Regulatory Guide 7.0

Radioactive Material Guidance for

Medical Use Licenses

Nebraska Department of Health and Human Services
Division of Public Health
Office of Radiological Health
P.O Box 95026
Lincoln, NE 68509-5026

Nebraska Department of Health and Human Services Regulation and Licensure, Regulatory Guides

Regulatory Guides are issued to describe and make available to the public acceptable methods of implementing specific parts of 180 NAC (Nebraska Regulations for Control of Radiation-Ionizing), to delineate techniques used by the staff in evaluating specific problems or postulated accidents, or to provide guidance to applicants, licensees, or registrants. Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the Nebraska Department of Health and Human Services, Division of Public Health, Office of Radiological Health to make necessary determination to issue or continue a license or certificate of registration.

Comments and suggestions for improvements in these Regulatory Guides are encouraged at all times and they will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments should be sent to Nebraska Department of Health and Human Services, Division of Public Health, Office of Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, NE 69509-5026.

Requests for single copies of issued guides (which may be reproduced) can be made in writing to Nebraska Department of Health and Human Services, Division of Public, Office of Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, NE 69509-5026 or refer to http://www.dhhs.ne.gov/rad.

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Abbreviations

AAPM	American Association of Physicist in Medicine
ACMUI	Advisory Committee on the Medical Use of Isotopes
ACR	American College of Radiology
ALARA	as low as is reasonably achievable
ALI	Annual limit on intake
AMP	Authorized Medical Physicist
ANP	Authorized Nuclear Pharmacist
ANSI	American National Standards Institute
AU	authorized user
Bkg	Background
BPR	business process redesign
CFR	Code of Federal Regulations
Ci	Curie
Cc	centimeter cubed
cm^2	square centimeter
Co-57	Colbalt-47
Co-60	Cobalt-60
Cpm	Counts per minute
Cs-137	Cesium-137
DAC	derived air concentration
DOT	United States Department of Transportation
Dpm	disintegrations per minute
FDA	United States Food and Drug Administration
GM	Geiger-Mueller
GSR	gamma sterotactic radiosurgery
I-125	iodine-125
I-131	Iodine-131
IN	Information Notice
IP	Inspection Procedure
Ir-192	iridium-192
LDR	low-dose-rate
mCi	millicurie
Ml	milliliter
Mo-99	Molybdenum-99

mR	milliroentgen
Mrem	millirem
mSv	millisievert
NaI(Tl)	Sodium iodide (thallium doped)
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OCR	optical character reader
OSL	optically stimulated luminescence dosimeters
P-32	phosphorus-32
Pd-103	palladium-103
PDR	pulsed dose-rate
QA	quality assurance
Ra-226	Radium-226
RG.	Regulatory Guide
RSC	radiation safety committee
RSO	radiation safety officer
SDE	shallow-dose equivalent
SI	International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites)
Sr-90	strontium-90
SSDR	Sealed Source and Device Registration
std	Standard
Sv	Sievert
Tc-99m	technetium-99m
TEDE	total effective dose equivalent
TI	transportation index
TLD	thermoluminescent dosimeters
U-235	Uranium-235
WD	written directive
Xe-133	Xenon-133
µCi	microcurie
%	percent

Definition

Department	Nebraska Department of Health and Human Services

Contact the Department at:

Nebraska Health and Human Services
Division of Public Health
Radioactive Materials Program
301 Centennial Mall South
P.O. Box 95026
Lincoln, NE 68509-5026
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Radiation.programs@dhhs.ne.gov

Regulatory Guide Summary

This Regulatory Guide 7.0 has been developed to streamline the application process for a medical use license for the applicant. A copy of the application NRH-7 "Application for Material License-Medical" is located in Appendix A and copy of the NRH-7A "Medical Use Training & Experience and Preceptor" is located in Appendix B.

Appendix C is a checklist to help the applicant complete NRH-7 Each section of the Appendix C's checklist refers to a number on the application NRH-7. Part III of this guide gives detailed explanation concerning how to complete each part and an explanation.

Appendix D through AA provide examples, models and additional information that can be used when completing the application.

"Regulatory Guide for Form NRH 7A Medical Use Training & Experience and Preceptor Statement" is an additional guide to use when completing NRH 7A. A NRH-7A needs to be completed for each individual user including radiation safety officers, authorized medical physicist and authorized nuclear pharmacists.

It typically takes 60-90 days for a license to be issued plus additional time if the application is not complete. When submitting the application be sure to include the appropriate application fee for a medical radioactive material application. The fee is located in 180 NAC 18.

In summary the applicant will need to do the following to submit an application for a medical radioactive material application.

- **Use this regulatory guide to prepare the application NRH-7.**
- **Complete the application NRH-7 (Appendix A), NRH-7A for each individual user and the checklist (Appendix C.) See Part III of this guide for additional information.**
- **In addition to NRH-7 and NRH-7A each application will need to include the appendixes and/or procedures requested.**
  -All supplemental pages should be typed on 8 ½" x 11" paper.
  -Please identify all attachments with the applicants name and license number (if a renewal), item number which it relates to, page number and application date.
- **Avoid submitting proprietary information unless it is absolutely necessary.**
- **Submit an original signed application along with attachments and if possible an electronic copy on a diskette or CD.**
- **Submit the application fee.**
- **Retain one copy of the license application and attachments for future reference.**
- **The license will require that radioactive material be possessed and used in accordance with statements, representation and procedures provided in the application and supporting documentation.**

If you have any questions about the applications process please contact this office at (402) 471-2168 or by e-mail at radiation.programs@nebraska.gov

Our website is located at: http://www.dhhs.ne.gov/rad

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I. Overview

Nebraska signed an agreement with the Atomic Energy Commission (now the U.S. Nuclear Regulatory Commission (NRC)) on October 1, 1966. The agreement gave Nebraska the authority to license and regulate radioactive material users in the State of Nebraska. With the exception of nuclear power plants and federally controlled facilities, the Nebraska Department of Health and Human Services, Division of Public Health (DHHS) or (Department), regulates the possession and use of radioactive material within the state. The NRC has signed similar agreements with other states. These states are referred to as Agreement States.

Under authority of the "Revised Statutes of Nebraska 1943 Article 35 (the Radiation Control Act), the Agency issues licenses to users of radioactive material and performs inspections to ensure compliance with Title 180 Nebraska Administrative Code (NAC) Nebraska Regulations for Control of Radiation.

This document, "Regulatory Guide 7.0, "Guidance for Radioactive Material – Medical Use Licenses" is intended for use by applicants, licensees, DHHS, Office of Radiological Health, license staff reviewers. It supersedes the guidance for applicants and licensees previously found in Regulatory Guide 7.0 (Rev 1), "Guide for Application Preparation for Medical Use Programs."

This guide uses current information found in the U.S. Nuclear Regulatory Commissions (NRC) NUREG 1556, Vol. 9 "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses" and other sources.

I.A. Purpose of Guide

This report 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:

1. Preparation of a license application using NRH 7"Application for Radioactive Material License – Medical," including NRH 7A; and
2. The Department's criteria for evaluating a medical use license application.

This guide provides guidance for the following types of medical uses of radioactive material:

- Use of unsealed radioactive material for uptake, dilution, and excretion studies for which a written directive is not required in 180 NAC 7-019 (see 180 NAC 7-041 through 7-043);
- Use of unsealed radioactive material for imaging and localization studies for which a written directive is not required in 180 NAC 7-019 (see 180 NAC 7-044 through 7-047);
- Use of unsealed radioactive material for which a written directive is required in 180 NAC 7-019 (see 180 NAC 7-048 through 7-054);
- Use of sources for manual brachytherapy (see 180 NAC 7-055 through 7-064);
- Use of sealed sources for diagnosis (see 180 NAC 7-065 through 7-066);
- Use of a sealed source in a photon emitting remote afterloader unit, teletherapy unit, or

gamma stereotactic radiosurgery unit (see 180 NAC 7-067 through 7-084); and

- Other medical uses of radioactive material or radiation from radioactive material not specifically covered by 180 NAC 7-041 through 7-084 (see 180 NAC 7-085).

To assist license applicants, this guide includes text boxes at the beginning of each section to indicate the type of use to which the guidance pertains (identified by the pertinent section of 180 NAC 7). 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 check indicates that applicants for that type of use should review the guidance section. Some of the checks 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. Table 1.1 summarizes the material in the text boxes.

Table 1.1 Section of Regulatory Guide 7.0 that Applicants for a Particular Type of Use Should Review

		Type of Use in 180 NAC 7						
		041	**044**	**048**	**055**	**065**	**067**	**085**
1.a.	**Legal Name and Street address of Applicant**	√	√	√	√	√	√	√
1.b.	**Street Address at Which Radioactive Material Will be Used and/or Stored, If Different From 1a.**	√	√	√	√	√	√	√
2.	**Person to Contact Regarding this Application**	√	√	√	√	√	√	√
3.	**License Action Type**	√	√	√	√	√	√	√
4.	**Individual User(s)**	√	√	√	√	√	√	√
4.A.	Individual(s) Responsible for Radiation Safety Program and Their Training and Experience	√	√	√	√	√	√	√
4.B	Authorized User	√	√	√	√	√	√	√
4.C	Authorized Nuclear Pharmacist	√	√	√				√
4.D	Authorized Medical Physicist (AMP)				√		√	√
5.	**Radiation Safety**	√	√	√	√	√	√	√
5.A.	Radiation Safety Officer (RSO)	√	√	√	√	√	√	√
5.B.	Radiation Safety Committee	√	√	√	√	√	√	√
6.A.	Radioactive Material for Medical Use	√	√	√	√	√	√	√
6.B.	Radioactive Material for Uses, not Listed in Item 6.a.	√	√	√	√	√	√	√
6.C	Recordkeeping for Decommissioning and Financial Assurance	√	√	√	√	√	√	√
7.	**Facilities and Equipment**	√	√	√	√	√	√	√
7.A.	Facility Diagram	√	√	√	√	√	√	√
7.B	Radiation Monitoring Instruments	√	√	√	√	√	√	√
7.C.	Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Radioactive Material	√[1]	√[1]	√[1]				√[1]
7.D.	Therapy Unit – Calibration and Use				√[2]		√[2]	√
7.E.	Other Equipment and Facilities				√	√	√	√
8.	**Radiation Protection Program**	√	√	√	√	√	√	√
8.A.	Safety Procedures and Instructions						√	√
8.B.	Safety Instructions for individuals working in or frequenting restricted area	√	√	√	√	√	√	√

8.C.	Operating and Emergency procedures	√	√	√	√	√	√	√
8.D.	Safe Use of Unsealed Licensed Material	√	√	√				√
8.E.	Radioactive Gases and Aerosol		√					
8.F.	Minimization of contamination	√	√	√	√	√	√	√
8.G.	Order and receiving	√	√	√	√	√	√	√
8.H.	Opening Packages	√	√	√	√	√	√	√
8.I.	ALARA	√	√	√	√	√	√	√
8.J.	Occupational Dose	√	√	√	√	√	√	√
8.K.	Area Surveys	√	√	√	√	√	√	√
8.L.	Installation, maintenance, adjustment, repair and inspection of therapy devices containing sealed sources						√	√
8.M.	Procedures for Administrations when a written directive is required			√	√		√	√
8.N.	Safety Procedures for treatment when patients are hospitalized			√	√		√	√
8.O.	Release of Patients or human research subjects			√	√			√
8.P.	Mobile Medical service	√	√	√	√	√	√	√
8.Q.	Leak Tests	√[4]	√[4]	√[4]	√	√	√	√
	Do not need to submit info with application for 8R – 8AA but required to have, to satisfy regulatory requirements							
8.R.	Public Dose	√	√	√	√	√	√	√
8.S.	Audit program	√	√	√	√	√	√	√
8.T.	Sealed Source Inventory	√[5]	√[5]	√[5]	√	√	√	√
8.U.	Records of dosages and use of brachtherapy source	√	√	√	√			√
8.V.	Recordkeeping	√	√	√	√	√	√	√
8.W.	Reporting	√	√	√	√	√	√	√
8.X	Transportation	√	√	√	√	√	√	√
9.	**Waste Management**	√	√	√	√	√	√	√
10.	**Citizenship Attestation**	√	√	√	√	√	√	√
11.	**Certification**	√	√	√	√	√	√	√

[1]If applicant will measure patient dosages or use other than unit dosages
[2]Special requirement re: Brachytheraphy and LDR afterloader sources and Sr-90 sources.
[3]If source does not meet sealed source definition in 180 NAC 7.
[4]If posses sealed sources under 180 NAC 7-032
[5]Sealed sources for calibration, transmission, and reference use 180 NAC 7-032

Applicants or licensees wishing to renew their licenses should submit a complete application according to this Regulatory Guide.

Regulatory Guide 7.0, "Radioactive Material - Guidance for Medical Use Licenses", is also available electronically by visiting the Agency's Radioactive Materials Page http://www.dhhs.ne.gov/puh/enh/rad/rg/rgindex.htm

This guide identifies the information needed to complete Form NRH 7(Appendix A), "Application for Radioactive Material License – Medical."

Parts I and II of this document provide background information.

Part III describes the information that should be provided in Item 1 through 10 of NRH 7, in completing a license application.

- **Regulations** – references the regulations applicable to the item;
- **Criteria** – outlines the criteria used to judge the adequacy of the applicant's response;
- **Discussion** – provides additional information on the topic sufficient to meet the needs of most readers; and
- **Response from Applicant** – provides suggested response(s) or indicates that no response is needed on that topic during the initial licensing process.

Parts IV, and V of this document provides additional information on amendments, renewals, and termination of licenses.

Some sections of the guidance include references to other documents that may be useful to the applicant.

Refer to Regulatory Guide for Form NRH 7A – Medical Use Training & Experience and Preceptor Statement" for guidance on completing Form NRH 7A "Medical Use Training and Experience and Preceptor Attestation."

When NRH 7 does not have sufficient space to provide full responses to Items 4 through 9, provide the information on separate attachments, label the attachments to indicate which item is being addressed, and submit the attachments with the completed NRH 7.

Appendices to this report provide the following supplementary information:

- Appendix A provide sample application forms;
- Appendix B provide sample "Medical Use Training and Experience and Preceptor Attestation" form,
- Appendix C provides license application checklists for responding to Items 4-9 on NRH 7, provides information on what is needed to complete the application. The applicant should use this Appendix C as a checklist to ensure completeness of their submittal. Each sections of the checklist refers to a number on the application (Appendix A).

If the applicant needs to provide supplemental information make sure that the supplemental information and attachments each have the applicants name and license number (if a renewal), item number which it relates to on Appendix C, page number and application date.

NRH 7A Supplement to this Regulatory Guide published as a separate document, describes how to fill out NRH 7A "Medical Use Training and Experience and Preceptor Attestation**."**

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 180 NAC 4 and are expressed in units of rem and its SI equivalent, the Sievert (Sv) (1 rem = 0.01 Sv). (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.

The information submitted in the application must be sufficient to demonstrate that proposed equipment, facilities, personnel and procedures are adequate to protect the health and property of the citizens of Nebraska according to the Agency's guidelines. 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 has been established. 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.

Radioactive Material Licensees from other agreement states and NRC licensees who wish to conduct operations at temporary job sites in Nebraska should contact the Agency. A licensee should request authorization well in advance of scheduled use to ensure compliance with Nebraska's reciprocity requirements.

I.B. Types of Licenses

The Agency 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" (180 NAC 7-002).

An Authorized User is defined as "a physician, who":

1. Meets the requirements in 180 NAC 7-027 and 7-043, 7-047, 7-051, 7-052, 7-053, 7-063, 7-066 or 7-084; or
2. Is identified as an authorized user on a specific license or equivalent permit issued by the Agency, Nuclear Regulatory Commission or Agreement State; or
3. Is identified as an authorized user on a permit issued by an Agency, Nuclear Regulatory Commission or Agreement State specific license of broad scope that is authorized to permit the medical use of radioactive material.

The Agency 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 I.B.1.), and
- the specific license of broad scope (see Section I.B.2.).

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

The Agency also issues a general license pursuant to 180 NAC 3-008.09, under which a physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital may use raadioactive 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.

Only the facility's management may sign the license application.

Applicants should study this Guide, the guide for NRH 7, related guidance, and all applicable regulations carefully before completing 180 NAC 7 and 7A. The Agency expects licensees to provide information on specific aspects of the proposed radiation protection program in attachments to NRH 7 and 7A.

When necessary, Agency 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 Agency, when incorporated into a license by reference;
- Terms and conditions of the license; and
- Agency regulations.

I.B.1 Specific License of Limited Scope

The Agency 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 180 NAC 3-011, item 2 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 180 NAC 7-037, 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 180 NAC 7-037 cannot be performed.

A specific license of limited scope may also be issued to an entity requesting to perform mobile medical services (180 NAC 7-038, 180 NAC 7-079). A medical institution or a private or group practice may apply for authorization to use radioactive material in a mobile medical service.

I.B.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. No medical use of radioactive material, including research involving human subjects, may be conducted without an authorization in a license from the Agency, the NRC or an Agreement State as provided in 180 NAC 7.

I.B.3. Research Involving Human Subjects

180 NAC 7-002 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."

The research needs to be conducted, funded, supported or regulated by a Federal agency which has implemented the "Federal Policy for the Protection of Human Research Subjects." Other wise, a licensee may apply for and receive approval of a specific amendments to its Agency license 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 180 NAC 7-004.01, research involving human subjects shall be conducted only with radioactive materials listed in the license for the uses authorized in the license.

I.B.4. General *In Vitro* License

In 180 NRH 3-008.09, "General License for Use of Radioactive Material for Certain *In Vitro* Clinical or Laboratory Testing," the Agency 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). 180 NAC 3-005 explains the requirements for using the materials listed. If the general license alone meets the applicant's needs, only NRH 17,"Certificate – *In Vitro* Testing With Radioactive Material General License," need be filed. Medical-use licensees authorized pursuant to 180 NAC 7 do not need to file the form.

The Agency limits possession to a total of 200 microcuries of photon-emitting materials listed in 180 NAC 3-008.09 at any one time, at any one location of storage or use. The use of materials listed in 180 NAC 3-008.09 within the inventory limits of that section is subject only to the requirements of that section and not to the requirements of 180 NAC 4 and 180 NAC 10, except as set forth in 3-008.09.

An applicant needing more than 200 microcuries of these materials must apply for a specific license. If requesting an increased inventory limit, the applicant will be subject to the requirements of 180 NAC 4 and 180 NAC 10, including the requirements for waste disposal.

I.C. Other Requirements

I.C.1 The "As Low as is Reasonably Achievable (ALARA)" Concept

180 NAC 4-004, "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 ALARA." This section 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.

Applicants should consider the ALARA philosophy detailed in these reports when developing plans to work with licensed radioactive materials.

I.C.2 Written Directive (WD) Procedures

180 NAC 7-020 requires certain medical use licensees to develop, implement, and maintain written procedures to provide high confidence that before each administration requiring a WD, the patient's identity is verified and the administration is in accordance with the WD. This regulation also specifies what an applicant must, at a minimum, address in these procedures. Appendix P provides further information on developing these procedures.

I.C.3. Timely Notification of Transfer of Control

Under 180 NAC 3-017.02 and 180 NAC 7-011.02 licensees must provide full information and obtain Agency's *written consent* before transferring control of the license, or, as some licensees refer to the process, "transferring the license."

Control may be transferred as a result of mergers, buyouts, or majority stock transfers. Although it is not Agency's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain Agency's written consent before transferring control of the license. This is to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid Agency licenses;
- Materials are properly handled and secured;
- Persons using these materials are competent and committed to implementing appropriate radiological controls;
- A clear chain of custody is established to identify who is responsible for final disposal of the material;
- Public health and safety are not compromised by the use of such materials.

As provided in 180 NAC 7-011, if only the licensee's name or mailing address changes, and the name change does not constitute a transfer of control of the license as described in 180 NAC 3-017.02, a licensee must file a written notification with Agency no later than 30 days after the date(s) of the change(s). Otherwise, prior Agency written consent must be given prior to the transfer.

Licensees must provide full information and obtain Agency's *prior written consent* before transferring control of the license. Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

1. Provide a complete description of the transaction (transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact whom the Agency may contact if more information is needed.
2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.
3. Describe any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.
4. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.
5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to the Agency, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.
6. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

I.C.4 Timely Notification of Bankruptcy Proceedings

Immediately following filing of a voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee is required by 180 NAC 3-017.05 to notify the Agency, in writing, identifying the bankruptcy court in which the petition was filed and the date of the filing.

Even though the licensee may have filed for bankruptcy, the licensee remains responsible for compliance with all regulatory requirements. The Agency needs to know when licensees are in bankruptcy proceedings in order to determine whether all licensed material is accounted for and adequately controlled and whether there are any public health and safety concerns (e.g., contaminated facility). The Agency shares the results of its determinations with other entities involved (e.g., trustees) so that health and safety issues can be resolved before bankruptcy actions are completed.

I.D. Management Responsibility

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

The Agency recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. The Agency also believes that consistent compliance with its regulations provides reasonable assurance that licensed activities will be conducted safely.

"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 180 NAC 7-002).

To ensure adequate management involvement a management representative (i.e., chief executive

officer or delegate) must sign the submitted application acknowledging management's commitments to and responsibility for the following:

- Radiation safety, security and control of radioactive materials, and compliance with regulations;
- Completeness and accuracy of the radiation safety records and information provided.
- Knowledge about the contents of the license and application;
- Compliance with current Agency, NRC 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.

I.E. Applicable Regulations

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

The following portions of the regulations are applicable to the use of radioactive material in the form of sealed sources in fixed devices and should be used in conjunction with this guide:

- 180 NAC 1 "General Provisions"
- 180 NAC 3 "Licensing of Radioactive Material"
- 180 NAC 4 "Standards for Protection Against Radiation"
- 180 NAC 7 "Medical Use of Radioactive Material"
- 180 NAC 10 "Notices, Instructions and Reports to Workers: Inspections"
- 180 NAC 13 "Transportation of Radioactive Material"
- 180 NAC 15 "Training and Experience Requirements for Use of Radiation Sources"
- 180 NAC 17 "Enforcement of Radiation Control Act and Rights to Hearing Procedures for Licensees and Registrants; Penalties"
- 180 NAC 18 "Fees for Certificates of Registration, Radioactive Material(s) Licenses, Environmental Surveillance, Emergency Response and other Regulatory Services"

The Agency amends the regulations periodically. Notification of changes will be provided as they occur; when applicable, the changes should be incorporated into the radiation safety program.

A current copy of Title 180, is also available on the Internet at http://dhhs.ne.gov/publichealth/Pages/puh_enh_rad_regs_regindex.aspx

To order a federal publication, see http://www.access.gpo.gov/ Title 10 Code of Federal Regulations, Parts 0-50 and 51-199 is also available on the Internet at http://www.nrc.gov/reading-rm/doc-collections/cfr

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

II. How To File

II.A. Preparing an Application

The applicant should do the following:

- Be sure to use the most recent guidance in preparing an application.
- Complete NRH 7(Appendix A) Items 1, 2, 3, and 10 on the form itself;
- Item 4-6 can be completed on the NRH 7 form or on supplementary pages;
- Complete NRH 7 Items 7 through 9 on supplementary pages, or use Appendix C;
- Complete NRH 7A (Refer to Regulatory Guide for Form NRH 7A for a form for the different use and information of completing the form.) to document training and experience and preceptor attestation;
- Provide sufficient detail for the Agency to determine that equipment, facilities, training, experience, and the radiation safety program are adequate to protect health and safety and minimize danger to life and property;
- For each separate sheet, other than NRH 7 and NRH 7A, that is submitted with the application, identify and cross-reference it to the item number on the application or the topic to which it refers;
- Submit all documents, typed, on 8-1/2 x 11-inch paper;
- If submitted, proprietary information must be clearly identified;
- Avoid submitting proprietary information unless it is absolutely necessary;
- Submit an original, signed application and if possible one electronic copy on a diskette or CD; and
- Retain one copy of the license application for future reference.

Applications must be signed by the applicant's or licensee's management as required by 180 NAC 7-008, see Section 11 "Certification."

All license applications are public information. If it is necessary to submit proprietary information, please contact the Agency for specific information. Employee personal information, i.e., home address, home telephone number, social security number, date of birth, radiation dose[1] information, should not be submitted unless specifically requested by the Agency.

Mail the original application with all attachments to:

Nebraska Department of Health and Human Services
Office of Radiological Health
Radioactive Materials Program
301 Centennial Mall South
P.O. Box 95026
Lincoln, NE 68509.

[1] In this document, dose or radiation dose is used as defined in 180 NAC 1-002, i.e., a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent. These latter terms are also defined in 180 NAC 1-002.

II.B. License Fees

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

The following fees are assessed:

Application fee: A non-refundable fee for processing the license application. The amount is dependent on the category of license the applicant is seeking. Refer to 180 NAC 18-005.05 for the application fees. Review of the application will not begin until the proper fee is received by the department. Once technical review has begun, no fees will be refunded; application fees will be charged regardless of the Agency's disposition of an application or the withdrawal of an application. An application fee is also required to process an application for a new license replacing an existing license due to a change of ownership.

Annual fee: An annual fee covers department costs for administration of the materials licensing program. The amount is dependent on the license category. Refer to 180 NAC 18-005.05. Annual fees are due within 30 days of issuance of the new license; an invoice for this fee is included with the cover letter accompanying a new license.

Note: Fees are not charged for license renewals, amendment requests, routine inspections, license terminations, or requests for regulatory information (except for document copying costs).

Please make check or money order payable to "**Nebraska Department of Health and Human Services.**"

Direct all questions about the Agency's fees to the Radioactive Materials Program in the Nebraska Department of Health and Human Services, Office of Radiological Health, Radioactive Materials Program.

III. Contents of an Application

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Item 1 – Name and Addresses

Item 1.A. Legal Name and Street Address

List the legal name and mailing address of the applicant's corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. An applicant corporation or other legal entity must be specified by legal name as registered with the Nebraska's Secretary of State (402) 471-4079. 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.

Response from Applicant:
Provide the mailing address where correspondence should be sent. This may or may not be the same as the address at which the material will be used as specified in Item 1.b.

Note: The Agency must be notified in the event of change of ownership or control and bankruptcy proceedings; see below for more details.

Note: The Agency must be notified before control of the license is transferred or whenever bankruptcy proceedings are initiated. See Section I.C.4. and 6.C. for more details.

Timely Notification of Change of Ownership or Control

Regulations: 180 NAC 3-017.02; 180 NAC 7-011.

Criteria: *Licensees must provide full information and obtain the Agency's prior written consent before transferring ownership or control of the license, or, as some licensees call it, "transferring the license."*

Changes in ownership may be the results of mergers, buyouts, or majority stock transfers. Although it is not the Agency's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain prior Agency written consent. This is to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid Agency licenses;
- Materials are properly handled and secured;
- Persons using these materials are competent and committed to implementing appropriate radiological controls;
- A clear chain of custody is established to identify who is responsible for final disposal of the radioactive material; and
- Public health and safety are not compromised by the use of such materials.

Response from applicant: None from an applicant for a new license.

Notification of Bankruptcy Proceedings

Regulation: 180 NAC 3-017.05

Criteria: *Immediately following filing of voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify the Agency in writing, identifying the bankruptcy court in which the petition was filed and the date of filing.*

Response from applicant. None at time of application for a new license.

Item 1.B. Street Address at Which Radioactive Material Will Be Used. (If Different From 1A.)

Response from Applicant:

In order to ensure compliance with 180 NAC 3-011, item 2 and as referenced in NRH 7A, Item l.b., specify the street address, city, and state or other descriptive address (e.g., on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each facility. The descriptive address should be sufficient to allow an Agency inspector to find the facility location. A post office box address is not acceptable. If radioactive material is to be used at more than one location under the license, the specific address (e.g., street and building) must be provided for each facility. If applying for a license for mobile medical services as authorized pursuant to 180 NAC 7-013.02, the applicant should refer to Section 8.P.and Appendix E of this report for specific licensing guidance. The Agency must be notified if the mailing address changes.

Being granted a Nebraska Radioactive Material license does not relieve a licensee from complying with other applicable Federal, state, or local regulations (e.g., local zoning requirements; etc.).

Note: As discussed in Section 6.C. "Recordkeeping for Decommissioning and Financial Assurance," licensees must maintain permanent records on where the licensed material was used or stored while the license was in effect. These records are important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). For medical use licensees, acceptable records include sketches and written descriptions of the specific locations where material is (or was) used or stored and any information relevant to spills (e.g., where contamination remains after cleanup procedures or when there is reasonable likelihood that contaminants may have spread), damaged devices, or leaking radioactive sources.

Item 2. Department To Use Radioactive Material – Contact Person

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Response from Applicant:

Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the radiation safety officer, unless the applicant has named a

different person as the contact. The Agency will contact this individual if there are questions about the application.

Notify the Agency if the contact person or his or her telephone number changes so that the Agency can contact the applicant or licensee in the future with questions, concerns, or information. This notice is for "information only" and does not require a license amendment.

Item 3. License Action Type

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Response from Applicant:

Mark the appropriate choice; if submitting an amendment request or a renewal application, indicate the applicable radioactive materials license number.

Items 4-9 may be addressed by completing Appendix C "Supporting Information Requested in Items 4 through 9 of Form NRH 7."

Refer to "Regulatory Guide for Form NRH 7A – Medical Use Training and Experience and Preceptor Attestation" for additional information that will be needed to complete Form NRH 7A.

Item 4. Individual User(s)

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Item 4.A. Individual(s) Responsible for Radiation Safety Program and their Training and Experience

Regulations: 180 NAC 3-011, 3-013.02, 180 NAC 7-015, 7-022, 7-023, 7-024, 7-026, 7-027, 7-043, 7-047, 7-051, 7-0052, 7-053, 7-063, 7-064, 7-066, 7-084

Criteria: *The RSO, AUs, AMPs, and ANPs must have adequate training and experience*.

Discussion: 180 NAC 7-015 provides 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. Other personnel who have a role in the radiation protection program are AUs, AMPs, ANPs, and members of the Radiation Safety Committee (RSC) (if the licensee is required to establish a RSC). In 180 NAC 3-011, the Agency requires that an applicant be qualified by training and experience to use licensed materials for the purposes requested in such a manner as to protect health and minimize danger to life or property. 180 NAC 7-022 through 7-027 give specific criteria for acceptable training and experience for AUs for medical use, ANPs, the RSO, and AMPs.

A résumé or a curriculum vitae is likely to be insufficient because such documents usually do not supply all the information needed to evaluate an individual's training and experience for the Agency purposes. Applicants should ensure that they submit the specific training information required by Agency regulations in 180 NAC 7. NRH 7A provides a convenient format for

submitting this information.

Licensees are responsible for their radiation protection programs; it is essential that strong management control and oversight exist to ensure that licensed activities are conducted properly. The licensee's 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 Agency 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.

Training for experienced RSO, teletherapy or medical physicist, authorized user or nuclear pharmacist; recentness of training. 180 NAC 7-026 provides that experienced individuals, who may be candidates to serve as RSO, AMP, or ANP, are not required to meet the requirements of 180 NAC 7-022, 7-023 or 7-024, respectively, (are "grandfathered") under certain conditions, e.g., the individual is named on an Agency, NRC or Agreement State license. AUs are also not required to meet the requirements in 7-041 through 7-084 under certain conditions, e.g., if they are named on an Agency, NRC or Agreement State License. The individuals must have been named on a license or permit before the applicable date in 180 NAC 7-026. Regulations in 180 NAC 7-027 require that the training and experience specified in 180 NAC 7-015 through 7-027 and 7-041 through 7-084 must have been obtained within 7 years preceding the date of application or the individual must have related continuing education and experience.

Response from Applicant: Refer to the subsequent sections specific to the individuals described above in "Regulatory Guide for Form NRH-7A – Medical Use Training & Experience and Preceptor Statement.".

Item 4.B. - Authorized User(s)

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Regulations: 180 NAC 3-011, 180 NAC 7-002, 7-007, 7-0011, 7-018, 7-026, 7-027, 7-043, 7-047, 7-051, 7-052, 7-0532, 7-063, 7-064, 7-066 and 7-084

Criteria: *Training and experience requirement for Authorized Users (AUs) are described in 180 NAC 7-43, 7-047, 7-051, 7-052, 7-053, 7-063, 7-064 , 7-066 and 7-084*

Discussion: The responsibilities of AUs 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 AU's supervision in the preparation of radioactive material for medical use and in the medical use of radioactive material;
- Preparation of written directives (WDs), if required.

Applicants must meet recentness of training requirements described in 180 NAC 7-027. AU applicants must have successfully completed the applicable training and experience criteria described in 180 NAC 7 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.

180 NAC 7-026 provides that experienced AUs who are named on a license or permit are not required to comply with the training requirements in 180 NAC 7-041 through 7-084 to continue performing those medical uses for which they were authorized before the effective date of changes to the regulations in 180 NAC 7-026 (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 180 NAC 7-019), would continue to be authorized for this use.

Technologists, therapists, or other personnel may use radioactive material for medical use under an AU's supervision in accordance with 180 NAC 7-018, "Supervision," and in compliance with applicable FDA, other Federal, and State requirements (180 NAC 7-0005). 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 Agency requirement that an AU must render an interpretation of a diagnostic image or results of a therapeutic procedure. The Agency recognizes that the AU may or may not be the physician who interprets such studies. Additionally, Agency 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.

Refer to "Regulatory Guide 7.0 Supplement for NRH 7A" for details in completing NRH 7A.

Item 4.C. – Authorized Nuclear Pharmacist (ANP)

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	
7-065	
7-067	
7-085	√

Regulations: 180 NAC 3-011, 3-014.10, 7-002, 7-007, 7-011, 7-018, 7-024, 7-026, 7-027

Criteria: *Training and experience requirements for ANPs are described in 180 NAC 7-024.*

Discussion: At many licensed medical facilities, an ANP is directly involved with the preparation and administration of radiopharmaceuticals. Technologists, or other personnel, may prepare radioactive material for medical use under an ANP's supervision in accordance with 180 NAC 7-018, "Supervision," and in compliance with applicable FDA, other Federal, and State requirements (180 NAC 7-004). (Preparation of radioactive material for medical use may also be performed under the supervision of a physician who is an authorized user.)

Applicants are reminded of recentness of training requirements described in 180 NAC 7-027. Specifically, nuclear pharmacist applicants must have successfully completed the applicable training and experience criteria described in 180 NAC 7 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.

Response from Applicant: Provide the following:

- Name of the proposed ANP.

AND

For an individual previously identified as an ANP on a Agency, NRC, or Agreement State license or permit or by a commercial nuclear pharmacy that has been authorized to identify ANPs:

- Previous license number (if issued by the Agency) or a copy of the license (if issued by the NRC or an Agreement State) or a copy of 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 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 180 NAC 7-024:

- Copy of the certification(s) of the specialty board whose certification process has been recognized[2] under 180 NAC 7-024.01.

AND

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

OR

- Description of the training and experience specified in 180 NAC 7-024.02 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 180 NAC 7-027.

***Notes**:*

[2] The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's web page < http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.

