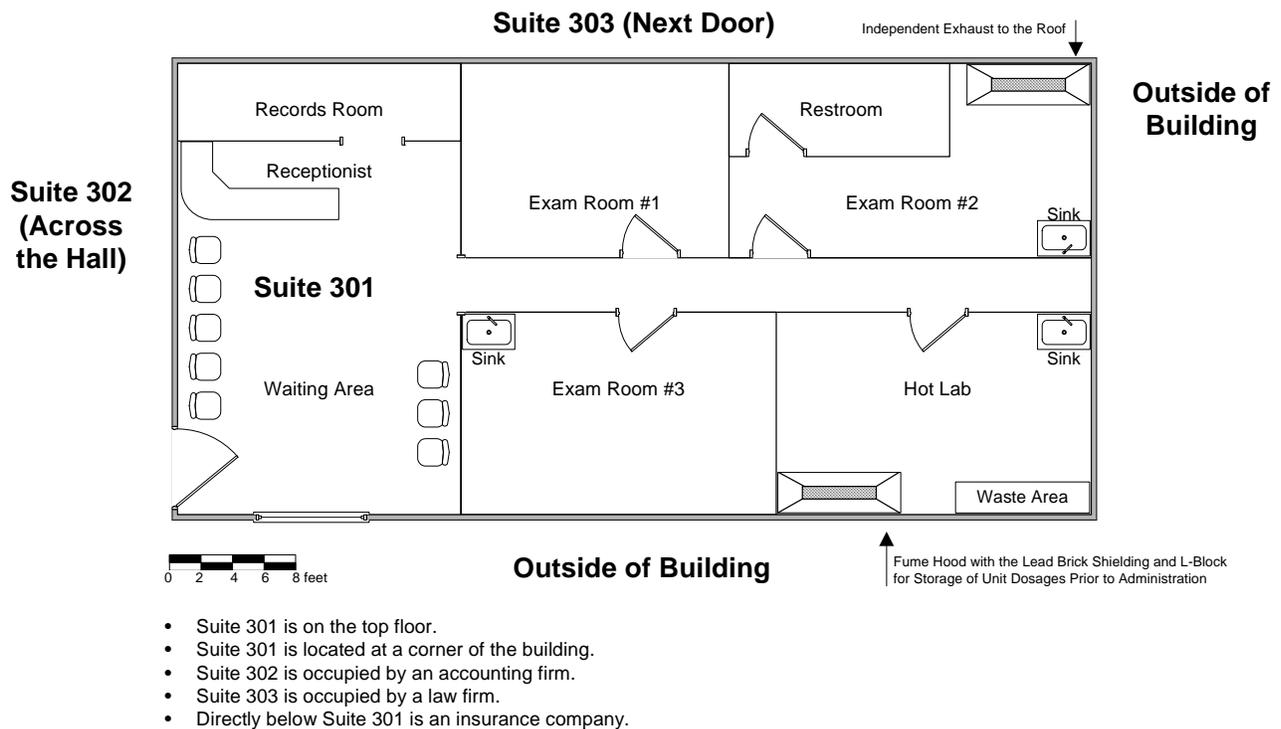


Figure 16.1 Facility Diagram for an Example Nuclear Medicine Suite

Special Requirements Related to the Type of Radioactive Material

Additionally, the following special requirements, which are dependent on the types of radioactive material and the specific use of the material, must be addressed in the facility description.

- A. For **Uptake, Dilution, or Excretion Studies** permitted by RH-8500 and RH-8530, Applicants must provide room numbers for areas in which radioactive materials are used or prepared for use (i.e., “hot labs”). When information regarding an area or room is provided, adjacent areas and rooms, including those above and below, should be described.

- B. For use of **Unsealed Radioactive Material-Written Directive Required** permitted by RH-8550 and **Sealed Sources** permitted by RH-8600, Applicants must provide the above information and in addition, they must provide the locations where sources are stored. Describe the rooms where patients will be housed if they cannot be released under RH-8420. The discussion must include a description of shielding, if applicable. Regulatory requirements, the ALARA principle, good medical care, and access control must be considered when determining the location of the therapy patient's room or a therapy treatment room.

The applicant must describe additional facilities and equipment for the radiopharmaceutical therapy program to safely receive, use, store, and dispose of radioactive material. The applicant should focus on facilities to be used for radioactive drug therapy administration and patient accommodations (i.e., private room with private bath). I-131 sodium iodide is the most widely used source of radiopharmaceutical therapy. If the radionuclide is administered in volatile liquid form, it is important to place the patient dosage in a closed environment (i.e., a fume hood). Also note, there are hazards associated with volatile iodine in pill form; applicants should consider this in establishing their radiological controls. When patients are treated with I-131 sodium radioiodide, sources of contamination include airborne I-131, urine, perspiration, saliva, and other secretions.

- C. For use of **Sealed Source for Diagnosis** permitted by RH-8620, the applicant must provide the room numbers of use.
- D. For use of **Photon Remote Afterloader Units, Teletherapy Units, or Gamma Stereotactic Radiosurgery Units** permitted by RH-8630, the Applicant must provide all of the information discussed above and the shielding calculations for the facility as described in the diagram.

For **teletherapy, GSR, and HDR facilities**, the licensee shall require any individual entering the treatment room to ensure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels. One method of meeting the requirements of RH-8634 is a beam-on radiation monitor permanently mounted in each therapy treatment room that is equipped with an emergency power supply separate from the power supply for the therapy unit. Such beam-on monitors can provide a visible indication (e.g., flashing light) of an exposed or partially exposed source. Applicants may propose an alternative to a permanently mounted monitor.

Paragraph RH-8634 requires that, except for LDR units, each licensee shall construct or equip each treatment room so as to permit continuous observation of the patient while the patient is in the treatment room. If a shielded viewing window will be used, the thickness, density, and type of material used should be specified. If a closed-circuit television system (or some other electronic system)

will be used to view the patient, the backup system or procedure to be used in case the electronic system malfunctions should be specified, or the applicant must commit to suspending all treatments until the electronic system is repaired and functioning again. The communication system should allow the patient to communicate with the unit operator in the event of medical difficulties. An open microphone system can be used to allow communication without requiring a patient to move to activate controls.

The regulations require adequate equipment and controls to maintain exposures of radiation to workers ALARA and within regulatory limits. Paragraph RH-8634, in part, requires that each door leading into the treatment room be provided with an electrical interlock system to control the on-off mechanism of the therapy unit. The interlock system must cause the source(s) to be shielded if the door to the treatment room is opened when the source is exposed. The interlock system must also prevent the operator from initiating a treatment cycle unless the treatment room entrance door is closed. Further, the interlock must be wired so that the source(s) cannot be exposed after interlock interruption until the treatment room door is closed and the source(s) on-off control is reset at the console.

Due to the unique characteristics of **PDR remote afterloaders** and the lack of constant surveillance of their operation, a more sophisticated alarm system is essential to ensure the patient is protected during treatment. In addition to the above, consider the following:

- The PDR device control console is *not* accessible to unauthorized personnel during treatment;
- A primary care provider checks the patient to ensure that the patient's device has not been moved, kinked, dislodged, or disconnected;
- A more sophisticated interlock/warning system is normally installed for PDR devices. This system should perform the following functions or possess the following characteristics:
 - The signal from the PDR device and the signal from the room radiation monitor should be connected in such a manner that an audible alarm sounds if the room monitor indicates the presence of radiation and the device indicates a "safe" or retracted position;
 - The alarm circuit should also be wired in such a manner that an audible alarm is generated for any device internal error condition that could indicate the unintended extension of the source. This would constitute a circuit that generates the audible alarm when either the "source retracted and radiation present" or appropriate internal error condition(s) exist;

- The “source safe and radiation present” signal should also be self-testing. If a “source not safe” input is received without a corresponding “radiation present” signal, the circuit should generate an interlock/warning circuit failure signal that will cause the source to retract. Reset this circuit manually before attempting to continue treatment;
- The audible alarm should be sufficiently loud to be clearly heard by the facility’s responsible device/patient monitoring staff at all times; and
- No provisions for bypassing this alarm circuit or for permanently silencing the alarm should be made to the circuit as long as the room radiation monitor is indicating the presence of radiation. If any circuitry is provided to mute the audible alarm, such circuitry should not mute the alarm for a period of more than 1 minute. Controls that disable this alarm circuit or provide for silencing the alarm for periods in excess of 1 minute should be prohibited.

If the alarm circuit is inoperative for any reason, licensees shall prohibit further treatment of patients with the device until the circuit has been repaired and tested. If the alarm circuit fails during the course of a patient treatment, the treatment in progress may continue as long as continuous surveillance of the device is provided during each treatment cycle or fraction.

Applicants may submit information on alternatives to fixed shielding as part of their facility description. This information must demonstrate that the shielding will remain in place during the course of patient treatment.

For patient rooms where **LDR remote afterloader** use is planned, neither a viewing nor an intercom system is required. However, the applicant must describe how the patient and device will be monitored during treatment to ensure that the sources and catheter guide tube are not disturbed during treatment and to provide for prompt detection of any operational problems with the LDR device during treatment.

- E. For **Other Medical Uses of Radioactive Material or Radiation** under RH-8670, Applicants must review the above to determine the type of information appropriate to evaluate the adequacy of the facilities.

The applicant must demonstrate that the limits specified in RH-1208 will not be exceeded. If the calculations demonstrate that these limits cannot be met, indicate any further steps that will be taken to limit exposure to individual members of the public. The applicant may consider the following options:

- Adding shielding to the barrier in question, with corresponding modification of the facility description if necessary.
- Requesting prior Department authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv) and demonstrating that the requirements of RH-1208 will be met. The applicant must demonstrate the need for and the expected duration of operations that will result in an individual dose in excess of the limits specified in RH-1208. A program to assess and control dose within the 0.5 rem (5 mSv) annual limit and procedures to be followed to maintain the dose ALARA (RH-1004) must be developed (see RH-1208).

If applicants are proposing to use portable shielding to protect health and minimize danger to life or property, they must describe the alternative equipment and administrative procedures they propose to use for evaluation and approval by Department. If applicants elect to use portable shielding, they shall commit to having administrative procedures to control configuration management to maintain dose within regulatory limits.

If radiopharmaceutical therapy and brachytherapy patient rooms are added after the initial license is issued, additional room diagrams, along with a written description of the changes, must be submitted if the room design (including shielding) and the occupancy of adjacent areas are significantly different from the original diagrams provided.

For teletherapy units, it may be necessary to restrict use of the unit's primary beam if the treatment room's walls, ceiling, or floor will not adequately shield adjacent areas from direct or scattered radiation. Electrical, mechanical, or other physical means (rather than administrative controls) must be used to limit movement or rotation of the unit (e.g., electrical or mechanical stops). Some applicants have found it helpful to have a sample response for guidance. The following is an example of an acceptable response on the use of a rotational unit with an integral beam absorber (also called a beam catcher).

- For the primary beam directed toward the integral beam absorber, electrical or mechanical stops are set so that the primary beam must be centered (within plus or minus 2 degrees) on the integral beam absorber and, in that configuration, the attenuated primary beam may be rotated 360 degrees pointing toward the floor, east wall, ceiling, and west wall.
- For the primary beam directed away from the integral beam absorber, electrical or mechanical stops permit the unattenuated primary beam to be directed in a 95-degree arc from 5 degrees toward the west wall to vertically down toward the floor to 90 degrees toward the east wall.

Experience has shown that, given this type of example, many applicants can make changes to accommodate their own situations (e.g., use of a vertical unit, use of a rotational unit without an integral beam absorber).

The following References are provided to assist the Applicants

- National Council on Radiation Protection and Measurements (NCRP)
 - Report 49, “Structural Shielding Design and Evaluation for Medical Use of X-Rays and Gamma Rays of Energies up to 10 MeV”;
 - Report 102, “Medical X-Ray, Electron Beam and Gamma Ray Protection for Energies up to 50 MeV (Equipment Design, Performance and Use)”;
 - Report 40, “Protection Against Radiation from Brachytherapy Sources,”
 - Report 151, “Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities”.
- NUREG/CR-6276, “Quality Management in Remote Afterloading Brachytherapy”,
- NUREG/CR-6324, “Quality Assurance for Gamma Knives”.

Note: The NUREGs may be outdated because the revised Rules and Regulations for Control Of Sources of Ionizing Radiation were amended after these documents were published.

APPENDIX K

RADIATION SURVEY PROGRAM

General Information

Radioactive Material Licensees are required to make radiation surveys of potential radiological hazards in the workplace. Paragraph RH-8408 establishes the requirements for ambient radiation dose rate and contamination surveys. It also specifies that the Licensee shall establish “action levels” and requirements for notification of the Radiation Safety Officer if the survey results exceed the action levels.

There are many different kinds of surveys that must be performed by the licensee, including:

- Contamination (Fixed and Removable)
- Water Effluent
- Air Effluent
- Leak Test of Sealed Sources
- Bioassays
- Air Samples
- Area Surveys (Restricted Areas and Unrestricted Areas)
- Personnel (during use, transfer, or disposal of radioactive material)

Radiological surveys are required when it is reasonable under the circumstances to evaluate a radiological hazard and when it is necessary for the licensee to comply with the appropriate regulations. The most important types of surveys are as follows:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment,
- Measurements of radioactive material concentrations in air for areas where radiopharmaceuticals are handled or processed in unsealed form and where operations could expose workers to the inhalation of radioactive material (e.g., radioiodine) or where radioactive material is or could be released to unrestricted areas,
- Bioassays to determine the kinds, quantities, or concentrations, and in some cases, the location of radioactive material in the human body. Radioiodine uptake in a worker’s thyroid gland is commonly measured by external counting using a specialized thyroid detection probe,

- Surveys of external radiation exposure levels in both restricted and unrestricted areas, and,
- Surveys of radiopharmaceutical packages entering (e.g., from suppliers) and departing (e.g., returned radiopharmaceuticals to the supplier).

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect workers and the public from external and internal exposure. Also, the frequency of the survey depends on the type of survey. Later in this Appendix, the Section, **Additional Guidance**, contains model procedures that represent one acceptable method of establishing survey frequencies for ambient radiation level and contamination surveys.

For example, licensees are required to perform daily surveys in all areas used for the preparation and administration of radiopharmaceuticals. Licensees must perform surveys after the patient's release. Licensees must perform surveys prior to the release of the room for unrestricted use. Licensees must be cognizant of the requirement to perform surveys to demonstrate the public dose limits are not exceeded.

In addition, licensees must also perform the following surveys:

- Immediately following implantation or administration, areas of public access in and around the patient's room (in order to demonstrate compliance with public dose limits),
- The therapy patient's bed linens before removing them from the patient's room,
- All trash exiting the patient's room.

Because therapy sealed sources (including applicators and catheters) may become dislodged during implantation or after surgery, and inadvertently lost or removed, the following surveys shall be performed:

- Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted,
- The operating room and the patient's room after source implantation,
- Immediately after removing the last temporary implant source from a patient or human research subject, the licensee shall make a survey of the patient or human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

Additional Guidance

This model provides acceptable procedures for performing area radiation surveys. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of RH-1004, RH-1300, and RH-8408. Guidance for developing alternate trigger levels for contamination in restricted areas is also included.

Ambient Radiation Level Surveys

Procedures for ambient radiation level surveys (reference RH-1004, RH-1300, and RH-8408):

- Perform surveys of dose rates in locations where:
 - Workers are exposed to radiation levels that might result in radiation doses in excess of 10% of the occupational dose limits; or
 - An individual is working in an environment with a dose rate of 2.5 mrem/hour or more (5 rem/year divided by 2,000 hour/year).
- Paragraph RH-1208 requires that the TEDE to an individual member of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, and that the dose in any unrestricted area from external sources does not exceed 0.002 rem (0.02 mSv) in any one hour. Appropriate surveys will be conducted to assure that the requirements of RH-1208 are met.

Perform radiation level surveys with a survey meter sufficiently sensitive to detect 0.1 millirem (mrem) per hour in the following areas, at the frequency specified:

- Survey at the end of each day of use all radiopharmaceutical elution, preparation, assay and administration areas.
- Survey monthly all laboratory areas where only small quantities of gamma-emitting radioactive material are used (< 200 μ Ci at a time).
- Survey weekly all radionuclide use, storage, and waste storage areas. If diagnostic administrations are occasionally made in patients' rooms (e.g., bone scan injections, Tc-99m heart agents) and special care is taken to remove all work materials, those rooms need not be surveyed.
- Survey quarterly all sealed source and brachytherapy source storage areas.
- If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Example trigger levels for restricted and unrestricted areas are presented in Table K-1.

Table K-1 Ambient Dose Rate Trigger Levels		
Type of Survey	Area Surveyed	Trigger Level
Ambient Dose Rate	Unrestricted	2 x Background Radiation Level
Ambient Dose Rate	Restricted	2.0 mR/hr

Contamination Surveys

Facilities and equipment for contamination surveys:

To ensure achieving the required sensitivity of measurements, analyze survey samples in a low-background area. Table F-1 entitled “Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples” in Appendix F provides examples of appropriate instruments.

Perform contamination surveys using instruments suitable for removable and fixed contamination to identify areas of contamination that might result in doses to workers or to the public. Removable contamination can be detected and measured by conducting a wipe test of the surface, counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

Procedures for contamination surveys:

- Contamination surveys are performed in areas where unsealed forms of materials are used:
 - To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment;
 - After any spill or contamination event;
 - When procedures or processes have changed;
 - To evaluate contamination of users and the immediate work area, at the end of the day, when licensed material is used;
 - In unrestricted areas at frequencies consistent with the types and quantities of materials in use, but not less frequently than monthly;
 - In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.
- Use methods for conducting surveys for removable contamination that are sufficiently sensitive to detect contamination at the levels listed in Tables K-2 for restricted areas and K-3 for unrestricted areas. Removable contamination survey samples should be measured in a low-background area.

- The following areas and frequencies should be followed:
 - Removable contamination surveys weekly for radiopharmaceutical elution, preparation, assay, and administration areas. If diagnostic administrations are occasionally made in patients' rooms (i.e., bone scan injections, Tc-99m heart agents, etc.), with special care taken to remove all work materials, those rooms need not be surveyed.
 - Removable contamination surveys monthly of laboratory areas where only small quantities of photon-emitting radioactive material are used (<200 microcuries at a time).
 - Removable contamination surveys weekly for radionuclide storage and radionuclide waste storage areas.
 - A radioactive source with a known amount of activity should be used to convert sample measurements (usually in cpm) to dpm.
- The area should be decontaminated, shielded, or posted and restricted from use if it cannot be decontaminated.
- If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Example trigger levels are presented in Table K-2 and Table K-3. Contamination found in unrestricted areas and on personal clothing will be immediately decontaminated to background levels.

Table K-2 Surface Contamination Levels in <u>Restricted Areas</u> (dpm/100 cm²)	
Location/Item	Any Radionuclide
Restricted Areas Or Item	2200

Table K-3 Surface Contamination Levels in <u>Unrestricted Areas</u> (dpm/100 cm²)	
Radionuclide	Maximum Removable
Any	220

NOTES FOR CONTAMINATION LEVEL SURVEYS FOR TABLE K-3

1. As used in this table, dpm means the rate of emission by radioactive material, as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.
2. The contamination level applies to an area of not more than 100 cm².
3. The amount of removable radioactive material per 100 cm² of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.
4. The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 millirad/hour at 1 centimeter and 1.0 millirad/hour at 1 centimeter, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.

Establishing Alternate Trigger Levels for Restricted Areas

The following guidance is provided for those applicants who plan to develop procedures for surveying and controlling contamination using action levels for controlling contamination that differ from those provided in Tables K-1 and K-2:

Alternate action levels for cleanup of contamination restricted areas may be developed without prior Department approval if

- acceptable unrestricted area trigger levels are implemented (e.g., Tables K-1 and K-3);
- the action levels maintain occupation doses ALARA;
- the action levels meet all other regulatory requirements (e.g., they should also be designed to minimize, to the extent practicable, contamination of the facility, and the environment; facilitate eventual decommissioning; and minimize, to the extent practicable, the generation of radioactive waste).

Contents of Survey Records

- A diagram of the area surveyed;
- A list of items and equipment surveyed;
- Specific locations on the survey diagram where wipe tests were taken;
- Ambient radiation levels with appropriate units;
- Contamination levels with appropriate units;
- Make and model number of instruments used;
- Calibration dates of instruments used;
- Background levels;
- Name of the person making the evaluation and recording the results and date.

Record contamination levels observed and procedures followed for incidents involving contamination of individuals. Include names of individuals involved, description of work activities, calculated dose, probable causes (including root causes), steps taken to reduce future incidents of contamination, times and dates, and the surveyor's signature.

APPENDIX L

ORDERING, RECEIVING, OPENING, AND SHIPPING PACKAGES CONTAINING RADIOACTIVE MATERIAL

To insure radioactive material is properly ordered, received, opened, and shipped, the following information may be used to develop operating procedures.

General Information

1. Ordering and Receiving

- A. Radioactive material will be ordered by _____ (Name/Title).
- B. The Radiation Safety Officer (RSO) must approve or place all orders for radioactive material and insure that the requested radioactive material(s), quantities, manufacturer and model are authorized by the license and that possession limits are not exceeded.
- C. Transportation carriers will be provided instructions on when and where to deliver packages containing radioactive materials.

2. Receiving and Safely Opening Packages

- A. Only Authorized Users or specifically identified designees are permitted to open shipping packages (shipping/transport containers) containing radioactive material. If the RSO or an Authorized User is not available when the package is delivered, the package will be placed in a secure, pre-designated remote location of the facility awaiting the RSO or an Authorized User. The package will not be opened.
- B. Packages containing radioactive material shall be inspected and surveyed as soon as practical after receipt of the package, but not later than three (3) hours after the package is received at the licensee's facility if it is **received during normal working hours**.
- C. Packages containing radioactive material that are **received after normal working hours** at the licensee's facility shall be inspected and surveyed not later than three (3) hours from the beginning of the next working day.
- D. Each package will be visually inspected for any sign of damage. **If damage is noted, immediately notify the RSO.** If the RSO determines that the shielding may have been compromised, the RSO will survey the package to determine the presence and extent of any shielding failure or radioactive contamination. **If damage is noted, the package will immediately be placed in a secure storage area. The package of**

radioactive material will not be used. The RSO will notify the Department in accordance with the Emergency Procedures.

- E.** If the physical inspection indicates no damage, remove the packing slip. Open the container and verify the contents. Closely examine the package for damage and check to verify that the radioactive material is authorized by the radioactive materials license. If anything appears out of place or missing, notify the RSO.
- F.** If the inspection results are satisfactory, store and lock the package in the designated storage area.
- G.** Records of receipt and transfer shall be maintained for inspection purposes and shall be retained for at least 3 years following the date the record was created.

3. Preparing Packages for Shipment

- A.** Packages of radioactive material offered to common carriers for shipment will be prepared in accordance with applicable U.S. Department of Transportation regulations. Specific instructions for preparing packages for shipment are provided in the Transportation section of the Operating Procedures. Proper packaging, markings and labels will be used, and proper shipping papers and emergency response information will be provided with each package. Transfer records will be maintained on file for inspection purposes.
- B.** Packages of radioactive material will be prepared for shipment only by personnel that have completed hazmat employee training specified in the U.S. Department of Transportation, Subpart H, 49 CFR Part 172.

Additional Guidance

1. Ordering and Receiving Packages Containing Radioactive Material

This model provides critical information for ordering and receiving packages containing radioactive material that must be included in operating procedures. The Licensee must:

- Authorize, through a designee (e.g., Radiation Safety Officer), each order of radioactive material and ensure that the requested materials and quantities are authorized by the license for use by the requesting Authorized User and that possession limits are not exceeded.
- Establish and maintain a system for ordering and receiving radioactive material; include the following information:
 - Records that identify the Authorized User or department, radionuclide, physical and/or chemical form, activity, and supplier;

- Confirmation, through the above records, that material received was ordered through proper channels.
- For deliveries during normal working hours, inform carriers to deliver radioactive packages directly to a specified area.
- For deliveries during off-duty hours, inform security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum for delivery of packages to the Nuclear Medicine Division, provided in this Appendix. Develop a similar memorandum for delivery of packages to other divisions. A sample Memorandum is included on Page 5.

2. Safely Opening Packages Containing Radioactive Material

This model provides acceptable procedures for opening packages containing radioactive material. Applicants may either adopt this model procedure or develop an alternative procedure to meet the requirements of RH-1307.

Model Procedure

1. Put on gloves to prevent hand contamination.
2. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO or the designee of the RSO if the RSO is not present immediately.
3. Monitor the external surfaces of a labeled¹ package for radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form, as defined in RH-3100.
4. Monitor the external surfaces of a labeled¹ package for radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in RH-3100 and Table C-1 to RH-2700.
5. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels, if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.
6. Remove the packing slip.
7. Open the outer package, following any instructions that may be provided by the supplier.
8. Open the inner package and verify that the contents agree with the packing slip.

¹ Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in DOT regulations.

9. Check the integrity of the final source container. Notify the RSO of any broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
10. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe sample to determine if there is any removable radioactivity. An appropriate instrument with sufficient sensitivity will be used to assay the sample. For example, a NaI(Tl) crystal and rate meter, a liquid scintillation counter, or a proportional flow counter may be used for these assays. The detection efficiency will be determined to convert wipe sample counts per minute to disintegrations per minute. **Note: a dose calibrator is not sufficiently sensitive for this measurement.** Take precautions against the potential spread of contamination.
11. Check the user request to ensure that the material received is the material that was ordered.
12. Monitor the packing material and the empty packages for contamination with a radiation detection survey meter before discarding. If contaminated, treat this material as radioactive waste. If not contaminated, remove or obliterate the radiation labels before discarding in in-house trash.
13. Make a record of the receipt.

For packages received under the general license in RH-402.h, implement the following procedure for opening each package:

1. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO (or the RSO's designee) immediately.
2. Check to ensure that the material received is the material that was ordered.

MEMORANDUM**TO:** Chief of Security**FROM:** Radiation Safety Officer**DATE:****SUBJECT:** Receipt of Packages Containing Radioactive Material

The Security Personnel on duty will accept delivery of radioactive material that arrives outside normal working hours. Packages will be taken immediately to the Nuclear Medicine Division, Room ___. Unlock the door, place the package on top of the counter, and relock the door.

If the package appears to be damaged, immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that neither the driver nor the delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call the Radiation Safety Officer, at extension _____.

	<u>Name</u>	<u>Home Telephone</u>
Radiation Safety Officer:		
Director of Nuclear Medicine:		
Nuclear Medicine Technologist Supervisor:		
Nuclear Medicine Technologist on call (call page operator at extension _____)		
Nuclear Medicine Physician on call (call page operator at extension _____)		

APPENDIX M

DISPOSAL OR TRANSFER OF RADIOACTIVE MATERIAL

General Information

Paragraphs RH-1400 through RH-1407 of the Rules and Regulations for Control of Sources of Ionizing Radiation, address the transfer and disposal of radioactive material. In accordance with Paragraph RH-1400, radioactive material must be disposed of in accordance with Department requirements by:

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

Also, a company or person (Service Vendor) must be specifically licensed to receive radioactive waste from Licensees for the following:

- Treatment prior to disposal
- Treatment or disposal by incineration
- Decay in storage, or
- Taking possession (and ownership) of sealed sources or devices containing sealed sources.

The Applicant must thoroughly describe the waste transfer or disposal program that will be used to manage the radioactive waste generated during licensed operations. All phases of the waste transfer or disposal program must be addressed in written operating procedures. Like all operating procedures, these procedures will be incorporated into the Radioactive Material License.

Specific Guidance and Information

Applicants are reminded to consider the following information when they develop procedures (as applicable):

- Except for material suitable for decay-in-storage and some animal carcasses handled by the licensee, solids are transferred to an authorized recipient licensed to receive such waste in accordance with RH-1400, RH-1406, or in applicable regulations in Section 2, RH-407. Follow the packaging instructions received from the transfer agent and the burial site operator. Keep the consignment sheet from the transfer agent as the record of disposal.

- When setting up a program for decay-in-storage, consider short-term and long-term storage. Consider designing long-term storage to allow for segregation of wastes with different half-lives (e.g., the use of multiple shielded containers) and use of containers with shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location.
- Waste from *in vitro* kits (except mock iodine-125) that are generally licensed under RH-402.h is exempt from waste disposal regulations in Section 3, as set forth in RH-1402. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.
- Consider the monitoring and control mechanisms in place to ensure compliance with the appropriate requirements regarding the release of material into air and water under RH-1210 and RH-1402, respectively.
 - Regulations for disposal in the sanitary sewer appear in RH-1402. Material must be readily soluble or dispersible in the water. There are also monthly and annual limits, based on the total sanitary sewerage release of the facility. (Excreta from patients undergoing medical diagnosis or therapy are not subject to these limitations; see RH-1402).
 - Limits on permissible concentrations in effluents to unrestricted areas are enumerated in RH-2792. These limits apply at the boundary of the restricted area.
 - Liquid scintillation-counting media containing 0.05 μCi (1.85 kBq) per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (RH-1405).
- If applicants/licensees propose to treat or dispose of licensed material by incineration, they must comply with RH-1404. Contact the Department for guidance on treatment or disposal of material by incineration.
- Applicants that wish to use waste volume reduction operations (e.g., compactors) must provide a detailed description (as outlined below), along with their response to Item 16, Facilities and Equipment:
 - A description of the compactor to demonstrate that it is designed to safely compact the waste generated (e.g., manufacturer's specifications, annotated sketches, photographs);
 - The types, quantities, and concentrations of the waste to be compacted;
 - An analysis of the potential for airborne release of radioactive material during compaction activities;
 - The location of the compactors in the waste processing area(s), as well as a description of the ventilation and filtering systems used in conjunction with the compactors, and procedures for monitoring filter blockage and exchange;

- Methods used to monitor worker breathing zones and/or exhaust systems;
- The types and frequencies of surveys that will be performed for contamination control in the compactor area;
- The instructions provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, method of handling uncompacted waste, and examining containers for defects.

Nuclear pacemakers

Medical licensees are often the first to encounter plutonium-powered pacemakers or the first to be contacted by nursing homes and funeral homes when a patient with an implanted pacemaker dies. In such cases and when the licensee is not responsible for control or disposal of the pacemaker, notify the Department and attempt to contact the hospital where the pacemaker was implanted to arrange for explantation. The licensee who implanted the device is responsible for the follow-up, explantation, and return of the pacemaker to the manufacturer for proper disposal. (NRC Information Notice 98-12, "Licensees' Responsibilities Regarding Reporting and Follow-up Requirements for Nuclear-Powered Pacemakers", provides additional technical information.)

Model Procedures for Waste Disposal by Decay-In-Storage, Generator Return, and Licensed Material Return

This model provides acceptable procedures for waste disposal. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of RH-1400-1407, RH-1004, and RH-8410.

Model Procedure for Decay-In-Storage

Paragraph RH-8410 describes the requirements for decay-in-storage. Storage should be designed to allow for segregation of wastes with different half-lives (e.g., multiple shielded containers). Containers should have shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location.

- If possible, use separate containers for different types of waste, e.g., needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container. Because the waste will be surveyed with all shielding removed, the containers in which the waste will be disposed of must not provide any radiation shielding for the material.
- When the container is full, seal it and attach an identification tag that includes the date sealed and the longest-lived radionuclide in the container. The container may then be transferred to the decay-in-storage area.
- Prior to disposal as in-house waste, monitor and record the results of monitoring of each container as follows:

- Use a survey instrument that is appropriate for the type and energy of the radiation being measured;
- Check the radiation detection survey meter for proper operation and current calibration status;
- Monitor in a low-level radiation (<0.05 millirem per hour) area away from all sources of radioactive material, if possible;
- Remove any shielding from around the container or generator column;
- Monitor, at contact, all surfaces of each individual container;
- Remove or deface any radioactive material labels (unless the containers will be managed as biomedical waste after they have been released from the licensee as described in RH-8410);
- Discard as in-house waste only those containers that cannot be distinguished from background radiation. Containers may include trash bags full of waste, generator columns, and biohazard (needle) boxes. Record the disposal date, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal;
- Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred to an authorized radioactive material recipient.

Model Procedure for Returning Generators to the Manufacturer

Used Mo/Tc-99m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with 10 CFR Part 71 and DOT regulations. Perform the following actions when returning generators:

- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container;
- Assemble the package in accordance with the manufacturer's instructions;
- Perform the dose rate and removable contamination measurements;
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions;
- Retain records of receipts and transfers in accordance with RH-600.

Model Procedure for Return of Radioactive Material to Authorized Recipients

Perform the following steps when returning licensed material to authorized recipients:

- In accordance with RH-500-502, confirm that persons are authorized to receive radioactive material prior to transfer (e.g., obtain a copy of the transferee's Department, NRC, or Agreement State license that authorizes the radioactive material);
- Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container;
- Assemble the package in accordance with the manufacturer's instructions;
- Perform the dose rate and removable contamination measurements;
- Label the package and complete the shipping papers in accordance with the manufacturer's instructions;
- Retain records of receipts and transfers in accordance with RH-600.

APPENDIX N

INCREASED CONTROLS FOR LICENSEES THAT POSSESS SOURCES CONTAINING RADIOACTIVE MATERIAL QUANTITIES OF CONCERN

The purpose of the increased controls (ICs) for radioactive sources is to enhance control of radioactive material in quantities greater than or equal to values described in Table 1, to reduce the risk of malevolent use of radioactive materials, through access controls to aid prevention, and prompt detection, assessment, and response to mitigate potentially high consequences that would be detrimental to public health and safety. These ICs for radioactive sources are established to delineate licensee responsibility to maintain control of licensed material and secure it from unauthorized removal or access. The following ICs apply to licensees who, at any given time, possess radioactive sources greater than or equal to the quantities of concern of radioactive material defined in Table 1.

1. In order to ensure the safe handling, use, and control of licensed material in use and in storage each licensee shall control access at all times to radioactive material quantities of concern and devices containing such radioactive material (devices), and limit access to such radioactive material and devices to only approved individuals who require access to perform their duties.
 - a. The licensee shall allow only trustworthy and reliable individuals, approved in writing by the licensee, to have unescorted access to radioactive material quantities of concern and devices. The licensee shall approve for unescorted access only those individuals with job duties that require access to such radioactive material and devices. Personnel who require access to such radioactive material and devices to perform a job duty, but who are not approved by the licensee for unescorted access, must be escorted by an approved individual.
 - b. For individuals employed by the licensee for three years or less, and for non-licensee personnel, such as physicians, physicists, housekeeping personnel, and security personnel under contract, trustworthiness and reliability shall be determined, at a minimum, by verifying employment history, education, and personal references. The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the employee (i.e., seeking references not supplied by the individual). For individuals employed by the licensee for longer than three years, trustworthiness and reliability shall be determined, at a minimum, by a review of the employees' employment history with the licensee.
 - c. Service providers shall be escorted unless determined to be trustworthy and reliable by an NRC-required background investigation as an employee of a manufacturing or distribution (M&D) licensee. Written verification attesting to or certifying the person's trustworthiness and reliability shall be obtained from the manufacturing/distribution licensee providing the service.
 - d. The licensee shall document the basis for concluding that there is reasonable assurance an individual granted unescorted access is trustworthy and reliable, and does not constitute an unreasonable risk for malevolent use of radioactive material quantities of concern.

The licensee shall maintain a list of persons approved for access to such radioactive material and device(s) by the licensee.

2. In order to ensure the safe handling, use, and control of licensed material in use and in storage, each licensee shall have a documented program to monitor and immediately detect, assess, and respond to unauthorized access to radioactive material quantities of concern and devices. Enhanced monitoring shall be provided during periods of source delivery or shipment, where the delivery or shipment exceeds 100 times the Table 1 values.
 - a. The licensee shall respond immediately to any actual or attempted theft, sabotage, or diversion of such radioactive material or of the devices. The response shall include requesting assistance from Local Law Enforcement Agency (LLEA).
 - b. The licensee shall have a pre-arranged plan with LLEA for assistance in response to an actual or attempted theft, sabotage, or diversion of such radioactive material or of the devices which is consistent in scope and timing with realistic potential vulnerability of the sources containing such radioactive material. The pre-arranged plan shall be updated when changes to the facility design or operation affect the potential vulnerability of the sources. Pre-arranged LLEA coordination is not required for temporary job sites.
 - c. The licensee shall have a dependable means to transmit information between, and among, the various components used to detect and identify an unauthorized intrusion, to inform the assessor, and to summon the appropriate responder.
 - d. After initiating appropriate response to any actual or attempted theft, sabotage, or diversion of radioactive material or of the device(s), the licensee shall, as promptly as possible, notify Arkansas Department of Health and Human Services, Radioactive Materials Program at 1-800-633-1735.
 - e. The licensee shall maintain documentation describing each instance of unauthorized access and any necessary corrective actions to prevent future instances of unauthorized access.
3. a. In order to ensure the safe handling, use, and control of licensed material in transportation for domestic highway and rail shipments by a carrier other than the licensee, for quantities that equal or exceed those in Table 1 but are less than 100 times Table 1 quantities, per consignment, the licensee shall:
 - (1.) Use carriers which:
 - A. Use package tracking systems,
 - B. Implement methods to assure trustworthiness and reliability of drivers,
 - C. Maintain constant control and/or surveillance during transit, and
 - D. Have the capability for immediate communication to summon appropriate response or assistance.

The licensee shall verify and document that the carrier employs the measures listed above.

- (2.) Contact the recipient to coordinate the expected arrival time of the shipment;

- (3.) Confirm receipt of the shipment; and
 - (4.) Initiate an investigation to determine the location of the licensed material if the shipment does not arrive on or about the expected arrival time. When, through the course of the investigation, it is determined the shipment has become lost, stolen, or missing, the licensee shall immediately notify the Arkansas Department of Health and Human Services, Radioactive Materials Program at 1-800-633-1735. If after 24 hours of investigating, the location of the material still cannot be determined, the radioactive material is deemed missing and the licensee shall immediately notify the Arkansas Department of Health and Human Services, Radioactive Materials Program at 1-800-633-1735.
- b. For domestic highway and rail shipments, prior to shipping licensed radioactive material that exceeds 100 times the quantities in Table 1 per consignment, the licensee shall:
- (1.) Notify NRC*, in writing, at least 90 days prior to the anticipated date of shipment. The NRC will issue the order requiring implementation of Additional Security Measures (ASMs) for the transportation of Radioactive Material Quantities of Concern (RAM QC). The licensee shall not ship this material until the ASMs for the transportation of RAM QC are implemented or notified otherwise, in writing, by NRC.
 - (2.) Once the licensee has implemented the ASMs for the transportation of RAM QC, the notification requirements of 3.b.1 shall not apply to future shipments of licensed radioactive material that exceed 100 times the Table 1 quantities. The licensee shall implement the ASMs for the transportation of RAM QC.
- c. If a licensee employs a M&D licensee to take possession of the licensed radioactive material and ship it under its M&D license, the requirements of 3.a. and 3.b above shall not apply (because the M&D licensee will have to comply with equivalent requirements).
- d. If the licensee is to receive radioactive material greater than or equal to the Table 1 quantities, per consignment, the licensee shall coordinate with the originating licensee to:
- (1.) Establish an expected time of delivery; and

* Director, Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

- (2.) Confirm receipt of transferred radioactive material. If the material is not received at the expected time of delivery, notify the originating licensee and assist in any investigation.

4. In order to ensure the safe handling, use, and control of licensed material in use and in storage each licensee who possesses mobile or portable devices containing radioactive material in quantities greater than or equal to Table 1 values, shall:
 - a. For portable devices, have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee.
 - b. For mobile devices:
 - (1.) that are only moved outside of the facility (e.g., on a trailer), have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee.
 - (2.) that are only moved inside a facility, have a physical control that forms a tangible barrier to secure the material from unauthorized movement or removal when the device is not under direct control and constant surveillance by the licensee.
 - c. For devices in or on a vehicle or trailer, licensees shall also utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee.
5. The licensee shall retain documentation required by these increased controls for three years after they are no longer effective:
 - a. The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for three years after the individual's employment ends.
 - b. Each time the licensee revises the list of approved persons required by 1.d., or the documented security program required by 2, the licensee shall retain the previous documentation for three years after the revision.
 - c. The licensee shall retain documentation on each radioactive material carrier for three years after the licensee discontinues use of that particular carrier.
 - d. The licensee shall retain documentation on shipment coordination, notifications, and investigations for three years after the shipment or investigation is completed.
 - e. After the license is terminated or amended to reduce possession limits below the quantities of concern, the licensee shall retain all documentation required by these increased controls for three years.
6. Detailed information generated by the licensee that describes the physical protection of radioactive material quantities of concern, is sensitive information and shall be protected from unauthorized disclosure.
 - a. The licensee shall control access to its physical protection information to those persons who have an established need to know the information, and are considered to be trustworthy and reliable.
 - b. The licensee shall develop, maintain and implement policies and procedures for controlling access to, and for proper handling and protection against unauthorized

disclosure of, its physical protection information for radioactive material covered by these requirements. The policies and procedures shall include the following:

- (1.) General performance requirement that each person who produces, receives, or acquires the licensee's sensitive information, protect the information from unauthorized disclosure,
- (2.) Protection of sensitive information during use, storage, and transit,
- (3.) Preparation, identification or marking, and transmission,
- (4.) Access controls,
- (5.) Destruction of documents,
- (6.) Use of automatic data processing systems, and
- (7.) Removal from the licensee's sensitive information category.

Table 1

Radionuclide	Minimum Quantity of Concern ¹ (TBq)	Minimum Quantity of Concern ² (Ci)
Am-241	0.6	16
Cf-252	0.2	5.4
Cm-244	0.5	14
Co-60	0.3	8.1
Cs-137	1	27
Gd-153	10	270
Ir-192	0.8	22
Pm-147	400	11,000
Pu-238	0.6	16
Pu-239	0.6	16
Se-75	2	54
Sr-90 (Y-90)	10	270
Tm-170	200	5,400
Yb-169	3	81
Combinations	Unity ³	

Notes:

1. The aggregate activity of multiple, co-located sources of the same radionuclide should be included when the total activity exceeds the quantity of concern. Radioactive materials are considered aggregated or co-located if breaching a common physical barrier (e.g., a locked storage room door) would allow access to the material.
2. The primary values used for compliance are TBq. The curie (Ci) values are rounded to two significant figures for informational purposes only.
3. Use the following method to determine which sources of radioactive material require increased controls (ICs):
 - Include any single source larger than the quantity of concern in Table 1
 - Include multiple co-located sources of the same radionuclide when the combined quantity exceeds the quantity of concern

For combinations of radionuclides, include multiple co-located sources of different radionuclides when the aggregate quantities satisfy the following unity rule: [(amount of nuclide A) ÷ (quantity of concern of nuclide A)] + [(amount of nuclide B) ÷ (quantity of concern for nuclide B)] + etc ... ≥ 1

Guidance for Aggregation of Sources

The NRC supports the use of the IAEA's source categorization methodology as defined in TECDOC-1344, "Categorization of Radioactive Sources," (July, 2003) (see http://www-pub.iaea.org/MTCD/publications/PDF/te_1344_web.pdf) and as endorsed by the agency's Code of Conduct for the Safety and Security of Radioactive Sources, January, 2004 (see <http://www-pub.iaea.org/MTCD/publications/PDF/Code-2004.pdf>). The Code defines a three-tiered source categorization scheme. Category 1 corresponds to the largest source strength (greater than 100 times the quantity of concern values listed in Table 1) and Category 3, the smallest (equal or exceeding one-tenth the quantity of concern values listed in Table 1). Increased controls (ICs) apply to sources that are greater than the quantity of concern values listed in Table 1, plus aggregations of smaller sources that add up to greater than the quantities in Table 1. Aggregation only applies to sources that are co-located.

Licensees who possess sources in total quantities that exceed the Table 1 quantities are required to implement ICs. Where there are many small (less than the quantity of concern values) co-located sources whose total aggregate activity exceeds the Table 1 values, licensees are to implement ICs.

Some source handling or storage activities may cover several buildings, or several locations within specific buildings. The question then becomes: When are sources considered co-located for purposes of aggregation? For purposes of the ICs, sources are considered co-located if breaching a single barrier (e.g., a locked door at the entrance to a storage room) would allow access to the sources. Sources behind an outer barrier should be aggregated separately from those behind an inner barrier (e.g., a locked source safe inside the locked storage room). However, if both barriers are simultaneously open, then all sources within these two barriers are considered to be co-located. This logic should be continued for other barriers within or behind the inner barrier. The following example illustrates the point: A lockable room has sources stored in it. Inside the lockable room, there are two shielded safes with additional sources in them. Inventories are as follows:

The room has the following sources outside the safes: Cf-252, 0.12 Tbq (0.3 Ci); Po-210, 0.36 TBq (10 Ci), and Pu-238, 0.3 Tbq (8 Ci). Application of the unity rule yields: $(0.012 \div 0.2) + (0.36 \div 0.6) + (0.3 \div 0.6) = 0.06 + 0.6 + 0.5 = 1.2$. Therefore, the sources would require ICs. If the sources are distributed and shipped individually, ICs would not apply because they do not exceed the quantities in Table 1.