- NRH 7A is used to document training and experience

- Licensees must notify the Agency within 30 days if an ANP permanently discontinues his or her duties under the license or has a name change under 180 NAC 7-011.

- Descriptions of training and experience will be reviewed using the criteria listed above. The Agency will review the documentation to determine if the applicable criteria in 180 NAC 7-015 to 7-027 are met. If the training and experience do not appear to meet the criteria in 180 NAC 7-015 to 7-027, the Agency may request additional information from the applicant or may request the assistance of the ACMUI in evaluating such training and experience.

Item 4.D. – Authorized Medical Physicist (AMP)

180 NAC 7	Applicability
7-041	
7-044	
7-048	
7-055	√
7-065	
7-067	√
7-085	√

Regulations: 180 NAC 3-011, 7-002, 7-011, 7-023, 7-026, 7-027, 7-060

Criteria: *Training and experience requirements for AMPs are described in 180 NAC 7-023.*

Discussion: At many 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.

Applicants are reminded of recentness of training requirements described in 180 NAC 7-027. Specifically, medical physicist applicants must have successfully completed the applicable training and experience criteria described in 180 NAC 7 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.

Response from Applicant: Provide the following:

- Name of the proposed AMP.

AND

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

- Previous license number (if issued by the Agency) or a copy of the license (if issued by the NRC or an Agreement State) or a copy of a permit issued by a NRC master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a NRC master material license broad scope permittee on which the individual was specifically named an AMP for the uses requested.

For an individual qualifying under 180 NAC 7-023:

- Copy of the certification(s) of the specialty board(s) whose certification process has been recognized[6] under 180 NAC 7-023.01.

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 180 NAC 7-023.03 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 180 NAC 7-023.02 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 180 NAC 7-023.03 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 180 NAC 7-027.

Notes:

- NRH 7A is used to document training and experience.

- Licensees must notify Agency within 30 days if an AMP permanently discontinues his or her duties under the license or has a name change under 180 NAC 7-011.

- Descriptions of training and experience will be reviewed using the criteria listed above. The Agency will review the documentation to determine if the applicable criteria in 180 NAC 7-015 to 7-027 are met. If the training and experience do not appear to meet the criteria in 180 NAC 7-014 to 7-027, the Agency may request additional information from the applicant or may request the assistance of the ACMUI in evaluating such training and experience.

Item 5. Radiation Safety

Item 5. A. Radiation Safety Officer (RSO)

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Regulations: 180 NAC 7-015.04, 7-015.06, 7-015.07

Criteria: *RSO's must have adequate training and experience.*

Submit training and experience on NRH 7A, and refer to "Regulatory Guide 7.0 Supplement for NRH 7A" for information on how to complete NRH 7A.

Discussion: All licensees must have an RSO designated by and responsible to the corporation's management for the coordination of the radiation protection program and for ensuring compliance with the applicable regulations and license provision.

A licensee must establish in writing the authority, duties and responsibilities of the RSO.

The RSO is responsible for day-to-day oversight of the radiation protection program. In accordance with 180 NAC 7-015, 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 180 NAC 7-015 to ensure that radioactive materials are used in a safe manner. The Agency requires the name of the RSO 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.

Usually, the RSO is a full-time employee of the licensed facility. The Agency 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 180 NAC 7-015. Appendix F contains a model RSO Delegation of Authority. Appendix B contains "NRH 7A – Medical Use Training & Experience and Preceptor Statement." A which should be used to document the RSO's training and experience. Refer to "Regulatory Guide for Form NRH 7A - Medical Use Training & Experience and Preceptor State" for additional information and forms.

RSO Responsibilities: Some of the typical duties and responsibilities of RSOs include ensuring the following:

- Unsafe activities involving licensed materials are stopped;
- Radiation exposures are ALARA;

- Material accountability and disposal;
- Interaction with NRC;
- 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 F contains a detailed list of typical duties and responsibilities of the RSO. Applicants are reminded of recentness of training requirements described in 180 NAC 7-027. Specifically, RSO applicants must have successfully completed the applicable training and experience criteria described in 180 NAC 7 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.

Response from Applicant: Provide either of the following:

- List name of the RSO and telephone number

AND

- Complete Form NRH 7A.

Note:

- It is important to request an amendment to the license as soon as possible for changes in the designation of the RSO.

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Item 5.B. Radiation Safety Committee

Regulations: 180 NAC 7-015.08

Criteria: *A radiation safety committee is described in 180 NAC 7-015.08*

Licensees that are authorized for one more different types of uses of radioactive material under 180 NAC 7-048, 7-055, 7-067 and 7-085, or one more types of units under 180 NAC 7-067 are required under 180 NAC 7-015.08 to establish a Radiation Safety Committee (RSC) to oversee all uses of radioactive material permitted 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.

Response from Applicant: Provide a description of the radiation safety committee if required.

Item 6. Radioactive Material Data

Item 6.A. Radioactive Material for Medical Use

Regulation: 180 NAC 3-010, 180 NAC 7-032, 7-041, 7-044, 7-048, 7-055, 7-065, 7-067, 7-085

Criteria*: 180 NAC 7 divides radioactive material for medical use into seven types of use (180 NAC 7-032, 7-041, 7-044, 7-048, 7-055, 7-065, 7-067, 7-085)*

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

The applicant should indicate the radioactive material requested . The amount and type of information necessary will vary according to the type of use requested.

180 NAC 7-041 and 7-044 Use: For 180 NAC 7-041 and 7-044 use, the chemical/physical form may be "Any" unsealed radioactive material permitted by 180 NAC 7-041 or 7-044, as appropriate. For 180 NAC 7-041 and 7-044 use, the total amount requested may be "As Needed."

The applicant should define the purpose of use by stating the applicable section of 180 NAC 7 (e.g., 180 NAC 7-041, 7-044) and the description of the applicable modality (e.g., any uptake, dilution, and excretion procedure for which a written directive is not required).

The following format may be used:

Radioactive Material	Chemical/Physical Form	Maximum Possession Limits	Use of Each Form
Any radioactive material permitted by 180 NAC 7-041	Any	As needed	Any use described in 180 NAC 7-041
Any radioactive material permitted by 180 NAC 7-044	Any	As needed	Any use described in 180 NAC 7-044

180 NAC 7-048 Use: For 180 NAC 7-048 use, the chemical/physical form may be "Any" unsealed radioactive material permitted by 180 NAC 7-048. The total amount requested must be specified.

The use of unsealed radioactive material in therapy (180 NAC 7-048) involves administering a 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 180 NAC 7-048 use, the applicant should define the purpose of use by stating the applicable section of 180 NAC 7 (i.e., 180 NAC 7-048). 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 6 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 Agency's sealed source and device evaluation on radiation safety issues, intraluminal use is considered analogous to intracavitary use.
- Topical (Surface) Applications

The following format may be used:

Radioactive Material	Chemical/Physical Form	Maximum Possession Limits	Use of Each Form
Any radioactive material permitted by 180 NAC 7-048	Any	300 millicuries	Any use described in 180 NAC 7-048

180 NAC 7-055, 7-065, 7-067 and 7-085 Use: For 180 NAC 7-055, 7-065, 7-067 and 7-085 use, the radionuclide, the chemical/physical form (i.e., sealed source or device identified by manufacturer and model number), the total amount in Becquerels (Bq), microcuries (µCi), millicuries (mCi), or curies (Ci), 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.

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.

180 NAC 7-065 Use: For 180 NAC 7-065 use, the applicant should define the purpose of use by 7stating the applicable section of 180 NAC 7 (i.e., 180 NAC 7-065) 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 6 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.

180 NAC 7-067 Use: For 180 NAC 67 use, the applicant should define the purpose of use by stating the applicable section of 180 NAC 7-067 (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 6 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.

180 NAC 7-085 Use: Applicants must apply for authorization to use radioactive material, or radiation therefrom, in medical applications under 180 NAC 7-085 when the type of use is not covered under 180 NAC 7-041, 7-044, 7-048, 7-055, 7-065, and 7-067.

When applying for use under provisions of 180 NAC 7-085, applicants should describe the purpose of use and submit the information required under 180 NAC 7-008.02 through 7-008.04, review regulatory requirements in other 180 NAC 7, and use them as a guide on how to determine what should be included in an application that is required in 180 NAC 7-008. It is anticipated that many of the uses of radioactive material under the provisions of 180 NAC 7-085 may involve research or product development; thus, applicants should ensure review and compliance with 180 NAC 7-004, "Provisions for the protection of human research subjects,"and 180 NAC 7-005, "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 180 NAC 7.

If the source for the type of use sought under 180 NAC 7-085 is a sealed source, Section 6.a. of this guide describes the information that must be provided at the time of application. Broad scope licensees are exempted under 180 NAC 7-012.01 from requirements of 180 NAC 7-012.04 (which relates to including certain information in an application about radiation safety aspects of medical use under 180 NAC 7-085).

However, broad scope licensees should make sure that the quantity needed for the proposed use is authorized on their license or apply for an increase if not.

Applicants for uses under 180 NAC 7-085 should consult with the Agency 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.

The following format may be used:

Radioactive Material	Chemical/Physical Form	Maximum Possession Limits	Use of Each Form
I-125 (specific radiation therapy system liquid brachytherapy source)	Liquid source (Manufacturer Name, Model #XYZ)	2 curies total	For medical use permitted by 180 NAC 7-055
Cesium 137 (i.e., specific Brachytherapy radionuclide)	Sealed source or device (Manufacturer Name, Model #XYZ)	2 curies total	For medical use permitted by 180 NAC 7-055
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	For medical use permitted by 180 NAC 7-065
Cobalt 60 (i.e., specific teletherapy sealed source radionuclide)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 9,000 curies per source and 18,000 curies total	For medical use permitted by 180 NAC 7-067
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	For medical use permitted by 180 NAC 7-067
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 medical use permitted by 180 NAC 7-067

Calibration, Transmission, and Reference Sources: For calibration, transmission, and reference sources covered under 180 NAC 7-032, the specific sources do not need to be listed on the license as long as the licensee is authorized pursuant to 180 NAC 7-007 for medical use of radioactive material.

Shielding Material/Depleted Uranium: Some high activity radionuclide generators used to produce radioactive materials for 180 NAC 7-044 and 7-048 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 should 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: (1) if depleted uranium is used to shield the source(s) within the device; and (2) 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 Possession Limits	Use of Each Form
Depleted Uranium	Metal	999 kilograms	Shielding in a teletherapy or linear accelerator

Other 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 180 NAC 3-008.09, 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 Possession Limits	Use of Each Form
Any radioactive material permitted by 180 NAC 3-008.09	**Prepackaged kits**	50 millicuries	Any use described in 180 NAC 3-008.09

Sources that are authorized by 180 NAC 7-032, "Authorization for calibration, transmission, and reference sources," should *not* be listed.

Applicants should number each line entry consecutively, following the 180 NAC 7 material.

When determining both individual radionuclide and total quantities, all materials to be possessed at any one time under the license should 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].

Response from Applicant: The applicant should submit the information as described above and submit information regarding the purpose for which the licensed material will be used. The applicant should consider including the information described above, as applicable to the type of use(s) proposed.

Item 6.B. Sealed Sources and Devices

Regulations: 180 NAC 3-010.08, 3-011, item 2

Criteria: *In accordance with 180 NAC 3-10.08, 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 180 NAC 7-032). Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by Agency, NRC or an Agreement State.*

Discussion: The Agency, 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 Agency can verify that they have been evaluated in an SSDR Certificate or specifically approved on a 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.

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 Agency, 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 Agency'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 want to obtain copies of the appropriate sections of the Registry certificates and review or discuss them with the manufacturer.

Response from Applicant: If possession of sealed source(s) or device(s) is requested, the applicant shall submit the information described above.

Item 6.C. Recordkeeping for Decommissioning and Financial Assurance

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Regulations: 180 NAC 3-017.02, 3-018

Criteria: *All licensees are required to maintain records important to decommissioning. Licensees authorized to possess licensed material in excess of the limits specified in 180 NAC 3-018 must provide evidence of financial assurance for decommissioning.*

Discussion: All licensees are required, under 180 NAC 3-018.07, to maintain records important to decommissioning in an identified location. These records must, in part, identify all areas where licensed material is (or was) used or stored and any information relevant to spills (e.g., where contamination remains after cleanup procedures or when there is a reasonable likelihood that contaminants may have spread) and leaking sealed sources. As an alternative to the potential need for site characterizations, some licensees prefer to maintain information on surveys and leak tests on an ongoing basis and as a low-cost means of providing evidence and assurance of an appropriate decommissioning status upon the termination of licensed activities and/or release of a site for non-licensed use. 180 NAC 3-018.07, licensees must transfer the records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with 180 NAC 3-017.02, and must transfer records to the Agency before the license is terminated (see 180 NAC 3-30.03).

Licensees using sealed sources authorized by 180 NAC 7 generally use licensed material in a manner that would preclude releases into the environment, would not cause the activation of adjacent materials, or would not contaminate work areas. The licensee's most recent leak test should demonstrate that there has been no leakage from the sealed sources while the sealed sources were in the licensee's possession. However, any leakage of the sealed source in excess of the regulatory limits would warrant further Agency review of decommissioning procedures on a case-by-case basis.

Licensees authorized to possess radioactive material in excess of the limits specified in 180 NAC 3-018 must also provide evidence of financial assurance for decommissioning. The requirements for financial assurance are specific to the types and quantities of radioactive material authorized on a license. Some medical use applicants and licensees may not need to take any action to comply with the financial assurance requirements because their total inventory of licensed material does not exceed the limits in 180 NAC 7-018 or because the half-life of the unsealed radioactive material used does not exceed 120 days. Applicants requesting licensed material with a half-life in excess of 120 days should determine whether financial assurance is necessary. In addition, applicants requesting more than one radionuclide must use the sum-of-the-ratios method to determine if financial assurance is needed.

Applications for authorization to possess and use unsealed radioactive material with a half-life exceeding 120 days must be accompanied by a decommissioning funding plan or certification of financial assurance when the trigger quantities given in 180 NAC 3-018.01 are exceeded. Acceptable methods of providing financial assurance include trust funds, escrow accounts, government funds, certificates of deposit, deposits of government securities, surety bonds, letters of credit, lines of credit, insurance policies, parent company guarantees, self guarantees, external sinking funds, statements of intent, special arrangements with government entities, and standby trust funds. The Agency will authorize sealed source possession exceeding the limits given in 180 NAC 3-018.04 without requiring decommissioning financial assurance, for the purpose of normal sealed source exchange, for no more than 30 days.

Determining Need for Financial Assurance for Decommissioning

The half-lives of unsealed radioactive material used by medical licensees have traditionally been less than 120 days. Therefore, most medical use applicants need only consider licensed material in sealed sources to evaluate the need for financial assurance. Use Table 6.1 to determine if financial assurance is required for the sealed sources listed. If requesting sealed sources other than those listed or any other unsealed radioactive material with a half-life greater than 120 days, refer to 180 NAC 3-018 and Appendix 4F to 180 NAC 4 for possession limits requiring financial assurance. The sum of the fractions procedure is also depicted in Table 6.1 and must be used to determine the need for financial assurance for both sealed and unsealed radioactive material.

Table 6.1 Worksheet for Determining Need for Financial Assurance for Sealed Sources

Step Number	Description	Cobalt-60	Cesium-137	Strontium-90
1	Activity possessed, in curies*			
2	2 Activity requiring financial assurance, in curies	10,000	100,000	1,000
3	Divide data in Step 1 by data in Step 2= FRACTION			
4	Add the fractions determined in Step 3			

* This table uses only conventional units. The conversion to the International System of units (SI) is: 1 Curie = 37 gigabecquerel.

As 180 NAC 7, describes, if the sum of the fractions is greater than or equal to 1, the applicant will need to submit a decommissioning funding plan or financial assurance, as applicable.

Response from Applicants: No response is needed from most applicants. If financial assurance is required, applicants must submit evidence as described above.

Item 7 Facilities and Equipment

Regulations: 180 NAC 3-011, item 2, 180 NAC 7-008.04, 7-013

Criteria: *Facilities and equipment must be adequate to protect health and minimize danger to life or property.*

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Discussion: Requirements to provide information about the design and construction of facilities and safety equipment are contained in 180 NAC 3-011, item 2, 180 NAC 7-008.04, 7-013. 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 (e.g., planned use of the material, the types of radioactive emissions, the quantity and form of radioactive materials possessed, etc.). 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.

Response from Applicant: Refer to Sections 7A through 7E for guidance.

Item 7.A. Facility Diagram

Regulations: 180 NAC 3-011, item 2, 180 NAC 4-002, 4-004, 4-005, 4-013, 4-014, 4-023, 4-024, 4-033, 4-034, 4-047, 180 NAC 7-008, 7-011, 7-013, 7-037, 7-049, 70-59, 7-071

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Criteria : *In order to issue a license, the Agency must find that facilities and equipment must be adequate to protect health and minimize danger to life or property as by 180 NAC 3-011, item 2) and/or 180 NAC 7-013.*

Discussion: Applicants must describe the proposed facilities and equipment as required by 180 NAC 7-008. The facility diagram 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.

For types of use permitted by 180 NAC 7-041 and 7-044, applicants should 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. For types of use permitted by 180 NAC 7-048 and 7-055, applicants should provide the above information and in addition they should provide the locations where sources are stored. Describe the rooms where patients will be housed if they cannot be released under 180 NAC 7-037. The discussion should include a description of shielding, if applicable. For types of use permitted by 180 NAC 7-065, the applicant should provide the room numbers of use.

For types of use permitted by 180 NAC 7-067, the applicant should provide all of the information discussed above and the shielding calculations for the facility as described in the diagram. When preparing applications for use under 180 NAC 7-085, applicants should review the above to determine the type of information appropriate to evaluate the adequacy of the facilities.

Licensees are required by 180 NAC 7-010 to obtain a license amendment before adding to or changing an area of use identified in the application or on the license, except for areas of use where radioactive material is used only in accordance with 180 NAC 7-041 or 7-044. Licensees are required by 180 NAC 7-011 to notify Agency within 30 days following changes in areas of use for 180 NAC 7-041 and 7-044 radioactive material.

Regulatory requirements, the principle of ALARA, good medical care, and access control should be considered when determining the location of the therapy patient’s room or a therapy treatment room.

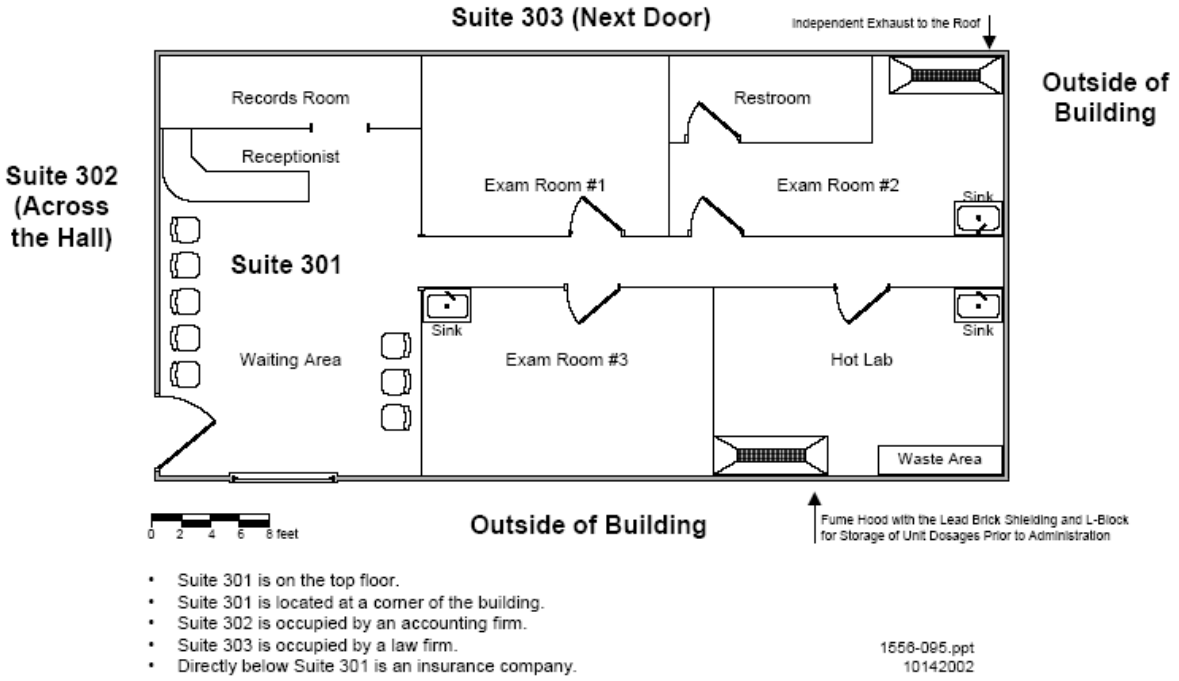

Figure 7.1 Facility Diagram for Nuclear Medicine Suite

The applicant should demonstrate that the limits specified in 180 NAC 4-013 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 Agency authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem) and demonstrating that the requirements of 180 NAC 4-013 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 180 NAC 4-013. A program to assess and control dose within the 5 mSv (0.5 rem) annual limit and procedures to be followed to maintain the dose ALARA (180 NAC 4-004) must be developed (see 180 NAC 4-013.03).

If applicants are proposing to use portable shielding to protect health and minimize danger to life or property, they should describe the alternative equipment and administrative procedures they propose to use for evaluation and approval by Agency. If applicants elect to use portable shielding they should 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 should be submitted if the room design (including shielding) and the occupancy of adjacent areas are significantly different from the original diagrams provided. A written description should be submitted for simple changes.

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).

Response from Applicant: Provide the following:

- A diagram and description are enclosed that describes the facilities and identifies activities conducted in all contiguous area surrounding the area(s) of use. The following information is included.
  - 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 under the heading "Discussion"
  - 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 180 NAC 4-002; 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 should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.

Item 7.B. Radiation Monitoring Instruments

Regulations: 180 NAC 3-011, item 2, 180 NAC 4-004, 4-021, 4-022, 4-046, 4-048,

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

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

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 180 NAC 4-004 must include provisions for survey instrument calibration (180 NAC 4-021). Licensees shall possess instruments used to measure radiation levels, radioactive contamination, and radioactivity, as applicable. Instruments used for quantitative radiation measurements must be calibrated for the radiation measured. The instruments should be available for use at all times when radioactive material is in use. The licensee should 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 the operating room or patient's room.

Usually, it is not necessary for a licensee to possess a survey meter solely for use during sealed source diagnostic procedures, since it is not expected that a survey be performed each time such a procedure is performed. In these cases, it is acceptable for the meter to be available on short notice in the event of an accident or malfunction that could reduce the shielding of the sealed source(s). Surveys may be required to verify source integrity of the diagnostic sealed source and to ensure that dose rates in unrestricted areas and public and occupational doses are within

regulatory limits.

Survey meter calibrations must be performed by persons, including licensed personnel, who are qualified to perform calibrations. One method a licensee may use to determine if the service is qualified to perform these activities is to determine that it has an Agency (NRC or an equivalent Agreement State) license. Alternatively, an applicant may choose to develop, implement, and maintain procedures to ensure instruments are calibrated, or propose an alternate method for calibration. Appendix G provides guidance regarding appropriate instrumentation and model survey instrument calibration procedures to meet the requirements detailed in 180 NAC 7-030.

Facilities and Equipment

- To reduce doses received by individuals not calibrating instruments, calibrations should be conducted in an isolated area of the facility or at times when no one else is present.
- Individuals conducting calibrations will wear assigned dosimetry, if required.

Equipment Selection

- 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 should be taken and counted on 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:

Typical Survey Instruments			
Portable Instruments Used for Contamination and Ambient Radiation Surveys Detectors Radiation Energy Range Efficiency			
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	Moderate

		thickness)	
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	All energies	Moderate
Gamma Counter (NaI)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	<1%

Detailed information about survey instrument calibration may be obtained by referring to ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments." Copies may be obtained from the American National Standards Institute at 25 West 43rd Street, 4th Floor, New York, NY 10036 or by ordering electronically from <http://www.ansi.org>.

Response from Applicant: Provide the following:

Attach Part 1 of Appendix G if Table C-3 of appendix C is not attached as part of the application.

AND

We will attach a list of survey instruments possessed. The list will include the manufacturer, model, instrument type, sensitivity, range for each type of radiation detected and state whether the instrument will be used for 'measuring' or 'detection.' Additionally if only one survey instrument is to be used we will describe what is done when the survey instruments is being calibrated or repaired

AND

We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.

AND

We will use radiation monitoring instruments that will be calibrated by a person authorized by the Department, U.S. NRC or an Agreement State to perform survey meter calibrations. A copy of the license authorizing such services will be maintained.

OR

We will provide a description of the instrumentation (e.g. gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys or leak testing and analysis.

AND ONE OF THE FOLLOWING

We will follow survey meter calibration procedures in accordance with Appendix G of Regulatory Guide 7.0.

OR

We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirement in 180 NAC 4-021 and that meet the requirements of 180 NAC 7-030 and the procedure is attached."

Item 7.C. Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Radioactive Material

Regulations: 180 NAC 3-001.01, 3-011, 180 NAC 7-018, 7-020, 7-029, 7-031, 7-091, 7-093

Criteria: *In 180 NAC 7-029 and 7-031, the Agency describes requirements for the use, possession, calibration, and check of instruments (e.g., dose calibrators) used to measure patient dosages.*

180 NAC 7	Applicability
7-041	√*
7-044	√*
7-048	√*
7-055	
7-065	
7-067	
7-085	√*

*If applicant will measure patient dosages or use other than unit dosages.

Discussion: As described in 180 NAC 7-031, dosage measurement is required for licensees who prepare patient dosages.

- If the licensee uses only unit dosages made by a manufacturer or preparer licensed under 180 NAC 3-014.10, (and does not split, combine, or otherwise modify unit dosages) the licensee is not required to possess an instrument to measure the dosage. Furthermore, licensees may rely on the provider's dose label for the measurement of the dosage and decay-correct the dosage to the time of administration.
- If the licensee performs direct measurements of dosages in accordance with 180 NAC 7-031 (e.g., prepares its own dosages, breaks up unit dosages for patient administration, or decides to measure unit dosages) the licensee is required to possess and calibrate all instruments used for measuring patient dosages.

Currently, no Agency-regulated alpha-emitting nuclides are used in unsealed form in medicine. This document, therefore, does not provide guidance on the measurement of these radionuclides.

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.

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.

Response from Applicant: If applicable, provide the following:

- The facility will perform dose calibrator calibrations using Appendix H Procedures.

OR

- This facility will perform dose calibrator calibrations using equivalent procedures which are attached.

Item 7.D. Therapy Unit – Calibration and Use

Regulations: 180 NAC 3-011, item 2, 180 NAC 7-018, 7-060, 7-072, 7-073, 7-074, 7-075, 7-076, 7-077, 7-078, 7-0104, 7-107, 7-108, 7-109, 7-110, 7-111

Criteria: *The above regulations contain Agency 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 applicablerequirements.*

180 NAC 7	Applicability
7-041	
7-044	
7-048	
7-055	√*
7-065	
7-067	√*
7-085	√*

Special requirements re: brachytheraphy and LDR afterloader sources and Sr.-90 sources

Discussion: Except for manual brachytherapy sources and low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer in 180 NAC 7, 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, per 180 NAC 7. 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 (180 NAC 7-076 through 7-078).

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 must be performed before first medical use[1], 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 180 NAC 7-076 through 7-078. 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 should select dosimetry equipment that will accurately measure the output or the activity of the source. Contact Agency for additional assistance.

Response from Applicant: Provide the following:

- We have attached procedures per 189 NAC 7-076, 77 and 78 (for Remote Afterloader Units, Teletherapy Units and Gamma Sterotactic Radiosurgery Units..

References:

- 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."

Copies of these documents and many other documents from AAPM referenced in this guide may be obtained from Medical Physics Publishing (MPP), 4513 Vernon Boulevard, Madison, WI 53705-4964 or ordered electronically from <http://www.medicalphysics.org>.

Item 7.E. Other Equipment and Facilities

180 NAC 7	Applicability
7-041	
7-044	
7-048	
7-055	√
7-065	√
7-067	√
7-085	√

Regulations: 180 NAC 3-011, item 2, 3-017, 180 NAC 4-004, 4-031, 180 NAC 7-008, 7-049, 7-059, 7-061, 7-071, 7-079, 7-082

Criteria: *Facilities and equipment must be adequate to protect health and minimize danger to life or property.*

[1] For brachytherapy sources, "first medical use" is defined as the first use following the (effective date) of the revised 180 NAC 7.

Discussion: The applicant should describe, in Item 7.E. of the application, other equipment and facilities available for safe use and storage of radioactive material listed in Item 6 of this application.

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 radioidide, sources of contamination include airborne I-131, urine, perspiration, saliva, and other secretions.

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 180 NAC 7-071.03 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.

180 NAC 71.04 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. 180 NAC 7-71.02, 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 should 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 should 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.

Response from Applicant: If applicable.
Appendix X is attached if Table C-3 of Appendix C is not attached as part of the application"

AND

We have attached detailed descriptions of additional equipment and facilities available for the safe use and storage of radioactive materials requested are attached. (Place checkmark by items included.)

For manual brachytherapy facilities, we are providing a description of the emergency response equipment.

For teletherapy, GSR, and remote afterloader facilities, we are providing 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.

Item 8 Radiation Protection Program

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Regulations: 180 NAC 3-011, 3-017, 180 NAC 4-04, 4-047, 180 NAC 7-015, 7-016, 7-070, 7-086, 7-087

Criteria: *180 NAC 4-004 states that each licensee must develop, document, and implement a radiation protection program commensurate with the scope of the licensed activity. The program must be sufficient to ensure compliance with the provisions of 180 NAC 4. The licensee is responsible for the conduct of all licensed activities and the acts and omissions of individuals handling licensed material. 180 NAC 3-017 provides that the Agency 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. 180 NAC 7-015 describes the licensee management's authorities and responsibilities for the radiation protection program. 180 NAC 7-016 sets forth four circumstances in which the licensee may revise its radiation protection program without Agency approval. For example, no Agency approval is required when the revision does not require a license amendment.*

Discussion: 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. Table C-1 and item 6 in Table C-2 of Appendix C may be helpful in determining what information should be provided when requesting a license.

Response from Applicant: Respond to subsequent sections of this document regarding Item 8 of the application.

Item 8.A. Safety Procedures and Instructions

180 NAC 7	Applicability
7-041	
7-044	
7-048	
7-055	
7-065	
7-067	√
7-085	√

Regulations: 180 NAC 7-008.03, 7-070, 7-076, 7-078

Criteria: *Before using materials under 180 NAC 7-067, the applicant must develop, document, submit, and implement written safety procedures for emergency response. 180 NAC 7-070 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 180 NAC 7-070 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 AUs, AMPs, and the RSO to be contacted if the unit or console operates abnormally.*

A copy of these 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.

Discussion: 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 should 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.

Response from Applicant: If Applicable:

Attach Safety Procedures and Instruction per 180 NAC 7-070 (For Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Unit)

Item 8.B. Safety Instruction for Individuals Working or Frequenting Restricted Areas

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Regulations: 180 NAC 7-018, 7-049, 7-058, 7-070, 7-101 and 180 NAC 10-002

Criteria: *Individuals working with or in the vicinity of licensed material must have adequate safety instruction as required by 180 NAC 7 and 180 NAC 10. For individuals who, in the course of employment, are likely to receive in a year an occupational dose of radiation over 1 millisievert (mSv) [100 millirem (mrem)], the licensee must provide safety instructions as required by 180 NAC 10-002. Additional requirements for training in radiation safety for individuals involved with therapeutic treatment of patients are described in 180 NAC 7-049, 7-058, 7-070. 180 NAC 7-018 requires the licensee's AUs and ANPs to provide safety instruction to all personnel using radioactive material under their supervision.*

Discussion: AUs, ANPs, AMPs, RSOs, and their supervised employees are most likely to receive doses in excess of 1 mSv (100 mrem) in a year. However, licensees also must evaluate potential radiation doses received by any individual working in or frequenting restricted areas. All individuals working with or around licensed materials should receive safety instruction commensurate with their assigned duties, and if it is likely that they could receive doses over 1 mSv (100 mrem) in a year, they must receive instruction as specified by 180 NAC 10.002. For

example, a licensee might determine that housekeeping staff, while not likely to receive doses over 1 mSv (100 mrem), should be informed of the nature of the licensed material and the meaning of the radiation symbol, and instructed not to touch the licensed material and to remain out of the room if the door to the licensed material storage location is open. Providing minimal instruction to ancillary staff (e.g., housekeeping, security, etc.) may assist in controlling abnormal events, such as loss of radioactive material.`

In addition to safety instruction required by 180 NAC 10.002 and in accordance with 180 NAC 7-049, 7-058 and 7-070, 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 180 NAC 7-037. 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 AU if the patient has a medical emergency or dies.
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In accordance with 180 NAC 7-018.01, individuals working with licensed material under the supervision of an AU must receive instruction on the licensee's written radiation protection procedures, written directive procedures, and Agency regulations and license conditions with respect to the use of radioactive material.

In accordance with 180 NAC 7-018.02, a licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an ANP or an AU, as allowed by 180 NAC 7-007.03, 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 Agency regulations. 180 NAC 7-018.03 states that a licensee that permits supervised activities, under paragraph 180 NAC 7-018.01 and 018.02, is responsible for the acts and omissions of the supervised individuals.

Appendix I provides a model training program that provides one way to satisfy the requirements referenced above.

Response from Applicant:
Will follow Appendix I procedures of RG 7.0 and will implement and maintain procedures for a training program for safe use of radioactive materials
OR
Equivalent procedures have be developed and will be implement and maintain for a training program for safe use of radioactive materials. The safety training procedures for individuals working or frequenting restricted areas meet the requirements of 180 NAC 10-002, 7-049, 7-058, 7-070 and 7-018. Equivalent procedures are attached.

Item 8.C. Operating and Emergency Procedures

Regulations: 180 NAC 3-10, 3-018.07, 3-026, 3-30, 180 NAC 4-004, 4-20, 4-023, 4-024, 4-031, 4-032, 4-038, 4-047, 4-056, 4-057, 4-058, 7-008, 7-018, 7-020, 7-037, 7-049, 7-056, 7-057, 7-058, 7-059, 7-070,7-071, 7-0114, 7-117, 7-118, 180 NAC 10-002

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Criteria: *This section summarizes operating and emergency procedures. Many of these procedures are covered in greater detail in other sections of this document.*

- *Develop, implement, and maintain specific operating and emergency procedures containing the following elements:*
  - *– Instructions for opening packages containing licensed material (see Section 8.H.);– Using licensed 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 Section 8.L.);*
  - *– Instructions for conducting area radiation level and contamination surveys (see Section 8.K.);*
  - *– Instructions for administering licensed material in accordance with the WD (see Section 8.M.);*
  - *– Steps to ensure that patient release is in accordance with 180 NAC 7-037 (see Section 8.N,);*
  - *– Instructions for calibration of survey and dosage measuring instruments (see Sections 7.B. and 7.C.);*
  - *– Periodic spot checks of therapy device units, sources, and treatment facilities (see Section 7.D.);*
  - *– Instructions for radioactive waste management (see Section 9.);*
  - *– Steps to take, and whom to contact (e.g., RSO, local officials), when the following has occurred: (a) leaking or damaged source, (b) device malfunction and/or damage, (c) licensed material spills, (d) theft or loss of licensed material, or (e) any other incidents involving licensed material (see Section, 8.W.);*
  - *– Steps for source retrieval and access control of damaged sealed source(s) and/or malfunctioning devices containing sealed source(s) (see Section 8.A.);*
  - *– Steps to take if a therapy patient undergoes emergency surgery or dies.*

AND

- *Make operating procedures, including emergency 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 180 NAC 4-004.02 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 it must be licensed to possess the radioactive material and that the radioactive material must be secured (or controlled) and accounted for at all times.*

Discussion: Sealed sources and unsealed radioactive material used for therapy can deliver significant doses in a short time. 180 NAC 4-023, 4-024, 4-031 and 4-032 describe access control to high and very high radiation areas and the security of licensed material. Unauthorized access to licensed 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 licensed material (e.g., keys, lock combinations, security badges). Accountability of licensed material may be ensured by conducting physical inventories, controlling receipt and disposal, and maintaining use records.