Shielded safe #1 has a 1.9 Tbq (51 Ci) Cs-137 source and a 0.75 Tbq (20 Ci) Ra-226 source. In this case, both sources would require PMs, because they exceed the quantities in Table 1. The Ra-226 source, although not licensed by the NRC, was colocated with an NRC licensed source and, therefore, would need to be similarly protected.

Shielded safe #2 has two Po-210 sources, each having an activity of 0.2 Tbq (5 Ci). In this case, neither source would require ICs. (Total activity = 0.4 Tbq (10 Ci)). They do not exceed the threshold quantity 0.6 Tbq (20 Ci).

Because certain barriers may cease to exist during source handling operations (e.g., a storage location may be unlocked during periods of active source usage), licensees should, to the extent practicable, consider two modes of source usage — "operations" (active source usage) and "shutdown" (source storage mode). Whichever mode results in the greatest inventory (considering barrier status) would require ICs for each location.

APPENDIX O

TRANSPORTATION REGULATIONS

The following Technical References are provided to assist the Applicants

- “A Review of Department of Transportation Regulations for Transportation of Radioactive Materials” can be obtained by calling DOT’s Office of Hazardous Material Initiatives and Training at (202) 366-4425.
- U.S. Department of Transportation Regulations (49CFR), Superintendent of Documents, U.S. Government Printing Office, P.O. Box 371954, Pittsburgh, PA 15250-1954. The web site for the U.S. Department of Transportation is www.dot.gov.
- NRC Document, Memorandum of Understanding with DOT on the Transportation of Radioactive Material, signed June 6, 1979 (www.nrc.gov/reading-rm).
- NRC Document, Revision 1 of Regulatory Guide 7.10, “Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material”, dated June 1986
- NRC Document, NUREG-1556, Vol. 18, “Program-Specific Guidance about Service Provider Licenses”.

Summary of DOT Requirements for Transportation of Type A or Type B Quantities of Radioactive Material

Radioactive material must be transported in accordance with DOT regulations. The major areas in the DOT regulations that are most relevant for transportation of Type A or Type B quantities of radioactive material are:

- Table of Hazardous Materials and Special Provisions 49 CFR 172.101: Purpose and use of hazardous materials table;
- Shipping Papers 49 CFR 172.200-204: Applicability, general entries, description of hazardous material on shipping papers, additional description requirements, shipper’s certification;
- Package Marking 49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324: Applicability, general marking requirements for non-bulk packaging, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging;

- Package Labeling 49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440: General labeling requirements, prohibited labeling, Class 7 (radioactive) material, placement of labels, label specifications, radioactive white-I label, radioactive yellow-II label, radioactive yellow-III label;
- Placarding of Vehicles 49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556: Applicability of placarding requirements, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, general specifications for placards, RADIOACTIVE placard;
- Emergency Response Information 49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604: Applicability and general requirements, emergency response information, emergency response telephone number;
- Training 49 CFR 172.702, 49 CFR 172.704: Applicability and responsibility for training and testing; training requirements;
- Shippers -- General Requirements for Shipments and Packaging 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.411, 49 CFR 173.412, 49 CFR 173.413, 49 CFR 173.415, 49 CFR 173.416, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.471, 49 CFR 173.475, 49 CFR 173.476: Definitions, general design requirements, industrial packages, additional design requirements for Type A packages, requirements for Type B packages, authorized Type A packages, authorized Type B packages, requirements for determining A1 and A2 values for radionuclides and for the listing of radionuclides on shipping papers and labels, table of A1 and A2 values for radionuclides, radiation level limitations, requirements for U.S. NRC-approved packages, quality control requirements prior to each shipment of Class 7 (radioactive) materials, approval of special form Class 7 (radioactive) materials; and
- Carriage by Public Highway 49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842: Driver training, shipping papers, general requirements (packages secured in a vehicle), Class 7 (radioactive) material.

For additional transportation information, licensees may consult DOT's "A Review of the Department of Transportation Regulations for Transportation of Radioactive Materials" or contact the DOT at www.dot.gov.

APPENDIX P

**RADIATION SAFETY PROGRAM
AND
OPERATING PROCEDURES**

I. Radiation Safety Program

According to the Rules and Regulations, RH-1004, Radioactive Material Licensees are required to “develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities...to insure compliance with the provisions of this Part” (Section 3). According to RH-8300, medical use licensees shall implement and maintain a program that will help insure the protection of the public and licensee personnel who are occupationally exposed to ionizing radiation. As a minimum, the Radiation Safety Program shall include the following elements:

- Description of the organizational structure and the management commitment for ensuring implementation of the Radiation Safety Program (See Item 25)
- Policy statement and requirement to maintain radiation dose ALARA (Appendix A)
- Description of equipment and facilities adequate to protect personnel, the public, and the environment (See Item 16)
- Conduct of licensed medical activities by individuals qualified by training and experience (See Item 10)
- Written operating and emergency procedures (See Items 22 and 23)
- Program to annually review the Radiation Safety program (See Item 25)
- Records management (See Item 24)

II. Operating Procedures

Operating procedures must be developed, implemented, and maintained current. The purpose of operating procedures is to provide Authorized Users and licensee personnel with specific instructions and guidance on how to safely perform all required operations, including radioactive material storage and transportation. **A complete copy of all Radiation Safety Operating Procedures must be submitted to the Department as part of the application.**

This section summarizes operating procedures. Many of these procedures are covered in greater detail in other sections of this document.

- The Licensee must develop, implement, and maintain specific operating procedures which contain the following elements:
 - Steps to take to maintain radiation dose ALARA (see Appendix A)
 - Institutional Radiation Safety Committee operation (as required by RH-8300)
 - Instructions for the appropriate handling and use of radioactive material so that no person is likely to be exposed to a radiation dose in excess of the limits prescribed in the Rules and Regulations
 - Instructions for opening packages containing licensed material (see Appendix L);
 - Using radioactive material, operating therapy treatment devices, and performing routine maintenance on devices containing sealed sources, according to the manufacturer's written recommendations and instructions and in accordance with regulatory requirements (see Sub-Appendices P-2 and P-7).
 - Instructions and methods for conducting area radiation and contamination surveys; instructions for performing operability checks of radiation survey instruments (see Appendix K);
 - Instructions for administering licensed material in accordance with the Written Directives (see Sub-Appendix P-2);
 - Steps to ensure that patient release is in accordance with RH-8420 (see Sub-Appendix P-3);
 - Instructions for calibration of survey and dosage measuring instruments (see Appendix G);
 - Instructions for maintaining accountability of radioactive material during use, transport and storage (see Sub-Appendix P-6).
 - Instructions for maintaining security of radioactive material during use and while in transport and storage (see Appendix N).
 - Periodic spot checks of therapy device units, sources, and treatment facilities (see Item 14.C.);

- Instructions for radioactive waste management (see Appendix M);
- Personnel monitoring and the use of personnel monitoring equipment (see Appendix H).

AND

The licensee must insure the following:

- Make Operating Procedures available to all users (e.g., post the procedures or the location of procedure storage);
- Maintain a current copy of the procedures at each location of use (or, if this is not practicable, post a notice describing the procedures and stating where they may be examined).
- When developing the procedures described above, the licensee is reminded that RH-1004 requires that the licensee use, to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA.
- When receiving and using radioactive material, the licensee is reminded that they must be licensed to possess the radioactive material and that the radioactive material must be secured (or controlled) and accounted for at all times.
- Sealed sources and unsealed radioactive material used for therapy can deliver significant doses in a short time period. The Rules and Regulation, Paragraphs RH-1303.c, RH-1303.d, RH-1306.a, and RH-1308 describe access control to high and very high radiation areas and the security of radioactive material. Unauthorized access to radioactive material by untrained individuals could lead to a significant radiological hazard. Many licensees achieve access control by permitting only trained individuals to have access to radioactive material (e.g., keys, lock combinations, security badges). Accountability of radioactive material may be ensured by conducting physical inventories, controlling receipt and disposal, and maintaining use records.

III. Additional Procedural Guidance (not covered elsewhere in the Licensing Guide)

The following Table lists additional topics that must be included/incorporated in the Operating Procedures. These topics are not addressed elsewhere in the Licensing Guide. Additional discussion and procedural guidance is provided on each topic, as noted in the Table P-1, Sub-Appendix. The Licensee may incorporate the guidance provided in the Sub-Appendix or may develop and submit equivalent procedures.

Table P-1. Additional Guidance for Topics to be Included in Operating Procedures

Topic	Sub-Appendix
Safe Use of Unsealed Radioactive Material	P-1
Procedures for Administrations When a Written Directive is Required	P-2
Release of Patients or Human Research Subjects	P-3
Records of Dosages and Use of Brachytherapy Source	P-4
Safety Procedures for Treatments when Patients Are Hospitalized	P-5
Sealed Source Inventory	P-6
Installation, Maintenance, Repair, and Inspection Of Therapy Devices containing Sealed Sources	P-7
Minimization of Contamination	P-8
Mobile Medical Service	P-9

The following technical references are provided to assist the Applicant.

- NCRP Report No. 37, “Precautions In The Management of Patients Who Have Received Therapeutic Amounts of Radionuclides”
- NCRP Report No. 105, “Radiation Protection for Medical and Allied Health Personnel”, 1989,
- NCRP Report No. 107, “Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel” 1990,

These references may be obtained from the
National Council on Radiation Protection and Measurements,
7910 Woodmont Avenue,
Suite 800,
Bethesda, MD 20814-3095,

or ordered electronically at <http://www.ncrp.com>.

APPENDIX P-1

SAFE USE OF UNSEALED RADIOACTIVE MATERIAL

The Radioactive Material Licensee must develop and implement a procedure in the radiation safety program that includes safe use of unsealed radioactive material. Licensees are responsible for developing, documenting, and implementing procedures to ensure the security and safe use of all radioactive material from the time it arrives at their facilities until it is used, transferred, and/or disposed. The written procedures must provide reasonable assurance that only appropriately trained personnel will handle and use radioactive material without undue hazard to themselves, other workers, or members of the public.

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

In addition, licensees must develop, implement, and maintain procedures for protective measures to be taken by occupational workers to maintain their doses ALARA. Protective measures may include:

- Use of syringe shields and/or vial shields;
- Wearing laboratory coats and gloves when handling unsealed radioactive material; and
- Monitoring hands after handling unsealed radioactive material.

Example Procedures for Safe Use of Unsealed Licensed Material

This example provides acceptable procedures for safe use of unsealed licensed material.

- Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
- Wear disposable gloves at all times while handling radioactive materials.
- Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area using an appropriate survey instrument.
- Use syringe shields for reconstitution of radiopharmaceutical kits and administration of radiopharmaceuticals to patients, except when their use is contraindicated (e.g., recessed veins, infants). In these and other exceptional cases, use other protective methods, such as remote delivery of the dose (e.g., use a butterfly needle.)

- Do not eat, store food, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
- Wear personnel monitoring devices, if required, at all times while in areas where radioactive materials are used or stored. These devices shall be worn as prescribed by the RSO. When not being worn to monitor occupational exposures, personnel monitoring devices shall be stored in the work place in a designated low-background area.
- Wear extremity dosimeters, if required, when handling radioactive material.
- Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
- Never pipette by mouth.
- Wipe-test unsealed radioactive material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate the area.
- Survey with a radiation detection survey meter all areas of radioactive material use, including the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate the area. Areas used to prepare and administer therapy quantities of radiopharmaceuticals must be surveyed daily in accordance with RH-8408 (except when administering therapy dosages in patients' rooms when patients are confined).
- Store radioactive solutions in shielded containers that are clearly labeled.
- Radiopharmaceutical multi-dose diagnostic and therapy vials must be labeled in accordance with RH-8406 and RH-1303.
- Syringes and unit dosages must be labeled in accordance with RH-8406 and RH-1303. Mark the label with the radionuclide, the activity, the date for which the activity is estimated, and the kind of materials (i.e., radiopharmaceutical). If the container is holding less than the quantities listed in RH-2793, the syringe or vial need only be labeled to identify the radioactive drug (RH-8406). To avoid mistaking patient dosages, label the syringe with the type of study and the patient's name.
- For prepared dosages, assay each patient dosage in the dose calibrator (or instrument) before administering it (RH-8403).
- Do not use a dosage if it does not fall within the prescribed dosage range or if it varies more than 20% from the prescribed dosage, except as approved by an authorized user.

- When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle.
- Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering. If the prescribed dosage requires a written directive, the patient's identity must be verified and the administration must be in accordance with the written directive (RH-8308).
- Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
- Secure all radioactive material when not under the constant surveillance and immediate control of an individual authorized under the Department license (or such individual's designee).

APPENDIX P-2

PROCEDURES FOR ADMINISTRATIONS WHEN A WRITTEN DIRECTIVE IS REQUIRED

The Rules and Regulations, RH-8307, establishes the requirements for Written Directives and RH-8308 states that the licensee “shall develop, implement, and maintain written procedures to provide high confidence that radioactive material is administered as directed by authorized users.

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

Example Procedures for Developing, Maintaining, and Implementing Written Directives

This example provides acceptable procedures for administrations that require written directives to meet the requirements of RH-8307 and RH-8308.

Written Directive Procedures

This example provides guidance to licensees and applicants for developing, maintaining, and implementing procedures for administrations that require written directives (WD). This example does not restrict the use of other guidance in developing, implementing, and maintaining written procedures for administrations requiring a WD. Such procedures are to provide high confidence that the objectives specified in RH-8308 will be met.

The WD must be prepared for any administration of I-131 sodium iodide greater than 30 μCi (1.11 MBq), any therapeutic dosage of a radiopharmaceutical, and any therapeutic dose of radiation from radioactive material. The WD must contain the information described in RH-8307 and be retained in accordance with RH-8702.

Discussion

The administration of radioactive materials can be a complex process for many types of diagnostic and therapeutic procedures in nuclear medicine or radiation oncology departments. A number of individuals may be involved in the delivery process. For example, in an oncology department, when the authorized user (AU) prescribes a teletherapy treatment, the delivery process may involve a team of medical professionals such as an Authorized Medical Physicist (AMP), a dosimetrist, and a radiation therapist. Treatment planning may involve a number of measurements, calculations, computer-generated treatment plans, patient simulations, portal film verifications, and beam-modifying devices to deliver the prescribed dose. Therefore, instructions must be clearly

communicated to the professional team members with constant attention devoted to detail during the treatment process. Complicated processes of this nature require good planning and clear, understandable procedures. To help ensure that all personnel involved in the treatment fully understand instructions in the WD or treatment plan, the licensee must instruct all workers to seek guidance if they do not understand how to carry out the WD. Specifically, workers should ask if they have any questions about what to do or how it should be done before administration, rather than continuing a procedure when there is any doubt. Licensees must also consider verification of WDs or treatment plans by at least one qualified person (e.g., an oncology physician, AMP, nuclear medicine technologist, or radiation therapist), preferably other than the individual who prepared the dose, the dosage, or the treatment plan.

The administration of radioactive materials can involve a number of treatment modalities, e.g., radiopharmaceutical therapy, teletherapy, brachytherapy, gamma stereotactic radiosurgery (GSR), and future emerging technologies. For each such modality for which RH-8307 requires, or would require, a written directive (as defined in RH-8100), the licensee must develop, implement, and maintain written procedures for WDs to meet the requirements and/or objectives of RH-8307, RH-8308, and RH-8403, outlined below:

- Have an authorized user date and sign a written directive prior to the administration that includes the information in RH-8307, including the patient or human research subject's name;
- Verify the patient's or human research subject's identity prior to each administration;
- Verify that the administration is in accordance with the treatment plan, if applicable, and the written directive;
- Check both manual and computer-generated dose calculations;
- Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices; and
- Determine and record the activity of the radiopharmaceutical dosage or radiation dose before medical use.

The following example procedures are provided as assistance in meeting the above objectives.

Procedures for Any Therapeutic Dose or Dosage of a Radionuclide or Any Dosage of Quantities Greater than 30 microCuries of Sodium Iodide I-131

Develop, implement, and maintain the following procedures to meet the objectives of RH-8307 and RH-8308:

- An Authorized User (AU) must date and sign a WD prior to the administration of any dose or dosage. Written directives may be maintained in patients' charts.
- Prior to administering a dose or dosage, the patient's or human research subject's identity will be positively verified as the individual named in the WD. Examples of positive patient identity verification include examining the patient's ID bracelet, hospital ID card, driver's license, or social security card. Asking or calling the patient's name does not constitute positive patient identity verification.
- The specific details of the administration will be verified, including the dose or dosage, in accordance with the WD or treatment plan. All components of the WD (radionuclide, total dose or dosage, etc.) will be confirmed by the person administering the dose or dosage to verify agreement with the WD. Appropriate verification methods include: measuring the activity in the dose calibrator, checking the serial number of the sealed sources behind an appropriate shield, using color-coded sealed sources, or using clearly marked storage locations.

Additional Procedures for Sealed Therapeutic Sources and Devices Containing Sealed Therapeutic Sources

Licenses are required under RH-8307 and RH-8308 to have written directives for certain administrations of doses and to have procedures for administrations for which a written directive is required. Example procedures for meeting these requirements follow.

- To ensure that the dose is delivered in accordance with the WD, the AU (and the neurosurgeon for GSR therapy) must date and sign (indicating approval of) the treatment plan that provides sufficient information and direction to meet the objectives of the WD.
- For sealed sources inserted into the patient's body, radiographs or other comparable images (e.g., computerized tomography) will be used as the basis for verifying the position of the non-radioactive dummy sources and calculating the administered dose before administration. However, for some brachytherapy procedures, the use of various fixed geometry applicators (e.g., appliances or templates) may be required to establish the location of the temporary sources and to calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary, provided the position of the sources is known prior to insertion of the radioactive sources and calculation of the exposure time (or, equivalently, the total dose).

- Dose calculations will be checked before administering the prescribed therapy dose. An AU or a qualified person under the supervision of an AU (e.g., an Authorized Medical Physicist (AMP), oncology physician, dosimetrist, or radiation therapist), preferably one who did not make the original calculations, will check the dose calculations. Methods for checking the calculations include the following:
 1. For computer-generated dose calculations, examining the computer printout to verify that correct input data for the patient was used in the calculations (e.g., source strength and positions).
 2. For computer-generated dose calculations entered into the therapy console, verifying correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times).
 3. For manually generated dose calculations, verifying:
 - a. No arithmetic errors;
 - b. Appropriate transfer of data from the WD, treatment plan, tables and graphs
 - c. Appropriate use of nomograms (when applicable); and
 - d. Appropriate use of all pertinent data in the calculations.

The therapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer-generated outputs (or vice versa), verify the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual). Parameters such as the transmission factors for wedges and applicators and the source strength of the sealed source used in the dose calculations will be checked.

- After implantation but before completion of the procedure: record in the written directive the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose) as required by RH-8307. For example, after insertion of permanent implant brachytherapy sources, an AU should promptly record the actual number of radioactive sources implanted and the total source strength. The written directive may be maintained in the patient's chart.
- Acceptance testing will be performed by a qualified person (e.g., an AMP) on each treatment planning or dose calculating computer program that could be used for dose calculations. Acceptance testing will be performed before the first use of a treatment planning or dose calculating computer program for therapy dose calculations. Each treatment planning or dose calculating computer program will be assessed based on specific needs and applications. A check of the acceptance

testing will also be performed after each source replacement or when spot check measurements indicate that the source output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay.

- Independent checks on full calibration measurements will be performed. The independent check will include an output measurement for a single specified set of exposure conditions and will be performed within 30 days following the full calibration measurements. The independent check will be performed by either:
 1. An individual who did not perform the full calibration (the individual will meet the requirements specified in RH-8316) using a dosimetry system other than the one that was used during the full calibration (the dosimetry system will meet the requirements specified in RH-8635); or
 2. An AMP (or an oncology physician, dosimetrist, or radiation therapist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming therapy doses and that is accurate within 5%.
- For GSR, particular emphasis will be directed on verifying that the stereoscopic frame coordinates on the patient's skull match those of the treatment plan.
- A physical measurement of the teletherapy output will be made under applicable conditions prior to administration of the first teletherapy fractional dose, if the patient's treatment plan includes:
 1. Field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration; or
 2. Transmission factors for beam-modifying devices (except non-recastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.
- A weekly chart check will be performed by a qualified person under the supervision of an AU (e.g., an AMP, dosimetrist, oncology physician, or radiation therapist) to detect mistakes (e.g., arithmetic errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative dose administrations from all treatment fields or in connection with any changes in the WD or treatment plan.

- Treatment planning computer systems using removable media to store each patient's treatment parameters for direct transfer to the treatment system will have each card labeled with the corresponding patient's name and identification number. Such media may be reused (and must be relabeled) in accordance with the manufacturer's instructions.

Review of Administrations Requiring a Written Directive

Conduct periodic reviews of each applicable program area, e.g., radiopharmaceutical therapy, high-dose-rate brachytherapy, implant brachytherapy, teletherapy, gamma stereotactic radiosurgery, and emerging technologies. The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and be representative of each treatment modality performed in the institution, e.g., radiopharmaceutical, teletherapy, brachytherapy and gamma stereotactic radiosurgery.

If feasible, the persons conducting the review should not review their own work. If this is not possible, two people should work together as a team to conduct the review of that work. Regularly review the findings of the periodic reviews to ensure that the procedures for administrations requiring a WD are effective.

As required by RH-8308, a determination will be made as to whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or treatment plan, as applicable. When deviations from the WD are found, the cause of each deviation and the action required to prevent recurrence should be identified.

Reports of Misadministration

Notify by telephone the Department no later than the next calendar day after discovery of a medical event and submit a written report to the Department within 15 days after the discovery of the medical event, as required by RH-8703. Also, notify the referring physician and the patient as required by RH-8703.

APPENDIX P-3

RELEASE OF PATIENTS OR HUMAN RESEARCH SUBJECTS

Radioactive Material Licensees authorized for medical use may release from confinement patients or human research subjects (patients) who have been administered radioactive material if the TEDE to any other individual from exposure to the released patient is not likely to exceed 0.5 rem(5 mSv). Licensees must provide radiation safety instructions to patients released (or their parent or guardian) in accordance with RH-8420.

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

RH-8420 requires that the licensee provide the released individual (patient) with instructions, including written instructions, on actions recommended to maintain doses to other individuals ALARA. If a breast-feeding infant or a child could receive a radiation dose as a result of the release of the patient, the instructions also shall also include:

- Guidance on the interruption or discontinuation of breast-feeding; and
- Information on the potential consequences of failure to follow the guidance.

The following example procedure provides guidance to the Applicant on a method for determining when:

- The licensee may authorize the release of a patient who has been administered radiopharmaceuticals or who has been treated with implants containing radioactive material (Section 1), and
- Instructions to the patient are required by RH-8420 (Section 2).
- The procedure lists activities for commonly used radionuclides and the corresponding dose rates with which a patient may be released in compliance with the dose limits in RH-8420.

Example Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials

RH-8420, “Release of Individuals Containing Radioactive Drugs or Implants”, permits a licensee to “...authorize the release from its control any individual who has been administered Iodine 131 as Sodium Iodide if:

1. The total patient concentration has been determined to be [33 milliCuries (1.22 gigabecquerels)] or less, or
2. If the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed [0.5 rem five (5) millisievert] **and the criteria outlined in Arkansas’ Standard for Radiological Protection for Release of Patient Administered I-131 Sodium Iodide have been met.”**

NOTE: The Applicant must contact the Department for a copy of the “Standard for Radiological Protection for Release of Patient Administered I-131 Sodium Iodide”. The Applicant must commit in writing to follow the Department Standard if they are requesting approval to release patients who have been administered ≥ 33 millicuries of I-131 Sodium Iodide.

And,

“A licensee may authorize the release from its control of any individual who has been administered radioactive drugs other than Iodine 131 as Sodium Iodide or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (five (5) millisievert.”

The following dose calculations may be used to assist the Licensee in determining if a patient can be released in compliance with RH-8420. In this Sub-Appendix, the individual or human research subject to whom the radioactive material has been administered is called the “patient”.

Release Equation

The activities at which patients could be released were calculated by using, as a starting point, the method discussed in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, “Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides”.

NCRP Report No. 37 uses the following equation to calculate the exposure until time t at a distance r from the patient:

Equation 1:

$$D(t) \equiv \frac{34.6\Gamma Q_0 T_p (1 - e^{-0.693t/T_p})}{r^2}$$

Where:

- D(t) = Accumulated exposure at time t, in roentgens
- 34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44)
- Γ = Specific gamma ray constant for a point source, R/mCi-hr at 1 cm
- Q_0 = Initial activity of the point source in millicuries, at the time of the release
- T_p = Physical half-life in days
- r = Distance from the point source to the point of interest, in centimeters
- t = Exposure time in days.

This appendix uses the NCRP equation (Equation 1) in the following manner to calculate the activities at which patients may be released.

- The dose to an individual likely to receive the highest dose from exposure to the patient is taken to be the dose to total decay. Therefore, $(1 - e^{-0.693t/T_p})$ is set equal to 1.
- It is assumed that 1 roentgen is equal to 1 rem (10 millisieverts).
- The exposure-rate constants and physical half-lives for radionuclides typically used in nuclear medicine and brachytherapy procedures are given in Supplement A to this appendix.
- Default activities at which patients may be released are calculated using the physical half-lives of the radionuclides and do not account for the biological half-lives of the radionuclides.
- When release is based on biological elimination (i.e., the effective half-life) rather than just the physical half-life of the radionuclide, Equation 1 is modified to account for the uptake and retention of the radionuclide by the patient, as discussed in Supplement B.2.
- For radionuclides with a physical half-life greater than 1 day and no consideration of biological elimination, it is assumed that the individual likely to receive the highest dose from exposure to the patient would receive a dose of 25% of the dose to total decay (0.25 in Equation U.2), at a distance of 1 meter. Selection of 25% of the dose to total decay at 1 meter for estimating the dose is based on measurements discussed in the supporting regulatory analysis that indicate the dose calculated using an occupancy factor, E , of 25% at 1 meter is conservative in most normal situations.
- For radionuclides with a physical half-life less than or equal to 1 day, it is difficult to justify an occupancy factor of 0.25, because relatively long-term averaging of behavior cannot be assumed. Under this situation, occupancy factors from 0.75 to 1.0 may be more appropriate.

Thus, for radionuclides with a physical half-life greater than 1 day:

Equation 2:

$$D(\infty) = \frac{34.6 \Gamma Q_0 T_p (0.25)}{(100 \text{ cm})^2}$$

For radionuclides with a physical half-life less than or equal to 1 day, and if an occupancy factor of 1.0 is used:

Equation 3:

$$D(\infty) = \frac{34.6 \Gamma Q_0 T_p (1)}{(100 \text{ cm})^2}$$

Equations 2 and 3 calculate the dose from external exposure to gamma radiation. These equations do not include the dose from internal intake by household members and members of the public, because the dose from intake by other individuals is expected to be small for most radiopharmaceuticals (less than a few percent), relative to the external gamma dose (see “Internal Dose” of Supplement B). Further, the equations above do not apply to the dose to breast-feeding infants or children who continue to breast-feed. Patients who are breast-feeding an infant or child must be considered separately, as discussed in Item.1.1, “Release of Patients Based on Administered Activity”.

1. Release Criteria

Licensees should use one of the following options to release a patient to whom unsealed radioactive material or implants containing radioactive material have been administered in accordance with regulatory requirements.

1.1 Release of Patients Based on Administered Activity

In compliance with the dose limit in RH-8420.b, licensees may release patients from licensee control if the activity administered is no greater than the activity in Column 1 of Table P-3.1. The activities in Table P-3.1 are based on a total effective dose equivalent of 0.5 rem (5 millisieverts) to an individual using the following conservative assumptions:

- Administered activity;
- Physical half-life;
- Occupancy factor of 0.25 at 1 meter for physical half-lives greater than 1 day and, to be conservative, an occupancy factor of 1 at 1 meter for physical half-lives less than or equal to 1 day; and
- No shielding by tissue.

The total effective dose equivalent is approximately equal to the external dose because the internal dose is a small fraction of the external dose (see Section B.3, “Internal Dose” of Supplement B). In this case, no record of the release of the patient is required unless the patient is breast-feeding an infant or child, as discussed in Item 3.2, “Records of Instructions for Breast-Feeding Patients”. The licensee may demonstrate compliance by using the records of activity that are already required by RH-8307 and RH-8403.

If the activity administered exceeds the activity in Column 1 of Table P-3.1, the licensee may release the patient when the activity has decayed to the activity in Column 1 of Table P-3.1. In this case, RH-8420 requires a record because the patient’s release is based on the retained activity rather than the administered activity. The activities in Column 1 of Table P-3.1 were calculated using either Equation 2 or 3, depending on the physical half-life of the radionuclide.

If a radionuclide that is not listed in Table P-3.1 is administered, the licensee can demonstrate compliance with the regulation by maintaining, for Department inspection, calculation of the release activity that corresponds to the dose limit of 0.5 rem (5 millisieverts). Equation 2 or 3 may be used, as appropriate, to calculate the activity Q corresponding to 0.5 rem (5 millisieverts).

The release activities in Column 1 of Table P-3.1 do not include consideration of the dose to a breast-feeding infant or child from ingestion of radiopharmaceuticals contained in the patient's breast milk. When the patient is breast-feeding an infant or child, the activities in Column 1 of Table P-3.1 are not applicable to the infant or child. In all cases, it is necessary to give instructions as described in Items 2.2 and 2.3 as a condition for release. If failure to interrupt or discontinue could result in a dose to the breast-feeding infant or child in excess of 0.5 rem (5 millisieverts), a record that instructions were provided is required by RH-8420.

1.2 Release of Patients Based on Measured Dose Rate

Licenseses may release patients to whom radionuclides have been administered in amounts greater than the activities listed in Column 1 of Table P-3.1, provided the measured dose rate at 1 meter (from the surface of the patient) is no greater than the value in Column 2 of Table P-3.1 for that radionuclide. In this case, however, RH-8420 requires a record because the release is based on considering shielding by tissue.

If a radionuclide not listed in Table P-3.1 is administered and the licensee chooses to release a patient based on the measured dose rate, the licensee should first calculate a dose rate that corresponds to the 0.5 rem (5 millisieverts) dose limit. If the measured dose rate at 1 meter is no greater than the calculated dose rate, the patient may be released. A record of the release is required by RH-8420. The dose rate at 1 meter may be calculated from Equation 2 or 3, as appropriate, because the dose rate at 1 meter is equal to $\Gamma Q / 10,000 \text{ cm}^2$.

NOTE: Additional requirements must be met for I-131 as Sodium Iodide. Licensees must commit to follow the "Standard for Radiological Protection for Release of Patient Administered I-131 Sodium Iodide". (RH-8420.a.2.)

1.3 Release of Patients Based on Patient-Specific Dose Calculations

Licenseses may release patients based on dose calculations using patient-specific parameters. With this method, based on RH-8420.b, the licensee must calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis. If the calculated maximum likely dose to an individual is no greater than 0.5 rem (5 millisieverts), the patient may be released. Using this method, licenseses may be able to release patients with activities greater than those listed in Column 1 of Table P-3.1 by taking into account the effective half-life of the radioactive material and other factors that may be relevant to the particular case. In this case, a record of the release is required by RH-8420. If the dose calculation considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required by RH-8420.

Supplement B contains procedures for performing patient-specific dose calculations, and it describes how various factors may be considered in the calculations.

NOTE: Additional requirements must be met for I-131 as Sodium Iodide. Licensees must commit to follow the "Standard for Radiological Protection for Release of Patient Administered I-131 Sodium Iodide". (RH-8420.a.2.)

Table P-3.1 Activities and Dose Rates for Authorizing Patient Release				
Radionuclide	COLUMN 1 Activity at or Below Which Patients May Be Released		COLUMN 2 Dose Rate at 1 Meter, at or Below Which Patients May Be Released*	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	19	520	0.08	8
Au-198	3.5	93	0.21	21
Cr-51	4.8	130	0.02	2
Cu-64	8.4	230	0.27	27
Cu-67	14	390	0.22	22
Ga-67	8.7	240	0.18	18
I-123	6	160	0.26	26
I-125	0.25	7	0.01	1
I-125 implant	0.33	9	0.01	1
I-131	1.2	33	0.07	7
In-111	2.4	64	0.2	20
Ir-192 implant	0.074	2	0.008	0.8
P-32	**	**	**	**
Pd-103 implant	1.5	40	0.03	3
Re-186	28	770	0.15	15
Re-188	29	790	0.2	20
Sc-47	11	310	0.17	17
Se-75	0.089	2	0.005	0.5
Sm-153	26	700	0.3	30
Sn-117m	1.1	29	0.04	4
Sr-89	**	**	**	**
Tc-99m	28	760	0.58	58
Tl-201	16	430	0.19	19
Y-90	**	**	**	**
Yb-169	0.37	10	0.02	2

Footnotes for Table P-3.1

The activity values were computed based on 0.5 rem (5 millisieverts) total effective dose equivalent.

- * If the release is based on the dose rate at 1 meter in Column 2, the licensee must maintain a record as required by RH-8420, because the measurement includes shielding by tissue. See Item 3.1, “Records of Release”, for information on records.
- ** Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

Notes: The milliCurie values were calculated using Equations 2 or 3 and the physical half-life. The gigabecquerel values were calculated using the milliCurie values and the conversion factor from milliCurie to gigabecquerel. The dose rate values are calculated using the milliCurie values and the exposure rate constants.

In general, the values are rounded to two significant figures; however, values less than 10 millicuries (0.37 gigabecquerel) or 10 millirem (0.1 millisieverts) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492.

2. Instructions for Release of Patients

This Section provides acceptable instructions for release of patients administered radioactive materials.

2.1 Basis for Requiring Instructions

Based on RH-8420, the released patients must be given instructions, including written instructions, on how to maintain doses to other individuals ALARA after the patients are released. If the patient is breast-feeding an infant or child, additional instructions must also be provided (see Item 2.2, “Additional Instructions for Release of Patients Who Could be Breast-Feeding After Release”).

2.2 Additional Instructions for Release of Patients Who Could Be Breast-Feeding After Release

The requirement in RH-8420 that a licensee provide instructions on the discontinuation or the interruption period of breast-feeding, and the consequences of failing to follow the recommendation, presumes that the licensee will inquire, as appropriate, regarding the breast-feeding status of the patient. The purpose of the instructions (e.g., on interruption or discontinuation) is to permit licensees to release a patient who could be breast-feeding an infant or child when the dose to the infant or child could exceed 0.5 rem (5 millisieverts) if there is no interruption of breast-feeding.

If the patient could be breast-feeding an infant or child after release the licensee must give the patient instructions on the discontinuation or interruption period for breast-feeding and the consequences of failing to follow the recommendation. The patient should also be informed if there would be no consequences to the breast-feeding infant or child. If information on the excretion of the radiopharmaceutical is not available, an acceptable method is to assume that 50% of the administered activity is excreted in the breast milk. The dose to the infant or child can be calculated by using the dose conversion factors given for a newborn infant by Stabin.

2.3 Content of Instructions

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations; however, the instructions should not interfere with or contradict the best medical judgment of physicians. The instructions may include the name of a knowledgeable contact person and that person's telephone number, in case the patient has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided (refer to 2.3.1 and 2.3.2).

2.3.1 Instructions Regarding Radiopharmaceutical Administrations

For procedures involving radiopharmaceuticals, additional instructions may include the following:

- Maintaining distance from other persons, including separate sleeping arrangements.
- Minimizing time in public places (e.g., public transportation, grocery stores, shopping centers, theaters, restaurants, sporting events).
- Precautions to reduce the spread of radioactive contamination.
- The length of time each of the precautions should be in effect.

The Society of Nuclear Medicine published a pamphlet in 1987 that provides information for patients receiving treatment with radioiodine. This pamphlet was prepared jointly by the Society of Nuclear Medicine and NRC. The pamphlet contains blanks for the physician to fill in the length of time that each instruction should be followed. Although this pamphlet was written for the release of patients to whom less than 30 millicuries (1,110 megabecquerels) of iodine-131 had been administered, the Department still considers the instructions in this pamphlet to be an acceptable method for meeting the requirements of RH-8420, provided the times filled in the blanks are appropriate for the activity and the medical condition.

If additional instructions are required because the patient is breast-feeding, the instructions should include appropriate recommendations on whether to interrupt breast-feeding, the length of time to interrupt breast-feeding, or, if necessary, the discontinuation of breast-feeding. The instructions should include information on the consequences of failure to follow the recommendation to interrupt or discontinue breast-feeding. The consequences should be explained so that the patient will understand that, in some cases, breast-feeding after an administration of certain radionuclides should be avoided. For example, a consequence of procedures involving iodine-131 is that continued breast-feeding could harm the infant's or child's thyroid. Most diagnostic procedures involve radionuclides other than radioiodine and

there would be no consequences; guidance should simply address avoiding any unnecessary radiation exposure to the infant or child from breast-feeding. If the Society of Nuclear Medicine's pamphlet is given at release to a patient who is breast-feeding an infant or child, the pamphlet should be supplemented with information specified in RH-8420.

The requirement of RH-8420 regarding written instructions to patients who could be breast-feeding an infant or child is not in any way intended to interfere with the discretion and judgment of the physician in specifying the detailed instructions and recommendations.

2.3.2 Instructions Regarding Implants

For patients who have received implants, additional instructions may include the following:

A small radioactive source has been placed (implanted) inside your body. The source is actually many small metallic pellets or seeds, which are each about 1/3 to 1/4 of an inch long, similar in size and shape to a grain of rice. To minimize exposure to radiation to others from the source inside your body, you should do the following for days.

- **Stay at a distance of _____ feet from _____.**
- **Maintain separate sleeping arrangements.**
- **Minimize time with children and pregnant women.**
- **Do not hold or cuddle children.**
- **Avoid public transportation.**
- **Examine any bandages or linens that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.**
- **If you find a seed or pellet that falls out:**
 - **Do not handle it with your fingers. Use something like a spoon or tweezers to place it in a jar or other container that you can close with a lid**
 - **Place the container with the seed or pellet in a location away from people.**

Notify _____ at telephone number _____ .

3. Records

3.1 Records of Release

RH-8420 requires that the licensee "...maintain a record of the basis for authorizing the release of an individual..." and "...a record of instructions provided to breast-feeding women..."

This record should include the patient identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radioactive material administered, the administered activity, and the date of the administration. In addition, depending on the basis for release, records should include the following information:

- **For Immediate Release of a Patient Based on a Patient-Specific Calculation:** The equation used, including the patient-specific factors and their bases that were used in calculating the dose to the person exposed to the patient, and the calculated dose. The patient-specific factors (see Supplement B of this appendix) include the effective half-life and uptake fraction for each component of the biokinetic model, the time that the physical half-life was assumed to apply to retention, and the occupancy factor. The basis for selecting each of these values should be included in the record.
- **For Immediate Release of a Patient Based on Measured Dose Rate:** The results of the measurement, the specific survey instrument used, and the name of the individual performing the survey.
- **For Delayed Release of a Patient Based on Radioactive Decay Calculation:** The time of the administration, date and time of release, and the results of the decay calculation.
- **For Delayed Release of a Patient Based on Measured Dose Rate:** The results of the survey meter measurement, the specific survey instrument used, and the name of the individual performing the survey.

In some situations, a calculation may be case-specific for a class of patients who all have the same patient-specific factors. In this case, the record for a particular patient's release may reference the calculation for the class of patients.

Records, as required by RH-8420, must be kept in a manner that ensures the patient's confidentiality, that is, the records should not contain the patient's name or any other information that could lead to identification of the patient. These recordkeeping requirements may also be used to verify that licensees have proper procedures in place for assessing potential third-party exposure associated with and arising from exposure to patients who were administered radioactive material.

3.2 Records of Instructions for Breast-Feeding Patients

Records of instructions provided to breast-feeding women shall be maintained.

The record should include the patient's identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radiopharmaceutical administered, the administered activity, the date of the administration, and whether instructions were provided to the patient who could be breast-feeding an infant or child.

Implementation

The purpose of this section is to provide information to licensees and applicants regarding the Department's intent for using this Sub-Appendix. Except in those cases in which a licensee proposes an acceptable alternative method for complying with RH-8420, the methods described in this Sub-Appendix will be used in the evaluation of a licensee's compliance with RH-8420.

The following references are provided to assist the Applicant/Licensee:

- National Council on Radiation Protection and Measurements (NCRP), "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides", NCRP Report No. 37, October 1, 1970. (Available for sale from the NCRP, 7910 Woodmont Avenue, Suite 400, Bethesda, MD 20814-3095.)
- M. Stabin, "Internal Dosimetry in Pediatric Nuclear Medicine", in *Pediatric Nuclear Medicine*, edited by S. Treves, Springer Verlag, New York, 1995.
- "Guidelines for Patients Receiving Radioiodine Treatment", *Society of Nuclear Medicine*, 1987. This pamphlet may be obtained from the Society of Nuclear Medicine, 1850 Samuel Morse Drive, Reston, VA 20190-5316.

Supplement A

Table P-3.2 Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine		
Radionuclide	Physical Half-Life (days)¹	Exposure Rate Constant² (R/mCi-h at 1 cm)
Ag-111	7.45	0.15
Au-198	2.696	2.3
Cr-51	27.704	0.16
Cu-64	0.529	1.2
Cu-67	2.578	0.58
Ga-67	3.261	0.753
I-123	0.55	1.61
I-125	60.14	1.42
I-125 implant	60.14	1.114
I-131	8.04	2.2
In-111	2.83	3.21
Ir-192 implant	74.02	4.594
P-32	14.29	N/A ⁵
Pd-103 implant	16.96	0.865
Re-186	3.777	0.2
Re-188	0.708	0.26
Sc-47	3.351	0.56
Se-75	119.8	2
Sm-153	1.946	0.425
Sn-117m	13.61	1.48
Sr-89	50.5	N/A ⁵
Tc-99m	0.251	0.756
Tl-201	3.044	0.447
Yb-169	32.01	1.83
Y-90	2.67	N/A ⁵
Yb-169	32.01	1.83

Footnotes for Table P-3.2

- ¹ K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, “Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion”, Report No. EPA-520/1-88-020, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, DC, 1988.
- ² Values for the exposure rate constant for Au-198, Cr-51, Cu-64, I-131, Sc-47, and Se-75 were taken from the *Radiological Health Handbook*, U.S. Department of Health, Education, and Welfare, pp. 135, 1970. For Cu-67, I-123, In-111, Re-186, and Re-188, the values for the exposure rate constant were taken from D.E. Barber, J.W. Baum, and C.B. Meinhold, “Radiation Safety Issues Related to Radiolabeled Antibodies”, NUREG/CR-4444, U.S. NRC, Washington, DC, 1991. For Ag-111, Ga-67, I-125, Sm-153, Sn-117m, Tc-99m, Tl-201, and Yb-169, the exposure rate constants were calculated because the published values for these radionuclides were an approximation, presented as a range, or varied from one reference to another. Details of the calculation of the exposure rate constants are shown in Table A.2 of Appendix A to NUREG-1492, “Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material”, U.S. NRC, February 1997.
- ³ R. Nath, A.S. Meigooni, and J.A. Meli, “Dosimetry on Transverse Axes of ¹²⁵I and ¹⁹²Ir Interstitial Brachytherapy Sources”, *Medical Physics*, Volume 17, Number 6, November/December 1990. The exposure rate constant given is a measured value averaged for several source models and takes into account the attenuation of gamma rays within the implant capsule itself.
- ⁴ A.S. Meigooni, S. Sabnis, R. Nath, “Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants”, *Endocurietherapy Hyperthermia Oncology*, Volume 6, April 1990. The exposure rate constant given is an Aapparent@ value (i.e., with respect to an apparent source activity) and takes into account the attenuation of gamma rays within the implant capsule itself.
- ⁵ Not applicable (N/A) because the release activity is not based on beta emissions.

Supplement B

Procedures for Calculating Doses Based on Patient-Specific Factors

A licensee may release a patient to whom an activity with a value higher than the values listed in Column 1 of Table P-3.1 of this supplement has been administered if dose calculations using patient-specific parameters, which are less conservative than the conservative assumptions, show that the potential total effective dose equivalent to any individual would be no greater than 0.5 rem (5 millisieverts).

A record of the basis of the release is required by RH-8420 when the release of a patient is based on a patient-specific calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, biological or effective half-life, or shielding by tissue. The following equation can be used to calculate doses:

Equation B-1:

$$D(t) = \frac{34.6 \Gamma Q_0 TE (1 - e^{-0.693t/T_p})}{r^2}$$

Where:

- D(t) = Accumulated dose to time t, in rem;
- 34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44);
- Γ = Exposure rate constant for a point source, R/mCi x hr at 1 cm;
- Q_0 = Initial activity at the start of the time interval;
- T_p = Physical half-life, in days;
- E = Occupancy factor that accounts for different occupancy times and distances when an individual is around a patient;
- r = Distance in centimeters. This value is typically 100 cm; and
- t = Exposure time in days.