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."

The radiation protection program that licensees are required to develop, document, and implement in accordance with 180 NAC 4-004 must include provisions for responding to spills or other contamination events in order to prevent the spread of radioactive material. Appendix J contains model emergency response procedures, including model spill procedures. Spill procedures should address all types and forms of licensed material used and should be posted in restricted areas where licensed 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 Agency, 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).

Applicants should develop emergency procedures that address a spectrum of incidents (e.g., major spills, leaking source, medical events, interlock failure, stuck source, etc.). After its occurrence becomes known to the licensee, the Agency must be notified when an incident involving licensed material occurs. Refer to the regulations (180 NAC 3-026, 180 NAC 4-057, 4-058, 4-059, 7-115, 7-117 7-118) for a description of when notifications are required.

Response from Applicant:
Will provide Operating and Emergency Procedures.

And

We will use Appendix J for spill procedures.

OR

Equivalent spill procedures are attached that will be used.

And one of the following

Attachment 1 of Appendix J will be used.

OR

Equivalent attachment is attached that will be used.

Reference: Copies of 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, and NCRP Report No. 107, "Implementation of the Principle of As Low As Reasonably Achievable (ALARA) for Medical and Dental Personnel," 1990, 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>.

Item 8.D Safe Use of Unsealed Licensed Material

Regulations: 180 NAC 3-011, item 2, 3-17.05, 180 NAC 4-004, 4-013, 4-014, 4-047, 4-048, 7-018, 7-034, 7-036, 7-049

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	
7-065	
7-067	
7-085	√

Criteria: *Before using licensed material, the licensee must develop and implement a radiation protection program that includes safe use of unsealed licensed material.*

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 180 NAC 4-004 must include provisions for safe use of licensed material. Licensees are responsible for developing, documenting, and implementing procedures to ensure the security and safe use of all licensed material from the time it arrives at their facilities until it is used, transferred, and/or disposed. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to themselves, other workers, or members of the public.

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.

Appendix K contains model procedures that provide one method for safe use of unsealed licensed material.

Response from Applicant: If applicable provide:
Appendix K procedures of RG 7.0 will be implemented and maintained for safe use of unsealed radioactive material.

OR

We have developed and will implement and maintain procedures for safe use of unsealed radioactive material that meet the requirements of 180 NAC 4-004 and 4-013. AND they are provided.

Item 8.E. Radioactive Gases & Aerosols (e.g. Xenon-133)

180 NAC 7	Applicability
7-041	
7-044	√
7-048	
7-055	
7-065	
7-067	
7-085	

Regulations: 180 NAC 7-039

Discussion: The use of radioactive gases (e.g., Xe-133 gas or gas in saline) and aerosols requires attention not only to the standard radiation safety considerations but also to an evaluation of expected air concentrations of the radioactive gas or aerosol in restricted

and unrestricted areas. The department requires that each applicant make such determinations for their own unique situation and submit evidence to the department sufficient to adequately support the request.

Response from Applicant: If applicable

Appendix Y Procedures of RG 7.0 will be implemented and maintained for safe use of radioactive gases and aerosols.
OR
"We have developed and will implement and maintain written procedures for safe use of radioactive gases and aerosols and the procedures are attached.:

Item 8.F. Minimization of Contamination

Regulations: 180 NAC 4-020, 180 NAC 7-033

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Criteria: *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*.

Discussion: All applicants for new licenses need to 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 8.C., "Operating and Emergency Procedures," cleanup procedures should be implemented for contamination events. Recommended limits for acceptable levels of surface contamination in restricted and unrestricted areas are provided in Appendix O, Tables O.2. and O.3.

Sealed sources and devices that are approved by the Agency, 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 Agency requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts.

Response from Applicant:
We have attached a description of 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.

Item 8.G. Ordering and Receiving

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Regulations: 180 NAC 3-026, 180 NAC 4-031, 4-032, 4-038 AND 180 NAC 3-018.07, 3-025, 3-30, 180 NAC 4-031, 4-032, 4-038, 4-057, 180 NAC 7-033, 7-057

Criteria: 180 NAC 4-038 contains the requirements for receiving packages containing licensed material. Additionally, the security of licensed material, required by 180 NAC 4-031 and 4-032, must be considered for all receiving areas.

180 NAC 3-026 requires licensees, in part, to maintain records showing the receipt of radioactive material.

To maintain accountability of licensed material, licensees must do the following:

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

Discussion: Licensees must ensure that the type and quantity of licensed material possessed is in accordance with the license. Additionally, licensees must ensure that packages are secured and radiation exposure from packages is minimized.

Appendix L contains model procedures that are one method for ordering and receiving licensed material.

Licensed materials must be tracked from "cradle to grave" to ensure accountability, identify when licensed material could be lost, stolen, or misplaced, and ensure that possession limits listed on the license are not exceeded.

Response from Applicant:
We have attached procedures for receipt and accountability of radioactive material.

AND

Appendix L of RG 7.0 will be implemented and maintained for opening and receiving packages that contain radioactive material.

OR

Equivalent procedures for receiving and opening packages that contain radioactive material are attached.

Item 8.H. Opening Packages Containing Radioactive Material

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Regulations: 180 NAC 4-038, 4-048.

Criteria: *Licensees must ensure that packages are opened safely and that the requirements of 180 NAC 4-038 are met. Licensees must retain records*

of package surveys in accordance with 180 NAC 4-048.

Discussion: Licensees must establish, maintain, and retain written procedures for safely opening packages to ensure that the monitoring requirements of 180 NAC 4-038 are met and that radiation exposure to personnel coming near or in contact with the packages containing radioactive material are ALARA.

Appendix M contains model procedures that represent one method for safely opening packages containing radioactive materials. Applicants are reminded that 180 NAC 4-038.02 requires, in part, that licensees monitor the external surfaces of a labeled package for radioactive contamination within 3 hours of receipt if it is received during normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

Response from Applicant:
Appendix M of RG 7.0 will be implemented and maintained for Opening and Receiving Packages containing radioactive material. **OR**
We have attached procedures that will be implemented and maintained for Opening and Receiving Packages containing radioactive material.

Item 8.I. ALARA

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Regulations: 180 NAC 4-004, NAC 7-15

Criteria: 180 NAC 4-004, "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 ALARA."

Applicants should consider the ALARA philosophy detailed in these reports when developing plans to work with licensed radioactive materials.

Discussion: When developing the procedures described above, the licensee is reminded that 180 NAC 4-004.02 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.

This section 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.

Applicants should consider the ALARA philosophy detailed in these reports when developing plans to work with licensed radioactive materials.

Response from Applicant:

Applications for new licenses, renewal requests, and requests for significant license amendments (i.e., to broaden program; to increase possession limits) should be accompanied by a description of the applicant's ALARA program. Applicants/licensees may adopt the model program described in Appendix Z.

Appendix Z will be used form maintaining and implementing procedures and precautions for the use of Radioactive Gases. **OR**
We have attached equivalent procedures that will be implemented and maintained for ALARA.

Item 8.J. Occupation Dose

Regulations: 180 NAC 4-002, 4-004, 4-005, 4-006, 4-008, 4-011, 4-012, 4-021, 4-022, 4-047, 4-052

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Criteria: Applicants must do either of the following:

- *Demonstrate that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10 % of the allowable limits as shown in Figure 8.1.*

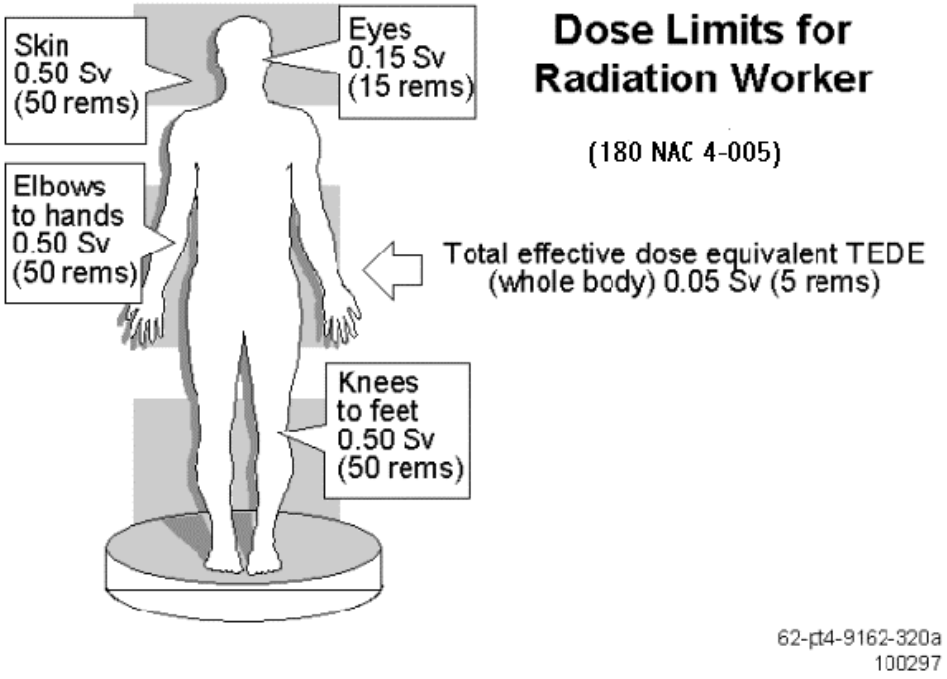

Figure 8.1 Annual Occupational Dose Limits for Adults

OR

- *Monitor external and/or internal occupational radiation exposure, if required by 180 NAC 4-022.*

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 180 NAC 4-004, must include provisions for monitoring

occupational dose. The licensee must evaluate the exposure of all occupational workers (e.g., nurses, technologists) to determine if monitoring is required to demonstrate compliance with 180 NAC 4-021 and 4-022. 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.

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 180 NAC 4 limits.

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 180 NAC 4 limits.

Appendix N provides a model procedure for monitoring external occupational exposure. If external dose monitoring is necessary, the applicant should describe the type of personnel dosimetry, such as film badges, optically stimulated luminescence dosimeters (OSL), and thermoluminescent dosimeters (TLDs), that personnel will use. If occupational workers handle licensed material, the licensee should evaluate the need to provide extremity monitors, which are required if workers are likely to receive a dose in excess of 0.05 Sv (5 rems) shallow-dose equivalent (SDE), in addition to whole-body badges. Additionally, applicants should ensure that their 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.

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 (180 NAC 4-021.02).

When personnel monitoring is needed, most licensees use either film badges or TLDs that are supplied by a processor holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP). Under 180 NAC 4-021.02, licensees must verify that the processor is accredited by NVLAP for the type of radiation for which monitoring will be performed. Consult the NVLAP-accredited processor for its recommendations for exchange frequency and proper use.

It may be necessary to assess the intake of radioactivity for occupationally exposed individuals in accordance with 180 NAC 4-008 and 4-022. 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 should describe in its procedures the criteria used to determine the type of 77 and the frequencies at which bioassay (both *in vivo* and *in vitro*) will be performed to evaluate intakes. The criteria also should 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 should ensure that the service is licensed by the Agency (or NRC or an equivalent Agreement State) license or provide another alternative for the Agency to review.

Note: The definition of "shallow-dose equivalent" in 180 NAC 4-002 was revised, (effective date of regulations) to change the area for averaging dose to skin from 1 square centimeter to 10 square centimeters.

Response from Applicant:
Part 1 of Appendix N is attached if Table c-3 of appendix C is not attached as part of the application.

AND

We will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 180 NAC 4. The evaluation is attached."

OR

Appendix N of RG 7.0 will be used and maintained for Occupational Dose Procedures.

OR

"We will provide dosimetry that meets the requirements of 180 NAC 4 and will attach equivalent procedures for an Occupation Dose Program.

References:

- National Institute of Standards and Technology (NIST) Publication 810, "National Voluntary Laboratory Accreditation Program Directory," is published annually and is available for purchase from GPO and on the Internet at <http://ts.nist.gov/ts/htdocs/210/214/scopes/programs.htm>.
- Copies of ANSI N322 may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or ordered electronically from <http://www.ansi.org>.
- NUREG/CR-4884, "Interpretation of Bioassay Measurements;"
- RG 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program;" Regulatory Issue Summary 2002-06;
- "Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays;"
- NRC Regulatory Issue Summary 2002-06, "Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays;"
- NRC Regulatory Issue Summary 2002-10, "Revision of the Skin Dose Limit in 10 CFR Part 20."

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Item 8.K. Area Surveys

Regulations: 180 NAC 4-002, 4-004, 4-005, 4-013, 4-014, 4-015, 4-

031, 4-032, 4-047, 4-048, 4-053, 7-037, 7049, 7-056, 7-068, 7-085

Criteria: *Licensees are required to make surveys of potential radiological hazards in their workplace. For example, licensees must perform surveys to:*

- *Ensure that licensed material will be used, transported, and stored in such a way that doses to members of the public do not exceed 1 mSv per year (100 millirem/year) and that the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any 1 hour from licensed operations;*
- *Ensure that licensed material will be used, transported, and stored in such a way that occupational doses to individuals will not exceed the limits specified in 180 NAC 4-005; and*
- *Control and maintain constant surveillance over licensed material that is not in storage and secure licensed material from unauthorized access or removal.*
- *Ensure that licensed material will be used, transported, and stored in such a way that the air emissions do not exceed the constraint value in 180 NAC 4-004.*

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 180 NAC 4-004 must include provisions for area surveys. Surveys are evaluations of radiological conditions and potential hazards. These evaluations may be measurements (e.g., radiation levels measured with 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.

There are many different kinds of surveys performed by licensees:

- Contamination:
  – Fixed;
  – Removable.
- Air Effluent;
- Water Effluent;
- Leak Test;
- Bioassays;
- Air Sample;
- Restricted Areas;
- Unrestricted Areas; and
- Personnel (during use, transfer, or disposal of licensed material).

Surveys are required when it is reasonable under the circumstances to evaluate a radiological hazard and when 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

licensed 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. Appendix O 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 for which a written directive is required (diagnostic activities exceeding 30 μCi of I-131 and all therapy treatments); when the licensee administers radiopharamaceuticals requiring a WD in a patient's room, the licensee is not required to perform a survey of the patient's room. Licensees should perform surveys after the patient's release. Licensees must perform surveys prior to the release of the room for unrestricted use. Licensees should be cognizant of the requirement to perform surveys to demonstrate the public dose limits are not exceeded.

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; and
- 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.

In addition, licensees should also consider the following:

- The therapy patient's bed linens before removing them from the patient's room;
- The operating room and the patient's room after source implantation (e.g., radiation level and/or visual check);
- All trash exiting the patient's room; and
- Areas of public access in and around the patient's room.

Appendix O is a sample of an area survey procedure.

Response from Applicant:
"We will implement and use Appendix "O" for area surveys."

OR

"We have developed and will implement and maintain written procedures for area surveys in accordance with 180 NAC 4-004 that meet the requirements of 180 NAC 4-021 and 180 NAC 7-0036."**And** provide the procedures.

Item 8.L. Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources

Regulations: 180 NAC 3-010, 3-017, 180 NAC 4-004, 180 NAC 7-069, 7-081, 7-106, 7-114

180 NAC 7	Applicability
7-041	
7-044	
7-048	
7-055	
7-065	
7-067	√*
7-085	√

Criteria: *In accordance with 180 NAC 7-069 and 180 NAC 7-081, 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 should be conducted according to the manufacturers' written recommendations and instructions and according to the SSDR. In addition, 180 NAC 7-081 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.*

Discussion: 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 Agency requires that maintenance and repair (as defined above) be performed only by persons specifically licensed by the Agency, NRC or an Agreement State to perform such services. Most 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 180 NAC 7-069 before responding to this item. 180 NAC 7-069 allows for an AMP to perform certain service activities with regard to LDR remote afterloader units.

Response from Applicant:
Not applicable (no therapy devices containing sealed sources)

OR

Will contract with personnel who are licensed by the Department, the NRC or an Agreement State to perform maintenance and repair services on the specific therapy device(s) possessed by the licensee.

Or the following three conditions must be met

Will name the proposed employee or employees and types of maintenance and repair requested.
AND

Will provide a description of the training and experience demonstrating that the proposed employee or employees is/are qualified by training and experience for the use requested.
AND
Will provide a copy of the manufacturer's training certification and an outline of the training.

Item 8.M. Procedures for Administration When a Written Directive is Required

180 NAC 7	Applicability
7-041	
7-044	
7-048	√
7-055	√
7-065	
7-067	√
7-085	√

Regulations: 180 NAC 7-018, 7-019, 7-020, 7-088

Criteria: *180 NAC 7-019 sets forth the requirements for WDs. 180 NAC 7-020 requires medical use licensees to develop, maintain, and implement written procedures to provide high confidence that licensed material is administered as directed by authorized users*.

Discussion: The procedures need to be submitted to the Agency. But the procedures can be revised without a license amendment. This gives licensees the flexibility to revise the procedures to enhance effectiveness without obtaining Agency approval. Appendix P provides guidance on developing the procedures.

Response from Applicant: (If applicable)
We will use Appendix P for developing, maintaining and implementing written procedures.

OR

An equivalent procedure will be attached. However the licensee can revise the procedures to enhance effectiveness without obtaining Agency approval as long as health and safety is not compromised.

Item 8.N. Safety Procedures for Treatments When Patients are Hospitalized

180 NAC 7	Applicability
7-041	
7-044	
7-048	√
7-055	√
7-065	
7-067	√
7-085	√

Regulations: 180 NAC 4-004, 4-013, 4-021, 4-031, 4-059, 180 NAC 7-049, 7-050, 7-056, 7-058, 7-059, 7-068, 7-070, 7-071, 7-102

Criteria: 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.

Discussion: 180 NAC 7-050, 7-059, and 7-071 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 180 NAC 7-037. This section of the guidance 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 180 NAC 4.

180 NAC 7-056.02 and 7-068 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. 180 NAC 7-071.05 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 180 NAC 7-037:

- Provide a room with a private sanitary facility for patients treated with a radiopharmaceutical therapy dosage (Note: 180 NAC 7-049.02, item 1 allows for a room shared with another radiopharmaceutical therapy patient);
- Provide a private room for patients implanted with brachytherapy sources (*Note:*180 NAC 7-059 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 (180 NAC 7-049 and 7-059);
- 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 (180 NAC 4-021 and 180 NAC 7-049); and
- Notify the RSO, or his/her designee, and AU as soon as possible if the patient has a medical emergency or dies (180 NAC 7-049, 7-059 and 7-071).

180 NAC 4-021 requires licensees to perform adequate surveys to evaluate the extent of radiation levels. Therefore, licensees must evaluate the exposure rates around patients who are hospitalized in accordance with 180 NAC 7-037 following the dosage administration or implant (e.g., measured exposure rates, combination of measured and calculated exposure rates).

180 NAC 4-031 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 exposures to individuals in accordance with 180 NAC 4, 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.

Response from Applicant: (If applicable)
Provide Safety Procedures for treatment when patients are hospitalized.

Item 8.O. Release of Patients or Human Research Subjects

180 NAC 7	Applicability
7-041	
7-044	
7-048	√
7-055	√
7-065	
7-067	
7-085	√

Regulations: 180 NAC 7-037, 7-096

Criteria*: Licensees may release from confinement patients or human research subjects (patients) who have been administered licensed material if the TEDE to any other individual from exposure to the released patient is not likely to exceed 5 mSv (0.5 rem). Licensees must provide radiation safety instructions to patients released (or their parent or guardian) in accordance with180 NAC 7-037.02.*

Discussion: 180 NAC 7-037 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 the TEDE to any other individual is likely to exceed 1 mSv (0.1 rem). If the dose to a breast-feeding infant or a child could exceed 1 mSv (0.1 rem), assuming there was no interruption of breast-feeding, the instructions also shall include:

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

Appendix Q provides guidance to the applicant on one way 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, and
- Instructions to the patient are required by 180 NAC 7-037.02.
- Appendix Q 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 180 NAC 7-037.

Response from Applicant: (If applicable)

We will implement and maintain Appendix Q for the release of patients or human research subjects.
OR
Equivalent Procedures that will be used are attached.

Item 8.P. Mobile Medical Service

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Regulations: 180 NAC 7-002, 7-008, 7-027, 7-038, 7-079, 7-97, 7-112, 180 NAC 13-004, 13-005,

Criteria: *In addition to the requirements in 180 NAC 7-038, and 7-079 as applicable, mobile medical service licensees must comply with all other applicable regulations*.

Discussion: Applicants for licensure of mobile medical services should review this Regulatory 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. "Temporary job site" means a location, other than specific location(s) of use authorized on the license, where mobile medical services are conducted. Mobile medical service licensees may transport licensed material and equipment into a client's building, or may bring patients into the transport (e.g., van). In either case, the van should 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 180 NAC 7. Before using a remote afterloader for this type of service, the device should 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 180 NAC 7-037 are met before releasing patients treated in their facilities.

Refer to Appendix E for additional guidance on information to provide in applications.

Response from Applicant: (If applicable)
Will provide mobile medical service procedures. Appendix E discusses additional information that will need to be provided with the application for mobile services.

Item 8.Q. Leak Tests

Regulations: 180 NAC 4-031, 4-032, 180 NAC 7-033, 7-094, 7-0118

Criteria: The Agency requires testing to determine if there is any radioactive leakage from sealed sources.

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Discussion: Licensees must perform leak testing of sealed sources, e.g., calibration, transmission, and reference sources, or brachytherapy sources in accordance with 180 NAC 7-033. Appendix R provides model procedures that are one way to perform leak testing. 180 NAC 7-033 requires licensees to perform leak tests at six-month intervals or at other intervals approved by the Agency, NRC or an Agreement State and specified in the SSDR 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 185 Bq (0.005 μCi) of radioactivity on the sample. Leak test samples should 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 a contractor who is authorized by the Agency, NRC or an Agreement State to perform leak tests as a service to other licensees.

The licensee or contractor does not need to leak-test sources if:

- Sources contain only radioactive material with a half-life of less than 30 days;
- Sources contain only radioactive material as a gas;
- Sources contain 3.7 MBq (100 μCi) or less of beta-emitting or gamma-emitting material, or 0.37 MBq (10 μCi) 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.

Response from Applicant: Provide:

We will implement and maintain Appendix R :

OR

We will provide Equivalent Leak Test Procedures and they are attached.

AND

Leak tests will be performed at intervals approved by the Department, an Agreement State or by the NRC and specified in the Sealed Source and Device Registration Certificate.

AND

Leak tests will be performed by an organization authorized by the Department, an Agreement State or the U.S. Nuclear Regulatory Commission to provide leak testing services for other licensees.

OR

Leak test kit will be supplied by an organization authorized by the Department, an Agreement State or U.S. Nuclear Regulatory Commission to provide leak test kits to other licensees and according to the kit supplier's instructions. Records for leak test results will be maintained.

Program-Related Guidance – No Response Required From Applicants on NRH 7A

The information provided in the following section is included because this topic is a key element of the licensee's program and the information is provided as guidance to applicants in setting up their program to satisfy regulatory requirement.

Item 8.R Public Dose

Regulations: 180 NAC 4-002, 4-004, 4-013, 4-014, 4-031, 4-032, 4-033

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Criteria: *Licensees must do the following:*

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

Discussion: Members of the public include persons who are not radiation workers. This includes workers who live, work or may be near locations where licensed material is used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where it is used or stored. Public dose is controlled, in part, by ensuring that licensed 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 licensed 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 AUs 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.

For areas adjacent to facilities where licensed material is used or stored, calculations or a combination of calculations and measurements (e.g., using an environmental TLD) are often used to show compliance.

The definition of "public dose" in 180 NAC 1-002 does not include doses received due to exposure to patients released in accordance with 180 NAC 7-037. The provisions of 180 NAC 4-14.01 should not be applied to radiation received by a member of the general public from patients released under 180 NAC 7-037. If a patient is released pursuant to 180 NAC 7-037,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 0.02mSv (2mrem) in any one hour. Patient waiting rooms need only be controlled for those patients not meeting the release criteria in 180 NAC 7-037. 180 NAC 4-013.03 allows licensees to permit visitors to a patient who cannot be released under 180 NAC 7-037 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 Section 7.A. and may find confirmatory surveys to be useful in assuring compliance with 180 NAC 4-013.

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 0.10 mSv (10 mrem) per year from those emissions. If exceeded, the licensee must report this in accordance with 180 NAC 4-059, and take prompt actions to ensure against recurrence.

Response from Applicant: No response required.

Item 8.S. Audit Program

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Regulations: 180 NAC 4-004, 4-058

Criteria: *Under 180 NAC 4-004, all licensees must annually review the content and implementation of the radiation protection program. The review should ensure the following:*

- *Compliance with Agency and applicable U.S. Department of Transportation (DOT) regulations and the terms and conditions of the license; and*
- *Occupational doses and doses to members of the public are ALARA (180 NAC 4-004).*

Discussion: The applicant should develop and implement procedures for the required review or audit of the radiation protection program's content and implementation. Appendix S contains model procedures that are only a suggested guide and are one way 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 Agency encourages licensee management to conduct performance-based reviews by observing work in progress, interviewing staff about the radiation protection 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 Agency's goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies.

Response from Applicant: No response is necessary.

Item 8.T Sealed Source Inventory

180 NAC 7	Applicability
7-041	√*
7-044	√*
7-048	√*
7-055	√
7-065	√
7-067	√
7-085	√

* Sealed sources for calibration, transmission, and reference use180 NAC 7-032

Regulations: 180 NAC 3-026, 180 NAC 4-031, 4-032, 180 NAC 7-033, 7-057, 7-094, 7-103

Criteria: *The Agency requires the licensee in possession of a sealed source or brachytherapy source to conduct a semi-annual physical inventory of all such sources in its possession.*

Discussion: According to 180 NAC 7-033, the licensee must conduct a semi-annual 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 180 NAC 7-033.04. However, the licensee must maintain records of GSR source receipt, transfer, and disposal, under 180 NAC 3-026, to indicate the current inventory of sources at the licensee's facility.

Response from Applicant: No response is necessary.

Item 8.U. Records of Dosages and Use of Brachytherapy Source

Regulations: 180 NAC 3-030, 180 NAC 7-031, 7-093, 7-099, 7-103

Criteria: *Licensees must record the use of licensed material to reflect proper use and accountability. Records of use must be maintained for 3 years.*

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	
7-067	
7-085	√

Discussion: Licensees are required to make and maintain records of each dosage and administration prior to medical use. The records must include:

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

Dosage determination for unit dosages may be made either by direct measurement or by a decay

correction based on the determination (e.g., measurement) made by the manufacturer or preparer licensed under 180 NAC 3-014.10 or equivalent NRC or Agreement State requirements.

If molybdenum concentration is measured under 180 NAC 7-045, records of molybdenum concentration must be made under 180 NAC 7-099 and must include, for each measured elution of technetium-99m:

- Ratio of the measurements expressed as kBq (μCi) 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.

Response from Applicant: No response is necessary.

Item 8.V. Recordkeeping

Regulations: 180 NAC 3-030, 180 NAC 4-046 through 4-056, 180 NAC 7-086 through 7-114

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Criteria: *Licensees must maintain records as provided in 180 NAC 3-030, 180 NAC 4-046 through 4-056, 180 NAC 7-086 through 7-114.*

Discussion: The licensee must maintain certain records to comply with the Agency regulations, the conditions of the license, and commitments made in the license application and correspondence with the Agency. Operating procedures should identify which individuals in the organization are responsible for maintaining which records.

A table of recordkeeping requirements appears in Appendix T.

Response from Applicant: No response is necessary.

Item 8.W. Reporting

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

*If possess sealed sources under
180 NAC 7-032

Regulations: 180 NAC 3-026, 180 NAC 4-057 through 4-064, 180 NAC 7-115 through 7-118

Criteria: *Licensees are required to report to Agency 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 180 NAC 3-026, 180 NAC 4-057 through 7-64 and 180 NAC 7-115 through 7-118 . The timing and type of report are specified within these parts*.

Discussion: The Agency requires licensees to report incidents that might compromise the health and safety of patients, health care providers, or the public. Therefore, 180 NAC 3, 4, and 7 include provisions that describe reporting requirements associated with the medical use of radioactive material.

A table of reporting requirements appears in Appendix U.

Response from Applicant: No response is necessary.

Item 8.X. Transportation

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Regulations: 180 NAC 3-025, 3-30, 180 NAC 4-004, 180 NAC 13-005, 10 CFR 71.9; 10 CFR 71.12; 10 CFR 71.13; 10 CFR 71.14; 10 CFR 71.37; 10 CFR 71.38; 10 CFR 71, Subpart H; 49 CFR Parts 171-178.

Criteria: *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 NRC and DOT regulations.*

Discussion: Most packages of licensed 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 0.005 mSv per hour (0.5 mrem per hour)).

The general license in 10 CFR 71.12, "General license: NRC-approved package," provides the authorization used by most licensees to transport, or to deliver to a carrier for transport, licensed 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. 10 CFR 71.5 sets forth the requirements for transportation of licensed material. 10 CFR 71.9 exempts any physician licensed by a state to dispense drugs in the practice of medicine, who is also licensed under 180 NAC 7, 10 CFR Part 35 or the equivalent Agreement State regulations from the requirements in 180 NAC 13-005 or 10 CFR 71.5. This exemption applies to transport by the physician of licensed material for use in the practice of medicine.

Some medical use licensees (e.g., teletherapy or gamma stereotactic radiosurgery) may need to ship licensed material in Type B packages. 10 CFR 71.12 - 71.14 sets forth the Type B package requirements for transporting or delivering the package to a carrier for transport. These include registration as a user of the package and having an NRC-approved quality assurance (QA) plan.

Some medical use licensees that ship radioactive material have chosen to transfer possession of radioactive materials to a manufacturer (or service licensee) with an NRC or Agreement State license, who then acts as the shipper. The manufacturer (or service licensee), who is subject to the provisions of 10 CFR 71.12 or 10 CFR 71.14, as appropriate, then becomes responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations.

Licensees who do this must ensure that the manufacturer (or service licensee):

- Is authorized to possess the licensed material (see 180 NAC 3-025).
- Actually takes possession of the licensed material under its license.

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

During an inspection, the Agency uses the provisions of 180 NAC 13-005 and a Memorandum of Understanding with DOT on the Transportation of Radioactive Material (signed June 6, 1979) to examine and enforce various DOT requirements applicable to medical use licensees.

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

Response from Applicant: No response is needed from applicants during the licensing phase.

However, before making shipments of licensed materials on its own in a Type B package, a licensee must have registered with NRC as a user of the package and obtained NRC's approval of its QA program. Transportation issues will be reviewed during inspection.

References:

- "A Review of Department of Transportation Regulations for Transportation of Radioactive Materials" can be obtained be calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4425.

Item 9: Waste Management

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Regulations: 180 NAC 3-008.09, 3-011, item 2, 3.015, 3-030, 180 NAC 4-004, 4-013, 4-014, 4-015, 4-036, 4-039 – 4-045, 4-047, 4-048, 4-053, 4-054, 180 NAC 7-040, 7-098, 180 NAC 12-004, 180 NAC 13-005

Criteria: *Licensed materials must be disposed of in accordance with Agency requirements by:*

- *Transfer to an authorized recipient (180 NAC 3-025.02);*
- *Decay-in-storage;*
- *Release in effluents within the limits in 180 NAC 4-013; or*
- *As authorized under 180 NAC 4-039 –4-045.*

Discussion: The radiation protection program that licensees are required to develop, document, and implement in accordance with 180 NAC 4-004 must include provisions for waste disposal of licensed material. Appendix W contains model procedures that represent one way to provide for decay-in-storage and generator or other licensed material return. Applicants are reminded to take into account 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 180 NAC 4-039.02, 4-044, or in applicable regulations in 180 NAC 3 or 12. 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 halflives (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 180 NAC 3-008.09 is exempt from waste disposal regulations in 180 NAC 4, as set forth in 180 NAC 3-008.09, item 6. 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 180 NAC 4-014 and 4-041, respectively.

  – Regulations for disposal in the sanitary sewer appear in 180 NAC 4-041. 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 180 NAC 4-041.02).
  – Limits on permissible concentrations in effluents to unrestricted areas are enumerated inTable II of Appendix B of 180 NAC 4. These limits apply at the boundary of the restricted area.

– Liquid scintillation-counting media containing 1.85 kBq (0.05 μCi) per gram of H-3 orC-14 may be disposed of without regard to its radioactivity (180 NAC 4-043.01, item 1).

- If applicants/licensees propose to treat or dispose of licensed material by incineration, they must comply with 180 NAC 4-0042. Contact the Agency for guidance on treatment or disposal of material by incineration.
- Applicants that wish to use waste volume reduction operations (e.g., compactors) should provide a detailed description (as outlined below), along with their response to Item 7.A. (Facility Diagram):
  – 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 come into contact with 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 Agency and attempt to contact the hospital where the pacemaker was implanted to arrange for explanation. The licensee which implanted the device is responsible for the follow-up, explanation, 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 information.

Response from Applicant: A statement that: "We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 180 NAC 4-0004, that also meet the requirements of the applicable section of 180 NAC 4-039 through 4-045 and 180 NAC 7-040."

AND

Provide the procedures (Appendix W can be used or equivalent procedures.)

Item 10: Citizenship Attestation

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Item 10 must be completed by all applicants.
Check the first box if the application is for a corporation or other separate legal entity (Continue to Item 11), otherwise

check the second box. If the second box is check, continue to the next section under the "United State Citizenship Attestation Form." Check the appropriate box and sign. Continue to item 11.

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Item 11: Certification

Item 10 must be completed on the form itself.

Individuals acting in a private capacity are required to date and sign NRH Form 5. Otherwise, representatives of the corporation or legal entity filing the application should date and sign NRH Form 5. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant such as the president, vice president, chief executive officer or principal/owner. As discussed previously in "Management Responsibility," signing the application acknowledges management's commitment and responsibilities for the radiation protection program. The Agency will return all unsigned applications for proper signature.