B.1 Occupancy Factor

B.1.1 Rationale for Occupancy Factors Used to Derive Table P-3.1

In Table P-3.1 in this Sub-Appendix, the activities at which patients could be released were calculated using the physical half-life of the radionuclide and an occupancy factor at 1 meter of either 0.25 (if the radionuclide has a half-life longer than 1 day) or 1.0 (if the radionuclide has a half-life less than or equal to 1 day). The basis for the occupancy factor of 0.25 at 1 meter is that measurements of doses to family members, as well as considerations of normal human behavior (as discussed in the supporting regulatory analysis (Ref. B-1)), suggest that an occupancy factor of 0.25 at 1 meter, when used in combination with the physical half-life, will produce a generally conservative estimate of the dose to family members when instructions on minimizing doses to others are given.

An occupancy factor of 0.25 at 1 meter may not be appropriate when the physical half-life is less than or equal to 1 day, and hence, the dose is delivered over a short time.

Specifically, the assumptions regarding patient behavior that led to an occupancy factor of 0.25 at 1 meter include the assumption that the patient will not be in close proximity to other individuals for several days; however, when the dose is from a short-lived radionuclide, the time that individuals spend in close proximity to the patient immediately following release will be most significant because the dose to other individuals could be a large fraction of the total dose from the short-lived radionuclide. Thus, to be conservative when providing generally applicable release quantities that may be used with little consideration of the specific details of a particular patient's release, the values calculated in Table P-3.1 were based on an occupancy factor of 1 at 1 meter when the half-life is less than or equal to 1 day. If information about a particular patient implies the assumptions were too conservative, licensees may consider case-specific conditions. Conversely, if young children are present in the household of the patient who is to be discharged, conservative assumptions about occupancy may be appropriate.

B.1.2 Occupancy Factors to Consider for Patient-Specific Calculations

The selection of an occupancy factor for patient-specific calculations will depend on whether the physical or effective half-life of the radionuclide is used and whether instructions are provided to the patient before release. The following occupancy factors, E , at 1 meter, may be useful for patient-specific calculations:

- $E = 0.75$ when a physical half-life, an effective half-life, or a specific time period under consideration (e.g., bladder holding time) is less than or equal to 1 day.
- $E = 0.25$ when an effective half-life is greater than 1 day, if the patient has been given instructions, such as:
 - Maintain a prudent distance from others for at least the first 2 days;
 - Sleep alone in a room for at least the first night;
 - Do not travel by airplane or mass transportation for at least the first day;
 - Do not travel on a prolonged automobile trip with others for at least the first 2 days;
 - Have sole use of a bathroom for at least the first 2 days; and
 - Drink plenty of fluids for at least the first 2 days.
- $E = 0.125$ when an effective half-life is greater than 1 day if the patient has been given instructions, such as:
 - Follow the instructions for $E = 0.25$ above;
 - Have few visits by family or friends for at least the first 2 days.
- In a two-component model (e.g., uptake of iodine-131 using thyroidal and extrathyroidal components), if the effective half-life associated with one component is less than or equal to one day but is greater than one day for the other component, it is more justifiable to use the occupancy factor associated with the dominant component for both components.

Example 1: Calculate the maximum likely dose to an individual exposed to a patient who has received 60 millicuries (2,220 megabecquerels) of iodine-131. The patient received instructions to maintain a prudent distance from others for at least 2 days, lives alone, drives home alone, and stays at home for several days without visitors.

Solution: The dose to total decay ($t = \infty$) is calculated based on the physical half-life using Equation B-1. (This calculation illustrates the use of physical half-life. To account for biological elimination, calculations described in the next section should be used.)

$$D(\infty) = \frac{34.6 \Gamma Q_0 T_p E}{r^2}$$

Because the patient has received instructions for reducing exposure as recommended for an occupancy factor of $E = 0.125$, the occupancy factor of 0.125 at 1 meter may be used.

$$D(\infty) = \frac{34.6 (2.2 R \cdot cm^2 / mCi \cdot hr)(60mCi)(8.04 d)(0.125)}{(100 cm)^2}$$

$$D(\infty) = 0.459 \text{ rem (4.59 millisieverts)}$$

Since the dose is less than 0.5 rem (5 millisieverts), the patient may be released, provided that the **Arkansas Standard for Radiological Protection for Release of Patient Administered I-131 Sodium Iodide** has been met.” Also, RH-8420 requires that instructions be given to the patient on maintaining doses to others as low as is reasonably achievable. A record of the calculation must be maintained, pursuant to RH-8420.

B.2 Effective Half-Life

A licensee may take into account the effective half-life of the radioactive material to demonstrate compliance with the dose limits for individuals exposed to the patient that are stated in RH-8420. The effective half-life is defined as:

Equation B-2:

$$T_{eff} = \frac{T_b \times T_p}{T_b + T_p}$$

Where:

T_b = Biological half-life of the radionuclide and

T_p = Physical half-life of the radionuclide.

The behavior of iodine-131 can be modeled using two components: extrathyroidal iodide (i.e., existing outside of the thyroid) and thyroidal iodide following uptake by the thyroid. The effective half-lives for the extrathyroidal and thyroidal fractions (i.e., F_1 and F_2 , respectively) can be calculated with the following equations.

Equation B-3:

$$T_{1eff} = \frac{T_{b1} \times T_p}{T_{b1} + T_p}$$

Equation B-4:

$$T_{2eff} = \frac{T_{b2} \times T_p}{T_{b2} + T_p}$$

Where:

T_{b1} = Biological half-life for extrathyroidal iodide;

T_{b2} = Biological half-life of iodide following uptake by the thyroid; and

T_p = Physical half-life of iodine-131.

However, simple exponential excretion models do not account for: (a) the time for the iodine-131 to be absorbed from the stomach to the blood; and (b) the holdup of iodine in the urine while in the bladder. Failure to account for these factors could result in an underestimate of the dose to another individual. Therefore, this supplement makes a conservative approximation to account for these factors by assuming that, during the first 8 hours after the administration, about 80% of the iodine administered is removed from the body at a rate determined only by the physical half-life of iodine-131.

Thus, an equation to calculate the dose from a patient administered iodine-131 may have three components. First is the dose for the first 8 hours (0.33 day) after administration. This component comes directly from Equation B-1, using the physical half-life and a factor of 80%. Second is the dose from the extrathyroidal component from 8 hours to total decay. In this component, the first exponential factor represents the activity at $t = 8$ hours based on the physical half-life of iodine-131. The second exponential factor represents the activity from $t = 8$ hours to total decay based on the effective half-life of the extrathyroidal component. The third component, the dose from the thyroidal component for 8 hours to total decay, is calculated in the same manner as the second component. The full equation is shown as Equation B-5.

Equation B-5:

$$D(\infty) = \frac{34.6 \Gamma Q_0}{(100 \text{ cm})^2} \{ E_1 T_p (0.8)(1 - e^{-0.693(0.33)/T_p}) \\ + e^{-0.693(0.33)/T_p} E_2 F_1 T_{1eff} + e^{-0.693(0.33)/T_p} E_2 F_2 T_{2eff} \}$$

Where:

- F_1 = Extrathyroidal uptake fraction;
- F_2 = Thyroidal uptake fraction;
- E_1 = Occupancy factor for the first 8 hours; and
- E_2 = Occupancy factor from 8 hours to total decay.

All the other parameters are as defined in Equations B-1, B-3, and B-4. Acceptable values for F_1 , $T_{1\text{ eff}}$, F_2 , and $T_{2\text{ eff}}$ are shown in Table 6 for thyroid ablation and treatment of thyroid remnants after surgical removal of the thyroid for thyroid cancer. If these values have been measured for a specific individual, the measured values may be used.

The record of the patient's release required by RH-8420.

Example 2, Thyroid Cancer: Calculate the maximum likely dose to an individual exposed to a patient to whom 150 milliCuries (5550 megabecquerels) of iodine-131 have been administered for the treatment of thyroid remnants and metastasis.

Solution: In this example, we will calculate the dose by using Equation B-5 to account for the elimination of iodine-131 from the body, based on the effective half-lives appropriate for thyroid cancer. The physical half-life and the exposure rate constant are from Table P-3.2. The uptake fractions and effective half-lives are from Table P-3.3. An occupancy factor, E , of 0.75 at 1 meter, will be used for the first component because the time period under consideration is less than 1 day; however, for the second and third components, an occupancy factor of 0.25 will be used, because: (1) the effective half-life associated with the dominant component is greater than 1 day; and (2) patient-specific questions were provided to the patient to justify the occupancy factor (see Section B.1.2, "Occupancy Factors to Consider for Patient-Specific Calculations", of this Supplement).

Table P-3.3 Uptake Fractions and Effective Half-Lives for Iodine-131 Treatments						
	Extrathyroidal Component			Thyroidal Component		
Medical Condition	Uptake Fraction F₁	Effective Half-Life (day)	T_{1eff}	Uptake Fraction F₂	Effective Half-Life (day)	T_{2eff}
Hyperthyroidism	0.201	0.322		0.801	5.21	
Post Thyroidectomy for Thyroid Cancer	0.953	0.322		0.053	7.32	

Footnotes for Table P-3.3

- ¹ M.G. Stabin et al., “Radiation Dosimetry for the Adult Female and Fetus from Iodine-131 Administration in Hyperthyroidism”, *Journal of Nuclear Medicine*, Volume 32, Number 5, May 1991. The thyroid uptake fraction of 0.80 was selected as one that is seldom exceeded by the data shown in Figure 1 in this referenced document. The effective half-life of 5.2 days for the thyroidal component was derived from a biological half-life of 15 days, which was obtained from a straight-line fit that accounts for about 75% of the data points shown in Figure 1 of the *Journal of Nuclear Medicine* document.
- ² International Commission on Radiological Protection (ICRP), “Radiation Dose to Patients from Radiopharmaceuticals”, ICRP Publication No. 53, March 1987. (Available for sale from Pergamon Press, Inc., Elmsford, NY 10523.) The data in that document suggest that the extrathyroidal component effective half-life in normal subjects is about 0.32 days. Lacking other data, this value is applied to hyperthyroid and thyroid cancer patients. For thyroid cancer, the thyroidal component effective half-life of 7.3 days is based on a biological half-life of 80 days (adult thyroid), as suggested in the ICRP document.
- ³ The thyroidal uptake fraction of 0.05 was recommended by Dr. M. Pollycove, M.D., NRC medical visiting fellow, as an upper-limit post-thyroidectomy for thyroid cancer.

Substituting the appropriate values into Equation B-5, the dose to total decay is:

$$\begin{aligned}
 D(\infty) &= \frac{(34.6) (2.2) (150)}{(100 \text{ cm})^2} \{ (0.75) (8.04) (0.8) (1 - e^{-0.693 (0.33) / 8.04}) \\
 &+ e^{-0.693 (0.33) / 8.04} (0.25) (0.95) (0.32) \\
 &+ e^{-0.693 (0.33) / 8.04} (0.25) (0.05) (7.3) \}
 \end{aligned}$$

$$D(\infty) = 0.340 \text{ rem (3.40 millisieverts)}$$

Therefore, thyroid cancer patients to whom 150 milliCuries (5550 megabecquerels) of iodine-131 or less has been administered would not have to remain under licensee control and could be released under RH-8420, provided that the criteria in **Arkansas Standard for Radiological Protection for Release of Patient Administered I-131 Sodium Iodide** has been met, and assuming that the foregoing assumptions can be justified for the individual patient's case and that the patient is given instructions.

In the example above, the thyroidal fraction, $F_2 = 0.05$, is a conservative assumption for persons who have had surgery to remove thyroidal tissue. If F_2 has been measured for a specific patient, the measured value may be used.

Example 3, Hyperthyroidism: Calculate the maximum likely dose to an individual exposed to a patient to whom 55 millicuries (2035 megabecquerels) of iodine-131 has been administered for the treatment of hyperthyroidism (i.e., thyroid ablation).

Solution: In this example, we will again calculate the dose using Equation B-5, Table P-3.2, and Table P-3.3, to account for the elimination of iodine-131 from the body by using the effective half-lives appropriate for hyperthyroidism. An occupancy factor, E , of 0.25 at 1 meter will be used for the second and third components of the equation because patient-specific instructions were provided to justify the occupancy factor (see Section B.1.2, "Occupancy Factors to Consider for Patient-Specific Calculations").

Substituting the appropriate values into Equation B-5, the dose to total decay is:

$$\begin{aligned}
 D(\infty) &= \frac{(34.6)(2.2)(55)}{(100 \text{ cm})^2} \{ (0.75)(8.04)(0.8)(1 - e^{-0.693(0.33)/8.04}) \\
 &+ e^{-0.693(0.33)/8.04} (0.25)(0.20)(0.32) \\
 &+ e^{-0.693(0.33)/8.04} (0.25)(0.80)(5.2) \}
 \end{aligned}$$

$$D(\infty) = 0.486 \text{ rem (4.86 millisieverts)}$$

Therefore, hyperthyroid patients to whom 55 millicuries (2035 megabecquerels) of iodine-131 has been administered would not have to remain under licensee control and could be released, under RH-8420, provided that the criteria in **Arkansas Standard for Radiological Protection for Release of Patient Administered I-131 Sodium Iodide** has been met, and when the occupancy factor of 0.25 in the second and third components of the equation is justified.

In the example above, the thyroidal fraction $F_2 = 0.8$ is a conservative assumption for persons who have this treatment for hyperthyroidism. If F_2 has been measured for a specific patient, the measured value may be used.

B.3 Internal Dose

For some radionuclides, such as iodine-131, there may be concerns that the internal dose of an individual from exposure to a released patient could be significant. A rough estimate of the maximum likely committed effective dose equivalent from internal exposure can be calculated from Equation B-6.

Equation B-6:

$$D_i = Q (10^{-5})(DCF)$$

Where:

- D = Maximum likely internal committed effective dose equivalent to the individual exposed to the patient in rem;
- Q = Activity administered to the patient in millicuries;
- 10^{-5} = Assumed fractional intake; and
- DCF = Dose conversion factor to convert an intake in milliCuries to an internal committed effective dose equivalent (such as tabulated in Reference B-2).

Equation B-6 uses a value of 10^{-5} as the fraction of the activity administered to the patient that would be taken in by the individual exposed to the patient. A common rule of thumb is to assume that no more than 1 millionth of the activity being handled will become an intake to an individual working with the material. This rule of thumb was developed in reference B-3 for cases of worker intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases from a facility, but it does not specifically apply to cases of intake by an individual exposed to a patient. However, two studies (Refs. B-4 and B-5) regarding the intakes of individuals exposed to patients administered iodine-131, indicated that intakes were generally of the order of 1 millionth of the activity administered to the patient and that internal doses were far below external doses. To account for the most highly exposed individual and to add a degree of conservatism to the calculations, a fractional transfer of 10^{-5} has been assumed.

Example 4, Internal Dose: Using the ingestion pathway, calculate the maximum internal dose to a person exposed to a patient to whom 33 millicuries (1221 megabecquerels) of iodine-131 has been administered. The ingestion pathway was selected because it is likely that most of the intake would be through the mouth or through the skin, which is most closely approximated by the ingestion pathway.

Solution: This is an example of the use of Equation B-6. The dose conversion factor DCF for the ingestion pathway is 53 rem/millicurie from Table 2.2 of Reference B-2.

Substituting the appropriate values into Equation B-6, the maximum internal dose to the person is:

$$D_i = (33 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$

$$D_i = 0.017 \text{ rem (0.17 millisieverts)}$$

Using Equation B-1 and assuming the patient has received instructions for reducing exposure as required by RH-8420 for an occupancy factor of 0.25, the external dose is approximately 0.5 rem (5 millisieverts). Thus, the internal dose is about 3% of the external dose due to gamma rays. Internal doses may be ignored in calculations of total dose if they are likely to be less than 10% of the external dose because the internal dose due to this source is small in comparison to the magnitude of uncertainty in the external dose.

The conclusion that internal contamination is relatively unimportant in the case of patient release was also reached by the NCRP. The NCRP addressed the risk of intake of radionuclides from patients' secretions and excreta in NCRP Commentary No. 11, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients" (Ref. B-6). The NCRP concluded, "Thus, a contamination incident that could lead to a significant intake of radioactive material is very unlikely.

Example 5, Internal Dose: Calculate the maximum internal dose to a person exposed to a patient to whom 150 millicuries (5550 megabecquerels) of iodine-131 has been administered for the treatment of thyroid remnants and metastasis.

Solution: In this example, we will again calculate the dose using Equation B-6 and selecting the ingestion pathway. Substituting the appropriate values into Equation B-6, the maximum internal dose to the person is:

$$D_i = (150 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$

$$D_i = 0.08 \text{ rem (0.80 millisieverts)}$$

In this case, the external dose to the other person from Example 2, Thyroid Cancer, was approximately 0.34 rem (3.4 millisieverts), while the internal dose would be about 0.08 rem (0.80 millisieverts). Thus, the internal dose is about 24% of the external gamma dose. Therefore, the internal and external doses must be summed to determine the total dose; 0.42 rem (4.2 millisieverts).

References for Supplement B

- B-1. S. Schneider and S.A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material", U.S. NRC, NUREG-1492, February 1997.
- B-2. K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion", Federal Guidance Report No.11, U. S. Environmental Protection Agency, Washington, DC, 1988.

- B-3. A. Brodsky, “Resuspension Factors and Probabilities of Intake of Material in Process (or ‘Is 10^{-6} a Magic Number in Health Physics?’),@ *Health Physics*, Volume 39, Number 6, 1980.
- B-4. R.C.T. Buchanan and J.M. Brindle, “Radioiodine Therapy to Out-patients - The Contamination Hazard”, *British Journal of Radiology*, Volume 43, 1970.
- B-5. A.P. Jacobson, P.A. Plato, and D. Toeroek, “Contamination of the Home Environment by Patients Treated with Iodine-131”, *American Journal of Public Health*, Volume 68, Number 3, 1978.
- B-6. National Council on Radiation Protection and Measurements, “Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients”, Commentary No. 11, February 28, 1995.

APPENDIX P-4

RECORDS OF DOSAGES AND USE OF BRACHYTHERAPY SOURCE

Radioactive Material Licensees who are authorized to use radioactive material for medical purposes must record the use of radioactive material to reflect proper use and accountability. Licensees are required to make and maintain records of each dosage and administration prior to medical use. Paragraphs RH-8403, RH-8707, RH-8713, and RH-8717 of the Rules and Regulation prescribe specific requirements. Records of use must be maintained for 3 years.

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

The records must include the following:

- Radiopharmaceutical;
- Patient's or human research subject's name or identification number (if one has been assigned) **Note: The Licensee Must Maintain Patient Confidentiality;**
- Prescribed dosage, determined dosage, or a notation that the total activity is less than 30 μCi (1.1 MBq);
- Date and time of dosage determination; and
- Name of the individual who determined the dosage.

Dosage determination for unit dosages for photon-emitting radionuclides shall be made by direct measurement. For other than photon-emitting radionuclides dose determination shall be made by either direct measurement or by a combination of decay correction based on the determination (e.g., measurement) made by the manufacturer or preparer licensed under NRC or equivalent Agreement State requirements.

If molybdenum concentration is measured under RH-8531, records of molybdenum concentration must be made under RH-8713 and must include, for each measured elution of technetium-99m:

- Ratio of the measurements expressed as μCi (kBq) of molybdenum-99 per MBq (mCi) of technetium-99m;
- Date and time of the measurement; and
- Name of the individual who made the measurement. If the licensee uses manual brachytherapy sources, the following records of use must be kept:

- When temporary implant brachytherapy sources are removed from storage, a record will include the number and activity of sources removed, the time and date they were removed from storage, the location of use, and the name of the individual who removed them from storage.
- When temporary implant brachytherapy sources are returned to storage, a record will include the number and activity of sources returned, the time and date they were returned to storage, and the name of the individual who returned them to storage.
- For permanent implants, a record will be made and will include the number and activity of sources removed from storage, the date they were removed from storage, the name of the individual who removed them from storage, the number and activity of sources not implanted, the date they were returned to storage, the name of the individual who returned them to storage, and the number and activity of sources permanently implanted in the patient or human research subject.

APPENDIX P-5

SAFETY PROCEDURES FOR TREATMENTS WHEN PATIENTS ARE HOSPITALIZED

Applicants must develop and implement procedures to ensure that access to therapy treatment rooms, and exposure rates from therapy treatments, are limited to maintain doses to occupational workers and members of the public within regulatory limits.

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

Paragraphs RH-8552, RH-8604, and RH-8634 require licensees to take certain safety precautions for uses of radioactive material involving radiopharmaceutical therapy, manual brachytherapy, or remote afterloader brachytherapy involving patients who cannot be released in accordance with RH-8420. This section of the Sub-Appendix does not include guidance on this subject for teletherapy or GSR outpatient treatments. The precautions described below are provided to help ensure compliance with the exposure limits in Section 3 of the Rules and Regulations.

Paragraphs RH-8601 and RH-8631 require licensees to perform a radiation survey of the patient (and the remote afterloader unit) immediately after removing the last temporary implant source from the patient and prior to releasing the patient from licensee control. This is done to confirm that all sources have been removed and accounted for. RH-8634 requires that when sources are placed within the patient's body, licensed activities be limited to treatments that allow for expeditious removal of a decoupled or jammed source.

In addition, applicants must take the following steps for patients who cannot be released under RH-8420:

- Provide a room with a private sanitary facility for patients treated with a radiopharmaceutical therapy dosage (Note: RH-8552 allows for a room shared with another radiopharmaceutical therapy patient);
- Provide a private room for patients implanted with brachytherapy sources (Note: RH-8604 allows for a room shared with another brachytherapy patient);
- Visibly post a "Radioactive Materials" sign on the patient's room and note on the door or in the patient's chart where and how long visitors may stay in the patient's room (RH-8552 and RH-8604);
- Either monitor material and items removed from the patient's room (e.g., patient linens, surgical dressings) with a radiation detection survey instrument set on its most sensitive scale with no interposed shielding to determine that their radioactivity cannot be distinguished from the natural background radiation level or handle them as radioactive waste (RH-8552 and RH-1300); and

- Notify the RSO, or his/her designee, and AU as soon as possible if the patient has a medical emergency or dies (RH-8552, RH-8604, and RH-8634).

Paragraph RH-1300 requires licensees to perform adequate surveys to evaluate the extent of radiation levels. Therefore, licensees must evaluate the dose rates around patients who are hospitalized in accordance with RH-8420 following the dosage administration or implant (e.g., measured dose rates, combination of measured and calculated dose rates).

Paragraph RH-1306 requires licensees to secure licensed material in storage from unauthorized access or removal. Access control and appropriate training of authorized personnel may prevent unauthorized removal of licensed material temporarily stored in the patient's room and unnecessary personnel exposures.

In order to control radiation dose to individuals in accordance with Section 3, the licensee should consider briefing patients on radiation safety procedures for confinement to bed, visitor control, identification of potential problems, notification of medical staff in the event of problems, and other items as applicable and consistent with good medical care.

APPENDIX P-6

SEALED SOURCE INVENTORY

The Department requires the licensee in possession of sealed sources and/or brachytherapy sources to conduct a quarterly physical inventory of all such sources in its possession.

According to RH-8405, the licensee must conduct a quarterly physical inventory of all sealed sources and brachytherapy sources in its possession. Individual GSR sources are exempt from this physical inventory requirement, as stated in RH-8405. However, the licensee must maintain records of GSR source receipt, transfer, and disposal, under RH-8708, to indicate the current inventory of sources at the licensee's 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

APPENDIX P-7

INSTALLATION, MAINTENANCE, REPAIR, AND INSPECTION OF THERAPY DEVICES CONTAINING SEALED SOURCES

In accordance with RH-8632 and RH-8646, licensees must ensure that therapy devices containing sealed sources are installed, maintained, adjusted, repaired, and inspected by persons specifically licensed to conduct these activities. The above activities must be conducted according to the manufacturers' written recommendations and instructions and according to the SSDR. In addition, RH-8646 requires that teletherapy and GSR units be fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to ensure that the source exposure mechanism functions properly. Maintenance is necessary to ensure that the device functions as designed and source integrity is not compromised.

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

Maintenance and repair includes installation, replacement, and relocation or removal of the sealed source(s) or therapy unit that contains a sealed source(s). Maintenance and repair also includes any adjustment involving any mechanism on the therapy device, treatment console, or interlocks that could expose the source(s), reduce the shielding around the source(s), affect the source drive controls, or compromise the radiation safety of the unit or the source(s).

The Department requires that maintenance and repair (as defined above) be performed only by persons specifically licensed by the Department, the NRC or an Agreement State to perform such services. Most medical use licensee employees do not perform maintenance and repair because they do not have the specialized equipment and technical expertise to perform these activities. Applicants requesting authorization to possess and use LDR remote afterloaders should review RH-8632 before responding to this item. Paragraph RH-8632 allows for an Authorized Medical Physicist to perform certain service activities with regard to LDR remote afterloader units.

The Applicant must include the maintenance and repair activities in written operating procedures describing the process the Licensee will use to insure the requirements of the Rules and Regulations will be met. The Applicant must commit in procedures that only properly licensed individuals will be employed to install, maintain, adjust, repair, and inspect the specific therapy device(s) possessed by the licensee. However, if the applicant requests that a Licensee employee who is trained by the manufacturer be authorized to perform the aforementioned activities, the Applicant must provide sufficient information to allow the Department to evaluate and approve such authorization (see RH-8632 and RH-8646). This information must include the following:

- Name of the proposed employee and types of activities requested;

AND

- Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested;

AND

- Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.

Note: The applicant must specify only those installation, maintenance, inspection, adjustment, and repair functions described in a certificate or letter from the manufacturer of the device that documents the employee's training in the requested function(s).

APPENDIX P-8

MINIMIZATION OF CONTAMINATION

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

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

All applicants for new licenses must consider the importance of designing and operating their facilities to minimize the amount of radioactive contamination generated at the site during its operating lifetime and to minimize the generation of radioactive waste during decontamination. This is especially important for licensed activities involving unsealed radioactive material. As described in Item 23, “Emergency Procedures”, Spill Procedures, cleanup procedures must be implemented for contamination events. Recommended limits for acceptable levels of surface contamination in restricted and unrestricted areas are provided in Appendix K, Tables K.2 and K.3.

Sealed sources and devices that are approved by NRC or an Agreement State and located and used according to their SSDR Certificates usually pose little risk of contamination. Leak tests performed as specified in the SSDR Certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and stored, repaired, or disposed of according to Department requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts.

APPENDIX P-9

MOBILE MEDICAL SERVICE

General Information

Radioactive Material Licensees who are authorized to perform mobile medical services must comply with the requirements of RH-8425 and RH-8647, as well as all other applicable regulations.

Applicants for licensure of mobile medical services must review other Items of this Licensing Guide for information to be submitted as part of their applications; many of the requirements in these sections are relevant to use of radioactive material by mobile medical service providers with details being dependent upon the scope of such programs. Mobile medical service licensees may transport radioactive material and equipment into a client's building, or may bring patients into the transport vehicle (e.g., van). In either case, the vehicle must be located on the client's property that is under the client's control.

Self-contained mobile medical service involves a mobile treatment or administration facility that provides ready-to-deliver mobile medical services on arrival at a client's site. Companies providing transportation only will not be licensed for medical use under Section 9. Before using a remote afterloader for this type of service, the device must be installed in an appropriately shielded treatment room.

The general types of services provided as mobile medical services are:

- Mobile medical services (radioactive material, trained personnel, and facility) that provide the device/facility (e.g., in-van use) and treatment of (or administration to) patients at the client site. These mobile medical service providers are responsible for all aspects of radioactive material use and authorized patient treatments (or administrations).
- Mobile medical service providers (radioactive material and trained personnel) that provide the transportation to and use of the radioactive material within the client's facility. These mobile medical service providers are also responsible for all aspects of radioactive material use and authorized patient treatments (or administrations).

Mobile medical service licensees must ensure that the criteria in RH-8420 are met before releasing patients treated in their facilities.

Guidance for Mobile Medical Services

Mobile medical service providers must comply with all applicable sections of Section 9 as well as DOT regulations with regard to approved source holders, placement of sources in approved containers prior to their transport, and hazardous materials training. For example, mobile medical service providers offering remote afterloaders must comply with paragraphs RH-8630 through RH-8670.

Type and Location of Use

In general, there are two types of mobile medical service. One type is transportation and use of radioactive material within a transport vehicle (e.g., in-van use). A second type is transportation of radioactive material to a client's facility for use within a client's facility by the mobile medical service's employees (i.e., transport and use).

For the first and second types, which include use by the service provider, the service provider should apply for full service authorization. Service providers who only transport and store a therapy device need only apply for authorization for possession and transport of the radioactive material. In this case, when the service provider is only transporting the therapy device for use, the client must possess a license for medical use of the radioactive material. Additionally, in this case, the client is authorized to provide the patient treatments and is responsible for all aspects of the radioactive material use and patient treatments upon transfer of the radioactive material to their possession.

For all types, licensed activities must be conducted in accordance with the regulations for compliance with RH-8425, which states that the licensee will obtain a letter signed by the management of each of its clients for which services are rendered. The letter will permit the use of radioactive material at the client's address and will clearly delineate the authority and responsibility of each entity. This agreement must be applicable for the entire period of time over which the service is to be provided. The letter will be retained for 3 years after the last provision of service, as required by RH-8425 and RH-8711. Additionally, as required by RH-8425, the licensee must survey to ensure compliance with the requirements in RH-1300 (e.g., ensure that all radioactive material, including radiopharmaceuticals, sealed sources, and all associated wastes have been removed) before leaving a client's address.

The location of use for mobile medical services is of two basic types. One type of location is the base location where licensed material is received, stored, and sometimes used. The other type of location is the temporary job site at client facilities. The following two sections describe the type of information necessary for base locations and temporary job sites.

Base Location

The base location (e.g., central radiopharmaceutical laboratory or storage location for the remote afterloader) for the mobile medical service must be specified. The base facility may be located in a medical institution, non-institutional medical practice, commercial facility, or mobile van. The Applicant must specify in what type of facility the proposed base facility is located. A mobile licensee cannot provide a service to a private practice (non-licensee) located within a licensed medical institution (e.g., hospital).

As required by RH-404 and RH-8010, the Applicant must submit a description and diagram(s) of the proposed base facility and associated equipment in accordance with Item 16 of the Application. The description and diagram of the proposed facility should demonstrate that the building (or van) is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensures security of licensed material to prevent unauthorized access (e.g., control of keys), and ensures that radiation levels in unrestricted areas are in compliance with RH-1208. A diagram showing the location of the licensed material, receipt, and use areas, and the identity of all areas adjacent to restricted areas, including areas above and below the restricted areas must be included. For storage locations within a van, the description of the van must address radiation levels in the van driver's compartment to demonstrate compliance with RH-1200.

- The Applicant may request multiple base locations. Radioactive material must be delivered only to a facility licensed to receive the type of radioactive material ordered.
- Base locations can include the use of a mobile van. When the base facility is in the van, and there is no permanent structure for the radioactive material storage, provide for the following:
 - Secured off-street parking under licensee control. Public rights-of-way are not considered part of the address of the client;
 - Secured storage facilities available for storage of radioactive material and radioactive waste if the van is disabled; and
 - Radioactive material delivered (if necessary) directly to the van only if the van is occupied by licensee personnel at the time of delivery.
- Perform required radiation surveys to show that exposure rates do not exceed 2 millirem in any one hour nor 100 millirem per year.

Client Site

For all types of radioactive material uses, the medical institutions, hospitals, or clinics and their addresses that comprise the client sites for mobile medical services must be listed.

For self-contained radioactive material services (e.g., in-van) the Applicant must provide the following additional facility information:

- A separate drawing for each client site showing the location of the treatment device/vehicle in relation to all nearby roads, sidewalks, structures, and any other locations accessible by members of the public.
- A signed agreement, as delineated in the letter required by RH-8425, that location of the device/vehicle will be on client-owned or controlled property.
- The protection from vehicular traffic that could adversely affect patient treatment(s), that could be accomplished either by locating the facility away from all vehicular traffic or by using barriers. Any protective measures must be shown on the facility/site drawings provided.
- A description of the emergency lighting system that automatically activates on detection of the loss of primary power during patient remote afterloader treatments. The system must provide sufficient light to perform any possible emergency procedures, including the removal of a detached or stuck source that remains within the patient.

If the Applicant will provide transportable services to the client's site for use within the client's facility by the mobile medical service's employees, the Applicant must provide the following client facility information and commitment:

- A detailed description and diagram(s) of the proposed use facility (e.g., client site) and associated equipment in accordance with Items 16 of the Application. The description and diagram of the proposed use facility must demonstrate that the facility is of adequate construction and design to protect its contents from the elements (e.g., high winds, rain), ensure security of licensed material to prevent unauthorized access, and ensure that radiation levels in unrestricted areas are in compliance with RH-1208. The Applicant must include a diagram showing the location of the equipment, receipt, and use areas, and identify all areas adjacent to restricted areas.
- A commitment, as delineated in the letter required by RH-8425 that the mobile medical service licensee has full control of the treatment room during radioactive material use for each client.
- The initial installation records and function checks of a remote afterloader device for each site of use, as required by RH-8641, RH-8644, and RH-8647.

For a transport-only mobile medical service for therapy devices that are transported to the client's facility, used by the client's staff (under their own license), and removed by the service provider, the Applicant must ensure the following:

- Each client is properly licensed for medical use of radioactive material. If applicable, the Applicant must ensure that each client has received the necessary initial and, if appropriate, recurrent training for the specific make and model of the remote afterloader device being provided. If the above applicable conditions are not met, the mobile medical service licensee must not transfer the remote afterloader device to the client.
- No signed agreement with a client may state or imply any assumption of responsibility on the part of the mobile medical service for the use of radioactive material for patient treatments. This includes such activities as dosage measurements, source calibrations, and remote afterloader device operational checks. Although these and other services may be provided to the client by the mobile medical service if the mobile medical service is specifically licensed to provide such services, the client (licensee) retains all of the responsibilities related to the use of the radioactive material for patient treatments. The responsibilities for supervising individuals who use the radioactive material, set forth in RH-8306, transfer to the client's Authorized Users upon transfer of the device to the client by the mobile medical service provider.
- The initial installation of a remote afterloader device at the client site may be performed by either the mobile medical service provider or the client, but all device function checks are the responsibility of the client (i.e., the licensee authorized to provide patient treatments at the client site).
- As required by RH-600, a formal record of the transfer of control of the radioactive material from the mobile medical service provider to the client, and from the client back to the mobile medical service provider, must be made for each transfer of radioactive material. A signed receipt of each transfer must be made and retained for inspection for 3 years.

Supervision

In addition to the requirements in RH-2803, RH-8306 requires that the Applicant will instruct supervised individuals in your written radiation protection procedures, written directive procedures, regulations, and license conditions with respect to the use of radioactive material. Additionally, as required by RH-8306, the Applicant will require the supervised individual to:

- Follow the instructions of the supervising Authorized User for medical uses of radioactive material;
- Follow the instructions of the supervising Authorized Nuclear Pharmacists or supervising Authorized User for preparation of radioactive material for medical uses;

- Follow the written radiation protection procedures and written directive procedures established by the licensee; and
- Comply with the provisions of Section 9, [e.g., RH-8425 and RH-8647 (if applicable)], and the license conditions with respect to the mobile medical use of radioactive material.

Training for Individuals Working in or Frequenting Restricted Areas

Drivers and technologists (or therapists) will be properly trained in applicable transportation regulations and emergency procedures in addition to the training requirements of RH-2803, RH-8306, RH-8551, RH-8603, and RH-8633 (as applicable). The training for these individuals will include, at a minimum, DOT regulations, shielding, ALARA, and basic radiation protection.

Survey Instrument and Dose Measurement Instrument Checks

As required by RH-8425, the Applicant must check instruments for proper operation before use at each address of use. You will check dosage measurement instruments before medical use at each address of use or on each day of use, whichever is more frequent. Additionally, all other transported equipment (e.g., cameras) should be checked for proper function before medical use at each address of use.

Order and Receipt of Radioactive Material

Radioactive material will be delivered by a supplier to the base location or to the client's address if the client is licensed to receive the type of radioactive material ordered. Delivery of radioactive material to a van that is not occupied by the mobile medical service personnel will not be permitted.

Alternatively, the Applicant may pick up the radioactive material (e.g., radiopharmaceuticals) from the supplier (e.g., nuclear pharmacy) en route to client facilities.

Emergency Procedures

Develop, implement, and maintain emergency procedures, in accordance with the radiation safety program required by RH-1004. The Applicant must indicate typical response times of the RSO and Authorized User in the event of an event and develop and implement procedures that include emergency response regarding an accident scenario. An accident is defined as a vehicle collision or other event, such as, wind, water, or fire that results in damage to exterior or interior portions of the vehicle or the radioactive

material used in the mobile medical service. The transportation emergency response plan must cover both the actions to be taken by the mobile medical service provider's headquarters emergency response personnel and the "on-scene" hazardous material-trained personnel, and it will be readily available to both transport vehicle personnel and headquarters emergency-response contacts. The plan should include the following:

- A 24-hour emergency contact telephone number for the mobile medical service provider's emergency response personnel;
- The emergency contact numbers for the Department;
- Procedures for restricting access to the transport vehicle until surveys have been made to determine if any radiological hazards exist;
- Procedures for retrieving and securing any radioactive material, including a sealed source that may become detached and/or dislodged to the extent that a radiological hazard is created, which may require one or more emergency shielded source containers;
- Predetermined (calculated) exposure rates for an unshielded therapy source (if applicable) as a function of distance for use in controlling the exposures of emergency response personnel to the maximum extent possible under various emergency response scenarios;
- Preplanned decontamination procedures, including ready access to all necessary materials;
- A calibrated, operational survey meter maintained in the cab of the transporting vehicle, which may be used at an accident scene for conducting surveys;
- Security of the transport vehicle against unauthorized access, including the driver's compartment; and
- Procedures to ensure that following any accident, no patient treatments with remote afterloaders will occur until all systems pertaining to radiation safety have been tested and confirmed to be operational by the RSO or Authorized Medical Physicist. If any problem is found, including remote afterloader device interlocks and operation, the remote afterloader device or facility will be repaired and re-certified by the device vendor prior to return to service. In addition, a copy of the report, generated in accordance with RH-1502, will be provided to clients following any accident in which there is actual or possible damage to the client's facility or the device.

Note: The type of response should be consistent with the level of the incident. The response may range from phone contact for minor spills to prompt on-site response (less than 3 hours) to events such as a medical event or lost radioactive material.

Transportation

Develop, document, and implement procedures to assure that the following takes place:

- Radioactive material is transported in accordance with 49 CFR Parts 170B189. Procedures will include:
 - Use of approved packages;
 - Use of approved labeling;
 - Conduct of proper surveys;
 - Complete and accurate shipping papers;
 - Bracing of packages;
 - Security provisions; and
 - Written emergency instructions.
- Management (or management's designee) will perform audits, at least annually, of transportation documentation (e.g., shipping papers and survey reports) and activities at client facilities.
- Licensed radioactive material is secured during transport and use at the client's facilities.
- Radioactive waste is handled properly during transport. The Applicant will describe the method of storage and final disposal.
- The transport vehicle, including the driver's compartment, if separate, will be secured at all times from any unauthorized access when the vehicle is unattended.

Note: The necessary DOT Type 7A package certification for remote afterloader devices is established by prior approval of the appropriate sealed source and device sheets; however, if the remote afterloader device is damaged in any way during use or transport, then the integrity of the DOT Type 7A packaging may be compromised, and the device must not be used or transported until checked by the vendor and certified as retaining its integrity as a Type 7A package.

Radioactive Waste Management

If waste will be stored in vans, the vans will be properly secured and posted as radioactive material storage locations. The Applicant will ensure that the van will be secured against unauthorized access and that the waste storage location will be posted as a radioactive material storage area.

Develop, document, and implement final waste disposal procedures in accordance with Item 19 of the Application.

Excreta from individuals undergoing medical diagnosis or therapy with radioactive material may be disposed of without regard to radioactivity if it is discharged into the sanitary sewerage system, in accordance with RH-1402. However, collecting excreta from patients in a van restroom with a holding tank is not considered direct disposal into the sanitary sewerage system. If restroom facilities are provided in the van for patient use, submit the following information for Department review:

- A description of the structure of the tank holding facility and the location of the tank in relation to members of the public, workers in the van, and the driver of the van; a description of procedures to assess the tank for possible leakage; and a description of any restroom ventilation if any I-131 will be held in the tank.
- A description of procedures to ensure doses to occupational workers and members of the public will not exceed the exposure limits in RH-1200 and RH-1208, that the external surfaces of the van do not exceed 2 millirem/hour, and that doses to members of the public and workers are maintained ALARA, including considerations of external dose rates in the restroom caused by the proximity of the holding tank to the toilet.
- A description of procedures for emptying and disposing of the contents of the holding tank, including the frequency of disposal, who empties the tank into the sanitary sewer system, and the location of disposal into the sanitary sewer, including precautions taken to minimize contamination in this process.

Mobile Medical Services With Remote Afterloader Devices

Because the movement of the remote afterloader device from one location to another increases the risk of electro-mechanical component failures or misalignments, it is important that the proper operation of the device be fully checked after each such relocation. Therefore, you will develop, document, and implement the following procedures to determine if a device is operating properly before the commencement of patient treatments:

- Safety checks conducted on a remote afterloader device and facility. The procedure will include the periodic spot checks required by RH-8644 and the additional spot checks required by RH-8647 before use at each address of use.

Additionally, the procedure should include provisions for prompt repair of any system not operating properly.

- The pretreatment operational function checks after each device move should include a review of any device alarm or error message and, if necessary, a resolution of problems indicated by such messages.
- Such tests should be performed in accordance with written procedures.
- The Applicant must maintain records, as described in RH-8726 and RH-8724, showing the results of the above safety checks for Department inspection and review for a period of 3 years.
- Perform surveys of the source housing and areas adjacent to the treatment room following relocation of a HDR unit. These surveys should include the source housing with the source in the shielded position and all areas adjacent to the treatment room with the source in the treatment position.

APPENDIX Q

EMERGENCY PROCEDURES

Emergency Procedures

Radioactive Material Licensees are required to develop, implement, and maintain Emergency Procedures, commensurate with the radioactive material possessed and used by the Licensee. The purpose of the emergency procedures is to provide Authorized Users and licensee personnel with specific instruction and guidance on how to safely respond to emergency or abnormal events that may occur at the licensee's facility. Applicants must develop emergency procedures that address a wide-spectrum of events (e.g., major spills, leaking source, medical events, interlock failure, stuck source, etc.). **A complete copy of the Emergency Procedures must be submitted to the Department as part of 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

This section summarizes emergency procedures. The Licensee must develop, implement, and maintain specific emergency procedures which contain the following elements:

- Steps to take, and who to contact (e.g., RSO, local officials), when the following has occurred:
 - Leaking or damaged radioactive source or package containing a radioactive source,
 - Device containing radioactive material malfunctions or is damaged,
 - Radioactive material spills,
 - Theft or loss of radioactive material, or
 - Any other events involving radioactive material
- Steps for sealed source retrieval and access control of damaged sealed source(s) and/or malfunctioning devices containing sealed source(s)
- Steps to take if a therapy patient undergoes emergency surgery or dies.

AND

The licensee must insure the following:

- Make Emergency Procedures available to all users
- Maintain a current copy of the procedures at each location of use (or, if this is not practicable, post a notice describing the procedures and stating where they may be examined).

- Provide annual training on the Emergency Procedures to licensee personnel
- When developing the procedures described above, the licensee is reminded that RH-1004 requires that the licensee use, to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA.
- Sealed sources and unsealed radioactive material used for therapy can deliver significant doses in a short time period. The Rules and Regulation, Paragraphs RH-1303.c, RH-1303.d, RH-1306.a, and RH-1308 describe access control to high and very high radiation areas and the security of radioactive material. Unauthorized access to radioactive material by untrained individuals could lead to a significant radiological hazard. This information must be incorporated into emergency procedures.

Additional Procedural Guidance (not covered elsewhere in the Licensing Guide)

The following Table lists additional topics that must be included/incorporated in the Emergency Procedures, as appropriate. These topics are not addressed elsewhere in the Licensing Guide. Additional discussion and procedural guidance is provided on each topic, as noted in the Table Q-1, Sub-Appendix. The Licensee may incorporate the guidance provided in the Sub-Appendix or may develop and submit equivalent procedures.

After the occurrence of an event becomes known to the Licensee, the Department must be notified that an event involving radioactive material has occurred. Refer to the Rules and Regulations, Sections 3 and 9 for a description of when notifications are required.

Table Q-1. Additional Guidance for Topics to be Included in Emergency Procedures, As Appropriate

Topic	Sub-Appendix
Safety Procedures and Instructions	Q-1
Spill Procedures	Q-2
Emergency Surgery	Q-3
Autopsy Procedures	Q-4

APPENDIX Q-1

SAFETY PROCEDURES AND INSTRUCTIONS

Prior to using radioactive material under RH-8630, the Applicant must develop, document, submit, and implement written safety procedures for emergency response. Paragraph RH-8633 requires, in part, that written procedures be developed, implemented, and maintained for responding to an abnormal situation involving a remote afterloader unit, a teletherapy unit, or a gamma stereotactic radiosurgery unit. The procedures needed to meet RH-8633 must include:

- Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
- The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
- The names and telephone numbers of Authorized Users, Authorized Medical Physicists, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

A copy of the procedures must be physically located at the therapy unit console. The instructions must inform the operator of procedures to be followed if the operator is unable to place the source(s) in the shielded position, or remove the patient from the radiation field with controls from outside the treatment room.