See Appendix AB for a sample of a delegation of authority form that must be completed and signed and attached to the application, if someone other than a corporate officer wants to correspond with the department as a certifying official.

Note:

- It is a severity level I violation to make a willful false statement or representation on applications or correspondence. (180 NAC 17, Appendix 17A)

- When the application references commitments, those items become part of the licenses conditions and regulatory requirements.

Response from Applicant: Sign the application by representative authorized to make binding commitments.

IV. Amendments and Renewals To a License

Regulations: 180 NAC 3-020 and 180 NAC 7-010,

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Discussion: After you are issued a license, you must conduct your program in accordance with (1) the statement, representation, and procedures contained in your application, (2) the terms and conditions of the license, and (3) Title 180.

It is the licensee's obligation to keep their license current. The license must be amended if any changes in the facilities, equipment, procedures, RSO or radioactive material used are planned. The license should anticipate the need for a license amendment insofar as possible. If any of the information provided in the application is to be modified or changed, submit an application for a license amendment. Submittal of an amendment request does not allow immediate implementation of proposed changes. Until the license has been amended to approve the change(s), the licensee must comply with the original terms and conditions of the license.

An application for a license amendment may be prepared either on the application Form NRH-5A or in letter form and should be submitted to the Agency. The application should identify the license by number and should clearly describe the exact nature of the changes, additions, or deletions. Reference to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page and paragraph. The licensee must maintain a copy of the submitted and referenced documentation on file for inspection.

180 NAC 7-010 requires a licensee to apply for and receive a license amendment before several activities can occur, including:

- Receipt or use of radioactive material for a type of use permitted by 180 NAC 7, but not authorized on the licensee's current 180 NAC 7 license;
- Permitting anyone to work as an AU, AMP, or ANP, unless the individual meets one of the exceptions listed in 180 NAC 7-010.02 (Supply information required to document training and experience on NRH 7A for change or addition of AU, AMP, ANP, or RSO);
- Changing the RSO;
- Receiving radioactive material in excess of the amount, or receiving radionuclides or forms different than currently authorized on the Agency license;
- Changing an area or address of use identified in the application or on the license, except for areas of use where radioactive material is used only in accordance with either 180 NAC 7-041 or 7-044; and
- Revising procedures required by 180 NAC 7-070, 7-076, 7-077, and 7-078, when the revision reduces the level of radiation safety.

In case of a medical emergency requiring an expedited license amendment, contact the Agency materials licensing staff.

Absent any actions by the department or the licensee, a license remains in effect for five years.

An application for license renewal must be received by the department at least 30 days prior to the expiration date to avoid a new application fee. If the licensee files the application for license renewal at least 30 days before the expiration date of the license, the present license will automatically remains in effect until the Agency takes final action on the renewal application. However, if the licensee files an application less than 30 days before the expiration date and the Agency cannot process it before that date, the licensee will be without a valid license when the license expires.

Renewals require submittal of an entire new application, completed as if it were an application for a new license. Renewal applications should be submitted without reference to documentation and information submitted previously.

For both renewal and amendment requests applicants must do the following:

- Be sure to use the most recent guidance in preparing an amendment request.
- Submit one original copy of the application on a Form NRH-7 and if possible one electronic copy on a diskette or CD. The licensee should maintain a copy of the submitted and referenced documentation on file.
- Provide the license number.
- Ensure that a person in a management position signs the amendment or a delegation of authority has been submitted.

Note: Delegation of authority is a statement signed by management stating the specified person or persons the authority to sign license amendments and make statements that affect the license document.

V. Applications for Exemptions

Regulations: 180 NAC 1-003.01, 180 NAC 7-012, 7-014, 180 NAC 10-004

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Criteria: *Licensees may request exemptions to regulations. The licensee must demonstrate that the exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest.*

Discussion: Various sections of the Agency's regulations address requests for exemptions (e.g., 180 NAC 1-003.01). These regulations state that the Agency may grant an exemption, acting on its own initiative or on an application from an interested person.

Exemptions are not intended to revise regulations, are not intended for large classes of licenses, and are generally limited to unique situations. Exemption requests should be accompanied by descriptions of the following:

- Exemption and justification of why it is needed.
- Proposed compensatory safety measures intended to provide a level of health and safety equivalent to the regulation for which the exemption is being requested.
- Alternative methods for complying with the regulation and why compliance with the existing regulations is not feasible.

Until the Agency has granted an exemption in writing, the Agency expects strict compliance with all applicable regulations.

Type A broad scope licensees are granted certain exemptions as described in 180 NAC 7-012.

VI. License Termination

180 NAC 7	Applicability
7-041	√
7-044	√
7-048	√
7-055	√
7-065	√
7-067	√
7-085	√

Regulations: 180 NAC 3-017.02, 180 NAC 3-018.07, 180 NAC 3-019.04, 3-019.10, 180 NAC 1-004.

Prior to license termination, the licensee must properly dispose of all licensed radioactive material possessed. The licensee will need to send a notification of disposition of the materials with a request for license termination before the expiration date. (See 180 NAC 3-019) NRH Form 60 "Certificate of Disposition of Materials will need to be submitted.

If the licensee can not dispose of all the licensed radioactive material in possession before the expiration date, the licensee will need to submit a license renewal for storage only of the radioactive material. The renewal is necessary to avoid violating Agency regulations that do not allow the licensee to possess licensable material without a valid license.

The licensee must do the following:

- Notify the Agency, in writing, within 60 days of:
  -the expiration of its license;
  - a decision to permanently cease licensed activities at the entire site (regardless of contamination levels)when a decision is made to permanently cease licensed activities.
  - a decision to permanently cease licensed activities in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to the Agency requirements;
  - no principal activities having been conducted at the entire site under the license for a period of 24 months; and
  - no principal activities having been conducted for a period of 24 months in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to Agency requirements.
- Submit a decommissioning plan, if required by 180 NAC 3-019.07;
- Conduct decommissioning, as required by 180 NAC 3-019.08 and 3-019.10; and
- Submit, to the appropriate Agency, a completed NRH Form 60-, "Certificate of Disposition of Materials," (or equivalent information) and demonstrate that the premises are suitable for release for unrestricted use (e.g., results of final survey).
- Before a license is terminated, send the records important to decommissioning to the Agency. If licensed activities are transferred or assigned in accordance with 180 NAC 3-017.02, transfer records important to decommissioning to the new licensee.

Refer to
Regulatory Guide For Form
NRH 7A
For Guidance on completing Form NRH 7A

Appendix A

NRH –7 Application for Radioactive Material License - Medical

Nebraska's Health and Human Services Regulation and Licensure

Radioactive Material Program

Nebraska Department of Health and Human Services

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
RADIOLOGICAL HEALTH
RADIOACTIVE MATERIALS PROGRAM

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE - Medical

INSTRUCTIONS - (Use additional sheets where necessary.)
Retain one copy for your files and submit original application to: Department of Health and Human Services, Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, NE 68509-5026.
Upon approval of this application, the applicant will receive a Radioactive Material License, issued in accordance with the requirements contained in Title 180, Regulations for Control of Radiation and the Nebraska Radiation Control Act.

1.a Legal Name and Street address of Applicant (Institution, Firm, Hospital, Person, etc.)

Applicant Name: _____

Address: _____

_____

City, State Zip +4: _____

Telephone #: _____

FAX #: _____

e-Mail Address:

1.b Street address(es) at which Radioactive Material will be used. (If different than 1.a)

(1) Permanent Address: _____

`

_____

City, State Zip +4: _____

(2) Temporary Job Sites Throughout Nebraska? ☐ Yes ☐ No

2. Person to Contact Regarding this Application

_____

Telephone #:_____

3. This is an application for:

☐ New License

☐ Amendment to License No._____

☐ Renewal of License No._____

☐ **Table C-2 "Checklist for Items 4-6 of NRH -7" of Regulatory Guide 7.0 (RG 7.0) Appendix C is attached and completed for Items 4-6 of this application instead of completing the items on this form or equivalent pages.** (check if used and attached.) R**G 7.0 Revision** _____ **Date** _____

4. Individual User(s) (Check two)
☐ Name and Title of individual(s) who will use or directly supervise use of, Radioactive Materials is listed below. **OR**
☐ A Equivalent list is attached on 8½" x 11" paper

AND

☐ Complete a NRH-7A for each individual listed below.

First Name + Middle Initial	Last Name	Title	Nebraska Medical License #	Place a checkmark for each use of material in 180 NAC 7-						
				041	044	048	055	065	067	085

5. Radiation Safety

5.A. Radiation Safety Officer (RSO)
(Name and Title of Individual designated as Radiation Safety Officer)

_____

Telephone #:_____

Complete a NRH-7A for the RSO.

5.B Radiation Safety Committee(If required by 180 NAC 7-015.08)
☐ A description of the Radiation Committee is attached.

Department Use Only

Date Received Stamp

6. Radioactive Material Data

6.A. Radioactive Material for Medical Use

(Can be completed on additional 8½" x 11" paper or use Appendix C of Regulatory Guide 7.0)

Radioactive Material (Elements and mass number)	**Chemical/Physical Form** (Make & Model if sealed source)	**Maximum Activity Requested** (Expressed as Curies, Millicuries, or Micorcuries)	**Use of Each Form** (If sealed source, also give Make and Model Number of the storage and/or device in which the sealed source will be stored and/or used)
Title 180 NAC 3-008.09			For In Vitro Studies
Title 180 NAC 7-041			
Title 180 NAC 7-044			
Title 180 NAC 7-048			
Title 180 NAC 7-055			
Title 180 NAC 7-065			
Title 180 NAC 7-067			
Title 180 NAC 7-085			

6.B. Radioactive Material for Uses not Listed in Item 6.a.

6.b.(1) Element and Mass Number	6.b.(2) Chemical or Physical Form (Make and Model if sealed source)	6.b.(3) Maximum Activity Requested (Expressed as Curies, Millicuries, or Microcuries)	6.b.(4) Use of Each Form (If sealed source, also give Make and Model Number of the storage and/or device in which sealed source will be stored and/or used)

6.C All licensees are required to maintain records important to decommissioning. Licensees authorized to possess licensed material in excess of the limits specified in 180 NAC 3-018 must provide evidence of financial assurance for decommissioning.

☐ **Table C-3 "Checklist for Items 7-9 of NRH -7" of Regulatory Guide 7.0 (RG 7.0) Appendix C is attached and completed for Items 7-9 of this application instead of completing the items on this form or equivalent pages.** (check if used and attached.) R**G 7.0 Revision _____ Date _____**

OR

The type and scope of information to be provided for items 7 through 9 is described in "Regulatory Guide 7.0 - Radioactive Material Guidance for Medical Use Programs" (RG 7.0)

The information required of the applicant can be submitted on separate sheets for each item. Identify the item number and date of the application in the lower right hand corner of each page OR the information can be submitted on the appropriate pages from the most recent revision of Regulatory Guide 7.0 (RG 7.0). Revision _____ Date_____. (Please indicate the most recent revision and date of RG 7.0 used to complete this application.)

7. FACILITIES AND EQUIPMENT

7.A. Facility Diagram (check two)
- ☐ Facility Diagrams are attached
- ☐ Facility Descriptions are attached

7.B. Instrumentation (check one)
- ☐ Part 1 of Appendix G of RG 7.0 is attached and will use Appendix G of RG 7.0; **OR**
- ☐ Part 1 of Appendix G of RG 7.0 is attached and Equivalent Procedures are attached

7.C. Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Radioactive Material (check one)
- ☐ Appendix H of RG 7.0 will be used **OR**
- ☐ Equivalent Procedures are attached **OR**
- ☐ Not applicable. (No unsealed radioactive material will be used.)

7.D. Therapy Unit – Calibration and Use (check one)
- ☐ Procedures are attached (For HDR, Gamma Stereotactic Radiosurgery Unit, Teletherapy or Brachytherapy Use) **OR**
- ☐ Not applicable.

7.E. Other Equipment and Facilities (check one)
- ☐ Appendix X is attached **OR**
- ☐ Not applicable.

8. Radiation Protection Program

8.A. Safety Procedures and Instructions (check one)
- ☐ Attached Safety Procedures and Instructions per 180 NAC 7-070 (For Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units) **OR**
- ☐ Not applicable

8.B. Safety Instructions for Individuals Working in or Frequenting Restricted Areas) (check one)
- ☐ Appendix I of R.G. 7.0 will be used; **OR**
- ☐ Equivalent Procedures are attached and will be used

8.C. Operating and Emergency Procedures (check three)
- ☐ Attach Operating and Emergency procedures

AND
- ☐ Appendix J of RG 7.0 will be used **OR**
- ☐ Equivalent Procedures are attached and will be used

AND ONE OF THE FOLLOWING (Check one)
- ☐ Attachment 1 of Appendix J will be used **OR**
- ☐ Equivalent Attachment is attached and will be used

8.D. Safe Use of Unsealed Radioactive Materials (check one)
- ☐ Appendix K of RG 7.0 will be used; **OR**
- ☐ Equivalent Procedures and are attached and will be used; **OR**
- ☐ Not applicable

8.E. Radioactive Gases and Aerosol (e.g., Xenon-133) (check one)
- ☐ Appendix Y is attached; **OR**
- ☐ Equivalent Supporting Information and Calculations Attached **OR**
- ☐ Not applicable

8.F. Minimization of Contamination (check one)
- ☐ Attach a description of how facility design and procedures of operation will minimize contamination

8.G. Ordering and Receiving (check two)
- ☐ Attach Procedures for receipt and accountability; **AND**
- ☐ Appendix L of RG 7.0 will be used; **OR**
- ☐ Equivalent Procedures are attached and will be used

8.H. Opening Packages Containing Radioactive Material (check one)
- ☐ Appendix M of RG 7.0 will be used **OR**
- ☐ Equivalent Procedures are attached and will be used

8.I. ALARA (check one)
- ☐ Appendix Z of RG 7.0 is attached **OR**
- ☐ Equivalent Procedures are attached and will be used

8.J. Occupational Dose Dosimetry, Internal and External Exposure) (check one)
- ☐ Part 1 of Appendix N is attached

8.K. Area Surveys (check one)
- ☐ Appendix O of RG 7.0 will be used; **OR**
- ☐ Equivalent Procedures are attached and will be used

8.L. Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources (check one)
- ☐ Appendix AA of RG 7.0 is attached **OR**
- ☐ Not applicable

8.M. Procedures for Administrations when a Written Directive is Required (check one)
- ☐ Appendix P of RG 7.0 will be used; **OR**
- ☐ Equivalent Procedures are attached and will be used **OR**
- ☐ Not applicable

8.N. Safety Procedures for Treatment When Patients are Hospitalized (check one)
- ☐ Procedures are attached **OR**
- ☐ Not applicable

8.O. Release of Patients or Human Research Subjects (check one)
- ☐ Appendix Q will be used; **OR**
- ☐ Equivalent Procedures are attached and will be used **OR**
- ☐ Not applicable

8.P. Mobile Medical Service (check one)
- ☐ Procedures are attached (See Appendix E of RG 7.0) **OR**
- ☐ Not applicable

8.Q. Leak Tests (check one)
- ☐ Part 1 of Appendix R of RG 7.0 is attached and will use Appendix R of RG 7.0; **OR**
- ☐ Part 1 of Appendix R of RG 7.0 is attached and Equivalent Procedures are attached and will be used

NOTE: No response is required for the following items but will be examined during an inspection.

Public Dose, Audit Program, Sealed Source Inventory, Records of Dosage and Use of Brachytherapy Sources, Recordkeepting, Reporting and Transportation.

9. <u>Waste Management</u> (check one)
- ☐ Appendix W will be used.; **OR**
- ☐ Equivalent Procedures attached

10. . **CITIZENSHIP ATTESTATION**

☐ It is not necessary to complete the Attestation part of this application below if the application is for a corporation or other separate legal entity. **Explain why:** (For example: This application is for a corporation, partnership, etc.) _____ _____

_____ **OR**

☐ **If the entity is owned by an individual, complete the United States Citizenship Attestation Form below.**

UNITED STATES CITIZENSHIP ATTESTATION FORM

For the purpose of complying with Neb. Rev Stat. §§ 4-108 through 4-114, I attest as follows:

☐ I am a citizen of the United States OR

☐ I am a qualified alien under the Federal Immigration and Nationality Act, my Immigration status and alien number are as follows and I am providing a copy of my USCIS documentation.

I hereby attest that my response and the information provided on this form and any related application for public benefits are true, complete and accurate and I understand that this information may be used to verify my lawful presence in the United States.

Name (Type or print first, middle, last)	Signature	Date

11.
CERTIFICATION
(This Item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1.a., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services, Title 180, Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief. I am authorized to make binding commitments and to sign official documents on the behalf of the applicant.

_____
Applicant Name From Item 1.a.

_____

By: _____ *Date:* _____
Signature

_____
Print Name and Title of certifying official authorized to act on behalf of the applicant

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Appendix B

NRH –7A Form
Medical Use Training and Experience and Preceptor Attestation

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE - MEDICAL
NRH - 7A
Medical Use Training and Experience and Preceptor Attestation
Part 1 - Training and Experience

Follow Regulatory Guide for NRH 7A "Medical Use Training & Experience and Preceptor Statement" when determining what information is needed for each type of medical use license.

Note: Description of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulations in 180 NAC 7.

1. Name of Individual: _____

Address:_____

Telephone Number: _____**FAX Number:**_____

E-Mail Address:_____

2. Is the individual a physician or pharmacist who is licensed to dispense drugs in the practice of medicine in Nebraska?

☐ YES (If Yes, list the Nebraska Medical or Pharmacist License #) License #:_____

☐ NO

3. Authorization

☐ **On a current license or permit** (Provide a copy of the license or broadscope permit listing the current authorization)

The individual is identified on a license or permit as a:

- ☐ Radiation Safety Officer for medical use licensee
- ☐ Authorized Medical Physicist
- ☐ Authorized Nuclear Pharmacist
- ☐ Authorized User for _____ use(s).

☐ The license or permit number _____.

☐ The individual is seeking additional authorization, as a:

- ☐ Radiation Safety Officer for medical use licensee
- ☐ Authorized Medical Physicist
- ☐ Authorized Nuclear Pharmacist
- ☐ Authorized User for _____ use(s).

4. Certification

Specialty Board	Category	Month and Year Certified

5. Classroom and laboratory training

Description of Training	Location of training	Dates of Training	Clock Hours in Lecture or Laboratory

6. Work Experience

6.A. Work Experience with Radiation.

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience

6.B. Supervised Clinical Experience (describe experience elements in 6.A.)

Isotope	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Radioactive Materials License Number	Date and/or Clock Hours of Experience

6.C. Training for Radiation Safety Officer, Medical Physicist, Authorized Use of sealed sources for diagnosis or Authorized User of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

Training Element	Type of Training*	Locations and Dates

*Types of training may include supervised didactic, or vendor training.

6.D. Formal Training

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Material License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education and the Applicable Regulation)

7. One Year Full-Time Experience and/or Training

7.A. Radiation Safety Officer

☐ YES
☐ NA

Completed one year of full-time radiation safety experience (in areas identified in 6.A.) under the supervision of_____ the RSO of License No. _____.

7.B. Medical Physicist

☐ YES
☐ NA

Completed one year of full-time training (in areas identified in 6a) in medical physics under the supervision of _____ who meets the requirements of a authorized medical physicist or meets the requirements for Authorized Medical Physicist.

AND

☐ YES
☐ NA

Completed one year of full-time experience (at location providing radiation therapy services described and for topic identified in item 5.A.) for (specify use or device)_____ under the supervision of _____ who is meets the requirements for Authorized Medical Physicists (180 NAC 7-023 (specify use or device) _____.

8. Supervising Individual – Identification and Qualifications

The training and experience indicated above was obtained under the supervision of (*if more than one supervising individual is needed to meet requirements in 180 NAC 7, provide the following information for each):*

8.A. Name of Supervisor

_____

8.B. Supervisor is:

☐ Authorized User ☐ Authorized Medical Physicist

☐ Radiation Safety Officer ☐ Authorized Nuclear Pharmacist

8.C. The supervisor meets the requirements of 180 NAC 7-_____ for medical uses in 180 NAC 7-_____.

8.D. Authorized User on Radioactive Material License Number:

8.E. Licensee Name:
Licensee Address:

Nebraska Department of Health and Human Services

SUPPLEMENT A Medical Use Training and Experience and Preceptor Attestation

Part 2—Preceptor Attestation

Note: *The individual's preceptor must complete this part. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.*

9. Preceptor Attestation

9.A. I attest that _____(name of individual named in Item 1):

☐ has satisfactorily completed the requirements in 180 NAC 7-_____, as documented in this application.

9.B. ☐ meets the requirements of 180 NAC 7-_____ for types of use, as documented in section(s)_____ of this form.

9.C. ☐ has achieved a level of competency and radiation safety knowledge sufficient to function independently as a: (check one)

☐ Radiation Safety Officer for a medical use licensee

☐ Authorized Medical Physicist

☐ Authorized Nuclear Pharmacist

☐ Authorized User for _____ uses.

9.D. I am a

☐ Authorized User ☐ Authorized Medical Physicist

☐ Radiation Safety Officer ☐ Authorized Nuclear Pharmacist

I meet the requirement of 180 NAC 7-_____ for medical uses in 180 NAC 7-_____.

9.E. Preceptor on Radioactive Material License #:	**9.F.** Licensee Name: Licensee Address:

9.G. Name of Preceptor (type or print clearly)	Signature --Preceptor	Date

Appendix C

Supportive Information Requested in Items 5 through 10 of NRH FORM 7

Appendix C
License Application Checklists
Items 4 through 10 of NRH FORM 7

This Appendix contains checklists that may be used to assist in organizing an application.

Table C-1, Applicability Table
Table C.1, Applicability Table, may be used to determine if particular information must be provided or if "N/A" (not applicable) may be the response to each item that follows. To determine those items to which you must respond, "highlight" the columns under the categories of materials you requested in Item 5 (e.g., 180 NAC 7-048, 7-055, etc.). If any "Y" beside an item is highlighted, you must provide detailed information in response to that item. If the letters "N/A" are highlighted, you may respond "N/A" on your application. If any "N" beside an item is highlighted, no information in response is required, but the Agency regulations that apply to the given category apply to your type of license. If any "G" beside an item is highlighted, see subsequent sections for required responses.

Table C.1 Applicability Table								
Item #	**Topic**	**180 NAC 7-041 & 7-044**	**180 NAC 7-048**	**180 NAC 7-055**	**180 NAC 7-065**	**180 NAC 7-067**	**180 NAC 7-085**	**APPENDIX**
II.B.	Fees	Y	Y	Y	Y	Y	Y	
4.A.	Training & Experience	G	G	G	G	G	G	See RG for Form NRH-7A
4.B.	Authorized User(s) (AUs)	Y	Y	Y	Y	Y	Y	
4.C.	Authorized Nuclear Pharmacist (ANP)	Y	Y	N/A	N/A	N/A	Y	
4.D.	Authorized Medical Physicist (AMP)	N/A	N/A	Y*	N/A	Y	Y	
5.A.	Radiation Safety Officer (RSO)	Y	Y	Y	Y	Y	Y	See RG for Form NRH7A & App. F
5.B.	Radiation Safety Comm.		Y	Y		Y	Y	
6.	Unsealed Radioactive Material – Uptake, Dilution, Excretion, Imaging and Localization Studies	Y						
6.	Unsealed Radioactive Material Written Directive Required		Y					
6.	Manual Brachytherapy			Y				
6.	Sealed Sources for Diagnosis				Y			
6.	Teletherapy Unit					Y		
6.	Remote Afterloader Unit					Y		
6.	Gamma Sterotactic Radiosurgery Units					Y		
6.	Other Medical Uses						Y	
6.	Sealed Sources and Devices	N	N	Y	Y	Y	Y	
6.	Financial Assurance Determination	Y	Y	Y	Y	Y	Y	
7	Facilities & Equipment	G	G	G	G	G	G	
7.A.	Facility Diagram	Y	Y	Y	Y	Y	Y	
7.B.	Instrumentation	Y	Y	Y	Y	Y	Y	G
7.C.	Dose Calibrator and Other Equipment	Y	Y	N/A	N/A	N/A	Y	H
7.D.	Therapy Unit-Calibration and Use	N/A	N/A	N	N/A	Y	N	
7.E.	Other Equipment and Facilities	N	N	N	N	Y	N	X
8.	Radiation Protection Program	G	G	G	G	G	G	
8.A	Safety Procedures and Instructions	NA	NA	NA	NA	Y	Y	
8.B	Safety Instruction of Individual in Restricted Areas	Y	Y	Y	Y	Y	Y	I
8.C.	Operating and Emergency Procedures	Y	Y	Y	Y	Y	Y	S
8.D.	Safe Use of Unsealed Licensed Material	Y	Y	NA	NA	NA	Y	K
8.E.	Radioactive Gases and Aerosols	Y	NA	NA	NA	NA		Y
8.F.	Minimization of Contamination	Y	Y	Y	Y	Y	Y	
8.G.	Ordering and Receiving	Y	Y	Y	Y	Y	Y	L

Item #	Topic	180 NAC 7-041 & 7-044	180 NAC 7-048	180 NAC 7-055	180 NAC 7-065	180 NAC 7-067	180 NAC 7-085	APPENDIX
8.H.	Opening Packages	Y	Y	Y	Y	Y	Y	M
8.I	ALARA	Y	Y	Y	Y	Y	Y	Z
8.J	Occupational Dose	Y	Y	Y	Y	Y	Y	N
8.K	Area Surveys	Y	Y	Y	Y	Y	Y	O
8.L.	Installation, Maintenance, Adjustment, Repair Service of Therapy Devices Containing Sealed Sources	NA	NA	NA	NA	Y	Y	AA
8.M.	Written Directive Procedures	Y	Y	Y	Y	Y	Y	P
8.N	Safety Procedures for Treatments when Patients are Hospitalized	NA	Y	Y	NA	Y**	Y	
8.O.	Release of Patients or Human Research Subjects	Y	Y	Y	Y	Y	Y	Q
8.P	Mobile Medical Service	Y	Y	Y	Y	Y	Y	E
8.Q	Leak Tests	Y	Y	Y	Y	Y	Y	R
8.R	Public Dose	N	N	N	N	N	N	
8.S.	Audit Program	N	N	N	N	N	N	S
8.T	Sealed Source Inventory	N	N	N	N	N	N	
8.U	Records of Dosages and Use of Brachytherapy Source	N	N	N	N	N	N	
8.V	Recordkeeping	N	N	N	N	N	N	T
8.W	Reporting	N	N	N	N	N	N	U
8.X	Transportation	N	N	N	N	N	N	V
9.	Waste Management	Y	Y	Y	Y	Y	Y	W
10.	Citizenship Attesation	Y	Y	Y	Y	Y	Y	
11.	Certification	Y	Y	Y	Y	Y	Y	

* Y beside item 4D for use under 180 NAC 7-055 applies to SR-90 only.
**N/A for teletherapy and gamma stereotactic radiosurgery outpatient treatments.

Table C-2
Check list for Items 4 through 6 on NRH 7:

Table C.2 contains a checklist that may be used to identify the attached documents that the applicant is supplying for items for which a response is required. For example, an applicant may check the box in Item 7A Facility Diagram and include a copy of the facility diagram. An applicant may attach the checklist and include it in the license application.

Table C.2 Item 4 through 6 on NRH-7: (Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate option being used by applicant	Check box to indicate material included in application
Item 4.A.: Individual User(s)			
	Listed the Name and Title of individual(s) who will use or directly supervise use of Radioactive Materials and for which uses. This can be completed on the NRH-7,or on additional 8½" x 11" paper Example below.	☐	☐

First Name & Middle Initial	Last Name	Title	Place a checkmark for each use of material in 180 NAC						
			7-041	7-044	7-048	7-055	7-065	7-067	7-085

	Completed a NRH-7A for each individual listed above. **AND**	☐	☐
	Referred to "Regulatory Guide for Form NRH 7A – Medical Training & Experience and Preceptor Statement" for information on completing NRH-7A	☐	☐
Item 5: Radiation Safety			
	5.A. Radiation Safety Officer (RSO)		
	List the Name and phone number of the Radiation Safety Officer on the NRH-7 or as an attachment	☐	☐
	Completed a NRH-7A for the RSO and attached **AND**	☐	☐
	Referred to "Regulatory Guide for Form NRH 7A – Medical Training & Experience and Preceptor Statement" for information on completing	☐	☐
	5.B. Radiation Safety Committee		
	A description of the Radiation Committee is attached per 180 NAC 7-015.08.	☐	☐

Item 6: Radioactive Material Data	

Below are detailed responses that may be used for Items 6 on Form NRH 7 for type of radioactive material requested and purposes for which it will be used. For example, if the applicant is seeking a license for unsealed radioactive material under 180 NAC 7-041 or 7-044, then the applicant should check the "yes" column next to NRH 7-041 and 7-044 below. The table then indicates appropriate responses for that type of use. An applicant may attach the checklist and include it in the license application

.Item 6 A. on NRH 7A: Radioactive Material and Use

(If using this checklist, check applicable rows and fill in details and attach to the application.)

Yes	Radioactive Material	Chemical/Physical Form	Maximum Activity Requested	Use of Each Form
☐	Any radioactive material permitted by 180 NAC 7-041	Any	As needed	Any uptake, dilution and excretion study permitted by 180 NAC 7-041
☐	Any radioactive material permitted by 180 NAC 7-044	Any	As needed	Any imaging and localization study permitted by 180 NAC 7-044
☐	Any radioactive material permitted by 180 NAC 7-048	Any	____millicuries	Any radiopharmaceutical therapy procedure permitted by 180 NAC 7-048
☐	Iodine-131	Any	____millicuries	Administration of I-131 sodium iodine
☐	Any radioactive material permitted by 180 NAC 7-055 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No._____)	____millicuries	Any brachytherapy procedure permitted by 180 NAC 7-055
☐	Any radioactive material permitted by 180 NAC 7-055 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No._____)	____millicuries	Any brachytherapy procedure permitted by 180 NAC 7-055
☐	Any radioactive material permitted by 180 NAC 7-055 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No._____)	____millicuries	Any brachytherapy procedure permitted by 180 NAC 7-055
☐	Any radioactive material permitted by 180 NAC 7-055 (Radionuclide _____)	Sealed source or device (Manufacturer _____, Model No._____)	____millicuries	Any brachytherapy procedure permitted by 180 NAC 7-055
☐	Strontium-90	Sealed source or device (Manufacturer _____, Model No._____)	____millicuries	Treatment of superficial eye conditions using an applicator distributed per 10 NAC 3-014.12
☐	Radioactive material permitted by 180 NAC 7-065 Check all that apply ☐ Gd-153 ☐ I-125 ☐ Other, describe	Sealed source or device (Manufacturer _____, Model No._____)	____curies per source and ____curies total	Diagnostic medical sue of sealed sources permitted by 180 NAC 7-065 in compatible devices registered per 180 NAC 3-010
☐	Iridium-192	Sealed source or device (Manufacturer _____, Model No._____)	____curies per source and ____curies total	One source for medical use permitted by 180 NAC 7-067, in a Manufacturer _____ Model No. _____ Remote afterloading brachytherapy device. One source in its shipping container as necessary for replacement of the source in the remote afterloader device.

.Item 6 A. on NRH 7A: Radioactive Material and Use *(If using this checklist, check applicable rows and fill in details and attach to the application.)*				
Yes	**Radioactive Material**	**Chemical/Physical Form.**	**Maximum Activity Requested**	**Use of Each Form**
☐	Cobalt-60	Sealed source or device (Manufacturer _____, Model No._____)	____curies per source and ____curies total	One source for medical use permitted by 180 NAC 7—067 in a Manufacturer _____ Model No. _____ therapy unit. One source in its shipping container as necessary for replacement of the source in the teletherapy unit.
☐	Cobalt-60	Sealed source or device (Manufacturer _____, Model No._____)	____curies per source and ____curies total	For medical use permitted by by 180 NAC 7—067 in a Manufacturer _____ Model No. _____ stereotactic radiosurgery device. Sources in the shipping container as necessary for replacement of the source in the stereotactic radiosurgery device.
☐	Any radioactive material under 180 NAC 3-008.09	Prepackaged kits	_____ millicuries	In vitro studies
☐	Depleted uranium	Metal	_____ kilograms	Shielding in teletherapy unit.
☐	Depleted uranium	Metal	_____ kilograms	Shielding in a linear accelerator.
☐	Any radionuclide in excess of 30 millicures for use in calibration, transmission, and reference sources. (List radionuclide: _____)	Sealed source or device (Manufacturer _____, Model No. _____)	_____ millicuries	For use in a Manufacturer_____ Model No. _____ Calibrated and checking of licensee's survey instruments.
☐	Americium-241	Sealed source or device (Manufacturer _____, Model No. _____)	_____ millicuries per source and _____ millicuries total	Use as an anatomical marker
☐	Plutonium (principal radionuclide Pu-238)	Sealed Sources	_____ millicuries per source and _____ grams total	As component of Manufacturer _____ Model No._____ Nuclear-powered cardiac pacemakers for clinical evaluation in accordance with manufacturer's protocol dated _____. This authorization includes: follow-up, explanation, recovery, disposal, and implantation.
☐	Other	Form or Manufacturer/ _____ Model No. _____	_____ millicuries	Purpose of use _____.

Item Number and Title	Suggested Response	Check box to indicate option being used by applicant	Check box to indicate material included in application
Item 6.B. Radioactive material for Uses not listed in Item 6.A.			
	Item 6B is completed on the NRH-7,or on additional 8½" x 11" paper	☐	☐

Radioactive Material	Chemical/Physical Form	Maximum Activity Requested	Use of Each Form

	Suggested Response	Check box to indicate option being used by applicant	Check box to indicate material included in application
Item 6.C. Decommissioning and Financial Assurance			
	All licensees are required to maintain records important to decommissioning. Licensees authorized to possess licensed material in excess of the limits specified in 180 NAC 3-018 must provide evidence of financial assurance for decommissioning.	☐	☐

Table C-3
Checklist for Items 7 through 9 on NRH 7

Table C-3 Checklist for Item 7 through 9 on NRH-7: (Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

	Suggested Response	Check box to indicate option being used by applicant	Check box to indicate material included in application
Item 7: Facilities and Equipment			
7.A: Facility Diagram	"A diagram is enclosed that describes the facilities and identifies activities conducted in all contiguous areas surrounding the area(s) of use. The following information is included:"	☐	☐
	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 under the heading "Discussion" in RG 7.0.		
	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.).		
7.B. Radiation Monitoring Instruments	Part 1 of Appendix G is attached if Table C-3 of Appendix C(checklist) is not attached as part of the application. **AND**	☐ **OR** ☐ NA if Table C-3 is being attached to application	☐
	"We are providing a list of radiation monitoring instruments. It includes manufacturer, model instrument type, sensitivity, range for each type of radiation detected and state whether the instrument will be used for measuring or detection." **AND**	☐	☐
	"If only one survey instrument is to be used describe what is done when the survey instrument is being calibrated or repaired." **AND**	☐	☐
	"We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used." **AND**	☐	
	"Radiation monitoring instruments will be calibrated by a person authorized by the Department, U.S. NRC or an Agreement State to perform survey meter calibrations. A copy of the license authorizing such services will be maintained." **OR**	☐	
	"A description of the instrumentation (e.g. gamma counter, solid state detector, portable of stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys." **AND ONE OF THE FOLLOWING**	☐	☐

	"We will follow survey meter calibration procedures in accordance with Appendix G of Regulatory Guide 7.0." **OR**	☐	
	"We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirement in 180 NAC 4-021 and that meet the requirements of 180 NAC 7-030. An the procedures are attached"	☐	☐
7.C.Dose Calibrator and Other Dosage Measuring Equipment	Not applicable. (Will only use unit doses or no unsealed radioactive material use.) **OR**	☐	
	"This facility will perform dose calibrator calibrations using the procedures in Appendix H.**"** **OR**	☐	
	"This facility will perform dose calibrator calibrations using equivalent procedures which are attached."	☐	☐
7.D. Therapy Unit – Calibration and Use	"We have attached Procedures per 180 NAC 7-076, 77 & 78 (For Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Unit.)" **OR**	☐	☐
	Not Applicable.	☐	
7E. Other Equipment and Facilities	Not Applicable. **AND**	☐	
	"Appendix X is attached if Table C-3 of Appendix C (checklist) is not attached as part of the application." **AND**	☐ **OR** ☐ NA if Table C-3 is being attached to application	☐
	"We have attached detailed descriptions of additional equipment and facilities available for the safe use and storage of radioactive materials requested are attached." (Place checkmark by items included.)	☐	☐
	For manual brachytherapy facilities, we are providing a description of the emergency response equipment.	☐	☐
	For teletherapy, GSR, and remote afterloader facilities, we are providing 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;	☐	☐
8. Radiation Protection Program			
8.A. Safety Procedures and Instructions	"We have attach Safety Procedures and Instructions per 180 NAC 7-070 (For Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Unit)." **OR**	☐	☐
	Not Applicable☐	☐	

8B. Safety Instructions for Individuals Working in or Frequenting Restricted Area	"We will follow Appendix I Procedures of RG 7.0 and will implement and maintain procedures for a training program for safe use of radioactive materials." **OR**	☐	
	"Equivalent procedures have be developed and will be implement and maintain for a training program for safe use of radioactive materials. The safety training procedures for individuals working or frequenting restricted areas meet the requirements of 180 NAC 10-002, 7-049, 7-058, 7-070 and 7-018. Equivalent procedures are attached."	☐	☐
8.C. Operating and Emergency Procedures	"We will provide Operating and Emergency Procedures" **AND**	☐	☐
	"We will use Appendix J for spill procedures" **OR**	☐	
	"Equivalent spill procedures are attached that will be used."	☐	☐
	And one of the following		
	"Attachment 1 of Appendix J will be used." **OR**	☐	
	"Equivalent attachment is attached that will be used."	☐	☐
8.D. Safe Use of unsealed Licensed Material	"Appendix K Procedures of RG 7.0 will be implemented and maintained for safe use of unsealed radioactive material." **OR**	☐	
	" We have developed and will implement and maintain equivalent procedures for safe use of unsealed radioactive material that meet the requirement of 180 NAC 4-004 and 4-013. Attach the procedures." **OR**	☐	☐
	Not Applicable	☐	
8.E. Radioactive Gases and Aerosols	"Appendix Y Procedures of RG 7.0 will be implemented and maintained for safe use of radioactive gases and aerosols." **OR**	☐	
	"We have developed and will implement and maintain written procedures for safe use of radioactive gases and aerosols and the procedures are attached. **OR**	☐	☐
	Not Applicable	☐	
8.F Minimization of Contamination	"We have attached a description of 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."	☐	☐
8.G Ordering and Receiving	"We have attached procedures for receipt and accountability of radioactive material." **AND**	☐	☐
	"Appendix L of RG 7.0 will be implemented and maintained for opening and receiving packages that contain radioactive materials." **OR**	☐	
	"Equivalent procedures for receiving and opening packages that contain radioactive material are attached ".	☐	☐
8.H. Opening and Receiving Packages	"Appendix M of RG 7.0 will be used and maintained for Opening and Receiving Packages containing radioactive material." **OR**	☐	
	"We have attached procedures will be implemented and maintained for Opening and Receiving Packages containing of radioactive material."	☐	☐

8.I. ALARA	"We used Appendix Z f RG 7.0 for developing, maintaining and implementing procedures and precautions for use of Radioactive Gases ." **AND**	☐	
	"We have attached procedures that will be implemented and maintained for ALARA. Procedures are attached	☐	☐
8.J. Occupational Dose	"Part 1 of Appendix N is attached if Table C-3 of Appendix C (checklist) is not attached as part of the application **AND**	☐ **OR** ☐ NA if Table C-3 is being attached to application	☐
	"We will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 180 NAC 4." The evaluation is attached. **OR**	☐	☐
	"Appendix N of RG7.0 will be used and maintained for Occupational Dose Procedures followed." **OR**	☐	
	"We will provide dosimetry that meets the requirement of 180 NAC 4 and will attach equivalent procedures for an Occupational Dose Program"	☐	☐
8.K. Area Surveys	"We will implement and maintain Appendix O of RG 7.0 for area surveys." **OR**	☐	
	"We have developed and will implement and maintain written procedures for area surveys in accordance with 180 NAC 4-004 that meet the requirements of 180 NAC 4-021 and 180 NAC 7-036."	☐	☐
8.L. Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources	Not Applicable **OR**	☐	
	"We will contract with personnel who are licensed by the Department, the NRC or an Agreement State to perform maintenance and repair services on the specific therapy device(s) possessed by the licensee." **Or the following three conditions must be met**	☐	
	"We will name the proposed employee or employees and types of maintenance and repair requested. AND Will provide a description of the training and experience demonstrating that the proposed employee or employees is/are qualified by training and experience for the use requested. AND Will provide a copy of the manufacturer's training certification and an outline of the training."	☐	☐
8.M. Procedures for Administration when a Written Directive is Required	"We will use Appendix P of RG 7.0 for developing, maintaining and implementing written procedures." **OR**	☐	
	"We will use equivalent procedure that are attached." However the licensee can revise the procedures to enhance effectiveness without obtaining Agency approval as long as health and safety is not compromised. **OR**	☐	☐
	Not Applicable	☐	

8.N Safety Procedure for Treatments when Patients are Hospitalized	"We have attached the safety procedures that will be used for treatments when patients are hospitalized." **OR**	☐	☐
	Not Applicable	☐	
8.O Release of Patients or Human Research Subjects	"We will implement and maintain Appendix Q of RG 7.0 for the release of patients or human research subjects." **OR**	☐	
	"We have attached the equivalent procedures for the release of patients or human research subjects that will be used and maintained." **OR**	☐	☐
	Not Applicable	☐	
8.P Mobile Medical Service	"We have attached Mobile Medical Service Procedures that will be used." (Check Appendix E for additional information that the applicant will need to be provided for a mobile medical service license.) **OR**	☐	☐
	Not Applicable	☐	
8.Q Leak Tests	Part 1 of Appendix R is attached if Table C-3 of Appendix C (checklist) is not attached as part of the application. **AND**	☐ **OR** ☐ NA if Table C-3 is being attached to application	☐
	"We will implement and maintain Appendix R of RG 7." **OR**	☐	
	"We will provide Equivalent Leak Test Procedures and they are attached."	☐	☐
	AND	☐	☐
	"Leak tests will be performed at intervals approved by the Department, an Agreement State or by the NRC and specified in the Sealed Source and Device Registration Certificate." **AND**	☐	
	"Leak tests will be performed by an organization authorized by the Department, an Agreement State or the U.S. Nuclear Regulatory Commission to provide leak testing services for other licensees." **OR**	☐	
	"Leak test kit will be supplied by an organization authorized by the Department, an Agreement State or U.S. Nuclear Regulatory Commission to provide leak test kits to other licensees and according to the kit supplier's instructions. Records for leak test results will be maintained."	☐	
8.R Public Dose	The applicant is not required to submit a response to the public dose section during the licensing phase. This matter will be examined during an inspection.		
8.S Audit Program	The applicant is not required to submit a response to the audit program during the licensing phase. This matter will be examined during an inspection.		
8..S. Sealed Source Inventory	The applicant is not required to submit a response to the sealed source inventory program during the licensing phase. This matter will be examined during an inspection.		
8.U. Records of Dosages and Use of Brachytherapy Source	The applicant is not required to submit a response to the records of dosages and use of brachytherapy source during the licensing phase. This matter will be examined during an inspection.		
8.V.Record-keeping	The applicant is not required to submit a response to the recordkeeping program during the licensing phase. This matter will be examined during an inspection.		
8.W. Reporting	The applicant is not required to submit a response to reporting during the licensing phase. This matter will be examined during an inspection.		

9. Waste Management			
	"We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 180 NAC 4-0004, that also meet the requirements of the applicable section of 180 NAC 4-039 through 4-045 and 180 NAC 7-040." And the procedures are attached. **OR**	☐	☐
	"We will implement and maintain Appendix W of RG 7.	☐	☐
10. Citizenship Attestation			
	Check appropriate box(s) and sign if required..	☐	☐
11. Certification			
	Sign the application by representative authorized to make binding commitments.	☐	☐

Appendix D

NRH-60
Certificate of Disposition of Materials

Form NRH-60
Effective Date July 11, 2009

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH
RADIOACTIVE MATERIALS PROGRAM

CERTIFICATION OF DISPOSITION OF MATERIALS

INSTRUCTIONS - (Use additional sheets where necessary.)
Type or Print except where indicated.
Retain one copy for your files and submit original application to: Department of Health and Human Services , Division of Public Health Radiological Health, 301 Centennial Mall South, P.O. Box 95026, Lincoln, NE 68509-5026.
Upon approval of this Certification of Disposition of Materials the licensee will receive a termination notice of this radioactive material license.

1. Licensee Information

Licensee Number:_____

License Expiration Date:_____

2. Person to Contact Regarding this Application

_____

Telephone #:_____

Licensee Name and Street Address:

Applicant Name: _____

Address: _____

_____

City, State Zip+4 _____

Telephone #: _____

FAX#: _____

E-mail Address:

3. Materials Data

☐ No Materials have ever been procured or possessed by the Licensee under this License.

☐ All Materials procured and/or possessed by the Licensee under the License Number cited above have been disposed of in the following manner:

☐ Transfer
Specify the date of the transfer, the name of the licensed recipient and the recipient's Agency, NRC or Agreement State license number.
Describe specific materials transfer actions and if there were radioactive wastes generated in terminating this license, the disposal actions, including the disposition of low-level radioactive waste, mixed waste, Greater-than-Class-C waste, and sealed sources, if applicable.

☐ Disposed of directly by Licensee
Describe specific disposal procedures (e.g. decay in storage).

4. Other Data

☐ Our License has not yet expired, please terminate it.
A Radiation Survey was conducted to confirm the absence of licensed radioactive materials and to determine whether any contamination remains on the premises covered by the license:

☐ NO (Attach Explanation)

☐ YES, the results:

☐ Are attached

☐ Were forwarded to the Agency on (Date)_____

4. Other Data *(Continued)*

Address all future correspondence regarding this license to:

Name:

Address:

City, State Zip+4:

Telephone #:

FAX#:

E-mail Address:

5. CERTIFICATION
(This item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services, Title 180, Regulations for the Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

Applicant Name From Item 1.

By: _____ *Date:* _____
Signature

_____
Print Name and Title of certifying official authorized to act on behalf of the applicant

Appendix E

Guidance for Mobile Medical Services

Appendix E
Guidance for Mobile Medical Services

Mobile medical service providers must comply with all applicable sections of 180 NAC 7 and 10 CFR 71 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 180 NAC 7-067 through 7-084.

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.

Licensees must 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 180 NAC 7-038.08 and 7-097. Additionally, as required by 180 NAC 7-038.06, the licensee must survey to ensure compliance with the requirements in 180 NAC 4 (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 are 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. You should 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 180 NAC 3-011 and 180 NAC 7-008, you must submit a description and diagram(s) of the proposed base facility and associated equipment in accordance with Items 7.A. through 7.E. of this report. 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 180 NAC 4-013. Include a diagram showing the location of the licensed material, receipt, and use areas, and identify all areas adjacent to restricted areas, including areas above and below the restricted areas. For storage locations within a van, the description of the van should address radiation levels in the van driver's compartment to demonstrate compliance with 180 NAC 4-005, "Occupational dose limits for adults."

- You 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.

- If a base facility is located in a residential area, provide the following information:
  - Justification of the need for a private residence location rather than for a commercial location.
  - Documentation of the agreement between the residence owner and the licensee. It is essential that the mobile medical service have access to the facility in the event of contamination. Provisions for decontamination of the mobile medical service van, etc., on the client property (if necessary) will be included. Documentation from both parties will illustrate the agreement between the client and the mobile medical service.
  - A description of the program demonstrating compliance with 180 NAC 4-013, "Dose limits for individual members of the public."
  - Verification that restricted areas do not contain residential quarters.

- Perform surveys necessary to show that exposure rates do not exceed 2 mrem in any one hour nor 100 mrem per year.

Client Site

This section applies only to therapeutic uses of radioactive material. For all types of therapy 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) you should provide the following additional facility information:

- For therapy treatments with radioactive material (e.g., high dose-rate remote afterloader), 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 180 NAC 7-009, 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 you will provide transportable services to the client's site for use within the client's facility by the mobile medical service's employees, you should 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 7.A. through 7.E.of this report. 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 180 NAC 4-013. You should 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 180 NAC 7-009, 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 180 NAC 7-074, 7-077 and 7-079.

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, you must ensure the following:

- Each client is properly licensed for medical use of radioactive material. If applicable, you should 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 180 NAC 7-018, transfer to the client's AUs 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 180 NAC 3-030, 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 180 NAC 10-003, 180 NAC 7-018 requires that you 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 180 NAC 7-018, you 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 180 NAC 7, [e.g., 180 NAC 7-038 and 7-079 (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 180 NAC 10-003, 180 NAC 7-018, 7-049, 7-058 and 7-070 (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 180 NAC 7-038, you will 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, you 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 your radiation protection program required by 180 NAC 4-004. You should indicate typical response times of the RSO and AU in the event of an incident 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 should 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 this Agency and all appropriate state radiological protection agencies; Radiological Health during office hours (Monday – Friday 8AM -5PM) (402)471-2168 OR After hours Nebraska State Patrol (402)471-4545 (Ask to speak to the NEMA Duty Officer as you have an incident involving radioactive material.)
- 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 AMP. If any problem is found, including remote afterloader device interlocks and operation, the remote afterloader device or facility will be repaired and recertified by the device vendor prior to return to service. In addition, a copy of the report, generated in accordance with 180 NAC 3-026, 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 170–189. 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 material is secured during transport and use at the client's facilities.
- Radioactive waste is handled properly during transport. You 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. You 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 Section 9

of this report.

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 180 NAC 4-041. 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 Agency 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 180 NAC 4-005 and 4-013, that the external surfaces of the van do not exceed 2 mrem/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 180 NAC 7-077 and the additional spot checks required by 180 NAC 7-079 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.
- You must maintain records, as described in 180 NAC 7-110 and 7-112, showing the results of the above safety checks for Agency 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 F

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Appendix F
Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Model RSO Duties and Responsibilities

The RSO's duties and responsibilities include ensuring radiological safety and compliance with Agency and DOT regulations and the conditions of the license. Model procedures for describing the RSO's duties and responsibilities appear below. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of 180 NAC 7-015. Typically, these duties and responsibilities include ensuring the following:

- Stopping unsafe activities involving licensed material;
- Radiation exposures are 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 licensed 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 an Agency, U.S. Nuclear Regulatory Commission or Agreement State license;
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed 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;
- Licensed 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 licensed material, damage to or malfunction of sealed sources, and fire;
- Medical events and precursor events are investigated and reported to Agency, 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;
- Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Licensed 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.

Model Delegation of Authority

Memo To: Radiation Safety Officer
From: Chief Executive Officer
Subject: Delegation of Authority
You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. 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 do not cooperate and do not address radiation safety issues. In addition, you are free to raise issues with the Nebraska's Radiation Control Program at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

I accept the above responsibilities,

_____	_____
Signature of Management Representative	Signature of Radiation Safety Officer
_____	_____
Date	Date

cc: Affected department heads

Appendix G

Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

Appendix G
Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program
PART 1

- ☐ We will attach a list of survey instruments possessed. The list will include the manufacturer, model, instrument type, sensitivity, range for each type of radiation detected and state whether the instrument will be used for 'measuring' or 'detection.' Additionally if only one survey instrument is to be used we will describe what is done when the survey instruments is being calibrated or repaired

AND

- ☐ We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.

AND

- ☐ We will use radiation monitoring instruments that will be calibrated by a person authorized by the Department, U.S. NRC or an Agreement State to perform survey meter calibrations. A copy of the license authorizing such services will be maintained.

OR

- ☐ We will provide a description of the instrumentation (e.g. gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys or leak testing and analysis.

AND ONE OF THE FOLLOWING

- ☐ We will follow survey meter calibration procedures in accordance with Appendix G of Regulatory Guide 7.0.

OR

- ☐ We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirement in 180 NAC 4-021 and that meet the requirements of 180 NAC 7-030 and the procedure is attached."

Part 2 of Appendix G
Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

Survey Instruments Records

The facility will assure that all survey instruments will be calibrated before first use and at least every 12 months thereafter and after repair. The calibration record will include:

1. A description of the source used;
2. The certified dose rates from the source;
3. The rates indicated by the instrument being calibrated;
4. The correction factors deduced from the calibration data;
5. The signature of the individual who performed the calibration; and
6. The date of the calibration.

The record will be maintained for three years for inspection.

Calibration of Survey Instruments
Exposure Rate and Contamination Instruments
(Does not include pocket dosimeters or chirpers)

1. ***Calibration of survey meters shall be performed with radionuclide sources***.

   A. The sources shall approximate point sources for dose rate instruments and planchet sources for beta detectors.

   B. The source activities, exposure rates, or beta emission rates at given distances shall be traceable by documented measurements to a standard source certified within five percent accuracy by the National Institute of Standards and Technology (NIST, formerly NBS).

   C. The frequency shall be at least every 12 months and after servicing.

   D. Each scale of the instrument shall be calibrated for at least at two points located at approximately 1/3 and 2/3 of full scale. Meters offering an automatically ranging digital display for indicating rates are calibrated at no less than one point on each decade and at not less than two oints on one of the decades. Those points are at approximately 1/3 and 2/4 of the decade.

   E. The exposure rate (mR/hr) for dose rate instruments measured by the instrument shall differ from the true exposure rate by less than 10 percent at the two points on each scale (read appropriate section of the instrument manual to determine how to make necessary adjustments to bring instrument into calibration). Readings within ± 20 percent will be considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret meter readings to within 10 percent accuracy for radiation protection purposes.

      Beta efficiency determination shall be used for calibration of contamination survey instruments.

   F. Records of required calibrations shall be maintained for inspection for a period of at least two years from the date of calibration.

NOTE: Sources of Cs-137, Ra-226, or Co-60 * are appropriate for use in dose rate calibrations. Since these sources emit rather high-energy photons, they are not suitable for low-energy or beta efficiency calibrations which may be required under special circumstances (see Item 3 below). The activity of the calibration standard should be sufficient to calibrate the survey meter on each scale to be used for radiation protection purposes. Scales up to 1 R/hr should be calibrated, but higher-range scales above 1 R/hr need not be calibrated when they will not be needed for radiation protection surveys. If there are higher ranges, they should at least be checked for operation and approximately correct response to radiation. Otherwise, a cautionary note that they have not been checked should be placed on the instrument.

2. A reference check source of long half-life, e.g., Cs-137 or Ra-226, shall also be read at the time of the above calibration or as soon as the instrument is received from a calibration vendor. The readings shall be taken with the check source placed in specific geometry relative to the detector. A reading of this reference check source shall be taken:

   A. Before each use to ensure that the instrument was operational during the survey.

   B. After each maintenance and/or battery change.

   C. At least every three months.

   If any reading using the same geometry is not within ± 20 percent of the reading measured immediately after calibration, the instrument must be recalibrated immediately (see Item 1).

   These procedures and standards are not appropriate for instruments used to detect or quantify measurements in the I-125 (approximately 30 KeV) energy range.

3. ***Calibration source energies must correspond to energies of radioactive materials to be detected*** if instrument response is energy dependent, and if the instrument is to be used for quantitative measurements in the Xe-133 or Tc-99m energy ranges.

   The calibration may be done either:

   A. As in Item 1 above, with NIST-traceable calibration standards of radionuclides at or near the desired energies, or

   B. As a relative intercomparison with an energy-independent instrument and unassumed or uncertified radionuclides.

      Alternatively, the manufacturer's energy response curve(s) may be used to correct instrument readings appropriately when lower-energy radiation is monitored.

4. Records of the above 1, 2B, 2C and 3 must be maintained. Attach a calibration sticker or tag to the instrument. The following information should be included on the sticker or tag:
   1. Date of calibration and the next calibration due date

---

* Minimum activities of typical dose rate sources are 85 mCi of Cs-137, 21 mCi of Co-60, or 3-4 mCi of Ra-226 (to give at least 700 mR/hr at 20 cm).

   2. Reading from the reference check source.
   3. Special use conditions (such as any scales checked for function but not calibrated.

5. **Use of Inverse Square Law and Radioactive Decay Law**

A. An approved calibration source will have a calibration certificate giving its exposure or beta emission rate at a given distance, or its activity, measured on a specified date by the manufacturer or NIST.

(1) The Inverse Square Law may be used with any point source to calculate the exposure rate at other distances.

(2). The Radioactive Decay Law may be used to calculate the exposure rates or source activities at times other than the calibration date.

B. **Inverse Square Law For Dose Rate Calibrations**

Consider a "point" * source of radiation at position S, as shown in Figure D-1. Then, the relationship between exposure rates R_1 and R_2 at detector positions P_1 and P_2, which are at distances D_1 and D_2 and S, respectively is given by the following equation:

$$R_2 = \frac{D_1^2 \times R_1}{D_2^2}$$

Where R1 and R2 are exposure rates in the same units (e.g., mR/hr, R/hr) and D1 and D2 are the distances in Figure D-1 in the same units (e.g., m, cm, ft).

FIGURE D-1

S P_1 P_2

•_____ • _____ •

< ----------D_1---------- > R_1

< ----------D_2 ---------- > R^2

C. **Radioactive Decay Law**

Exposure rate "t" units of time after specified calibration date

$$R_t = R_o \times e - \frac{(0.693)}{T_{½}} \times t$$

Where

R_0 and R_t are in the same units (e.g., mR/hr or R/hr)

R_0 is exposure rate on the specified calibration date.

R_t is exposure rate t units of time later

$T_{1/2}$ and t are in the same units (years, months, days, etc.)

$T_{1/2}$ is the radionuclide half-life.

t is number of units of time elapsed between calibration and present time.

D. **Example** Source output is given by calibration certificates as 100 mR/hr at 1 foot on March 10, 2005. Radionuclide half-life is 5.27 years.

Question What is the output at 3 feet on March 10, 2007 (2.0 years later)?

(1). Output at 1 foot, 2.0 years after calibration date:

$$R = 100 \text{ mR/hr} \times e^{-\frac{(0.693 \times 2.0)}{5.27}}$$

$$= 100 \times 0.77 = 77 \text{ mR/hr at 1 foot on March 10, 2007.}$$

(2). Output at 3 feet, 2.0 years after calibration date:

$$R_3 = \frac{(1 \text{ ft})^2}{(3 \text{ ft})^2} \times 77 \text{mR/hr}$$

$$= 1/9 \times 77 = 8.6 \text{ mR/hr at 3 feet, 2.0 years after calibration.}$$

* A Source may be considered a "point" source when the source and the radiation detector are small, in any dimension, compared to the distances at which radiation is to be measured. The center of the detector should be at distances D_1 or D_2 as shown in Figure D-1

CALIBRATION CHECK SHEET

Check appropriate items.

☐ **1**. ***Survey instruments will be calibrated at least every 12 months and immediately following repair.***

☐ **2.** ***Calibration will be performed at two points on each scale*** used for radiation protection purposes; i.e., at least up to 1R/hr for dose rate.

The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10 percent of the calculated or known values for each point checked. Readings within ± 20 percent are considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings to within ± 10 percent. Also, when higher scales are not checked or calibrated, an appropriate precautionary note will be posed on the instrument.

3. ***Survey instruments will be calibrated***:

☐ **A. By the manufacturer**

☐ **B. By the licensee**

☐ (1) Calibration source(s)

Manufacturer's name _____

Model No. _____

Activity in millicuries _____

OR

Exposure rate at a specified distance _____

Accuracy _____

Traceability to primary NIST standard _____

☐ (2) The calibration procedures in Attachment D, Section 1 will be used

OR

☐ (3) The step-by-step procedures, including radiation safety procedures, ate attached.

☐ **C.** ***By a consultant or outside firm***.

(1) Name & License Number_____

(2) Address _____

(3) Phone Number _____E-Mail_____

SAMPLE FORM
"CERTIFICATE OF INSTRUMENT CALIBRATION"

Licensee Name _____

Instrument:
Manufacturer_____
Type_____
Model No._____
Serial No._____

Probe (if detachable):
Manufacturer_____
Type_____
Model No. _____
Serial No._____

Calibration Data:

Scale	**Actual Exposure or Beta Emission Rate (mR/hr or CPM)**	**Initial Instrument Reading (mR/hr or CPM)**	**% Error**	**Adjusted Instrument Reading (mR/hr or CPM)**	Final % Error

Replace Batteries? ☐ Yes ☐ No

Comments:

Calibration Source:

Manufacturer/Model No._____ Serial No. _____

Nuclide _____ Accuracy _____ Original Activity/Date _____ / _____

Decay Factor _____ Current Activity _____

Exposure Rate at Specified Distance _____

CALIBRATED BY: _____ DATE: _____

Appendix H

Model Procedures for Calibrating Dose Calibrators

PROCEDURE FOR CALIBRATING DOSE CALIBRATORS

Procedures

1. Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. The name of the individual who performed the test will be recorded for all tests. (A licensee shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10% and shall mathematically correct dosage reading (for dosages greater than 30 microcuries) if the geometry or linearity error exceeds 10%.)

   a. Constancy at least once each day prior to assay of patient dosages (±10 percent).

   b. Linearity at installation and at least quarterly thereafter (±10 percent).

   c. Geometry dependence at installation (±10 percent).

   d. Accuracy at installation and at least annually thereafter (±10 percent).

2. After repair, adjustment, or relocation to another building of the dose calibrator, repeat the above tests before use.

3. Constancy means reproducibility in measuring a constant source over a long period time. Assay at least one relatively long-lived source such as Cs-137, Co-60, Co-57, or Ra-226 using a reproducible geometry each day before using the calibrator. Consider the use of two or more sources with different photon energies and activities. Use the following procedure:

   a. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).

   b. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit if it is used.

   c. For each source used, either plot on graph paper or log in a book the activity measured, the model and serial number of the instrument, the identity of the radionuclide contained in the check source, and the date of the check.

   d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.

   e. Notify the RSO or the AU if the test results fall outside +/- 10% of the expected results.

4. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. The linearity of a dose calibrator is ascertained over it's use range between the maximum activity administered and 30 microcuries. This test is done using a vial or

syringe of Tc-99m whose activity is at least as large as the maximum activity normally assayed for administration.

Time Decay Method

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity on the Dose Calibrator Linearity Test Form (see Exhibit H-1).

b. Repeat the assay at approximately four hour intervals during the workday. Continue on subsequent days until the assayed activity is less than 30 microcuries. For dose calibrators on which you select a range with a switch, select the range you would normally use for the measurement.

c. Convert the time and date information you recorded to hours elapsed since the first assay.

d. Record the measured activities, the calculated activities, the time elapsed between measurements, the model number and serial number of the dose calibrator, and the dates of the test.

e. Notify the RSO if the worst deviation is more than +/- 10%.

Shield Method If you decide to use a set of "sleeves" of various thickness to test for linearity, it will first be necessary to calibrate them. You should review the procedure for calibrating sleeves against the manufacturer's instructions. Some sleeve manufacturer's procedures indicate that various sleeves should be stacked to achieve a desired attenuation. In this case procedure modifications may be necessary.

a. Begin the linearity test as described in the decay method described above. After making the first assay, the sleeves can be calibrated as follows. Steps b through d below must be completed within 6 minutes (approximately 1% of the half-life of Tc-99m)

b. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

c. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

d. Continue for all sleeves.

e. Complete the decay method linearity test steps b through e above.

f. From the data recorded in step d of the decay method, find the decay time associated with the activity indicated with sleeve 1 in place. This is the "equivalent decay time" for sleeve 1. Record that time with the data recorded in

step b.

g. Find the decay time associated with the activity indicated with sleeve 2 in place. This is the "equivalent decay time" for sleeve 2. Record that time with the data recorded in step c.

h. Continue for all sleeves.

i. The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

The sleeve set may now be used to test dose calibrators for linearity.

a. Assay the Tc-99m syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.

b. Steps c through e below must be completed within 6 minutes.

c. Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

d. Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

e. Continue for all sleeves.

f. Record the measured activities, the calculated activities, the time elapsed between measurements, the model number and serial number of the dose calibrator, and the dates of the test.

g. Notify the RSO if the worst deviation is more than +/- 10%.

5. Geometry independence means that the indicated activity does not change with volume or configuration. This test should be done using syringes and vials that are representative of the entire range of size, shape, and constructions normally used for injections and a vial similar in size, shape, and construction to the generator and radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that radiopharmaceutical kits are made in 30-cc glass vials and the predetermined safety margin is +/- 10%. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

a. In a small beaker or vial, mix 2 cc of a solution of Tc-99m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with water.

b. Draw 0.5 cc of the Tc-99m solution into the syringe and assay it. Record the volume and activity (millicuries) indicated.

c. Remove the syringe from the calibrator, draw an additional 0.5 cc of water, and assay again. Record the volume and activity indicated.

d. Repeat the process until you have assayed a 2.0-cc volume.

e. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 5 percent error lines above and below the chosen "standard volume."

f. Record the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, and the date of the test.

g. Notify the RSO if any correction factors are greater than 1.1 or less than 0.9, or if any data points lie outside the +/- 10% percent error lines.

h. To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Tc-99m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and activity indicated.

i. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of water, and assay again. Record the volume and activity indicated.

j. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.

k. Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all the other volumes, divide the standard activity by the activity indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal 10 % error lines above and below the chosen "standard volume."

l. Record the model and serial numbers of the dose calibrator, the configuration of the source measured, the activity measured for the volume measured, and the date of the test.

m. Notify the RSO if any correction factors are greater than 1.1 or less than 0.9 or if any data points lie outside the +/- 10 percent error lines.

6. Accuracy means that, for a given calibrated reference source, the indicated activity (millicurie) value is equal to the activity value determined by the National Institute of Standards and Technology (NIST) or by the supplier who has compared that source to a source that was calibrated by the NIST. Certified sources are available from the NIST and from many radioisotope suppliers. At least one source with a principal photon energy between 100 keV and 500 keV (such as Co-57 or Ba-133) should be used. Consider using at

least one reference source whose activity is within the range of activities normally assayed.

a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record the net activity.

b. The measurement should be within +/-10% of the certified activity of the reference source mathematically corrected for decay.

c. Repeat the procedure for any other calibrated reference sources possessed.

d. Record the model and serial number of the dose calibrator, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, and the results of the test.

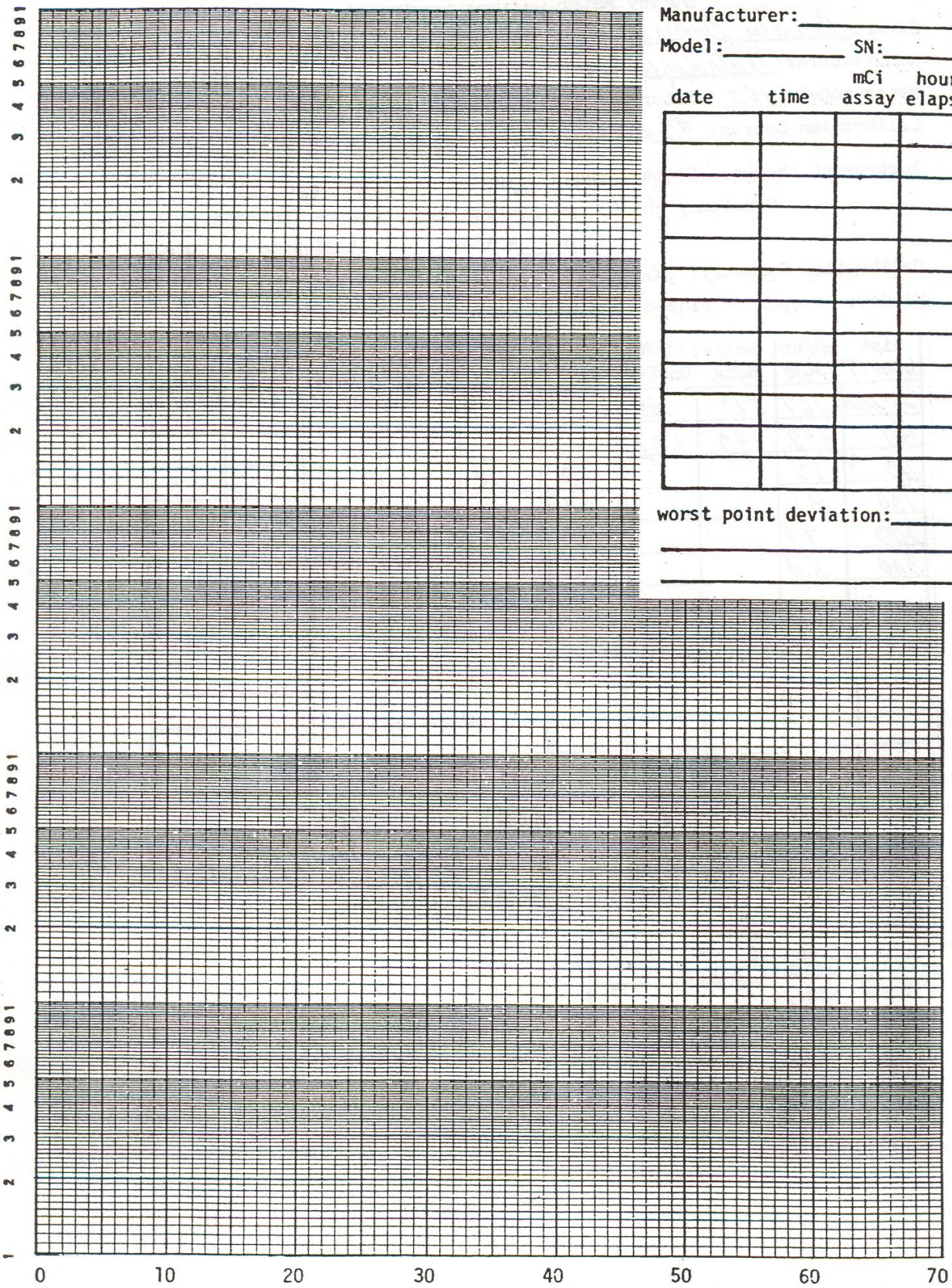
e. Notify the RSO if the test results do not agree, within +/-10%, with the certified value of the reference source(s).

f. At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings.

7. The licensee will through the RSO, ensure the operation of the dose calibrator is in accordance with approved procedures and regulatory requirements.

See Exhibits H-1 and H-2 for some forms you may want to use.

Exhibit H-1



Dose Calibrator Linearity Test

Manufacturer:_____

Model:_____ SN:_____

date	time	mCi assay	hours elapsed

worst point deviation:_____

Exhibit H-1 Example

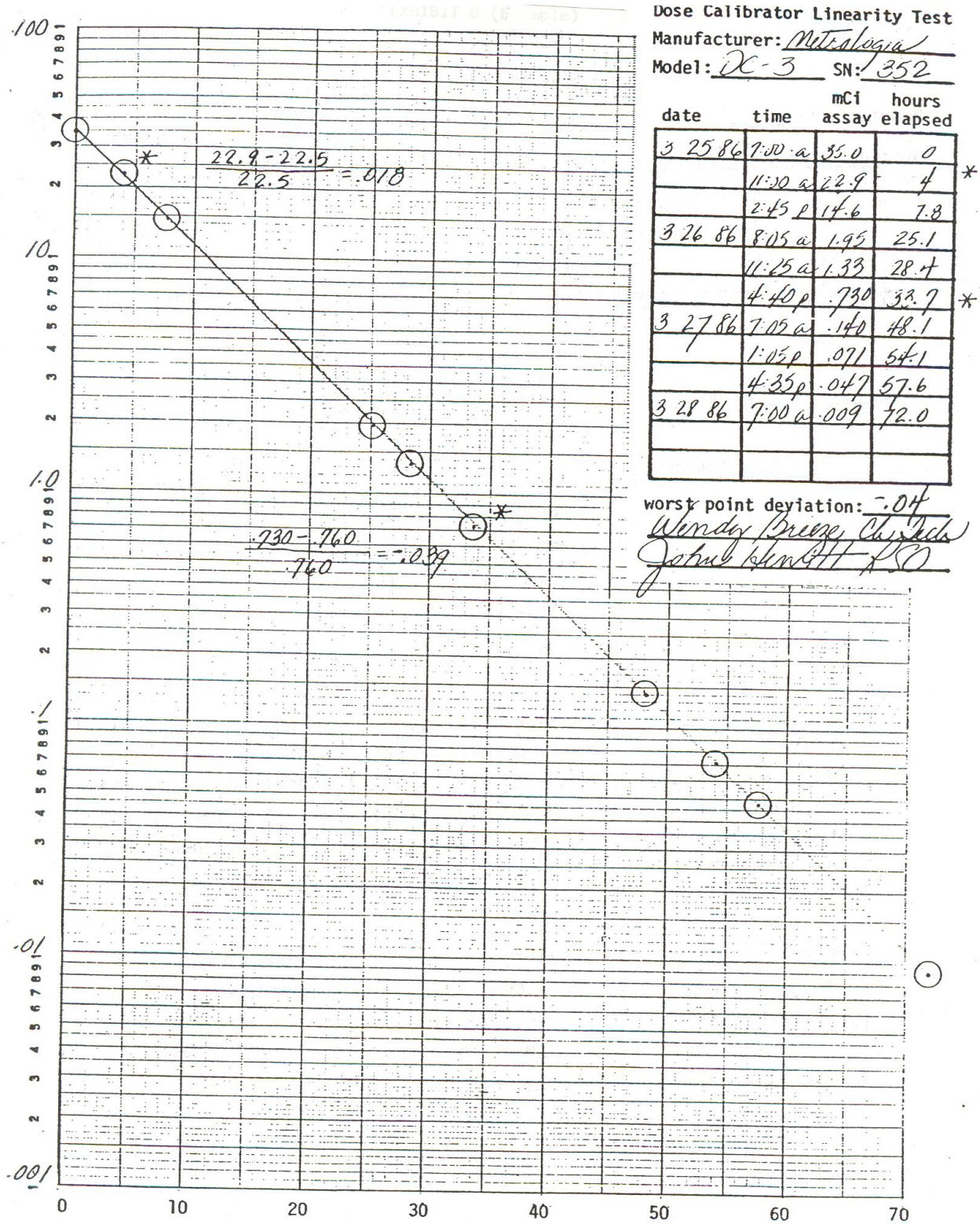
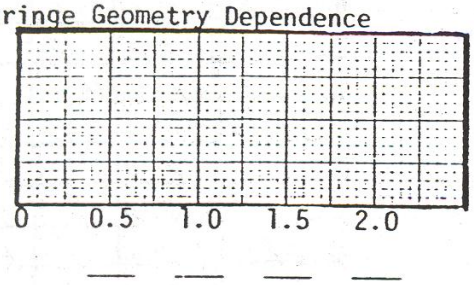


Exhibit H-2

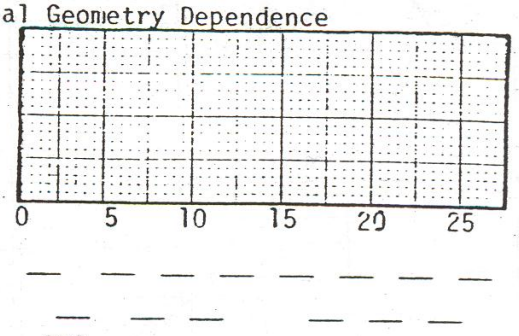
Dose Calibrator Geometry and Accuracy

Manufacturer:_____ Model:_____ SN:_____

Syringe Geometry Dependence



Vial Geometry Dependence



Date:_____ By:_____ RSO:_____

Accuracy Sources	19___	19___
_____mCi of _____ Model:_____ SN:_____ Calibration date: _____	first assay:_____mCi second assay:_____mCi third assay:_____mCi average:_____mCi _____mCi dev:_____	first assay:_____mCi second assay:_____mCi third assay:_____mCi average:_____mCi _____mCi dev:_____
_____mCi of _____ Model:_____ SN:_____ Calibration date: _____	first assay:_____mCi second assay:_____mCi third assay:_____mCi average:_____mCi _____mCi dev:_____	first assay:_____mCi second assay:_____mCi third assay:_____mCi average:_____mCi _____mCi dev:_____
_____mCi of _____ Model:_____ SN:_____ Calibration date: _____	first assay:_____mCi second assay:_____mCi third assay:_____mCi average:_____mCi _____mCi dev:_____	first assay:_____mCi second assay:_____mCi third assay:_____mCi average:_____mCi _____mCi dev:_____

Name: _____ _____

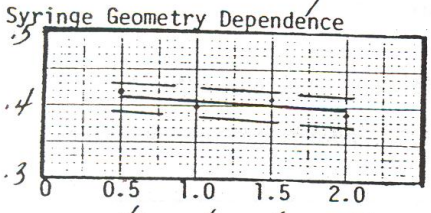
Date: _____ _____

Exhibit H-2 Example

Dose Calibrator Geometry and Accuracy

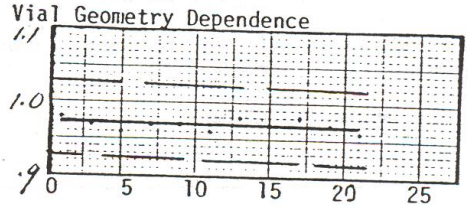
Manufacturer: Metrologia Model: DC-3 SN: 352

Syringe Geometry Dependence



.42 .40 .41 .39

Vial Geometry Dependence



.98 .96 .97 .98 .97 .97 — —

.97 .97 .96 .98 .96 —

Date: 3 29 85 By: Wendy Breeze Ch Tech RSO: J. Hewitt RSO

Accuracy Sources	1985	1986
4.72 mCi of Co-57 Model: S-57-A SN: 407 Calibration date: 1 31 85	first assay: 3.96 mCi second assay: 3.97 mCi third assay: 3.99 mCi average: 3.97 mCi 4.05 mCi dev: -.02	first assay: 1.53 mCi second assay: 1.54 mCi third assay: 1.55 mCi average: 1.54 mCi 1.59 mCi dev: -.03
.103 mCi of Cs-137 Model: S-137-A SN: 407 Calibration date: 1 31 85	first assay: .104 mCi second assay: .105 mCi third assay: .104 mCi average: .104 mCi .103 mCi dev: .01	first assay: .101 mCi second assay: .101 mCi third assay: .101 mCi average: .101 mCi .100 mCi dev: .01
____ mCi of ____ Model: ____ SN: ____ Calibration date: ____	first assay: ____ mCi second assay: ____ mCi third assay: ____ mCi average: ____ mCi ____ mCi dev: ____	first assay: ____ mCi second assay: ____ mCi third assay: ____ mCi average: ____ mCi ____ mCi dev: ____

Name: Wendy Breeze Ch Tech Wendy Breeze Ch Tech

Date: 3 29 85 3 28 86

ok-J Hewitt RSO ok-J Hewitt RSO

Appendix I

Model Training Program

Appendix I
Model Training Program

Model procedures for describing training programs appear below. These models provide examples of topics to be chosen from for training, based on the experience, duties, and previous training of trainees. 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 Agency requirements.

Guidance on requirements for training and experience for AMPs and AUs who engage in certain specialized practices is also included.

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 date of the instruction or training and the name(s) of the attendee(s) and instructor(s).

Training for Individuals Involved in the Usage of Radioactive Material

Training for professional staff (e.g., AU, AMP, ANP, RSO, nurse, dosimetrist, technologist, 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 (180 NAC 4-004);
- Risk estimates, including comparison with other health risks;
- Posting requirements (180 NAC 4-034);
- Proper use of personnel dosimetry (when applicable);
- Access control procedures (180 NAC 4-023, 4-32);
- Proper use of radiation shielding, if used;
- Patient release procedures (180 NAC 7-037);
- Instruction in procedures for notification of the RSO and AU, 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 (180 NAC 10-003, 180 NAC 7-049, 7-058, 7-070);
- Occupational dose limits and their significance (180 NAC 4-005);

- Dose limits to the embryo/fetus, including instruction on declaration of pregnancy (180 NAC 4-012);
- Worker's right to be informed of occupational radiation exposure (180 NAC 10-004);
- Each individual's obligation to report unsafe conditions to the RSO (180 NAC 10-003);
- Applicable regulations, license conditions, information notices, bulletins, etc. (180 NAC 10-003);
- Where copies of the applicable regulations, the NRC license, and its application are posted or made available for examination (180 NAC 10-002);
- Proper recordkeeping required by NRC regulations (180 NAC 10-003);
- Appropriate surveys to be conducted (180 NAC 4-021);
- Proper calibration of required survey instruments (180 NAC 4-021);
- Emergency procedures;
- Decontamination and release of facilities and equipment (180 NAC 4-020, 180 NAC 3-019);
- Dose to individual members of the public (180 NAC 4-013); and
- Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste management, sealed source leak testing) (180 NAC 7-018).

Training for the Staff Directly Involved in Administration to or Care of Patients Administered Radioactive Material for Which A Written Directive Is Required (Including Greater than 30 microcurie 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, RSO, AMP, AU, and dosimetrist) in the following topics, *commensurate with their duties*:

- Leak testing of sealed sources (180 NAC 7-033);
- Emergency procedures (including emergency response drills) (180 ANC 7-049, 7-058, 7-070);
- Operating instructions (180 NAC 7-018, 7-070);
- Computerized treatment planning system (180 NAC 7-082);
- Dosimetry protocol (180 NAC 7-072);
- Detailed pretreatment quality assurance checks (180 NAC 7-018, 7-070);
- 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

(180 NAC 7-049, 7-058);

- Patient control procedures (180 NAC 7-049, 7-058, 7-070);
- Visitor control procedures, such as visitors' stay times and safe lines in radiation control areas(patient's room) (180 NAC 7-049, 7-058, 7-070);
- Licensee's WD 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) (180 NAC 7-020);
- 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) (180 NAC 7-058, 7-070);
- Size and appearance of different types of sources and applicators (180 NAC 7-058, 7-070);
- 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 AMPs who plan to engage in certain tasks requiring special training should ensure that the AMP is trained in the activities specific to the different types of uses listed in 180 NAC 7-023.02. Note, for example, that additional training is necessary for AMP 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 opthalmic treatments (180 NAC 7-060). 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 180 NAC 7-023.03.

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 180 NAC 7-051, 7-053, 7-063, 7-064 and 7-084, 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 Sections 180 NAC 7-051, 7-063, 7-064 and 7-084.

Training for Ancillary Staff

For the purposes of this section, ancillary staff includes personnel engaged in janitorial and/housekeeping duties, dietary, laboratory, security and life-safety services. he training program for ancillary staff who perform duties that are likely to result in a dose in excess of 1 mSv (100 mrem) 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 (180 NAC 10-003);
- 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) (180 NAC 10-003);
- The applicable provisions of Agency regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material (e.g., posting and labeling of radioactive material) (180 NAC 10-003);
- Responsibility to report promptly to the licensee any condition that may lead to or cause a violation of Agency regulations and licenses or unnecessary exposure to radiation and/or radioactive material (e.g., notification of the RSO regarding radiation protection issues) (180 NAC 10-003);
- Appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material (180 NAC 10-003);
- Radiation exposure reports that workers may request, as per 180 NA 10-004(180 NAC 10-003).

Appendix J

Spill Emergency Surgery, and Autopsy Procedures

Appendix J
Spill, Emergency Surgery, and Autopsy Procedures

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.

Note: A report to Agency may be required pursuant to 180 NAC 3-026.

Use Table J.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.

Table J.1 Relative Hazards of Common Radionuclides			
Radionuclide	**Millicurie**	**Radionuclide**	**Radionuclide**
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;
- “Radioactive Material” labeling tape;
- 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.

Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radionuclides

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 eye wear 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 Staff 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.

Autopsy of Patients Who Have Received Therapeutic Amounts of Radionuclides

The following procedures should be followed:
1. Immediately notify the AU 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 eye wear should be worn by the pathologist and assisting staff for protection from possible splashing of radioactive material. Consider the need for protection against exposure 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 exposure of autopsy personnel. Shield and dispose of contaminated tissues in accord with license conditions. In some cases, exposure reduction may be accomplished by removing tissues for dissection to a location where the exposure rate is lower.
5. 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 radiation safety staff.

References: NRCP Report No. 111, “Developing Radiation Emergency Plans for Academic, Medical, and Industrial Facilities,” 1991, contains helpful information. It is available from the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 400, Bethesda, Maryland 20814-3095. NCRP’s telephone numbers are: (301) 657-2652 or 1-800-229-2652.

Attachment 1 of Appendix J
EMERENCY PROCEDURES

MINOR SPILLS

1. **Notify –** Notify persons in the area that a spill has occurred.

2. **Prevent the spread –** Cover the spill with absorbent paper.

3. **Clean up –** Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.

4. **Survey –** With a low-range, thin-window G-M survey meter, check the area around the spill, feet**,** hands, and clothing for contamination.

5. **Report –** Report incident to the Radiation Safety Officer.

MAJOR SPILLS

1. **Clear the area –** Notify all persons not involved in the spill to vacate the room.

2. **Prevent the spread –** Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all potentially contaminated personnel to prevent the spread.

3. **Shield the source –** If possible, the spill should be shielded, but only if it can be done without further contamination and without significantly increasing your radiation exposure.

4. **Close the room – Leave the room and lock the door(s) to prevent entry.**

5. **Call for help –** Notify the Radiation Safety Officer immediately.

6. **Personnel Decontamination -** Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water, then resurvey. Repeat as necessary.
   Radiation Safety Officer _____

   Office Phone _____

   Home Phone _____

LOSS, THEFT, FIRE, EXPLOSION, OR VEHICLE ACCIDENT

1. **Secure the area around the accident. Keep unauthorized people away. Alert people in vicinity of the presence of radioactivity and a possible hazard.**

2. **Do not leave the site -** Send a helper or onlooker to notify the following:

   A. Radiation Safety Officer _____

   Work phone _____Home phone _____

   B. Local Police _____

C. Local Fire Department, where applicable _____

3. The Radiation Safety Officer, in turn, must immediately notify the:

State of Nebraska, Office of Radiological Health:
(402)471-2168 (Monday – Friday 8AM – 5 PM)

OR Afterhours

Nebraska State Patrol
(402) 471-4545 (Ask to speak to the NEMA Duty Officer as you have an incident to report involving Radioactive Materials)

and other local authorities as indicated.

4. The radiation worker should inform emergency workers of the radiation hazard possibly existing, should help them keep the area secure, and should explain to the emergency personnel the location of the radioactive device or chemical and the extent of the possible hazard. **In no case should the radiation worker leave the site** until qualified experts arrive, unless, of course, the operator is seriously injured or incapacitated, and must be removed from the site by emergency personnel for medical treatment.

Alternate names and telephone numbers designated by Radiation Safety Officer.

_____ _____

_____ _____

_____ _____

_____ _____

Appendix K

Model Procedures for Safe Use of Unsealed Licensed Material

Appendix K
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 licensed material is stored or used.
- Do not store food, drink, or personnel effects in area where radioactive material is stored, used or disposed.
- 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 licensed 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 180 NAC 7-036 (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 180 NAC 7-034 and 180 NAC 4-036. Mark the label with the radionuclide, the activity, the date for which the activity is estimated and the kind of material (ie. Radiopharmaceutical).
- Syringes and unit dosages must be labeled in accordance with 180 NAC 7-034 and 180 NAC 4-036. 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 Appendix 4-C of 180 NAC 4, the syringe or vial need only be labeled to identify the radioactive drug (180 NAC 7-034). 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 (180 NAC 7-031).
- 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 (180 NAC 7-020).
- Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
- Secure all licensed material when not under the constant surveillance and immediate control of an individual authorized under the Agency license (or such individual's designee).

Appendix L

Model Procedures for Ordering and Receiving Packages

Appendix L
Procedures for Ordering and Receiving Packages

- Authorize, through a designee (e.g., RSO), each order of radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting AU 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 AU 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 below. Develop a similar memorandum for delivery of packages to other divisions.

Sample Memorandum

MEMO TO: Chief of Security
FROM: Radiation Safety Officer
SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard 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 our hospital Radiation Safety Officer, at extension .

	Name	**Home Telephone**
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

Model Procedure for Safely Opening Packages Containing Radioactive Material

Appendix M
Model Procedure for 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 180 NAC 4-038.

Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in the table below:

Type A Quantities				
Mo-99	20 curies (domestic use)		Xe-133	541 curies
Tc-99m	215 curies		Cs-137	13.5 curies
I-125	54.1 curies		Ir-192	13.5 curies
I-131	13.5 curies			

Such packages must be received expeditiously when the carrier offers it for delivery or when the carrier notifies the licensee that the package has arrived at the carrier's terminal.

For these and other packages for which monitoring is required, check for external radiation levels and surface contamination within 3 hours of receipt (if received during working hours) or no later than 3 hours from the beginning of the next working day (if received after working hours), in accordance with the requirements of 180 NAC 4-038.03. The Agency and the final delivery carrier must be notified if the following conditions apply:

- Removable radioactive surface contamination exceeds the limits of 180 NAC 13-015.08); and
- External radiation levels exceed the limits of (200 mrem/hr) 180 NAC 13-015.09.

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. Measure the exposure rate of the package at one meter (3.3 feet) from package surface. If reading is greater than 10 mR/hr, stop procedure and notify Radiation Safety Officer.
4. Measure the exposure rate at the surface of the package. If the reading is greater than 200 mR stop procedure and notify Radiation Safety Officer.
5. Record the survey results and compare to the limits on the below DOT shipping Level Chart.

DOT Shipping Label Chart

Label Category	**Surface Level (mR/hr)**	**Transportation Index (TI) at 1 meter (mR/hr)**
White	0.- 0.5	background

Yellow II	0.5 – 50	0.1 – 1.0
Yellow III	50- 200	1.0 -10

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.
9. Check the integrity of the final source container. Notify the RSO (or the RSO's designee) 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(T1) 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 180 NAC 3-008.09, 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.

SAMPLE
"RADIOACTIVE PACKAGE RECEIPT RECORD"

1. P.O. No. _____ Survey Date _____ Time: _____

   Surveyor _____

   Survey Instrument, serial #_____ and most recent calibration date _____

2. **Condition of Package**

   ☐ O.K. ☐ Punctured ☐ Wet ☐ Crushed

   ☐ (Other)

3. Radiation Units of Label (T.I.): _____(mR/hr)

4. Label: ☐ White-I ☐ Yellow-II ☐ Yellow-III

5. **Measured Radiation Levels**

   A. Package surface _____mR/hr

   B. 3 feet or 1 meter from surface _____mR/hr

6. Do packing slip and vial contents agree?

   A. Radionuclide _____ yes _____ no, difference _____

   B. Amount____ _____ yes _____ no, difference _____

   C. Chem Form _____ yes _____ no, difference _____

7. **Wipe results**

   A. Outer _____ NET CPM (x EFF:_____) = _____DPM

   B. Final source contained _____ NET CPM (x EFF:_____) = _____DPM

8. **Survey results of packing material and cartons** _____CPM

   Background is _____ CPM

9. **Disposition of package after inspection** _____

10. If Department/carrier notification required, give time, date and persons notified.

Appendix N

Model Procedures for an Occupational Dose Program

Appendix N
Model Procedures for an Occupational Dose Program

PART 1

☐ A statement that: "We will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 180 NAC 4. The evaluation is attached."

OR

☐ A statement that: "We will provide dosimetry that meets the requirements of 180 NAC 4 and will follow the Procedures in Appendix N "Model Procedures for an Occupation Dose Program" of Regulatory Guide 7.00 Rev. ____ Dated _____ and complete table below."

OR

☐ A statement that: "We will provide dosimetry that meets the requirements of 180 NAC 4 and will attach equivalent procedures for an Occupation Dose Program.

Appendix N
Model Procedures for an Occupational Dose Program

PART 2

This model provides acceptable procedures for an external occupational dose program and references for developing an internal occupational dose program. Applicants may either adopt these model procedures for an external occupational dose program or develop alternative procedures to meet the requirements of 180 NAC 4-004 through 4-012, 4-020 and 4-021. The model includes guidance as well as discussion of regulatory requirements that are to be reflected in the elements of an occupational dose 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 180 NAC 4-022.01. 180 NAC 4-005 provides the occupational dose limits for adults. 180 NAC 4-022 provides 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 180 NAC 4-002, "Definitions." In addition, if monitoring is required pursuant to 180 NAC 4-022, each licensee shall maintain records of doses received (see180 NAC 4-052) and individuals must be informed on at least an annual basis of their doses (see 180 NAC 10-004.02).

If an individual is likely to receive more than 10% of the annual dose limits, the Agency 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 his/her dose.

The As Low As Reasonably Achievable "ALARA" Program

180 NAC 4-004 states that "each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activitiesÿ" 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)." Additionally, 180 NAC 4-005 requires that licensees periodically review the content of the radiation protection program and its implementation.

External Exposure

It is necessary to assess doses to radiation 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 important that management recognize the importance of radiation monitoring in the overall requirements for radiation protection.

There are three dose limits included in 180 NAC 4-005 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 180 NAC 4-002, the (DDE) to the whole body is considered to be at a tissue depth of 1 cm (1000 mg/cm^2), shallow-dose equivalent to the skin or extremities at 0.007 cm (7 mg/cm^2), and eye dose equivalent at 0.3 cm (300 mg/cm^2). In evaluating the eye dose equivalent, it is acceptable to take credit for the shielding provided by protective lenses.

180 NAC 4-021.01 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 180 NAC 4-005.01. 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 demonstrated that doses will not exceed 10% of the applicable limits. In these cases, the Agency 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 level 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 (exposures associated with reasonable ‘accident’ scenarios should 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.

External dose is determined by using indvidual monitoirng devices, such as film badges,optically stimulated luminescence dosimeters (OSLs), or TLD's. These devices must be evaluated by a processor that is National Voluntary Laboratory Accrediation Program (NVLAP)-approved, as required by 180 NAC 4-021.

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 (1180 NAC 4-005.03).

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 exposure 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.

180 NAC 4-053 requires that the recording for individual doses received for the calendar year. The monitoring year may be adjusted as necessary to permit a smooth transition from one monitoring year to another, as long as the year begins and ends in the month of January, the change is made at the beginning of the year, and no day is omitted or duplicated in consecutive years.

Because evaluation of dose is an important part of the radiation protection program, it is important 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.

In order to demonstrate compliance with occupational dose limits of 180 NAC 4-005, the licensee needs to perform and document an evaluation of the dose the individual received and to add it to the employee's dose record, if an individual's dosimeter is lost. Sometimes the most reliable method for estimating an individual's dose is to use his/her recent dose history. In other cases, particularly if the individual does non-routine types of work, it may be better to use doses of co-workers as the basis for the dose estimate. It also may be possible to estimate doses by modeling and calculation (i.e., reconstruction) of scenarios leading to dose.

Investigational Levels – External Dose Monitoring

The Agency has emphasized that the investigational levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," investigational levels serve as check points above which the results are considered sufficiently important to justify investigation.

In cases where a worker's or a group of workers' doses need to exceed an Investigational Level, a new, higher Investigational Level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new Investigational Levels should be documented.
When the cumulative annual exposure to a radiation worker exceeds Investigational Level I in Table N.1 (i.e., 10% of the annual limit for occupational exposure), the RSO or the RSO's designee should investigate the exposure and review the actions that might be taken to reduce the probability of recurrence. When the cumulative annual exposure exceeds Investigational Level II in Table N.1 (i.e., 30% of the annual limit for occupational exposure), the RSO or the RSO's designee will investigate the exposure and review actions to be taken to reduce the probability of recurrence, and management should review the report of the actions to be taken to reduce the probability of occurrence.

Table N.1 Investigational Levels

Part of Body	Investigational Level I (mrem per year)	Investigational Level II (mrem per year)
Whole body; head; trunk including male gonads, arms above the elbow, or legs above the knee	500 (5 mSv)	1500 (15 mSv)
hands; elbows; arms below the elbow; feet; knee; leg below the knee; or skin	5000 (50 mSv)	15,000 (150 mSv)
lens of the eye	1500 (15 mSv)	4500 (45 mSv)

Review and record "Current Occupational External Radiation Exposures," or an form (e.g., dosimeter processor's report) results of personnel monitoring. Take the actions listed below when the investigation levels listed in Table N.1 are reached:

- Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO or the RSO's designee, no further action will be taken if an individual's dose is less than Table N.1 values for Investigational Level I.

- Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

When the dose of an individual whose dose equals or exceeds Investigational Level I, the RSO or the RSO's designee should conduct a timely investigation and review the actions that might be

taken to reduce the probability of recurrence, following the period when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the RSO or the RSO's designee. Consider investigating the factors that led to the radiation exposure and the radiation doses and work habits of other individuals engaged in similar tasks to determine if improvements additional safety measures are needed to reduce exposures. Evaluate in the context of ALARA program quality and record the results of investigations and evaluations.

- Personnel dose equal to or greater than Investigational Level II.

The RSO should investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II. A consideration of actions should be taken by the RSO to reduce the probability of occurrence, and a report of the actions should be reviewed by the licensee's management at its first meeting following completion of the investigation.

- Re-establishment of Investigational Level II to a level above that listed in Table N.1.

Declared Pregnancy and Dose to Embryo/Fetus

180 NAC 4-012 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.

References:

- 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).

Internal Exposure

With respect to internal exposure, 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 (180 NAC 4-022). 180 NAC 4 provides terms for radionuclide intakes by means of inhalation and ingestion, i.e.,derived air concentration (DAC) and ALI.

The DAC for each class of radionuclide is the concentration of airborne radioactivity in μCi/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 180 NAC 4, Appendix B.

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 180 NAC 4 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." 180 NAC 4, Appendix B, 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 manipulated 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:

i. adequate equipment to perform bioassay measurements,
ii. procedures for calibrating the equipment, including factors necessary to convert counts per minute into becquerel or microcurie units,
iii. the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue),
iv. the interval between bioassays,
v. action levels, and
vi. the actions to be taken at those levels.

For guidance on developing bioassay programs and determination of internal occupational dose and summation of occupational dose, refer to 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.

Recordkeeping

Records of measurement data, calculations of intakes, and methods for calculating dose must be maintained as required by 180 NAC 4-052. For additional information on recordkeeping and reporting occupational exposure data, including intakes, refer to Revision 1 of Regulatory Guide 8.7, "Instructions for Recording and Reporting Occupational Radiation Exposure Data."

Summation of External and Internal Doses

Pursuant to 180 NAC 4-006, the external and internal doses must be summed if required to monitor both under 180 NAC 4-022.

Two documents that contain helpful information regarding occupational doses are:

- NRC Regulatory Issue Summary 2002-06, "Evaluating Occupational Dose for Individuals Exposed to NRC-Licensed Material and Medical X-Rays;" and
- NRC Regulatory Issue Summary 2002-10, "Revision of Skin Dose Unit in 10 CFR Part 20." Copies of Regulatory Issue Summaries are available on the NRC web site in the Electronic Reading Room <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/>.

Appendix O

Model Procedure For Area Surveys

Appendix O
Procedure For Area Surveys

Procedures to meet the requirements of 180 NAC 4-004, 4-021 and 180 NAC 7-036. Guidance for developing alternate trigger levels for contamination in restricted areas is included below.

Ambient Radiation Level Surveys

Procedures for ambient radiation level surveys (reference 180 NAC 4-004, 4-021 and 180 NAC 7-036):

- 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).
- 180 NAC 4-013 requires that the TEDE to an individual member of the public from the licensed operation does not exceed 1 mSv (0.1 rem) in a year, and that the dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour. Appropriate surveys will be conducted to assure that the requirements of 180 NAC 4-013 are met.
- Perform radiation level surveys with a survey meter sufficiently sensitive to detect 0.1 milliroentgen (mR) 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 (except patient rooms, which will be surveyed at the end of the therapy instead of on the day of administration) when using radiopharmaceuticals requiring a written directive (e.g., all therapy dosages and any iodine-131 dosage exceeding 30 μCi).
  - Survey monthly all laboratory areas where only small quantities of gamma-emitting radioactive material are used (< 200 μCi 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 paraphernalia, 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 0.1.

Table O.1 Ambient Dose Rate Trigger Levels

Type of Survey	Type of Survey	Trigger Level
Ambient Dose Rate	Unrestricted	0.1 mR/hr
Ambient Dose Rate	Restricted	5.0 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 G-1 entitled "Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples" in Appendix G 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 for those radionuclides in use and for which the most restrictive limits apply, as listed in Tables O.2 for restricted areas and O.3 for unrestricted areas (e.g., 200 dpm/100 cm^2 for isotopes of iodine-131 in 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 paraphernalia, 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 either 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 for restricted areas are presented in Table O.2. Contamination found in unrestricted areas and on personal clothing will be immediately decontaminated to background levels.

Table O.2 Surface Contamination Levels in Restricted Areas (dpm/100 cm^2)		
Area, clothing	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, Y-90, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Lu-177, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
Restricted areas, protective clothing used only in restricted areas	2000	20000

Table O.3 Surface Contamination Levels in Unrestricted Areas (dpm/100 cm^2)			
Nuclide[1]	**Average**[2, 3, 6]	**Maximum**[2, 4, 6]	**Removable**[2, 5, 6]
I-125, I-126, I-131, I-133, Sr-90	1000	3000	200
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	5000	15000	1000

1 Where surface contamination by multiple nuclides exists, the limits established for each nuclide should apply independently.

2 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.

3 Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.

4 The maximum contamination level applies to an area of not more than 100 cm^2.

5 The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

6 The average and maximum radiation levels associated with surface contamination resulting from betagamma 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 O.1 and O.2:

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

- acceptable unrestricted area trigger levels are implemented (e.g., Tables R.1 and R.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).

Alternate Survey Frequency

An example alternate survey frequency is described below. The objective is to determine how often to survey the laboratory. To do this, multiply the activity range for the appropriate group under LOW, MEDIUM, and HIGH survey frequency by the appropriate Modifying Factor to construct a new set of mCi ranges for LOW, MEDIUM, and HIGH survey frequency. For instance, if 30 millicuries of iodine-131 is used in the hot laboratory, the survey frequency for the hot laboratory would be daily; since the group for iodine-131 is Group 2, the survey frequency category for an activity of greater than 10 millicuries is high, and the modifying factor is 1.

Table O.4 Grouping of Radioisotopes for Alternate Survey Frequency	
Group 1	Group 1, excerpted from IAEA Safety Series 115, does not include radioisotopes traditionally used in medicine.
Group 2	Group 2 Co-60 Sr-90 I-125 I-126 I-131 I-133 Cs-134 Cs-137 Eu-152 (13 y) Eu-154 Ir-192 T1-204
Group 3	Group 3 C-14 F-18 Na-24 P-32 S-35 Cr-51 Fe-59 Co-57 Co-58 Se-75 Sr-85 Y-90 Mo-99 Tc-99 Rh-105 Pd-103 In-115m Sn-113 Sm-153 Eu-152 Eu-155 Gd-153 Dy-165 Yb- 175 Lu-177 Au-198 Hg-197 Tl-201
Group 4	H-3 0-15 Rb-87 Tc-99m Rh-103m In-113m Xe-133 Cs-134m

Table O.5 Classification of Laboratories for Alternate Survey Frequency			
Group	**Low**	**Medium**	**High**
1	<0.1 mCi	0.1 mCi to 1 mCi	>1 mCi
2	<1 mCi	1 mCi to 10 mCi	>10 mCi
3	<100 mCi	100 mCi to 1 Ci	>1 Ci
4	<10 Ci	10 Ci to 100 Ci	>100 Ci

Survey Frequency:
- Low – Not less than once a month;
- Medium – Not less than once per week;
- High – Not less than once per normal working day.

Proportional fractions are to be used for more than one isotope.

Table O.6 Modifying Factors for Alternate Survey Frequency	
Modifying Factors	**Factors**
Simple storage	X 100
Very simple wet operations (e.g., preparation of aliquots of stock solutions)	X 10
Normal chemical operations (e.g., analysis, simple chemical preparations)	X 1
Complex wet operations (e.g., multiple operations, or operations with complex glass apparatus)	X 0.1

Simple dry operations (e.g., manipulation of powders) and work with volatile radioactive compounds	X 0.1
Exposure of non-occupational persons (including patients)	X 0.1
Dry and dusty operations (e.g., grinding)	X 0.01

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;
- 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 P

Model Procedures for Developing, Maintaining, and Implementing Written Directives

Appendix P
Model Procedures for Developing, Maintaining, and Implementing Written Directives

This model provides acceptable procedures for administrations that require written directives. You may either adopt this model procedure or develop your own procedure to meet the requirements of 180 NAC 7-019 and 7-020.

Written Directive Procedures

This model provides guidance to licensees and applicants for developing, maintaining, and implementing procedures for administrations that require written directives (WD). This model does not restrict your 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 180 NAC 7-019 will be met.

The WD must be prepared for any administration of I-131 sodium iodide greater than 1.11 MBq (30 μCi), any therapeutic dosage of a radiopharmaceutical, and any therapeutic dose of radiation from radioactive material. The WD must contain the information described in 180 NAC 7-019 and 7-020 and be retained in accordance with 180 NAC 7-088.

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 should 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 should 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 180 NAC 7-019 requires, or

would require, a written directive (as defined in 180 NAC 7-002), the licensee should develop, implement, and maintain written procedures for WDs to meet the requirements and/or objectives of 180 NAC 7-019, 7-020 and 7-031, outlined below:

- Have an authorized user date and sign a written directive prior to the administration that includes the information in 180 NAC 7-019.02, 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 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 Microcurie of Sodium Iodide I-131

Develop, implement, and maintain the following procedures to meet the objectives of 180 NAC 7-019 and 7-020:

- An 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

Licensees are required under 180 NAC 7-019 and 7-020 to have written directives for certain administrations of doses and to have procedures for administrations for which a written directive is required. Model procedures for meeting these requirements appear below.

A 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.

B 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).

C. 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 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.

D. 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 180 NAC 7-019.02, item 5. 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.

E. 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.

F. 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 180 NAC 7-023) using a dosimetry system other than the one that was used during the full calibration (the dosimetry system will meet the requirements specified in 180 NAC 7-072); 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%.

G. 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.

H. 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.

I. 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.

J. 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 180 NAC 7-020, 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 Medical Events

Notify by telephone the Agency no later than the next calendar day after discovery of a medical event and submit a written report to the Agency within 15 days after the discovery of the medical event, as required by 180 NAC 7-115.

Also notify the referring physician and the patient as required by 180 NAC 7-115.

Appendix Q

Release of Patients or Human Research Subjects

Appendix Q
Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials

180 NAC 7-037, "Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material," of 180 NAC 7, "Medical Use of Radioactive Material," permits a licensee to "authorize the release from its control any individual who has been administered unsealed radioactive material 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 5 millisieverts (0.5 rem)."

In this 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 Q.1:

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

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 Q.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 10 millisieverts (1 rem).
- 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 Q.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 Q.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 Q.2:

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

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 Q.3:

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

Equations Q.2 and Q.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 Q.1.1, “Release of Patients Based on Administered Activity.”

Q.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.

Q.1.1 Release of Patients Based on Administered Activity

In compliance with the dose limit in 180 NAC 7-037.01, licensees may release patients from licensee control if the activity administered is no greater than the activity in Column 1 of Table Q.1. The activities in Table Q.1 are based on a total effective dose equivalent of 5 millisieverts (0.5 rem) to a 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 Q.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 180 NAC 7-019 and 7-031.

If the activity administered exceeds the activity in Column 1 of Table Q.1, the licensee may release the patient when the activity has decayed to the activity in Column 1 of Table Q.1. In this case, 180 NAC 7-037.03 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 Q.1 were calculated using either Equation Q.2 or Q.3, depending on the physical half-life of the radionuclide.

If a radionuclide that is not listed in Table Q.1 is administered, the licensee can demonstrate compliance with the regulation by maintaining, for a Agency inspection, calculation of the release activity that corresponds to the dose limit of 5 millisievert (0.5 rem). Equation Q.2 or Q.3 may be used, as appropriate, to calculate the activity *Q* corresponding to 5 millisieverts (0.5 rem).

The release activities in Column 1 of Table Q.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 Q.1 are not applicable to the infant or child. In this case, it may be necessary to give instructions as described in Items Q.2.2 and Q.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 5 millisieverts (0.5 rem), a record that instructions were provided is required by 180 NAC 7-37.05.

Q.1.2 Release of Patients Based on Measured Dose Rate

Licensees may release patients to whom radionuclides have been administered in amounts greater than the activities listed in Column 1 of Table Q.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 Q.1 for that radionuclide. In this case, however, 180 NAC 7-037 requires a record because the release is based on considering shielding by tissue.

If a radionuclide not listed in Table Q.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 5 millisieverts (0.5 rem) 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 180 NAC 7-037.04. The dose rate at 1 meter may be calculated from Equation Q.2 or Q.3, as appropriate, because the dose rate at 1 meter is equal to ΓQ / 10,000 cm^2.

Q.1.3 Release of Patients Based on Patient-Specific Dose Calculations

Licensees may release patients based on dose calculations using patient-specific parameters. With this method, based on 180 NAC 7-037, 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 5 millisievert (0.5 rem), the patient may be released. Using this method, licensees may be able to release patients with activities greater than those listed in Column 1 of Table Q.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 180 NAC 7-037.04. 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 180 NAC 37.04.

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

Table Q.1 Activities and Dose Rates for Authorizing Patient Release†

Radionuclide	COLUMN ! Activity at or Below Which Patients May Be Released		COLUMN 2 Dose rate at 1 Meter, at or Below Which Patitnet 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	0.012	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 Q-1

The activity values were computed based on 5 millisieverts (0.5 rem) 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 180 NAC 7-037.04, because the measurement includes shielding by tissue. See Item Q.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 Q.2 or Q.3 and the physical half-life. The gigabecquerel values were calculated using the millicurie values and the conversion factor from millicurie to gigabecquerels. 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 0.37 gigabecquerel (10 millicuries) or 0.1 millisievert (10 millirems) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492.

Although non-radioactive materials are not regulated by the Agency, information on non-radioactive material is included for the convenience of the licensee.

Agreement State regulations may vary. Agreement State licensees should check with their State regulations before using these values.

Q.2 Instructions

This Section provides acceptable instructions for release of patients administered radioactive materials. You may either adopt these model instructions or develop your own instructions to meet the requirements of 180 NAC 7-037.

Q.2.1 Activities and Dose Rates Requiring Instructions

Based on 180 NAC 7-037.02, for some administrations the released patients must be given instructions, including written instructions, on how to maintain doses to other individuals ALARA after the patients are released[1]. Column 1 of Table Q.2 provides the activity above which instructions must be given to patients. Column 2 provides corresponding dose rates at 1 meter, based on the activities in Column 1. The activities or dose rates in Table Q.2 may be used for determining when instructions must be given. If the patient is breast-feeding an infant or child, additional instructions may be necessary (see Item Q.2.2, "Additional Instructions for Release of Patients Who Could be Breast-Feeding After Release").

When patient-specific calculations (as described in Supplement B) are used, instructions must be provided if the calculation indicates a dose greater than 1 millisievert (0.1 rem).

If a radionuclide not listed in Table Q.2 is administered, the licensee may calculate the activity or dose rate that corresponds to 1 millisievert (0.1 rem). Equation Q.2 or Q.3, as appropriate, may be used.

Q.2.2 Additional Instructions for Release of Patients Who Could Be Breast-

[1] The Agency does not intend to enforce patient compliance with the instructions nor is it the licensee's responsibility to do so.

Feeding After Release

The requirement in 180 NAC 7-037.02 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.[1] 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 5 millisieverts (0.5 rem) if there is no interruption of breast-feeding.

If the patient could be breast-feeding an infant or child after release, and if a radiopharmaceutical with an activity above the value stated in Column 1 of Table Q.3 was administered to the patient, 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. Table Q.3 also provides recommendations for interrupting or discontinuing breast-feeding to minimize the dose to below 1 millisievert (0.1 rem) if the patient has received certain radiopharmaceutical doses. The radiopharmaceuticals listed in Table Q.3 are commonly used in medical diagnosis and treatment.

If a radiopharmaceutical not listed in Table Q.3 is administered to a patient who could be breast-feeding, the licensee should evaluate whether instructions or records (or both) are required. 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.

Q.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 Q.2.3.1 and Q.2.3.2).

Table Q.2 Activities and Dose Rates for Above Which Instruction Should be Given When Authorizing Patient Release†

Radionuclide	COLUMN ! Activity Above Which Instructions Are		COLUMN 2 Dose rate at 1 Meter Above Which Instructions are Required	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	3.8	100	0.02	2
Au-198	0.69	19	0.04	4
Cr-51	0.96	26	0.004	0.4
Cu-64	1.7	45	0.05	5
Cu-67	2.9	77	0.04	4

Ga-67	1.7	47	0.04	4
I-123	1.2	33	0.05	5
I-125	0.05	1	0.002	0.2
I-125 implant	0.074	2	0.002	0.2
I-131	0.24	7	0.02	2
In-111	0.47	13	0.04	4
Ir-192 implant	0.011	0.3	0.002	0.2
P-32	**	**	**	**
Pd-103 implant	0.3	8	0.007	0.7
Re-186	5.7	150	0.03	3
Re-188	5.8	160	0.04	4
Sc-47	2.3	62	0.03	3
Se-75	0.018	0.5	0.001	0.1
Sm-153	5.2	140	0.06	6
Sn-117m	0.21	6	0.009	0.9
Sr-89	**	**	**	**
Tc-99m	5.6	150	0.12	12
Tl-201	3.1	85	0.04	4
Y-90	**	**	**	**
Yb-169	0.073	2	0.004	0.4

Footnotes for Table Q.2

* The activity values were computed based on 1 millisievert (0.1 rem) total effective dose equivalent.

** 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.

*** These radionuclides are not radioactive material and are not regulated by the Agency. Information is presented for the convenience of readers of this guide, who should be alert to differences that might exist between regulations of the Agency, the U.S. Nuclear Regulatory Commission and state requirements for non-NRC regulated material.

Notes: The values for activity were calculated using Equations Q.2 or Q.3 and the physical half-life. The values given in SI units (gigabecquerel values) were using conversion factors.

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

Although non-radioactive materials are not regulated by the Agency, information on non-radioactive material is included for the convenience of the licensee.

Agreement State regulations may vary. Agreement State licensees should check with their state regulations before using these values.

Table Q.3 Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who are Breast-Feeding an Infant or Child

Table Q.3 Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who are Breast-Feeding an Infant or Child					
Radionuclide	**COLUMN ! Activity Above Which Instructions Are**		**COLUMN 2 Dose rate at 1 Meter Above Which Instructions are Required**		**COLUMN 3 Examples of Recommend Duration of Interruption of Breast-Feeding**
	(GBq)	**(mCi)**	**(mSv/hr)**	**(mrem/hr)**	
I-131 NaI	0.01	0.004	0.07	0.002	Complete cessation (for this infant or child)
I-123 NaI**	20	0.5	100	3	
I-123 OIH**	100	4	700	20	
I-123 MIBG**	70	2	400	10	24 hours of 370 MBq (10 mCi) 12 hours for 150 MBq (4 mCi)
I-125 OIH	3	0.08	10	0.4	
I-131 OIH	10	0.3	60	1.5	
Tc-99m DTPA	1000	30	6000	150	
Tc-99m MAA	50	1.3	200	6.5	12.6 hours for 150 MBq (4 mCi)
TC-99m Pertechnetate	100	3	600	15	24 hours for 1,100 MBq (30 mCi) 12 hour for 440 MBq (12 mCi)
Tc-99m DISIDA	1000	30	6000	150	
Tc-99m Glucoheptonate	1000	30	6000	170	
Tc-99m MIBI	1000	30	6000	150	
Tc-99m MDP	1000	300	6000	150	
Tc-99m PYP	900	25	4000	120	
Tc-99m Red Blood Cell *In Vivo* Labeling	400	10	2000	50	6 hours for 740 MBq (20 mCi)
Tc-99m Red Blood Cell *In Vitro* Labeling	1000	30	1000	150	
Tc-99m Sulphur Colloid	300	7	1000	35	6 hours for 440 MBq (12 mCi)
TC-99m DTPA Aerosol	1000	30	6000	160	
Tc-99m MAG3	1000	30	6000	150	
Tc-99m White Blod Cells	100	4	600	15	24 hours for 1,100 MBq (30 mCi) 12 hours for 440 MBq (12 mCi)
Ga-67 Citrate**	1	0.04	7	.02	1 month for 150 MBq (30 mCi) 2 weeks for 50 MBq (1.3

					mCi) 1 week for 7 MBq (0.2 mCi)
Cr-51 EDTA	60	1.6	300	8	
In-111 White Blood Cells**	10	0.2	40	1	1 week for 20 MBq (0.5 mCi)
Tl-201 Chloride**	40	1	200	5	2 weeks for 110 MBq (3 mCi)

Footnotes for Table Q.3

* The duration of interruption of breast-feeding is selected to reduce the maximum dose to a newborn infant to less than 1 millisievert (0.1 rem), although the regulatory limit is 5 millisieverts (0.5 rem). The actual doses that would be received by most infants would be far below 1 millisievert (0.1 rem). Of course, the physician may use discretion in the recommendation, increasing or decreasing the duration of interruption.
** These radionuclides are not radioactive material and are not regulated by the Agency. Information is presented for the convenience of readers of this guide, who should be alert to differences that might exist between regulations of the Agency, the U.S. Nuclear Regulatory Commissionand state requirements for non-NRC regulated material.

Notes: Activities are rounded to one significant figure, except when it was considered appropriate to use two significant figures. Details of the calculations are shown in NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material."

If there is no recommendation in Column 3 of this table, the maximum activity normally administered is below the activities that require instructions on interruption or discontinuation of breast-feeding. Although non-radioactive materials are not regulated by the Agency, information on non-radioactive material is included for the convenience of the licensee. Agreement State regulations may vary. Agreement State licensees should check with their State regulations before using these values.

Q.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 1,110 megabecquerels (30 millicuries) of iodine-131 had been administered, NRC still considers the instructions in this pamphlet to be an acceptable method for meeting the requirements of 180 NAC 7-037.02, 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 180 NAC 7-037.02.

The requirement of 180 NAC 7-037.02 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.

Q.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 .

Q.3 Records

Q.3.1 Records of Release

There is no requirement for recordkeeping on the release of patients who were released in accordance with Column 1 of Table Q.1; however, if the release of the patient is based on a dose calculation that 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 180 NAC 7-037.03. 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 180 NAC 7-037.04, should 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.

Q.3.2 Records of Instructions for Breast-Feeding Patients

If failure to interrupt or discontinue breast-feeding could result in a dose to the infant or child in excess of 5 millisieverts (0.5 rem), a record that instructions were provided is required by 180 NAC 7-034.05. Column 2 of Table Q.3 states, for the radiopharmaceuticals commonly used in medical diagnosis and treatment, the activities that would require such records when administered to patients who are breast-feeding.

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.

Q.4 Summary Table

Table Q.4 summarizes the criteria for releasing patients and the requirements for providing

instructions and maintaining records.

Table Q.4 Summary of Release Criteria, Required Instructions to Patients, and Records to Be Maintained				
Patient Group	**Basis for Release**	**Criteria for Release**	**Instructions Needed?**	**Release Records Required**
All patients, including patients who are breast-feeding an infant or child	Administered activity	Administered activity ≤ Column 1of Table Q.1	Yes, if administered activity > Column 1of Table Q.2	No
Table Q.4 Summary of Release Criteria, Required Instructions to Patients, and Records to Be Maintained	Patient Group	Basis for Release	Criteria for Release	Instructions needed?
Release Records required?	All patients, including patients who are breast-feeding an infant or child	Administered activity	Administered activity ≤Column 1 of Table Q.1	Yes, if administered activity > Column 1 of Table Q.2
No	Required Instructions to Patients, and Records to Be Maintained	Patient Group	Basis for Release	Criteria for Release
Instructions needed?	Release Records required?	All patients, including patients who are breast-feeding an infant or child	Administered activity	Administered activity ≤ Column 1 of Table Q.1

Implementation

The purpose of this section is to provide information to licensees and applicants regarding Agency staff's plans for using this appendix. Except in those cases in which a licensee proposes an acceptable alternative method for complying with 180 NAC 7-037, the methods described in this appendix will be used in the evaluation of a licensee's compliance with 180 NAC 7-037.

References

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.)

S. Schneider and S. A. McGuire, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," NUREG-1492 (Final Report), NRC, February 1997.

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 Q.5 Half-Lives and Exposure Rate Constants of Radionuclides Used in Medicine		
Radionuclide[1]	**Physical Half-Life (days)[2]**	**Exposure Rate Constant[3] (R/mCi-h at 1 cm)**
Ag-111	7.45	0.15
Au-198	2.69	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[4]
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	1.956	0.425
Sn-117m	13.61	1.48
Sr-89	50.5	N/A[4]
Tc-99m	0.251	0.756
Tl-201	3.044	0.447
Yb-169	32.01	1.83
Y-90	2.67	N/A[4]
Yb-169	32.01	1.83

Footnotes for Table Q.5

1 Although non-radioactive materials are not regulated by the Agency information on non-radioactive material is included for the convenience of the licensee.

2 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.

3 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.

[4] 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 Q.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 5 millisieverts (0.5 rem).

If 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, a record of the basis of the release is required by 180 NAC 7-037.04. 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 Q.1

In Table Q.1 in this 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 Q.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.
- = 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;
  - Live alone for at least the first 2 days; and
  - 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 2,220 megabecquerels (60 millicuries) 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 = 4) 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 (∞) = 4.59 millisieverts (0.459 rem)

Since the dose is less than 5 millisievert (0.5 rem), the patient may be released, but 180 NAC 7-037.02 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 180 NAC 7-037.04, because an occupancy factor of less than 0.25 at 1 meter was used.

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 180 NAC 7-037. 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:

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

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_{1eff}, F_2, and T_{2eff} are shown in Table Q.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 180 NAC 7-037.04 is described in Item Q.3.1 of this appendix.

Example 2, Thyroid Cancer: Calculate the maximum likely dose to an individual exposed to a patient to whom 5550 megabecquerel (150 millicurie) 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 Q.5. The uptake fractions and effective half-lives are from Table Q.6. 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 Q.6 Uptake Fractions and Effective Half-Lives for Iodine-131 Treatments

	Extrathyroidal Component		**Thyroidal Component**	
Medical Condition	**Uptake Fraction F_1**	**F_1 Effective Half-Life T_{1eff} (day)**	**Uptake Fraction F_2**	**Effective Half-Life T_{2eff} (day)**
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 Q.6

[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:

$$D(\infty) = \frac{(34.6)\ (2.2)\ (150)}{(100\ cm)^2} \{(0.75)\ (8.04)\ (0.8)\ (1 - e^{-0.693\ (0.33)\ /\ 8.04})$$

$$+ e^{-0.693\ (0.33)\ /\ 8.04}\ (0.25)\ (0.95)\ (0.32)$$

$$+ e^{-0.693\ (0.33)\ /\ 8.04}\ (0.25)\ (0.05)\ (7.3)\}$$

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

Therefore, thyroid cancer patients to whom 5550 megabecquerel (150 millicurie) of iodine-131

or less has been administered would not have to remain under licensee control and could be released under 180 NAC 7-037, assuming that the foregoing assumptions can be justified for the individual patient's case and that the patient is given instructions. Patients administered somewhat larger activities could also be released immediately if the dose is not greater than 5 millisieverts (0.5 rem).

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 2035 megabecquerels (55 millicuries) 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 Q.5, and Table Q.6, 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:

$$D(\infty) = \frac{(34.6)\ (2.2)\ (55)}{(100\ cm)^2}\ \{(0.75)\ (8.04)\ (0.8)\ (1 - e^{-0.693\ (0.33)\ /\ 8.04})$$

$$+ e^{-0.693\ (0.33)\ /\ 8.04}\ (0.25)\ (0.20)\ (0.32)$$

$$+ e^{-0.693\ (0.33)\ /\ 8.04}\ (0.25)\ (0.80)\ (5.2)\}$$

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

Therefore, hyperthyroid patients to whom 2035 megabecquerels (55 millicuries) of iodine-131 has been administered would not have to remain under licensee control and could be released under 180 NAC 7-037 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_i = 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 millicurie 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 1221 megabecquerels (33 millicuries) 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:

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

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

Using Equation B-1 and assuming the patient has received instructions for reducing exposure as recommended for an occupancy factor of 0.25, the external dose is approximately 5 mSv (0.5 rem). 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 wasalso 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."

For additional discussion on the subject, see Reference B-1.

Example 5, Internal Dose: Calculate the maximum internal dose to a person exposed to a patient to whom 5550 megabecquerels (150 millicuries) 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:

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

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

In this case, the external dose to the other person from Example 2, Thyroid Cancer, was approximately 3.4 millisieverts (0.34 rem), while the internal dose would be about 0.80 millisievert (0.08 rem). 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; 4.2 millisieverts (0.42 rem).

References for Supplement B

B-1. S. Schneider and S.A. McGuire, "Regulatory Analysis on Criteria for the Release of PatientsAdministered 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.

“Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material” (NUREG-1492, February 1997) provides the regulatory basis and examines the costs and benefits. A copy of NUREG-1492 is available for inspection and copying for a fee at NRC’s Public Document Room, 2120 L Street NW, Washington, DC. Copies may be purchased at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202)512-2249), or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161.

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Appendix R

Model Leak Test Program

Appendix R

Model Leak Test Program
Part 1

☐ A statement that: "We will follow the Procedures in Appendix R :"Leak Tests" of Regulatory Guide 7.00 Rev. ____ Dated _____."

OR

☐ A statement that: We will provide Equivalent Leak Test Procedures and they are attached."

AND

☐ A statement that: "Leak tests will be performed at intervals approved by the Department, an Agreement State or by the NRC and specified in the Sealed Source and Device Registration Certificate."

AND

☐ A statement: "Leak tests will be performed by an organization authorized by the Department, an Agreement State or the U.S. Nuclear Regulatory Commission to provide leak testing services for other licensees."

OR

☐ A statement: "Leak test kit will be supplied by an organization authorized by the Department, an Agreement State or U.S. Nuclear Regulatory Commission to provide leak test kits to other licensees and according to the kit supplier's instructions. Records for leak test results will be maintained."

Appendix R

Model Leak Test Program
Part 2

This model provides acceptable procedures for sealed source leak testing and analysis. Applicants may either adopt these model procedures or develop alternative procedures.

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests should be analyzed in a low-background area.
- Consider using a NaI(Tl) well counter system with a single or multichannel analyzer to analyze samples obtained from gamma-emitting sources (e.g., Cs-137).
- Consider using a liquid scintillation or gas-flow proportional counting system to analyze samples obtained from beta-emitting sources (e.g., Sr-90).
- Instrumentation used to analyze leak test samples must be capable of detecting 185 Bq (0.005 μCi) of radioactivity.

Model Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as sealed source serial number, radionuclide, and activity.
- Use a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate identifying information for each source.
- Wear gloves.
- Obtain samples at the most accessible area where contamination would accumulate if the sealed source were leaking.
- Measure the background count rate and record.
- Check the instrument's counting efficiency, using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within ± 5% of the stated value and traceable to a primary radiation standard, such as those maintained by NIST.
- Calculate efficiency of the instrument.

  For example,

$$Eff = \frac{[(cpm\ from\ std) - (cpm\ from\ bkg)]}{(activity\ of\ std\ in\ microcurie)}$$

where:

Eff = efficiency, in cpm / microcurie,
cpm = counts per minute,
std = standard, and
bkg = background.

- Analyze each wipe sample to determine net count rate.
  For example:

$$\frac{\text{(cpm from wipe sample) – (cpm from bkg)}}{\text{Efficiency in cpm/microcuries}} = \text{micirocurie on wipe sample}$$

- For each sample, calculate the activity in microcurie and record.
- The activity on the wipe sample is given by:
- Leak test records will be retained in accordance with 180 NAC 7-094 for 3 years. Licensees should include the following in records:
  - The model number and serial number (if assigned) of each source tested;
  - The identity of each source radionuclide and its estimated activity;
  - The measured activity of each test sample expressed in microcurie;
  - A description of the method used to measure each test sample;
  - The date of the test; and
  - The name of the individual who performed the test.
- If the wipe test reveals 185 Bq (0.005 µCi) or greater:
  - Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in 180 NAC 3 and 4 [180 NAC 7-033].
  - File a report within 5 days of the leak test in accordance with 180 NAC 7-118.

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Appendix S

Model Medical Licensee Audit

Appendix S

Model Medical Licensee Audit

Annual Radiation Protection Medical Licensee Audit

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit. For example, licensees do not need to address areas which do not apply to the licensee's activities, and activities that have not occurred since the last audit need not be reviewed at the next audit.

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 [180 NAC 4-004]?

B. Were records of previous audits maintained [180 NAC 4-047]?

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 [180 NAC 7-010]?
2. Does new RSO meet Agency training requirements [180 NAC 7-022, 7-026, 7-027]?
3. Is RSO fulfilling all duties [180 NAC 7-015]?
4. Is the written agreement in place for a new RSO [180 NAC 7-015.04]?

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[180 NAC 3-018.01]? If so, is financial assurance adequate?

3. Calibration, transmission, and reference sources [180 NAC 7-032]?

   a. Sealed sources manufactured and distributed by a person licensed pursuant to 180 NAC 3-014.12, equivalent Agreement State regulations, or redistributed by a licensee authorized to redistribute sealed sources, and sources do not exceed 30 millicurie each [180 NAC 7-032.01]

   b. Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 15 millicurie [180 NAC 7-032.02]

   c. Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 200 microcurie or 1000 times the quantities in Appendix B of 180 NAC 3 [180 NAC 7-032.03]

   d. Technetium-99m in individual amounts as needed [180 NAC 7-032.04]?

4. Unsealed materials used under 180 NAC 7-041, 7-044, and 7-048 are:

   a Obtained from a manufacturer or preparer licensed under 180 NAC 3-014.12?

   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 180 NAC 7-041, 7-044, and 7-048, as applicable?

G. Are the sealed sources possessed and used as described in the Sealed Source and Device Registration (SSDR) Certificate [180 NAC 7-055, 180 NAC 7-065, 180 NAC 7-067]? 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 [180 NAC 7-010.05]?

J. If control of license was transferred or bankruptcy filed, was Agency prior consent obtained or notification made, respectively [180 NAC 3-017.02 and 3-017.05]?

Radiation Safety Program

A. Minor changes to program [180 NAC 7-016]?
B. Records of changes maintained for 5 years [180 NAC 7-087]?
C. Content and implementation reviewed annually by the licensee [180 NAC 4-004.03]?
D. Records of reviews maintained [180 NAC 4-047]?
E. Radiation Safety Committee (RSC) established if one or more different type of use under 180 NAC 7-048, 7-055, 7-067 and 7-085 or one or more types of units under 180 NAC 7-067. [180 NAC 7-015.08]
F. RSC will meet at least once every six months and maintain minuutes. [180 NAC 7-015.o9]
G. RSO will look at exposures on a quarterly bases to make sure exposures are within limits and the RSC will review than at least once every six months. [180 NAC 7-015.01]
H. RSO/RSC will inform works of ALARA. [180 NAC 7-015.01]

Use by Authorized Individuals

Compliance is established by meeting at least one criterion under each category.

A. Authorized Nuclear Pharmacist [180 NAC 7-024, 7-026, 7-027] (*Note:* Does not apply to facilities that are registered/licensed by FDA/State Agency as a Drug Manufacturer with distribution regulated under Part 32):

_____ 1. Certified by specialty board

_____ 2. Identified on a Agency, 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 [180 NAC 7-026, 7-027, 7-043, 7-047, 7-051, 7-052, 7-053, 7-063, 7-064, 7-66, 7-084]:

_____ 1. Certified by specialty board

_____ 2. Identified on Agency, 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 [7-023, 7-026, 7-027]:

_____ 1. Certified by specialty board

_____ 2. Identified on Agency, 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 180 NAC 7-038, 7-079?

B. Compliance with 180 NAC 4-013 evaluated and met?

C. Letter signed by management of each client [180 NAC 7-009/02]?

D. Licensed material was not delivered to client's address (unless client was authorized) [180 NAC 7-009.03]?

E. Dosage measuring instruments checked for proper function before used at each address of use or on each day of use, if more frequent [180 NAC 7-038.04]?

F. Survey instruments checked for proper operation before used at each address of use [180 NAC 7-038.05]?

G. Survey of all areas of use prior to leaving each client address [180 NAC 7-038.06]?

H. Additional technical requirements for mobile remote afterloaders per [180 NAC 7-079]?

Amendments Since Last Audit [180 NAC 7-010]

A. Any Amendments since last audit [180 NAC 7-010]?

Notifications Since Last Audit [180 NAC 7-011]

A. Any Notifications since last audit [180 NAC 7-011]?

B. Appropriate documentation provided to the Agency for authorized nuclear pharmacist, authorized medical physicists, or authorized user no later than 30 days after the individual starts work [180 NAC 7-011.01]?

C. The Agency notified within 30 days after: authorized user, authorized nuclear pharmacist, authorized medical physicist, or RSO stops work or changes name; licensee'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 180 NAC 7-041 or 7-044 use [180 NAC 7-011.02]?

Training, Retraining, And Instructions to Workers

A. Have workers been provided with required instructions [180 NAC 10-003, 180 NAC 7-018, 7-049, 7-058, 7-070]?

B. Is the individual's understanding of current procedures and regulations adequate?

C. Training program implemented?

1. Operating procedures [180 NAC 7-018, 7-049, 7-058 7-070]?

2. Emergency procedures [180 NAC 7-018, 7-049,. 7-058., 7-070]?

3. Periodic training required and implemented [180 NAC 7-049, 7-058, 7-070]?

4. Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed and was refresher training provided, as needed [180 NAC 10-003]?

5. Was each supervised user instructed in the licensee's written radiation protection procedures and administration of written directives, as appropriate [180 NAC 7-018]?

6. Are initial and periodic training records maintained for each individual [180 NAC 7-0101]?

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 [180 NAC 7-070]?

E. 180 NAC 4 – Workers cognizant of requirements for:

1. Radiation Safety Program [180 NAC 4-004, 180 NAC 7-015, 7-016]?

2. Annual dose limits [180 NAC 4-005, 4-013, 4-014]?

3. NRH Forms 1 and 2?

4. 10% monitoring threshold [180 NAC 4-022]?

5. Dose limits to embryo/fetus and declared pregnant worker [180 NAC 4-012]?

6. Grave Danger Posting [180 NAC 4-034.03]?

7. Procedures for opening packages [180 NAC 4-038]?

F. Supervision of individuals by authorized user and/or authorized nuclear pharmacist in accordance with 180 NAC 7-018?

Radioactive Gases and Aerosols

A. Check for negatives pressure in areas which radioactive gases is used. [180 NAC 7-039.06]

B. Measure air flow exhaust rate. [180 NAC 7-039.07]

C. Determine evacuation time from areas of where radioactive gases are used. [180 NAC 7-039.07 and 039.08]

D. Check operation of radioactive gases collection system monthly. [180 NAC 7-039.05]

E. Are ventilation rates measured in area of radioactive gases use at least every 6 months? [180 NAC 7-039.05]

Training for Manual Brachytherapy And Use Of Unsealed Radioactive Material for Which A Written Directive Is Required

A. Safety instruction to personnel provided include [180 NAC 7-049, 7-058]:

1. Control of patient and visitors?

2. Routine visitation to patients in accordance with 180 NAC 4-013?

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 [180 NAC 7-101]?

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 [180 NAC 7-059, 7-071]?

D. Storage areas:

1. Materials secured from unauthorized removal or access [180 NAC 4-031]?

2. Licensee controls and maintains constant surveillance of licensed material not in storage [180 NAC 4-032]?

E. Therapy unit operation:

1. Unit, console, console keys, and treatment room controlled adequately [180 NAC 4-031, 180 NAC 7-070.01, item 1]?

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 [180 NAC 7-070.01, item 3]?

Dose or Dosage Measuring Equipment

A. Possession, use, and calibration of instruments to measure activities of unsealed radionuclides [180 NAC 7-029]:

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 [180 NAC 7-091]?

B. Determination of dosages of unsealed radioactive material [180 NAC 7-031]?

1. Each dosage determined and recorded prior to medical use [180 NAC 7-031.01]?

2. Measurement of unit dosages made either by direct measurement or by decay correction [180 NAC 7-031.02]?

3. For other than unit dosages, measurement made by direct measurement of radioactivity or by combination of radioactivity or volumetric measurement and calculation [180 NAC 7-031.04)]?

C. Licensee uses generators?

1. First eluate after receipt tested for Mo-99 breakthrough [180 NAC 7-045.02)]?

2. No radiopharmaceuticals administered with Mo-99 concentrations over 0.15 μCi per mCi of Tc-99m [180 NAC 7-045.01]?

3. Records maintained [180 NAC 7-099]?

D. Dosimetry Equipment [180 NAC 7-072]:

1. Calibrated system available for use [180 NAC 7-072.01]?

2. Calibrated by NIST or an AAPM-accredited lab within previous 2 years and after servicing [180 NAC 7-072.01, item 1] OR calibrated by intercomparison per 180 NAC 7-072.01, item 2?

3. Calibrated within the previous 4 years [180 NAC 7-072.01, item 2]?

4. Licensee has available for use a dosimetry system for spot-check measurements [180 NAC 7-072.02]?

5. Record of each calibration, intercomparison, and comparison maintained [180 NAC 7-107]?

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 [180 NAC 7-033.02]?

2. Inventory of sealed sources and brachytherapy sources performed semiannually [180

NAC 7-033.04]?

3. Records maintained [180 NAC 7-094]?

Radiation Survey Instruments

A. Survey instruments used to show compliance with 180 NAC 4 and 180 NAC 3-011, item 2:

1. Appropriate operable survey instruments possessed or available [180 NAC 4]?

2. Calibrations [180 NAC 7-030.01 and 7-030.02]:

   a. Before first use, annually and after repairs?

   b. Within 20% on each scale or decade of interest?

3. Records maintained [180 NAC 7-092]?

B. Radiation surveys performed in accordance with the licensee's procedures and the regulatoryrequirements [180 NAC 4-021, 180 NAC 7-036]?

1. Daily in all areas where radiopharmaceuticals requiring a written directive are prepared or administered (except patient rooms) [180 NAC 7-036]?

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 sources(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry [180 NAC 7-080.01] and records maintained [180 NAC 7-0113]?

   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 1mSv (100 mrem) in a year [180 NAC 4-013.01]?

B. Has a survey or evaluation been performed per 180 NAC 4-021.01?

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 0.02 mSv (2 mrem) in any one hour [180 NAC 4-013.01]?

E. Is licensed material used or stored in a manner that would prevent unauthorized access or removal [180 NAC 4-031 and 4-032]?

F. Records maintained [180 NAC 4-048, 4-053]?

Patient Release

A. Individuals released when TEDE less than 0.5 rem [180 NAC 7-037.01]?

B. Instructions to the released individual, including breast-feeding women, include required information [180 NAC 7-037.02]?

C. Release records maintained [180 NAC 7-096.01]?

D. Records of instructions given to breast-feeding women maintained, if required [180 NAC 7-096.02]?

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 [180 NAC 7-049)]?

B. RSO and AU promptly notified if patient died or had a medical emergency [180 NAC 7-049]?

Brachytherapy

A. Safety precautions implemented to include patient facilities, posting, stay times, and emergency response equipment [180 NAC 7-059]?

B. Survey immediately after implant [180 NAC 7-056.01]?

C. Patients surveyed immediately after removing the last temporary implant source [180 NAC 7-056.02]?

D RSO and AU promptly notified if patient died or had a medical emergency [180 NAC 7-

059.03]?

E. Records maintained [180 NAC 7-102]?

Radioactive Waste

A. Disposal:

1. Decay-in-storage [180 NAC 7-040]

2. Procedures followed?

3. Labels removed or defaced [180 NAC 4-036, 180 NAC 7-040]?

B. Special procedures performed as required?

C. Authorized disposals [180 NAC 4-039]?

D. Records maintained [180 NAC 4-046.01, 4-054, 7-098]?

E. Effluents:

1. Release to sanitary sewer [180 NAC 4-041]?

   a. Material is readily soluble or readily dispersible [180 NAC 4-041]?

   b. Monthly average release concentrations do not exceed 180 NAC 4 App. B, Table 2 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 [180 NAC 4-041]?

   d. Procedures to ensure representative sampling and analysis implemented [180 NAC 4-021]?

2. Release to septic tanks [180 NAC 4-041]?

   a. Within unrestricted limits [180 NAC 4, App. B, Table 2]?

3. Waste incinerated?

   a. License authorizes [180 NAC 4-042]?

   b. Directly monitor exhaust?

   c. Airborne releases evaluated and controlled [180 NAC 4-014, 4-021]?

4. Air effluents and ashes controlled [180 NAC 4-004, 4-005, 4-013, 4-021]?

a. Air effluent less than 10 mrem constraint limit [180 NAC 4-004]?

b. If no, reported appropriate information to NRC.

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.) analyzedwith appropriate instrumentation?

F. Waste storage

1. Protection from elements and fire?

2. Control of waste maintained [180 NAC 4-031]?

3. Containers properly labeled and area properly posted [180 NAC 4-034, 4-036]?

4. Package integrity adequately maintained?

G. Waste disposal:

1. Sources transferred to authorized individuals [180 NAC 4-044, 4-039, 180 NAC 3-025]?

2. Name of organization:

H. Records of surveys and material accountability are maintained [180 NAC 4-048, 4-054, 180 NAC 7-098]?

Receipt And Transfer of Radioactive Material

A. Describe how packages are received and by whom.

B. Written package opening procedures established and followed [180 NAC 4-038.05]?

C. All incoming packages with a DOT label monitored for radioactive contamination, unless exempted (gases and special form) [180 NAC 4-038.02, item 1]?

D. Incoming packages surveyed [180 NAC 4-038.02, item 1]?

E. Monitoring in (C) and (D) performed within time specified [180 NAC 4-038.03]?

F. Transfer(s) performed per [180 NAC 3-025]?

G. All sources surveyed before shipment and transfer [180 NAC 4-021.01]?

H. Records of surveys and receipt/transfer maintained [180 NAC 4-048.01]?

I. Package receipt/distribution activities evaluated for compliance with 180 NAC 4-013?

Transportation

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 [180 NAC 7-081.01]?

B. Needed service arranged for as identified during the inspection?

C. Service performed by persons specifically authorized to do so [180 NAC 7-081.02]?

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 [180 NAC 7-073.01, item 1, 7-074.01, item 1, 7-075.01, item 1]?

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 [180 NAC 7-073.01, item 3, 7-074.02, item 3 and 4, 7-075.01, item 3]?

D. Whenever spot-checks indicate output differs from expected by ±5% [180 NAC 7-073.01, item 2.a., 7-075.01, item 2.a.]?

E. After source exchange, relocation, and major repair or modification [180 NAC 7-073.01, item 2, 7-074.01, item 2, 7-075.01, item 2]?

F. Performed with properly calibrated instrument [180 NAC 7-073.03, 7-04.04, 7-075.03]?

G. Includes:

1. For teletherapy:

a. Output measured within ±3% of expected for the range of field sizes, range of distances [180 NAC 7-073.02, item 1]?

b. Coincidence of radiation field and field light localizer [180 NAC 7-073.02, item 2]?

c. Uniformity of radiation field and beam angle dependence [180 NAC 7-073.02, item 3]?

d. Timer accuracy and linearity over the range of use [180 NAC 7-073.02, item 4]?

e. On-off error [180 NAC 7-073.02, item 5]?

f. Accuracy of all measuring and localization devices [180 NAC 7-073.02, item 6]?

2. For remote afterloaders:

a. Output measured within ±5% of expected [180 NAC 7-074.02, item 1]?

b. Source positioning accuracy within ±1 millimeter [180 NAC 7-074.02, item 2]?

c. Source retraction with backup battery upon power failure [180 NAC 7-074.02, item 3]?

d. Length of source transfer tubes [180 NAC 7-074.02, item 4]?

e. Timer accuracy and linearity over the typical range of use [180 NAC 7-074.02, item 4]?

f. Length of the applicators [180 NAC 7-074.02, item 6]?

g. Function of source transfer tubes, applicators, and transfer tube-applicator interfaces [180 NAC 7-074.02, item 7]?

h. Autoradiograph quarterly of the LDR source(s) to verify source(s) arrangement and inventory [180 NAC 7-074.03]?

3. For gamma stereotactic radiosurgery:

a. Output measured within ±3% of expected [180 NAC 7-075.02, item 1]?

b. Helmet factors [180 NAC 7-075.02, item 2)]?

c. Isocenter coincidence [180 NAC 7-075.02, item 3]?

d. Timer accuracy and linearity over the range of use [180 NAC 7-075.02, item 4]?

e. On-off error [180 NAC 7-075.02, item 5]?

f. Trunnion centricity [180 NAC 7-075.02, item 6]?

g. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off [180 NAC 7-075.02, item 7]?

h. Helmet microswitches [180 NAC 7-075.02, item 8]?

i. Emergency timing circuit [180 NAC 7-075.02, item 9]?

j. Stereotactic frames and localizing devices (trunnions) [180 NAC 7-075.02, item 10]?

H. Output corrected mathematically for decay [180 NAC 7-073.05, 7-074.07, 7-075.05]?

I. Records maintained [180 NAC 7-108]?

Periodic Spot Checks For Therapeutic Devices

A. Performed at required frequency [180 NAC 7-076.01, 7-077.01, 7-078.01]?

B. Procedures established by authorized medical physicist [180 NAC 7-076.02, 7-077.02, 7-078.02]?

C. Procedures followed?

D. Medical physicist reviews results within 15 days [180 NAC 7-076.03, 7-077.03, 7-078.02, item 2]?

E. Performed with properly calibrated instrument [180 NAC 7-076.01, item 5; 7-078.03, item 2.a.]?

F. Output and safety spot checks include:

1. For teletherapy:

a. Timer accuracy and linearity over the range of use [180 NAC 7-076.01, item 1]?

b. On-off error [180 NAC 7-076.01, item 2]?

c. Coincidence of radiation field and field light localizer [180 NAC 7-076.01, item 3]?

d. Accuracy of all measuring and localization devices [180 NAC 7-076.01, item 4]?

e. The output for one typical set of operating conditions [180 NAC 7-076.01, item 5]?

f. Difference between measured and expected output [180 NAC 7-076.01, item 6]?

g. Interlock systems [180 NAC 7-076.04, item 1]?

h. Beam stops [180 NAC 7-076.04, item 2]?

i. Source exposure indicator lights [180 NAC 7-076.04, item 3]?

j. Viewing and intercom systems [180 NAC 7-076.04, item 4]?

k. Treatment room doors, inside and out [180 NAC 7-076.04, item 5]?

2. Electrical treatment doors with power shut off [180 NAC 7-076.04, item 6]?

3. For remote afterloaders:

    a. Interlock systems [180 NAC 7-077.04, item 1]?

    b. Source exposure indicator lights [180 NAC 7-077.04, item 2]?

    c. Viewing and intercom systems, except for LDR [180 NAC 7-077.04, item 3]?

    d. Emergency response equipment [180 NAC 7-077.04, item 4]?

    e. Radiation monitors used to indicate source position [180 NAC 7-077.04, item 5]?

    f. Timer accuracy [180 NAC 7-077.04, item 6]?

    g. Clock (date and time) in the unit's computer [180 NAC 7-077.04, item 7]?

    h. Decayed source(s) activity in the unit's computer [180 NAC 7-077.04, item 8]?

3. For gamma stereotactic radiosurgery:

    a. Treatment table retraction mechanism [180 NAC 7-078.03, item 1.a.]?

    b. Helmet microswitches [180 NAC 7-078.03, item 1.b.]?

    c. Emergency timing circuits [180 NAC 7-078.03, item 1.c.]?

    d. Stereotactic frames and localizing devices [180 NAC 7-078.03, item 1.d.]?

    e. The output for one typical set of operating conditions [180 NAC 7-078.03, item 2.a.]?

    f. Difference between measured and expected output [180 NAC 7-078.03, item 2.b.)]?

    g. Source output compared against computer calculation of output [180 NAC 7-078.03, item 2.c.]?

    h. Timer accuracy and linearity over the range of use [180 NAC 7-078.03, item 2.d.]?

    i. On-off error [180 NAC 7-078.03, item 2.e.]?

    j. Trunnion centricity [180 NAC 7-078.03, item 2.f.]?

    k. Interlock systems [180 NAC 7-078.04, item 1]?

    l. Source exposure indicator lights [180 NAC 7-078.04, item 2]?

    m. Viewing and intercom systems [180 NAC 7-078.04, item 3]?

n. Timer termination [180 NAC 7-078.04, item 4]?

o. Radiation monitors used to indicate room exposures [180 NAC 7-078.04, item 5]?

p. Emergency off buttons [180 NAC 7-078.04, item 6]?

G. Licensee promptly repaired items found to be not operating properly and did not use unit until repaired, if required [180 NAC 7-076.05, 7-077.05, 7-078.06]?

H. Records maintained [180 NAC 7-109, 7-110, 7-111]?

Installation, Maintenance, and Repair of Therapy Devices

A. Only authorized individuals perform installation, maintenance, adjustment, repair, and inspection [35.605, 35.655]? Name of organization/individual:

B. Records maintained [180 NAC 7-069, 7-081, 7-0106, 7-114]?

Operating Procedures For Therapy Devices

A. Instructions on location of emergency procedures and emergency response telephone numbers are posted at the device console [180 NAC 7-070]?

B. Copy of the entire procedures physically located at the device console [180 NAC 7-070.02]?

C. Procedures include:

1. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions [180 NAC 7-070.01, item 4]?

2. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure [180 NAC 7-071.01, item 4]?

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 [180 NAC 7-071.01, item 4]?

D. Radiation survey of patient is performed to ensure source is returned to shielded position [180 NAC 7-068.01]?

E. Records of radiation surveys maintained for 3 years [180 NAC 7-102]?

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) [180 NAC 7-

071.05, item 1 and 2]?

2. Physically present throughout all patient treatments with a gamma stereotactic radiosurgery device [180 NAC 7-071.06, item 3]?

Personnel Radiation Protection

A. Exposure evaluation performed [180 NAC 4-021]?

B. ALARA program implemented [180 NAC 4-004.02]?

C. External Dosimetry:

1. Monitors workers per [180 NAC 4-022.01]?

2. External exposures account for contributions from airborne activity [180 NAC 4-007]?

3. Supplier Frequency

4. Supplier is NVLAP-approved [180 NAC 4-021.03]?

5. Dosimeters exchanged at required frequency?

D. Internal Dosimetry

1. Monitors workers per 180 NAC 4-022?

2. Briefly describe program for monitoring and controlling internal exposures [180 NAC 7-04-026, 4-027]?

3. Monitoring/controlling program implemented (includes bioassays)?

4. Respiratory protection equipment [180 NAC 4-028]?

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 [180 NAC 4-050]?

4. Maximum exposures TEDE Other

5. Maximum CDEs Organs

6. Maximum CEDE

7. Internal and external summed [180 NAC 4-006]?

8. Were occupational limits met [180 NAC 4-005]?

9. NRH forms or equivalent [180 NAC 4-009.04, 4-052.03]?

    a. NRH-1 Complete:

    b. NRH-2 Complete:

10. If a worker declared her pregnancy during the audit period, then was the dose in compliance [180 NAC 4-012] and were the records maintained [180 NAC 4-052.04]?

F. Who performed any planned special exposures at this facility (number of people involved and doses received) [180 NAC 4-010, 4-050, 4-051, 4-060]?

G. Records of exposures, surveys, monitoring, and evaluations maintained [180 NAC 4-047, 4-048, 4-052]?

Confirmatory Measurements

Detail location and results of confirmatory measurements.

Medical Events

If medical events [criteria in 180 NAC 7-115] 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

Nebraska's Department of Health and Human Services Regulation and Licensure – Radiation Control Program

Referring Physician Patient

In writing/By telephone

If notification did not occur, why not?

3. Written Reports [180 NAC 7-115]:
    a. Submitted to Region within 15 days?

Notification and Reports

A. In compliance with 180 NAC 10-004, 180 NAC 3-026 (reports to individuals, public and

occupational, monitored to show compliance with 180 NAC 4)?

B. In compliance with 180 NAC 4-057, 180 NAC 3-026 (theft or loss)?

C. In compliance with 180 NAC 4-058, 180 NAC 3-026 (incidents)?

D. In compliance with 180 NAC 4-059, 180 NAC 3-026 (overexposures and high radiation levels)?

E. Aware of Agency Emergency phone number?

F. In compliance with 180 NAC 4-059 (Constraint on air emissions)?

Posting and Labeling

A. NRH 3 "Notice to Workers" is posted [180 NAC 10-002]?
B. 180 NAC 4 and 10, and license documents are posted, or a notice indicating where documents can be examined is posted [180 NAC 10-002]?
C. Other posting and labeling per 180 NAC 4-034, 4-036 and not exempted by 180 NAC 4-035, 4-037?

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 [180 NAC 3-018.07)]?

B. Records include all information outlined in 180 NAC 3-018.07?

Bulletins and Information Notices

A. Bulletins, Information Notices, NMSS Newsletters, etc., received?

B. Appropriate action in response to Bulletins, Generic Letters, 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:

Appendix T

Recordkeeping Requirements

Appendix T

Recordkeeping Requirements

Table T.1 Typical Records and Retention Times			
Record Survey	**Survey Requirement**	**Recordkeeping Requirement**	**Retention Period**
Results of surveys and calibrations	180 NAC 4-021 180 NAC 4-038.02	180 NAC 4-048.01	3 years
Results of surveys to determine dose from external sources		180 NAC 4-048.02, item 1	Duration of license
Results of measurements and calculations used to determine individual intakes		180 NAC 4-048.02, item 2	Duration of license
Results of air samplings, surveys, and bioassays	180 NAC 4-028.01, item 3.a. and b.	180 NAC 4-048.02, item 3	Duration of license
Results of measurements and calculations used to evaluate the release of radioactive effluents to the environment		180 NAC 4-048.03, item 4	Duration of license
Determination of prior occupational dose		180 NAC 4-050	Duration of license
Planned special exposure	180 NAC 4-010	180 NAC 4-051	Duration of license
Individual monitoring results	180 NAC 4-022	180 NAC 4-052	Duration of license
Dose to individual members of the public	180 NAC 4-013	180 NAC 4-053	Duration of license
Waste disposal	180 NAC 4-040; 180 NAC 4-041; 180 NAC 4-042; 180 NAC 4-043;	180 NAC 4-054	Duration of license
Records of receipt of radioactive material		180 NAC 3-030.03	For a long as the material is possess until 5 years after transfer or disposal
Records of transfer of radioactive material		180 NAC 3-030.03, item 1	Until the Agency terminates each pertinent license requiring the record
Records of disposal of radioactive material		180 NAC 3-030.03, item 2	Duration of license
Authority and responsibilities of radiation protection program	180 NAC 7-015	180 NAC 7-086	5 years
Radiation protection program changes	180 NAC 7-016	180 NAC 7-087	5 years
Written directives	180 NAC 7-019	180 NAC 7-088	3years
Calibrations of instruments used to measure activity of unsealed radioactive material	180 NAC 7-029	180 NAC 7-091	3 years
Radiation survey instrument calibrations	180 NAC 7-030	180 NAC 7-092	3years
Dosages of unsealed radioactive material for medical use	180 NAC 7-031	180 NAC 7-093	3 years
Leak tests and inventory of sealed sources and brachytherapy sources	180 NAC 7-033.02	180 NAC 7-094	3 years
Surveys for ambient radiation exposure rate	180 NAC 7-036	180 NAC 7-095	3 years

Table T.1 Typical Records and Retention Times			
Record Survey	**Survey Requirement**	**Recordkeeping Requirement**	**Retention Period**
Release of individuals containing unsealed radioactive material or implants containing radioactive material	180 NAC 7-037	180 NAC 7-096	3 years
Mobile medical services	180 NAC 7-038.01	180 NAC 7-097	3 years
Decay-in-storage	180 NAC 7-040	180 NAC 7-098	Duration of license
Molybdenum-99 concentrations	180 NAC 7-045.02	180 NAC 7-099	3 years
Training	180 NAC 7-025	180 NAC 7-100	3 years
Safety instruction	180 NAC 7-049, 180 NAC 7-058, 180 NAC 7-070	180 NAC 7-101	3 years
Surveys after source implant and removal	180 NAC 7-056, 180 NAC 7-068	180 NAC 7-102	3 years
Brachytherapy source accountability	180 NAC 7-057	180 NAC 7-103	3 years
Calibration measurements of brachytherapy sources	180 NAC 7-060.05	180 NAC 7-104	3 years
Decay of strontium-90 sources for ophthalmic treatments	180 NAC 7-060	180 NAC 7-105	Life of source
Installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	180 NAC 7-068	180 NAC 7-106	3 years
Dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	180 NAC 7-072	180 NAC 7-107	Duration of license
Teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations	180 NAC 7-073, 180 NAC 7-074, 180 NAC 7-075	180 NAC 7-108	3 years
Periodic spot-checks of teletherapy units	180 NAC 7-076	180 NAC 7-109	3 years
Periodic spot-checks of remote afterloader units	180 NAC 7-077	180 NAC 7-110	3 years
Periodic spot-checks of gamma stereotactic radiosurgery units	180 NAC 7-078	180 NAC 7-111	3 years
Additional technical requirements for mobile remote afterloader units	180 NAC 7-079	180 NAC 7-112	3 years
Surveys of therapeutic treatment units	180 NAC 7-080	180 NAC 7-113	Duration of use of unit
5-year inspection for teletherapy and gamma stereotactic radiosurgery units	180 NAC 7-081	180 NAC 7-114	Duration of use of unit

Appendix U

Reporting Requirements

Appendix U

Reporting Requirements

Table U.1 Typical NRC Notifications and/or Reports			
Event Telephone	**Notification**	**Written Report**	**Regulatory Requirement**
Reports to individual workers none annually	None	Annually	180 NAC 10-004.02
Reports to former individual workers	None	Upon request	180 NAC 10-004.03
Notification of special circumstances to individuals	None	30 days	180 NAC 10-004.05
Reports to worker terminating employment none upon request	None	Upon request	180 NAC 10-004.06
Theft or loss of material	Immediate	30 days	180 NAC 4-057.01, item 1
Whole body dose greater than 0.25 Sv (25 rems)	Immediate	30 days	180 NAC 4-058.01, item 1.a. 180 NAC 4-059.01
Extremity dose greater than 2.5 Sv (250 rems)	Immediate	30 days	180 NAC 4-058.01, item 1.c. 180 NAC 4-059.01
Whole body dose greater than 0.05 Sv (5 rems) I 24 hours	24 hours	30 days	180 NAC 4-058.02, item 1.a. 180 NAC 4-059.01
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	180 NAC 4-058.02, item 1.c. 180 NAC 4-059.01
Doses in excess of specified criteria	None	30 days	180 NAC 4-059.01, item 2.
Levels of radiation or concentrations of radioactive material in excess of specified criteria	None	30 days	180 NAC 4-059.01, item 3
Planned special exposures	None	30 days	180 NAC 4-060
Report to individuals of exceeding dose limits	None	30 days	180 NAC 4-063
Report of individual monitoring	None	Annually	180 NAC 4-062
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	Immediate	30 days	180 NAC 3-026.01
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	180 NAC 3-026.02. item 2
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with icensed material	24 hours	30 days	180 NAC 3-026.02, item 4

Table U.1 Typical NRC Notifications and/or Reports			
Event Telephone	**Notification**	**Written Report**	**Regulatory Requirement**
Licensee permits individual to work as AU, ANP, or AMP	None	30 days	180 NAC 7-011.01
AU, ANP, or AMP discontinues performance of duties under license or has a name change	None	30 days	180 NAC 7-011.01
Licensee's mailing address changes	None	30 days	180 NAC 7-011.02, item 2
Licensee's name changes without constituting a transfer of control	None	30 days	180 NAC 011.02, item 3
Licensee adds or changes areas of 180 NAC 7-041 and 7-044 use of radioactive material identified in application or license	None	30 days	180 NAC 011.02, item 4
Medical event	1 day	15 days	180 NAC 7-115
Dose to embryo or nursing child	1 day	15 days	180 NAC 7-117
Leaking source	None	5 days	180 NAC 7-118

Note: Telephone notifications shall be made to:

Nebraska's DHHS, Office of Radiological Health (402)471-2168 (M-F 8AM to 5 PM)

After hours – Nebraska State Patrol (402)471-4545 (Ask to speak to the NEMA Duty Officer as you have an incident to report involving radioactive materials.) except as noted..

Appendix V

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

Appendix V

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

Licensed material must be transported in accordance with DOT regulations. The major areas in 180 NAC and the DOT regulations that are most relevant for transportation of Type A or Type B quantities of licensed 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 packagings, 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 <http://www.dot.gov>.

Appendix W

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

Appendix W

Model Procedure 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 alterative procedures to meet the requirements of 180 NAC 4-039 to 4-059, 4-004 and 180 NAC 7-040.

Model Procedure for Decay-In-Storage

180 NAC 7-040 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 180 NAC 7-040);
  - 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 180 NAC 13, 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 180 NAC 3-030.

Model Procedure for Return of Licensed Material to Authorized Recipients

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

- In accordance with 180 NAC 3-025.03, confirm that persons are authorized to receive radioactive material prior to transfer (e.g., obtain a copy of the transferee's Agency license, NRC license 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'sinstructions;
- Retain records of receipts and transfers in accordance with 180 NAC 3-030.

Appendix X

Other Equipment and Facilities

Appendix X
Other Equipment and Facilities

- ☐ Detailed descriptions of additional equipment and facilities available for the safe use and storage of radioactive materials requested are attached. (Place checkmark by items included.)
  - ☐ For manual brachytherapy facilities, we are providing a description of the emergency response equipment.
  - ☐ For teletherapy, GSR, and remote afterloader facilities, we are providing 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.

Appendix Y

Radioactive Gases and Aerosols

Appendix Y
RADIOACTIVE GAS AND AEROSOL SUPPORTING INFORMATION AND CONCENTRATION CALCULATIONS

1. **AEROSOL**

   ☐ A. Tc-99m aerosol shall be administered utilizing an approved and shielded device.

   ☐ B. Tc-99m aerosol waste shall be collected in the approved, shielded trap and held for decay/disposal, as appropriate.

2. **XENON 133**

   A. **Definition Of Variables**

   (1). Average number of studies expected per week: _____ = S.

   (2). Average activity per patient dose: _____ = A.

   (3). Desired possession limit: _____ mCi or Bq. (This should be sufficient to provide for shipments whose calibration dates are several days after receipt.)

   (4). Loss rate fraction is assumed to be 0.20 = f = 20%.

   (5). **Is use area under negative pressure?** ☐ Yes ☐ No

   (6). Measured airflow exhaust rate from Xenon 133 storage and use area: _____ ft^3 /min = r

   (7). Measured airflow exhaust rate of air potentially contaminated with Xe-133 at point of release to unrestricted area (exterior of building): ft^3 /min - R

   (If exhaust air from Xenon 133 use area is vented directly to roof of building without being mixed with additional exhaust air from building, R = r. If additional air is mixed in air from Xenon 133 use area,
   R will be greater than r.)

   (8). Dilution factor of exhaust air $D = \frac{R}{r}$ = _____

   Is the use area ventilated by a partially recirculating building ventilation system?
   ☐ Yes ☐ No If yes, complete Item (9).

   (9). The fraction of recirculated air is _____ % = 0._____ = F

B. **Occupational Exposure Concentration (C)**

The average concentration in restricted area is:

$$C_r = \frac{S.A.f}{r} \bullet \frac{1000\ \mu Ci}{mCi} \bullet \frac{ft^3/min}{6.797 \times 10^7\ ml/40\ hr\text{-}wk} = \frac{S.A}{r} \bullet 2.9424 \times 10^{-6} = \underline{\quad\quad}\ \frac{\mu Ci}{ml}$$

Calculated C_r should be less than 1×10^{-5} μCi/ml. If it is larger, the exhaust rate (r) must be increased, or the patient load (S) reduced.

If C_r is greater than 1×10^{-5} μCi/ml, and the hospital wants to keep the same patient load, the minimum exhaust rate from use area can be calculated as follows:

$$= S.A. \quad \frac{2.9424 \times 10^{-6}}{1 \times 10^{-5}} = S.A.\ 0.29424 = \underline{\quad\quad\quad}\ \frac{ft^3}{min}$$

If ventilation system in use area is non-recirculating, complete calculation 2.C.

C. **Unrestricted Release Concentration (Exterior of the Building)**
The average concentration in unrestricted area at point of release is:

$$C_u = (C_r/D) \bullet \frac{40\ hr\text{-}wk}{168\ hr\text{-}wk} = (Cr/D) \quad 0.238 = \underline{\quad\quad\quad}\ \frac{\mu Ci}{ml}$$

C_u should be less than 3×10^{-7} μCi/ml for Xe-133, or 8×10^{-2} μCi/ml for Technetium 99m aerosol. If it is not, the exhaust rate R must be increased either by reducing (r) or the dilution factor (D), or the patient load S must be reduced.

If (S) is kept constant, the minimum necessary total exhaust rate (R) can be calculated as follows:

$$R = S.A. \bullet 3 \bullet \frac{2.9424 \times 10\text{-}6 \bullet 0.238}{10^{-7}\ (Xe\text{-}133)\ \text{or}\ 8 \bullet 10^{-2}\ (Tc\text{-}99m)} = S.A. \bullet 2.334\ (Xe\text{-}133) = \underline{\quad\quad\quad}\ \frac{ft^3}{min.}$$

D. **Facilities**

Submit facilities diagram clearly showing the following information:

(1) Use area.

(2) Storage location.

(3) Shielding.

(4) Proximity to unrestricted areas.

(5) Ventilation.

(a) Supply vents

(b) Exhaust vents

(c) Measured airflow rates of each vent.

(6) State fraction of air that is re-circulated.

(7) Describe any changes in flow rates that may exist between heating and cooling seasons.

(8) Describe the release point of the exhaust ventilation (e.g., controlled roof top).

(9). State the type and frequency (at least semiannually) of periodic measurements that you will make to determine that airflow rates are maintained as described.

E. ADMINISTRATION APPARATUS FOR XE-133

Manufacturer: _____
Model: _____

Design description: _____
_____
_____

F. **PROCEDURE FOR SAFE USE**

☐ The following use procedures shall be followed:

☐ Equivalent procedures are attached.

Storage

Xenon 133 will always be stored in a well ventilated space in shielded containers. Radiation surveys of storage areas will be done to ensure that radiation levels are adequately controlled.

Precautions

The following steps will be taken to minimize leakage and accidental losses:

(1) The ventilation system shall be operating.

(2) Nose clips will be used when a mouthpiece is used, and a mask whenever the patient is unable or unwilling to retain the mouthpiece.

(3) The patient will be allowed to breathe into the device for a few moments before the

dose is administered so the patient will become used to it. **The dose shall not be administered if it appears the patient may panic and remove the mask or mouthpiece**.

(4) **No studies will be done if the ventilation system is down for repair or maintenance.**

(5) No more studies per week shall be performed than the patient load value found to be adequate in the preceding calculations.

Waste

Gas or aerosol is absorbed by organic materials especially rubber, so syringes, vials, tubing, etc., that may have contained gas or aerosol will be monitored and disposed as radioactive waste, if contaminated.

G. **EMERGENCY PROCEDURES**

☐ The following emergency procedures shall be followed.

☐ Equivalent emergency procedures are attached.

In the event a dose of gas or aerosol is released into the Imaging Room, the average concentration in the air will be many times the occupational exposure limit. The following action will be taken immediately:

(1) The technician shall take the patient out of the room immediately.

(2) The technician will shut and lock the door

(3) The technician will notify the Radiation Safety Officer.

(4) The technician will wait _____ minutes before re-entering the use area.

(5) The technician will then monitor the radiation level in the room. If it has returned to normal, it is safe to resume work.

H. **Disposal**

☐ Xenon will be disposed of by fume hood or exhaust vent to the exterior of the building (complete the following calculation).

Exhaust rate of fume hood or special vent at exterior of the building (including any dilution of other exhaust air) equals:

$$_____ \ \frac{ft^3}{min} = R$$

Patient load (S) and average dose activity per patient (A) are as defined in previous calculations.

$$C_u = \frac{S.A.}{R}$$

C_u must not exceed 3 x 10-7 mCi/ml. If it does, patient load (S) must be reduced, or ventilation rate (R) increased, or another method of disposal employed.

☐ Xenon will be disposed of by charcoal trap.

Trap manufacturer: _____

Model Number: _____ (inclusion of brochure would be helpful).

(1). The trap will be surveyed every week patients are examined.

(2). The manufacturer's specifications and frequency shall be followed in determining trapping efficiency and when trap is saturated.

(3). Traps will be disposed in accordance with waste disposal procedures in Attachment W.

Institution: _____
Date: _____

EMERGENCY XENON EXHAUST FACTOR

In the event of an accidental spill of Xenon-133 gas, exit the room and close all doors for a minimum of _____minutes.

For additional information, please see _____ in the _____.

Radiation Safety Officer

_____

Appendix Z

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

Appendix Z
MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

_____

(Name of Licensee and License Number)

_____

(Date)

1. **Management Commitment**

   A. We, the management of this (medical facility, hospital, etc) are committed to the program described in this Attachment for keeping exposures (individual and collective) **as low as is reasonably achievable (ALARA).** In accordance with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policies, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC) ***** and a Radiation Safety Officer (RSO).

   B. We will perform a documented formal annual review of the radiation safety program, including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.

   C. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented, or we will be prepared to describe the reasons for not implementing them.

   D. In addition to maintaining doses to individuals as far below the limit as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. **Radiation Safety Committee**

   A. **Review of Proposed Users and Uses**

***** Licensees with one or more different types of use under 180 NAC 7-048, 7-055, 7-067 and 7-085 will establish a Radiation Safety Committee.

(1). **The RSC will thoroughly review** the qualifications of each applicant with respect to the types and quantities of materials and uses for which they have applied, to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

(2). When considering a new use of radioactive material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematic procedures to ensure ALARA and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in the proposed use.

(3). **The RSC will ensure** that the user justifies their procedures and that doses will be ALARA (individual and collective),

B. **Delegation of Authority**

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program).

(1). **The RSC will delegate authority to the RSO** for enforcement of the ALARA concept.

(2). **The RSC will support the RSO** in those instances where it is necessary for the RSO to assert authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's next meeting.

C. **Review of ALARA Program**

(1). **The RSC will encourage all users** to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2). **The RSC will perform a documented quarterly review of occupational radiation exposure**, with particular attention to instances where Investigational Levels in Table W-1 (below) are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see Section 6).*

(3). **The RSC will evaluate and document our institution's overall efforts for maintaining exposures ALARA on an annual basis.** This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. **Radiation Safety Officer (RSO)**

A. **Annual review of the radiation safety program**. The RSO will perform a documented annual review of the radiation safety program for adherence to ALARA concepts. Review of specific procedures may be conducted on a more frequent basis.

B. **Education Responsibilities for ALARA Program**

(1). **The RSO will schedule** briefings and educational sessions to inform workers of ALARA program efforts.

(2). The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that **management, the RSC, and the RSO are committed to implementing the ALARA concept.**

C. **Cooperative Efforts for Development of ALARA Procedures**

(1). The **RSO will be in close contact with all users and workers** in order to develop ALARA procedures for working with radioactive materials.

(2). The **RSO will establish and document procedures** for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

D. **Reviewing Instances of Deviation from Good ALARA practices.**
The RSO will document and investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

4. **Authorized Users**

A. New Procedures Involving Potential Radiation Exposures

(1). **The authorized user will consult with,** and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.

(2). **The authorized user will evaluate** all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

B. Responsibility of Authorized User to Persons under Their Supervision.

(1). **The authorized user will explain the ALARA concept** and their commitment to maintain exposures ALARA to all persons under their supervision.

(2). **The authorized user will ensure** that persons under their supervision who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. **Persons Who Receive Occupational Radiation Exposure**

A. **The worker will be instructed** in the ALARA concept and its relationship to working

procedures and work conditions.

B. **The worker shall be informed** of recourses that are available if they feel that ALARA is not being promoted on the job.

6. **Establishment of Investigational Levels** in order to monitor individual occupational external radiation exposures.

This institution (or private practice) hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The Investigational Levels that we have adopted are listed in Table P-1 below. These levels apply to the exposure of individual workers.

Table P-1
INVESTIGATIONAL LEVELS
(MREMS PER CALENDAR QUARTER)

		Level I	Level II
(1)	Whole body; head and trunk, active blood-forming organs; lens of eyes; or gonads	125	375
(2)	Hands and forearms; feet, ankles	1875	5625
(3)	Skin of whole body *	750	2250

The Radiation Safety Officer should review results of personnel monitoring not less than once in any calendar quarter. The following actions should be taken at the Investigational Levels stated in Table P-1.

A. **Quarterly exposure of individuals to less than Investigational Level I.**

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table P-1 values for the Investigation Level I.

B. **Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.**

The RSO will review the exposure of each individual whose quarterly exposure equals or exceeds Investigational Level I and will report the results of the review at the first RSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

---

* Not normally applicable to nuclear medicine operations except those using significant quantities of beta-emitting nuclides.

C. **Exposure equal to or greater than Investigational Level II.**

The RSO will investigate and document in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, actions taken, if any, should be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes. **Committee minutes will be sent to the management of this institution for review.** The minutes, containing details of the investigation, will be made available to Department inspectors for review at the time of the next inspection.

D. **Reestablishment of an individual occupational worker's Investigational Level II to a level above that listed in Table P-1.**

In cases where a worker's, or a group of workers', exposures need to exceed Investigational Level II, a new, higher, Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

The RSC will review the justification for, and must approve any revisions of, Investigational Level II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in Paragraph 6.C above will be followed.

Appendix AA

Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources

Appendix AA
Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources

☐ Not Applicable

OR

☐ Will contract with personnel who are licensed by the Agency, NRC or an Agreement State to install, maintain, adjust, repair and inspect the specific therapy device.

Name _____

License #_____

OR THE FOLLOWING THREE CONDITIONS MUST BE MET

☐ Provide the name of the proposed employee and type of activities requested and license#:

_____

_____

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

Appendix AB

Delegation of Authority to Make Legally Binding Statements Form

Appendix AB
Delegation of Authority To Make Legally Binding Statements

Below is a sample copy of a delegation of authority to make legally binding statement.

Memo to: All Employees and Nebraska Office of Radiological Health

From: Chief Executive Officer

Subject: Delegation of Authority to Make Legally Binding Statements

_____ has been delegated the authority to make legally binding statements with regard to the radioactive materials license application, inspections, renewal, amendments and termination.

_____
License Certifying Official (signature)

_____
Name (type or printed)

_____
Title

_____
Date