The applicant must establish and follow written procedures for emergencies that may occur (e.g., a therapy source fails to retract or return to the shielded position, or a GSR couch fails to retract). A copy of the manufacturer's recommendations and instructions should be given to each individual performing therapy treatments or operating the therapy device. Practice drills, using nonradioactive (dummy) sources (when possible), must be practiced annually or more frequently, as needed. The drills should include dry runs of emergency procedures that cover stuck or dislodged sources and applicators (if applicable), and emergency procedures for removing the patient from the radiation field. Team practice may also be important for adequate emergency coordination for such maneuvers as removing a patient from a malfunctioning GSR unit and manual movement of the patient treatment table. These procedures, designed to minimize radiation exposure to patients, workers, and the general public must address the following points, as applicable to the type of medical use:

- When the procedures are to be implemented, such as any circumstance in which the source becomes dislodged, cannot be retracted to a fully shielded position, or the patient cannot be removed from the beam of radiation.

- The actions specified for emergency source recovery or shielding that primarily consider minimizing exposure to the patient and health care personnel while maximizing safety of the patient.
- The step-by-step actions for single or multiple failures that specify the individual(s) responsible for implementing the actions. The procedures should clearly specify which steps are to be taken under different scenarios. The procedure should specify situations in which surgical intervention may be necessary and the steps that should be taken in that event.
- Location of emergency source recovery equipment and specification of what equipment may be necessary for various scenarios. Emergency equipment should include shielded storage containers, remote handling tools, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient and tools necessary for removal of the patient from the device.
- Giving first consideration to minimizing exposure to the patient, usually by removing the patient from the room (rather than using tools to attempt to return the source to the off position).

NOTE: If the first step of the emergency procedures for teletherapy units specifies pressing the emergency bar on the teletherapy unit console, the applicant is advised that this action may cause the source to return to the off position but may also cut power to the entire teletherapy unit or to the gantry or the couch.

- Instructing the staff to act quickly and calmly, and to avoid the primary beam of radiation.
- Specifying who is to be notified.
- Requirements to restrict (lock, as necessary) and post the treatment area with appropriate warning signs as soon as the patient and staff are out of the treatment room.

The procedures required by RH-8633 must be included in Item 23 of the Application.

APPENDIX Q-2

SPILL PROCEDURES

Prior to using radioactive material, the Applicant must develop, document, and implement written emergency procedures for the proper response to spills of radioactive material.

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

The Emergency Procedures that licensees are required to develop, document, and implement must include provisions for responding to spills or other contamination events in order to prevent the spread of radioactive material. Spill procedures should address all types and forms of radioactive material used and should be posted in restricted areas where radioactive materials are used or stored. The instructions should specifically state the names and telephone numbers of persons to be notified (e.g., RSO, staff, state and local authorities, and the Department, when applicable). Additionally, the instructions should contain procedures for evacuation of the area, containment of spills and other releases, appropriate methods for reentering, and for decontaminating facilities when necessary.

Example Spill Procedures -- Low and High Dose Unsealed Sources

This example provides acceptable procedures for responding to events involving spilled radioactive material.

Minor Spills of Liquids and Solids

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Wearing gloves and protective clothing such as a lab coat and booties, clean up the spill using absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a "Caution Radioactive Material" labeled bag for transfer to a radioactive waste container. Also, put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detection survey instrument sufficiently sensitive to detect the radionuclide. Check for removable contamination to ensure contamination levels are below trigger levels. Check the area around the spill. Also, check hands, clothing, and shoes for contamination.
5. Report the incident to the RSO.

Major Spills of Liquids and Solids

1. Clear the area. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with “Caution Radioactive Material” labeled absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, clearly indicate the boundaries of the spill and limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. Do this only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the RSO immediately.
6. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with mild soap. If contamination remains, the RSO may consider inducing perspiration. Then wash the affected area again to remove any contamination that was released by the perspiration.

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables, such as the number of individuals affected, other hazards present, likelihood of contamination spread, types of surfaces contaminated and radiotoxicity of the spilled material. For some spills of radionuclides with half-lives shorter than 24 hours and in amounts less than five times the lowest ALI, an alternative spill procedure may be restricted access pending complete decay.

Guidance

Use Table Q-2.1 as general guidance to determine whether a major spill procedure or a minor spill procedure will be implemented.

Estimate the amount of radioactivity spilled. Initiate a major or minor spill procedure, based on the following information. Spills above these mCi amounts are considered major, and below these levels are considered minor.

Radionuclide	milliCurie	Radionuclide	milliCurie
P-32	1	Tc-99m	100
Cr-51	100	In-111	10
Co-57	10	I-123	10
Co-58	10	I-125	1
Fe-59	1	I-131	1
Co-60	1	Sm-153	10
Ga-67	10	Yb-169	10
Se-75	1	Hg-197	10
Sr-85	10	Au-198	10
Sr-89	1	Tl-201	100

Spill Kit

Assemble a spill kit that may contain the following items:

- Disposable gloves and housekeeping gloves;
- Disposable lab coats;
- Disposable head coverings;
- Disposable shoe covers;
- Roll of absorbent paper with plastic backing;
- Masking tape;
- Plastic trash bags with twist ties;
- Marking pen;
- Pre-strung “Radioactive Material” labeling tags;
- Contamination wipes;
- Instructions for “Emergency Procedures”;
- Clipboard with copy of Radioactive Spill Report Form;
- Pencil; and
- Appropriate survey instruments, including batteries.

APPENDIX Q-3

EMERGENCY SURGERY OF PATIENTS WHO HAVE RECEIVED THERAPEUTIC AMOUNTS OF RADIOACTIVE MATERIAL

Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radioactive Material

If a therapy patient undergoes emergency surgery or dies, it is necessary to ensure the safety of others attending the patient. As long as the patient's body remains unopened, the radiation received by anyone near it is due almost entirely to gamma rays. The change in emphasis when an operation or autopsy is to be performed is due to the possible exposure of the hands and face to relatively intense beta radiation. Procedures for emergency surgery or autopsy can be found in Section 5.3 of NCRP Report No. 37, "Precautions In The Management of Patients Who Have Received Therapeutic Amounts of Radionuclides".

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

The following procedures should be followed:

1. If emergency surgery is performed within the first 24 hours following the administration of I-131 sodium iodide, fluids (e.g., blood, urine) will be carefully removed and contained in a closed system.
2. Protective eyewear will be worn by the surgeon and any personnel involved in the surgical procedure for protection of the eyes from possible splashing of radioactive material and exposure from beta radiation (if applicable).
3. The Radiation Safety Officer will direct personnel in methods to keep doses ALARA during surgical procedures.
4. If an injury occurs during surgery that results in a cut or tear in the glove used, the individual involved will be monitored to determine if radioactive material was introduced into the wound. The RSO will be informed of any possible radiation hazard.

APPENDIX Q-4

AUTOPSY OF PATIENTS WHO HAVE RECEIVED THERAPEUTIC AMOUNT OF RADIOACTIVE MATERIAL

Autopsy of Patients Who Have Received Therapeutic Amounts of Radioactive Material

If a therapy patient undergoes emergency surgery or dies, it is necessary to ensure the safety of others attending the patient. As long as the patient's body remains unopened, the radiation received by anyone near it is due almost entirely to gamma rays. The change in emphasis when an operation or autopsy is to be performed is due to the possible exposure of the hands and face to relatively intense beta radiation. Procedures for emergency surgery or autopsy can be found in Section 5.3 of NCRP Report No. 37, "Precautions In The Management of Patients Who Have Received Therapeutic Amounts of Radionuclides".

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

The following procedures should be followed:

1. Immediately notify the Authorized User in charge of the patient and the RSO upon death of a therapy patient.
2. An autopsy will be performed only after consultation and permission from the RSO. Radiation safety staff should evaluate the radiation hazard(s), direct personnel in safety and protection, and suggest suitable procedures in order to keep doses ALARA during the autopsy.
3. Protective eyewear should be worn by the pathologist and assisting staff for protection from possible splashing of radioactive material. Consider the need for protection against radiation dose from high-energy beta rays in cases involving therapy with P-32 and Y-90.
4. Remove tissues containing large activities early to help reduce radiation dose of autopsy personnel. Shield and dispose of contaminated tissues in accord with license conditions. In some cases, dose reduction may be accomplished by removing tissues for dissection to a location where the dose rate is lower.

If an injury occurs during the autopsy that results in a cut or tear in the glove, monitor the wound and decontaminate as appropriate to the situation; inform the RSO.

The following reference is provided to assist the Applicant:

NCRP Report No. 111, "Developing Radiation Emergency Plans for Academic, Medical, and Industrial Facilities", 1991. This document is available from the

National Council on Radiation Protection and Measurements,
7910 Woodmont Avenue, Suite 400,
Bethesda, Maryland 20814-3095

APPENDIX R

ADMINISTRATIVE PROCEDURES

Radioactive Material Licensees are responsible for documenting, recording, and maintaining records of radiation safety activities, as well as informing/notifying employees of matters pertaining to radiation safety. The Licensee is also responsible for notifying the Department of emergency or abnormal events involving radioactive material.

Recordkeeping

Licensees must maintain records as required in RH-1500; RH-600 through RH-602; and RH-8700 through RH-8728

The licensee must maintain certain records to comply with Department regulations, the conditions of the license, and commitments made in the license application. Operating Procedures must identify the individuals in the Licensee's organization who are responsible for maintaining which records.

A table of recordkeeping requirements appears in Table R-1.

Reporting

Radioactive Material Licensees are required to report to Department via telephone, written report, or both in the event that the safety or security of radioactive material may be compromised. The specific events that require reporting are explained in RH-8800 through RH-8804, Section 3, Part F; and in Section 2, Part F, and RH-1502. The timing and type of report are specified within these parts.

The Department requires licensees to report incidents that might compromise the health and safety of patients, health care providers, or the public. Therefore, Sections 2, 3, and 9 of the Rules and Regulations include provisions that describe reporting requirements associated with the medical use of radioactive material.

A table of reporting requirements appears in Table R-2.

Communication with Workers

Radioactive Material Licensee are required to provide training and instructions to workers, provide information about the Radioactive Material License, the Rules and Regulations, and provide various other reports relating to the work activities and the workplace covered by the license and the regulations, and the Department inspections. These requirements are established in following parts of the regulations:

- Section 3, Part D, RH-1305
- Section 3, Part F, RH-1500 through 1506
- Section 3, Part N, RH-2801 through RH-2808

Table R-1 Typical Records and Retention Times			
Record	Requirement	Recordkeeping Requirement	Retention Period
Results of surveys and calibrations	RH-1300 RH-1307	RH-1500.c.1	3 years
Results of surveys to determine dose from external sources		RH-1500.c.2	duration of license
Results of measurements and calculations used to determine individual intakes		RH-1500.c.2	duration of license
Results of air samplings, surveys, and bioassays	RH-1303.f.5	RH-1500.c.2	duration of license
Results of measurements and calculations used to evaluate the release of radioactive effluents to the environment		RH-1500.c.2	duration of license
Determination of prior occupational dose		RH-1500.d	duration of license
Planned special exposure	RH-1205	RH-1500.e	duration of license
Individual monitoring results	RH-1302	RH-1500.f	duration of license
Dose to individual members of the public	RH-1208	RH-1500.g	duration of license
Waste disposal	RH-1401 RH-1402 RH-1404 RH-1405	RH-1500.h	duration of license
Records of receipt of radioactive material		RH-600.a.1	duration of possession and 3 years after transfer
Records of transfer of radioactive material		RH-600.a.2	3 years after transfer
Records of disposal of radioactive material		RH-600.a.3	duration of license
Authority and responsibilities of radiation protection program	RH-8300	RH-8700	5 years
Radiation protection program changes	RH-8301	RH-8701	5 years
Written directives	RH-8308	RH-8702	3 years
Procedures for administrations requiring a written directive	RH-8308	RH-8308	duration of license
Calibrations of instruments used to measure activity of unsealed radioactive material	RH-8401	RH-8705	3 years

Table R-1 Typical Records and Retention Times			
Record	Requirement	Recordkeeping Requirement	Retention Period
Radiation survey instrument calibrations	RH-8402	RH-8706	3 years
Dosages of unsealed radioactive material for medical use	RH-RH-8403	RH-8707	3 years
Leak tests and inventory of sealed sources and brachytherapy sources	RH-8405	RH-8708	3 years
Surveys for ambient radiation exposure rate	RH-8408	RH-8709	3 years
Release of individuals containing unsealed radioactive material or implants containing radioactive material	RH-8420	RH-8710	3 years
Mobile medical services	RH-8425	RH-8711	3 years
Decay-in-storage	RH-8410	RH-8712	3 years
Molybdenum-99 concentrations	RH-8531	RH-8713	3 years
Safety instruction	RH-8551 RH-8603 RH-8633	RH-8715	3 years
Surveys after source implant and removal	RH-8601 RH-8631	RH-8716	3 years
Brachytherapy source accountability	RH-8602	RH-8717	3 years
Calibration measurements of brachytherapy sources	RH-8605	RH-8718	3 years
Decay of strontium-90 sources for ophthalmic treatments	RH-8605	RH-8719	life of source
Installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	RH-8631	RH-8720	3 years
Safety procedures	RH-8633	RH-8633	duration of possession of specified equipment
Dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	RH-8635	RH-8721	duration of license
Teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations	RH-8640 RH-8641 RH-8642	RH-8722	3 years

Table R-1 Typical Records and Retention Times			
Record	Requirement	Recordkeeping Requirement	Retention Period
Periodic spot-checks of teletherapy units	RH-8643	RH-8723	3 years
Periodic spot-checks of remote afterloader units	RH-8644	RH-8724	3 years
Periodic spot-checks of gamma stereotactic radiosurgery units	RH-8645	RH-8725	3 years
Additional technical requirements for mobile remote afterloader units	RH-8647	RH-8726	3 years
Surveys of therapeutic treatment units	RH-8650	RH-8727	duration of use of unit
5-year inspection for teletherapy and gamma stereotactic radiosurgery units	RH-8649	RH-8728	duration of use of unit

Table R-2 Typical Department Notifications and/or Reports			
Event	Telephone Notification	Written Report	Regulatory Requirement
Reports to individual workers	none	annually	RH-2804.b
Reports to former individual workers	none	upon request	RH-2804.c
Notification of special circumstances to individuals	none	30 days	RH-2804.f
Reports to worker terminating employment	none	upon request	RH-2804.d & e
Theft or loss of material	immediate	30 days	RH-1501
Whole body dose greater than 25 rems (0.25 Sv)	immediate	30 days	RH-1502.a.1 RH-1504.a
Extremity dose greater than 250 rems (2.5 Sv)	immediate	30 days	RH-1502.a.1 RH-1504.a
Whole body dose greater than 5 rems(0.05 Sv) in 24 hours	24 hours	30 days	RH-1502.b.1 RH-1504.a
Extremity dose greater than 50 rems (0.5 Sv) in 24 hours	24 hours	30 days	RH-1502.b.1 RH-1504.a
Doses in excess of specified criteria	none	30 days	RH-1504.a.2
Levels of radiation or concentrations of radioactive material in excess of specified criteria	none	30 days	RH-1504.a.3
Planned special exposures	none	30 days	RH-1205.f
Report to individuals of exceeding dose limits	none	30 days	RH-1505.b
Report of individual monitoring	none	annually	RH-1509
Defect in equipment that could create a substantial safety hazard	2 days	30 days	NRC Regulations
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	immediate	30 days	RH-1502.e

Table R-2 Typical Department Notifications and/or Reports			
Event	Telephone Notification	Written Report	Regulatory Requirement
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	RH-1502.f.2
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	RH-1502.f.4
Licensee permits individual to work as AU, ANP, or AMP	none	30 days	RH-8020.a
AU, ANP, or AMP discontinues performance of duties under license or has a name change	none	30 days	RH-8020.b.1
Licensee's mailing address changes	none	30 days	RH-8020.b.2
Licensee's name changes without constituting a transfer of control	none	30 days	RH-8020.b.4
Licensee adds or changes areas of 35.100 or 35.200 use of radioactive material identified in application or license	none	Before Change	RH-8011
Medical event	1 day	15 days	RH-8800
Dose to embryo or nursing child	1 day	15 days	RH-8801
Leaking source	none	5 days	RH-8802

Note: Telephone notifications shall be made to the Department at the following 24-hour number

1-800-633-1735

APPENDIX S

ANNUAL RADIATION SAFETY PROGRAM AUDIT

As required by the Rules and Regulations, Paragraph RH-1004, all licensees must annually review the content and implementation of the Radiation Safety Program. The review must ensure the following:

- Compliance with Department and applicable DOT regulations and the terms and conditions of the license; and
- Occupational doses and doses to members of the public are ALARA.

The Applicant must develop and implement procedures for the required review or audit of the radiation protection program's content and implementation. Sub-Appendix S-1 contains an example audit that is a suggested guide to meet this requirement. Some sections of Appendix S may not be pertinent to every licensee or to each review or audit. For example, licensees do not need to address areas that do not apply to their activities, and activities that have not occurred since the last review or audit need not be reviewed at the next review or audit. Reviews or audits of the content and implementation of the radiation protection program must be conducted at least annually.

The Department encourages licensee management to conduct performance-based reviews by observing work in progress, interviewing staff about the Radiation Safety Program, and spot-checking required records. As part of their review programs, licensees should consider performing unannounced audits of authorized and supervised users to determine if, for example, Operating and Emergency Procedures are available and are being followed.

It is essential that once identified, violations and radiation safety concerns are corrected comprehensively and in a timely manner. The following three-step corrective action process has proven effective:

- Conduct a complete and thorough review of the circumstances that led to the violation.
- Identify the root cause of the violation.
- Take prompt and comprehensive corrective actions that will address the immediate concerns and prevent recurrence of the violation.

The Department's expectation is that Licensee's will promptly identify and initiate comprehensive correction of violations and deficiencies.

APPENDIX S-1

ANNUAL RADIATION SAFETY PROGRAM AUDIT FORM

Date of This Audit _____ **Date of Last Audit** _____

Next Audit Date _____

Auditor _____ **Date** _____
(Signature)

Management Review _____ **Date** _____
(Signature)

Audit History

- A. Were previous audits conducted annually [RH-1004]?
- B. Were records of previous audits maintained [RH-1500]?
- C. Were any deficiencies identified during previous audit?
- D. Were corrective actions taken? (Look for repeated deficiencies).

Organization and Scope of Program

- A. Radiation Safety Officer:
 - 1. If the RSO was changed, was license amended [RH-8011]?
 - 2. Does new RSO meet Department training requirements [RH-8315, RH-8318, and RH-8319]?
 - 3. Is RSO fulfilling all duties [RH-8300]?
 - 4. Is the written agreement in place for a new RSO [RH-8300]?
- B. Multiple places of use? If yes, list locations.
- C. Are all locations listed on license?
- D. Were annual audits performed at each location? If no, explain.
- E. Describe scope of the program (staff size, number of procedures performed, etc.).
- F. Licensed Material:
 - 1. Isotope, chemical form, quantity and use as authorized?
 - 2. Does the total amount of radioactive material possessed require financial assurance [RH-409.h]? If so, is financial assurance adequate?
 - 3. Calibration, transmission, and reference sources [RH-8404]?

- a. Sealed sources manufactured and distributed by a person licensed pursuant to NRC regulations (10 CFR 32.74), equivalent Agreement State regulations, or redistributed by a licensee authorized to redistribute sealed sources, and sources do not exceed 30 milliCurie each [RH-8404]?
 - b. Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 15 milliCurie [RH-8404]?
 - c. Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 200 microCuries or 1000 times the quantities in Appendix B of Part 30 [RH-8404]
 - d. Technetium-99m in individual amounts as needed [RH-8404]?
4. Unsealed materials used under RH-8500, RH-8530, and RH-8550 are:
- a. Obtained from a manufacturer or preparer licensed under Section 2 of the regulations?

OR

- b. Prepared by a physician authorized user, an authorized nuclear pharmacist, or an individual under the supervision of an authorized nuclear pharmacist or physician authorized user?

OR

- c. Obtained and prepared for research in accordance with RH-8500, RH-8530, and RH-8550, as applicable?

- G. Are the sealed sources possessed and used as described in the Sealed Source and Device Registration (SSDR) Certificate [RH-8404, RH-8600, RH-8620, RH-8630]? Are copies of (or access to) SSDR Certificates possessed? Are manufacturers' manuals for operation and maintenance of medical devices possessed?
- H. Are the actual uses of medical devices consistent with the authorized uses listed on the license?
- I. If places of use changed, was the license amended [RH-8011]?
- J. If control of license was transferred or bankruptcy filed, was Department prior consent obtained or notification made, respectively [RH-409.b and RH-409.g]?

Radiation Safety Program

- A. Minor changes to program [RH-8301]?
- B. Records of changes maintained for 5 years [RH-8701]?
- C. Content and implementation reviewed annually by the licensee [RH-1004]?
- D. Records of reviews maintained [RH-1500]?

Use by Authorized Individuals

Compliance is established by meeting at least one criterion under each category.

- A. Authorized Nuclear Pharmacist [RH-8317, RH-8318, RH-8319]
- _____ 1. Certified by specialty board
- _____ 2. Identified on Department, NRC or Agreement State license
- _____ 3. Identified on permit issued by broad scope or master materials licensee
- _____ 4. Listed on facility license
- B. Authorized User [RH-8318, RH-8319, and RH-8510, RH-8540, RH-8560, RH-8570, RH-8580, RH-8590, RH-8610, RH-8615, RH-8621, RH-8660]:
- _____ 1. Certified by specialty board
- _____ 2. Identified on Department, NRC or Agreement State license
- _____ 3. Identified on permit issued by broad scope or master materials licensee
- _____ 4. Listed on facility license
- C. Authorized Medical Physicist [RH-8316, RH-8318, RH-8319]:
- _____ 1. Certified by specialty board
- _____ 2. Identified on Department, NRC or Agreement State license
- _____ 3. Identified on permit issued by broad scope or master materials licensee
- _____ 4. Listed on facility license

Mobile Medical Service

- A. Operates services per RH-8425, RH-8647?
- B. Compliance with RH-1208 evaluated and met?
- C. Letter signed by management of each client [RH-8425]?
- D. Licensed material was not delivered to client's address (unless client was authorized) [RH-8425]?
- E. Dosage measuring instruments checked for proper function before used at each address of use or on each day of use, if more frequent [RH-8425]?
- F. Survey instruments checked for proper operation before used at each address of use [RH-8425]?
- G. Survey of all areas of use prior to leaving each client address [RH-8425]?
- H. Additional technical requirements for mobile remote afterloaders per [RH-8647]?

Amendments Since Last Audit [RH-8011]

- A. Any Amendments since last audit [RH-8011]?

Notifications Since Last Audit [RH-8020]

- A. Any Notifications since last audit [RH-8020]?
- B. Appropriate documentation provided to Department for authorized nuclear pharmacist, authorized medical physicists, or authorized user no later than 30 days after the individual starts work [RH-8020]?
- C. Department notified within 30 days after: authorized user, authorized nuclear pharmacist, authorized medical physicist, or RSO stops work or changes name; license's mailing address changes; licensee's name changes without a transfer of control of the license; or licensee has added to or changed an area of use for RH-8500 or RH-8530 use [RH-8020]?

Training, Retraining, and Instructions to Workers

- A. Have workers been provided with required instructions [RH-2803, RH-8306, RH-8551, RH-8603, RH-8633]?
- B. Is the individual's understanding of current procedures and regulations adequate?
- C. Training program implemented?
1. Operating procedures [RH-8306, RH-8551, RH-8603, RH-8633]?
 2. Emergency procedures [RH-8306, RH-8551, RH-8603, RH-8633]?
 3. Periodic training required and implemented [RH-8551, RH-8603, RH-8633]?
 4. Were all workers provided annual refresher training, as needed [RH-2803]?
 5. Was each supervised user instructed in the licensee's written radiation protection procedures and administration of written directives, as appropriate [RH-8306]?
 6. Are initial and periodic training records maintained for each individual [RH-8715]?
 7. Briefly describe training program:
- D. Additional therapy device instructions/training:
1. Unit operation, inspection, associated equipment, survey instruments?
 2. License conditions applicable to the use of the unit?
 3. Emergency drills [RH-8633]?
- E. Section 3 - Workers cognizant of requirements for:
1. Radiation Safety Program [RH-8300, RH-8301, RH-1004]?
 2. Annual dose limits [RH-1200, RH-1208, RH-1209]?
 3. Department Forms Y and Z?

4. 10% monitoring threshold [RH-1302]?
 5. Dose limits to embryo/fetus and declared pregnant worker [RH-1207]?
 6. Grave Danger Posting [RH-1303]?
 7. Procedures for opening packages [RH-1307]?
- F. Supervision of individuals by authorized user and/or authorized nuclear pharmacist in accordance with RH-8306?

Training for Manual Brachytherapy and Use of Unsealed Radioactive Material for Which a Written Directive Is Required

- A. Safety instruction to personnel provided include [RH-8551, RH-8603]:
1. Control of patient and visitors?
 2. Routine visitation to patients in accordance with RH-1208?
 3. Contamination control and size/appearance of sources?
 4. Safe handling and shielding instructions?
 5. Waste control?
 6. RSO and AU notification in emergency or death?
 7. Records retained [RH-8715]?

Facilities

- A. Facilities as described in license application?
- B. Therapy device facilities provided with electrical interlock system, viewing and intercom systems, radiation monitor, source retraction mechanism, and source indicator lights?
- C. Emergency source recovery equipment available [RH-8604, RH-8634]?
- D. Storage areas:
1. Materials secured from unauthorized removal or access [RH-1306]?
 2. Licensee controls and maintains constant surveillance of licensed material not in storage [RH-1308]?
- E. Therapy unit operation:
1. Unit, console, console keys, and treatment room controlled adequately [RH-1306, RH-8633]?
 2. Restricted to certain source orientations and/or gantry angles?
 3. Ceases to operate in restricted orientation(s)?
 4. Only one radiation device can be placed in operation at a time within the treatment room [RH-8633]?

Dose or Dosage Measuring Equipment

- A. Possession, use, and calibration of instruments to measure activities of unsealed radionuclides [RH-8401]:
 - 1. List type of equipment used:
 - 2. Approved procedures for use of instrumentation followed?
 - 3. Constancy, accuracy, linearity, and geometry dependence tests performed in accordance with nationally recognized standards or the manufacturer's instructions?
 - 4. Instrument repaired or replaced or dosages mathematically corrected, as required, when tests do not meet the performance objectives provided in the nationally recognized standard or manufacturer's instructions (e.g., 10%)?
 - 5. Records maintained and include required information [RH-8705]?
- B. Determination of dosages of unsealed radioactive material [RH-8403]:
 - 1. Each dosage determined and recorded prior to medical use [RH-8403]?
 - 2. Measurement of unit dosages made either by direct measurement or by decay correction [RH-8403]?
 - 3. For other than unit dosages, measurement made by direct measurement of radioactivity or by combination of radioactivity or volumetric measurement and calculation [RH-8403]?
- C. Licensee uses generators?
 - 1. First eluate after receipt tested for Mo-99 breakthrough [RH-8531]?
 - 2. No radiopharmaceuticals administered with Mo-99 concentrations over 0.15 μCi per mCi of Tc-99m [RH-8531]?
 - 3. Records maintained [RH-8713]?
- D. Dosimetry Equipment [RH-8635]:
 - 1. Calibrated system available for use [RH-8635]?
 - 2. Calibrated by NIST or an AAPM-accredited lab within previous 2 years and after servicing [RH-8635] OR calibrated by intercomparison per RH-8635?
 - 3. Calibrated within the previous 4 years [RH-8635]?
 - 4. Licensee has available for use a dosimetry system for spot-check measurements [RH-8635]?
 - 5. Record of each calibration, intercomparison, and comparison maintained [RH-8721]?

Radiation Protection and Control of Radioactive Material

- A. Use of radiopharmaceuticals:
 - 1. Protective clothing worn?
 - 2. Personnel routinely monitor their hands?
 - 3. No eating/drinking in use/storage areas?
 - 4. No food, drink, or personal effects kept in use/storage areas?
 - 5. Proper dosimetry worn?
 - 6. Radioactive waste disposed of in proper receptacles?
 - 7. Syringe shields and vial shields used?
- B. Leak tests and Inventories:
 - 1. Leak test performed on sealed sources and brachytherapy sources [RH-8405]?
 - 2. Inventory of sealed sources and brachytherapy sources performed semiannually [RH-8405]
 - 3. Records maintained [RH-8708]?

Radiation Survey Instruments

- A. Survey instruments used to show compliance with Section 3 and RH-404;
 - 1. Appropriate operable survey instruments possessed or available [Section 3]?
 - 2. Calibrations [RH-8402]:
 - a. Before first use, annually and after repairs?
 - b. Within 20% on each scale or decade of interest?
 - 3. Records maintained [RH-8706]?
- B. Radiation surveys performed in accordance with the licensee's procedures and the regulatory requirements [RH-1300, RH-8408]?:
 - 1. Daily in all areas where radiopharmaceuticals requiring a written directive are prepared or administered (except patient rooms) [RH-8408]?
 - 2. Weekly in all areas where radiopharmaceuticals or waste is stored?
 - 3. Weekly wipes in all areas where radiopharmaceuticals are routinely prepared, administered, or stored?
 - 4. Trigger levels established?
 - 5. Corrective action taken and documented if trigger level exceeded?
 - 6. Techniques can detect 0.1 mR/hr, 2000dpm?

7. Surveys made to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry [RH-8650] and records maintained [RH-8727]?
 - a. After new source installation?
 - b. Following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical mechanism that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s)?

Public Dose

- A. Is licensed material used in a manner to keep doses below 100 mrem (1mSv) in a year [RH-1208]?
- B. Has a survey or evaluation been performed per RH-1300?
- C. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?
- D. Do unrestricted area radiation levels exceed 2 mrem (0.02 mSv) in any one hour [RH-1208]?
- E. Is licensed material used or stored in a manner that would prevent unauthorized access or removal [RH-1306 and RH-1308]?
- F. Records maintained [RH-1500]?

Patient Release

- A. Individuals released when TEDE less than 0.5 rem [RH-8420]? Compliance with Department "Standards"?
- B. Instructions to the released individual, including breast-feeding women, include required information [RH-8420]?
- C. Release records maintained [RH-8710]?
- D. Records of instructions given to breast-feeding women maintained [RH-8710]?

Unsealed Radioactive Material for Which a Written Directive Is Required

- A. Safety precautions implemented to include patient facilities, posting, stay times, patient safety guidance, release, and contamination controls [RH-8552]?
- B. RSO and AU promptly notified if patient died or had a medical emergency [RH-8552]?

Brachytherapy

- A. Safety precautions implemented to include patient facilities, posting, stay times, and emergency response equipment [RH-8604]?
- B. Survey immediately after implant [RH-8601]?
- C. Patients surveyed immediately after removing the last temporary implant source [RH-8601]?
- D. RSO and AU promptly notified if patient died or had a medical emergency [RH-8601]?
- E. Records maintained [RH-8700]?

Radioactive Waste

- A. Disposal:
 - 1. Decay-in-storage [RH-8410]
 - 2. Procedures followed?
 - 3. Labels removed or defaced [RH-1303, RH-8410]?
- B. Special procedures performed as required?
- C. Authorized disposals [RH-1400]?
- D. Records maintained [RH-1500, RH-1500, RH-8712]?
- E. Effluents:
 - 1. Release to sanitary sewer [RH-1402]?
 - a. Material is readily soluble or readily dispersible [RH-1402]?
 - b. Monthly average release concentrations do not exceed RH-2792 values?
 - c. No more than 5 Ci of H-3, 1 Ci of C-14 and 1 Ci of all other radionuclides combined released in a year [RH-1402]?
 - d. Procedures to ensure representative sampling and analysis implemented [RH-1300]?
 - 2. Waste incinerated?
 - a. License authorizes [RH-1404]?
 - b. Directly monitor exhaust?
 - c. Airborne releases evaluated and controlled [RH-1209, RH-1300]?
 - 3. Air effluents and ashes controlled [RH-1004, RH-1200, RH-1208, RH-1300, RH-1400]?
 - a. Air effluent less than 10 mrem constraint limit RH-1004?

- b. If no, reported appropriate information to Department
 - i. Corrective actions implemented and on schedule?
 - c. Description of effluent program:
 - i. Monitoring system hardware adequate?
 - ii. Equipment calibrated, as appropriate?
 - iii. Air samples/sampling technique (i.e., charcoal, HEPA, etc.) analyzed with appropriate instrumentation?
- F. Waste storage
- 1. Protection from elements and fire?
 - 2. Control of waste maintained [RH-1306]?
 - 3. Containers properly labeled and area properly posted [RH-1303]?
 - 4. Package integrity adequately maintained?
- G. Waste disposal:
- 1. Sources transferred to authorized individuals [RH-1406, RH-1400, RH-500]?
 - 2. Name of organization: _____
- H. Records of surveys and material accountability are maintained [RH-1500, RH-1500, RH-8712]?

Receipt and Transfer of Radioactive Material

- A. Describe how packages are received and by whom.
- B. Written package opening procedures established and followed [RH-1307]?
- C. All incoming packages with a DOT label monitored for radioactive contamination, unless exempted (gases and special form) [RH-1307]?
- D. Incoming packages surveyed [RH-1307]?
- E. Monitoring in (C) and (D) performed within time specified [RH-1307]?
- F. Transfer(s) performed per [RH-500]?
- G. All sources surveyed before shipment and transfer [RH-1300]?
- H. Records of surveys and receipt/transfer maintained [RH-1500, RH-600]?
- I. Package receipt/distribution activities evaluated for compliance with RH-1208?

Transportation (Arkansas regulations and 49 CFR 171-189)

- A. Shipments are:
 - 1. Delivered to common carriers;
 - 2. Transported in own private vehicle;
 - 3. Both;
 - 4. No shipments since last audit.
- B. Return radiopharmacy doses or sealed sources?
 - 1. Licensee assumes shipping responsibility?
 - 2. If NO, describe arrangements made between licensee and radiopharmacy for shipping responsibilities:
- C. Packages:
 - 1. Authorized packages used?
 - 2. Performance test records on file?
 - a. DOT-7A packages
 - b. Special form sources
 - 3. Two labels (White-I, Yellow-II, Yellow-III) with TI, Nuclide, Activity, and Hazard Class?
 - 4. Properly marked (Shipping Name, UN Number, Package Type, RQ, "This End Up" (liquids), Name and Address of consignee)?
 - 5. Closed and sealed during transport?
- D. Shipping Papers:
 - 1. Prepared and used?
 - 2. Proper Shipping Name, Hazard Class, UN Number, Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, Category of Label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, "Limited Quantity" (if applicable), "Cargo Aircraft Only" (if applicable)?
 - 3. Readily accessible during transport?

Teletherapy and Gamma Stereotactic Radiosurgery Servicing

- A. Inspection and servicing performed following source replacement or at intervals not to exceed 5 years [RH-8646]?
- B. Needed service arranged for as identified during the inspection?
- C. Service performed by persons specifically licensed to perform work [RH-8646])?

Full Calibration-Therapeutic Medical Devices

- A. Proper protocol(s) used (e.g., TG-21, AAPM 54, TG-56, TG-40, etc.)?
- B. Performed prior to first patient use [RH-8640, RH-8641, RH-8642]?
- C. At intervals not to exceed one year for teletherapy, gamma stereotactic, and LDR remote afterloader; at intervals not exceeding one quarter for HDR, MDR, and PDR remote afterloaders [RH-8640, RH-8641, RH-8642]?
- D. Whenever spot-checks indicate output differs from expected by 5% [RH-8640, RH-8642]?
- E. After source exchange, relocation, and major repair or modification [RH-8640, RH-8641, RH-8642]?
- F. Performed with properly calibrated instrument [RH-8640, RH-8641, RH-8642]?
- G. Includes:
 - 1. For teletherapy:
 - a. Output measured within 3% of expected for the range of field sizes, range of distances [RH-8640]?
 - b. Coincidence of radiation field and field light localizer [RH-8640]?
 - c. Uniformity of radiation field and beam angle dependence [RH-8640]?
 - d. Timer accuracy and linearity over the range of use [RH-8640]?
 - e. On-off error [RH-8640]?
 - f. Accuracy of all measuring and localization devices [RH-8640]?
 - 2. For remote afterloaders:
 - a. Output measured within 5% of expected [RH-8641]?
 - b. Source positioning accuracy within 1 millimeter [RH-8641]?
 - c. Source retraction with backup battery upon power failure [RH-8641]?
 - d. Length of source transfer tubes [RH-8641]?
 - e. Timer accuracy and linearity over the typical range of use [RH-8641]?
 - f. Length of the applicators [RH-8641]?
 - g. Function of source transfer tubes, applicators, and transfer tube-applicator interfaces [RH-8641]?
 - h. Autoradiograph quarterly of the LDR source(s) to verify source(s) arrangement and inventory [RH-8641]?
 - 3. For gamma stereotactic radiosurgery:
 - a. Output measured within 3% of expected [RH-8642]?
 - b. Helmet factors [RH-8642]?

- c. Isocenter coincidence [RH-8642]?
 - d. Timer accuracy and linearity over the range of use [RH-8642]?
 - e. On-off error [RH-8642]?
 - f. Trunnion centricity [RH-8642]?
 - g. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off [RH-8642]?
 - h. Helmet microswitches [RH-8642]?
 - i. Emergency timing circuit [RH-8642]?
 - j. Stereotactic frames and localizing devices (trunnions) [RH-8642]?
- H. Output corrected mathematically for decay [RH-8640, RH-8641, RH-8642]?
- I. Records maintained [RH-8722]?

Periodic Spot Checks for Therapeutic Devices

- A. Performed at required frequency [RH-8643, RH-8644, RH-8645]?
- B. Procedures established by authorized medical physicist [RH-8643, RH-8644, RH-8645]?
- C. Procedures followed?
- D. Medical physicist reviews results within 15 days [RH-8643, RH-8644, RH-8645]?
- E. Performed with properly calibrated instrument [RH-8643, RH-8645]?
- F. Output and safety spot checks include:
 - 1. For teletherapy:
 - a. Timer accuracy and linearity over the range of use [RH-8643]?
 - b. On-off error [RH-8643(2)]?
 - c. Coincidence of radiation field and field light localizer [RH-8643]?
 - d. Accuracy of all measuring and localization devices [RH-8643]?
 - e. The output for one typical set of operating conditions [RH-8643]?
 - f. Difference between measured and expected output [RH-8643]?
 - g. Interlock systems [RH-8643]?
 - h. Beam stops [RH-8643]?
 - i. Source exposure indicator lights [RH-8643]?
 - j. Viewing and intercom systems [RH-8643]?
 - k. Treatment room doors, inside and out [RH-8643]?
 - l. Electrical treatment doors with power shut off [RH-8643]?

2. For remote afterloaders:
 - a. Interlock systems [RH-8644]?
 - b. Source exposure indicator lights [RH-8644]?
 - c. Viewing and intercom systems, except for LDR [RH-8644]?
 - d. Emergency response equipment [RH-8644]?
 - e. Radiation monitors used to indicate source position [RH-8644]?
 - f. Timer accuracy [RH-8644]?
 - g. Clock (date and time) in the unit's computer [RH-8644]?
 - h. Decayed source(s) activity in the unit's computer [RH-8644]?
 3. For gamma stereotactic radiosurgery:
 - a. Treatment table retraction mechanism [RH-8645]?
 - b. Helmet microswitches [RH-8645]?
 - c. Emergency timing circuits [RH-8645]?
 - d. Stereotactic frames and localizing devices [RH-8645]?
 - e. The output for one typical set of operating conditions [RH-8645]?
 - f. Difference between measured and expected output [RH-8645]?
 - g. Source output compared against computer calculation of output [RH-8645]?
 - h. Timer accuracy and linearity over the range of use [RH-8645]?
 - i. On-off error [RH-8645]?
 - j. Trunnion centricity [RH-8645]?
 - k. Interlock systems [RH-8645]?
 - l. Source exposure indicator lights [RH-8645]?
 - m. Viewing and intercom systems [RH-8645]?
 - n. Timer termination [RH-8645]?
 - o. Radiation monitors used to indicate room exposures [RH-8645]?
 - p. Emergency off buttons [RH-8645]?
- G. Licensee promptly repaired items found to be not operating properly and did not use unit until repaired, if required [RH-8643, RH-8644, RH-8645]?
- H. Records maintained [RH-8723, RH-8724, RH-8725]?

Installation, Maintenance, and Repair of Therapy Devices

- A. Only authorized individuals perform installation, maintenance, adjustment, repair, and inspection [RH-8632, RH-8646]?

Name of organization/individual: _____

- B. Records maintained [RH-8720, RH-8728]?

Operating Procedures for Therapy Devices

- A. Instructions on location of emergency procedures and emergency response telephone numbers are posted at the device console [RH-8633]?

- B. Copy of the entire procedures physically located at the device console [RH-8633]?

- C. Procedures include:

1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions [RH-8633]?
2. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure [RH-8633]?
3. The names and telephone numbers of the authorized users, the authorized medical physicist, and the RSO to be contacted if the unit or console operates abnormally [RH-8633]?

- D. Radiation survey of patient is performed to ensure source is returned to shielded position [RH-8631]?

- E. Records of radiation surveys maintained for 3 years [RH-8716]?

- F. Authorized medical physicist and authorized user:

1. Physically present during initiation of patient treatment with remote afterloaders (Note: for MDR and PDR, an appropriately trained physician under the supervision of the authorized user may be physically present instead of the authorized user) [RH-8634]?
2. Physically present throughout all patient treatments with a gamma stereotactic radiosurgery device [RH-8634]?

Personnel Radiation Protection

- A. Exposure evaluation performed [RH-1300]?

- B. ALARA program implemented [RH-1004]?

- C. External Dosimetry:

1. Monitors workers per [RH-1302]?
2. External exposures account for contributions from airborne activity [RH-1202]?
3. Supplier _____ Frequency _____

4. Supplier is NVLAP-approved [RH-1300]?
 5. Dosimeters exchanged at required frequency?
- D. Internal Dosimetry
1. Monitors workers per RH-1302?
 2. Briefly describe program for monitoring and controlling internal exposures [RH-1303]?
 3. Monitoring/controlling program implemented (includes bioassays)?
 4. Respiratory protection equipment [RH-1303]?
- E. Review of Records and Reports
1. Reviewed by _____ Frequency _____
 2. Auditor reviewed personnel monitoring records for period _____ to _____
 3. Prior dose determined for individuals likely to receive doses [RH-1500]?
 4. Maximum exposures TEDE _____ Other _____
 5. Maximum CDEs _____ Organs _____
 6. Maximum CEDE _____
 7. Internal and external summed [RH-1201]?
 8. Were occupational limits met [RH-1200]?
 9. Department forms or equivalent [RH-1500.d, RH-1500.f]?
 - a. Department - Z Complete:
 - b. Department - Y Complete:
 10. If a worker declared her pregnancy during the audit period, then was the dose in compliance [RH-1207] and were the records maintained [RH-1500]?
- F. Who performed any planned special exposures at this facility (number of people involved and doses received) [RH-1205, RH-1500, RH-1504]?
- G. Records of exposures, surveys, monitoring, and evaluations maintained [RH-1500, RH-1500]?

Confirmatory Measurements

Detail location and results of confirmatory measurements.

Medical Events

If medical events [criteria in 35.3045] have occurred since the last audit, evaluate the incident(s) and procedures for implementing and administering written directives using the existing guidance.

1. Event date _____ Information Source _____
2. Notifications
 Department Notification?
 Referring Physician?
 Patient?
 Method of Notification Telephone _____ Written _____
 If notification did not occur, why not?
3. Written Reports [RH-8800]:
 Submitted to Department within 15 days?

Notification and Reports

- A. In compliance with RH-1505, RH-1502(reports to individuals, public and occupational, monitored to show compliance with Section 3)?
- B. In compliance with RH-1501, RH-1502(theft or loss)?
- C. In compliance with RH-1502(incidents)?
- D. In compliance with RH-1504, RH-1502 (overexposures and high radiation levels)?
- E. Aware of Department's 24-hour Telephone number phone number?
- F. In compliance with RH-1504 (Constraint on air emissions)?

Posting and Labeling

- A. Department Form RH-11, "Notice to Employees" is posted [RH-2802]?
- B. Other posting and labeling per RH-1303 and not exempted by RH-1304, RH-1303?

Recordkeeping for Decommissioning

- A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [Section 2, Appendices A through D]?
- B. Records include all information outlined in Section 2, Appendices A through D?

Letter and Information Notices

- A. Department Letters, Information Notices, and other correspondence received?
- B. Appropriate action in response to Letters, Information Notices, etc.?

Special License Conditions or Issues

A. Special license conditions or issues to be reviewed:

B. Evaluation:

Audits and Findings

A. Summary of Findings:

B. Corrective and Preventive Actions: