



STATE OF OHIO
DEPARTMENT OF HEALTH

**GUIDANCE ABOUT OAC CHAPTER 3701:1-58 MEDICAL USE
LICENSES**

NMS-LIC-09

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This consolidated guidance is based on the NRC's NUREG 1556, Volume 9, Rev. 1 and along with the State of Ohio Radioactive Materials Licensing Program provides the applicants and reviewers with information concerning how to file a request, a listing of the applicable regulations and industry standards, policies affecting evaluation and registration, certain administrative procedures to be followed, information on how to perform the review and write a license and the responsibilities of the licensee.

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ABBREVIATIONS

AAPM	American Association of Physicists 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 Standard Institute
AU	Authorized User
bkg	Background
BPR	Business Process Redesign
Bq	Becquerel
CFR	Code of Federal Regulations
Ci	Curie
cc	Centimeter Cubed
cm ²	Square Centimeter
Co-57	Cobalt-57
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
GPO	Government Printing Office
GSR	Gamma Stereotactic Radiosurgery
HDR	High Dose-rate
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
OAC	Ohio Administrative Code
ODH	Ohio Department of Health
OCFO	Office of the Chief Financial Officer
OCR	Optical Character Reader
OMB	Office of Management and Budget
OSL	Optically Stimulated Luminescence Dosimeters
P-32	Phosphorus-32
Pd-103	Palladium-103
PDR	Pulsed Dose-rate
P&GD	Policy and Guidance Directive
QA	Quality Assurance
Ra-226	Radium-226
RG	Regulatory Guide
RIS	Regulatory Issue Summary
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
SDE	Shallow-dose Equivalent
SI	International System of Units (abbreviated SI from the French Le Système Internationale d'Unites)

Sr-90	Strontium-90
SSDR	Sealed Source and Device Registration
std	Standard
Sv	Sievert
TAR	Technical Assistance Request
Tc-99m	Technetium-99m
TEDE	Total Effective Dose Equivalent
TLD	Thermoluminescent Dosimeters
U-235	Uranium-235
WD	Written Directive
Xe-133	Xenon-133
μCi	Microcurie
%	Percent

1 OVERVIEW

1.1 PURPOSE OF REPORT

This report is intended to provide guidance in preparing a medical use of radioactive materials license application as well as Ohio Department of Health (ODH) criteria for evaluating a medical use license application. It is not intended to address the commercial aspects of manufacturing, distribution and service of sources in devices.

The term “patient” is used to represent “patient” or “human research subject” throughout this guide. The term “applicant” is used when describing the application process and the term “licensee” is used when describing a regulatory requirement.

This guide addresses the wide variety of radionuclides used in medicine. Typical uses are:

- Diagnostic studies with unsealed radionuclides.
- Therapeutic administrations with unsealed radionuclides.
- Diagnostic studies with sealed radionuclides.
- Manual brachytherapy with sealed sources.
- Therapeutic administrations with sealed sources in devices (i.e. teletherapy, remote afterloaders and gamma stereotactic radiosurgery (GSR) units).

This report identifies the information needed to complete the ODH Application for Radioactive Material License for medical uses of radioactive materials.

The format within this document for each item of technical information is as follows:

- Regulations – reference 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.
- Response from Applicant – provides suggested response(s), offers the option of an alternative reply or indicates no response is needed on that topic during the licensing process.

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 safety of the residents of Ohio according to ODH’s guidelines. The application form (Appendix A) does not have sufficient space for applicants to provide full response to Items 5 through 11; as indicated on the form, the answers to those items and any addition information are to be provided on separate sheets of paper and submitted with the completed application form. Additional information will be requested when necessary to ensure an adequate radiation safety program has been established.

Appendices H through Y contain additional information on various radiation safety topics. Appendix C is a checklist that Bureau of Radiation Protection (BRP) staff can use to review applications and applicants can use to check for completeness.

1.2 TYPES OF LICENSES

ODH defines “medical use” as “the intentional internal or external administration of radioactive material to patients or human research subjects under the supervision of an authorized user” (Ohio Administrative Code rule 3701:1-58-01). An “authorized user” is defined as “a physician, dentist or podiatrist” who meets the training and experience requirements specified in the board certification pathway in the applicable sections of OAC Chapter 3701:1-58 or who is identified as an authorized user on an Nuclear Regulatory Commission or Agreement State license; on a permit issued by an NRC master material licensee or an NRC master material permittee that is authorized to permit the medical use of radioactive material; or on a permit issued by a Commission or Agreement State broad scope licensee authorized to permit the medical use of radioactive material (OAC rule 3701:1-58-01).

ODH 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 1.2.1).
- The specific license of broad scope (see Section 1.2.2).

Medical use includes research involving human subjects, which may occur under either limited scope or broad scope specific licenses (see Section 1.2.3).

ODH also issues a general license pursuant to OAC rule 3701:1-46-11, under which a physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital may use radioactive material for certain *in vitro* clinical or laboratory testing. Such testing may not involve internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals (see Section 1.2.4).

ODH usually issues a single radioactive material license to cover an entire radionuclide program. (Note; however, that nuclear-powered pacemakers are licensed separately under OAC Chapter 3701:1-56.) A license including teletherapy may also contain the authorization for source material (i.e., depleted uranium) used as shielding in many teletherapy units and a license may include authorization for possession of sealed sources to be used to calibrate dose calibration devices.

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

Applicants should study this report, related guidance and all applicable regulations carefully before completing the ODH Application for Radioactive Material License. ODH expects licensees to provide information on specific aspects of the proposed radiation protection program in attachments to the ODH Application for Radioactive Material License. When necessary, ODH may ask the applicant for additional information in order to gain reasonable assurance 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 ODH, when incorporated into a license by reference.
- Terms and conditions of the license.
- ODH regulations.

In OAC rule 3701:1-40-05, ODH requires that the information in the application be complete and accurate in all material aspects. Information is considered material if it has the ability to change or affect an agency decision on issuing the license.

1.2.1 SPECIFIC LICENSE OF LIMITED SCOPE

ODH 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 OAC rule 3701:1-40-15(A)(2) refers to the applicant's facilities. Because 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 OAC rule 3701:1-58-30, 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 OAC rule 3701:1-58-30 cannot be performed.

A specific license of limited scope may also be issued to an entity requesting to perform mobile medical services (OAC rules 3701:1-58-31 and 3701:1-58-67). A medical institution or a private or group practice may apply for authorization to use radioactive material in a mobile medical service.

1.2.2 SPECIFIC LICENSE OF BROAD SCOPE

Medical institutions that provide patient care and conduct research programs that use radionuclides for *in vitro*, animal and medical procedures may request a specific license of broad scope in accordance with OAC Chapter 3701:1-40. No medical use of radioactive material including research involving human subjects may be conducted without an authorization in a

license from ODH, the NRC or an Agreement State as provided in OAC Chapter 3701:1-58. The criteria for the various types of broad scope licenses are found in OAC rules 3701:1-40-23 through 3701:1-40-26. Generally, ODH issues specific licenses of broad scope for medical use (i.e., licenses authorizing multiple quantities and types of radioactive material for medical use under OAC Chapter 3701:1-58 as well as other uses) to institutions that: (1) have experience successfully operating under a specific license of limited scope; and (2) are engaged in medical research and routine diagnostic and therapeutic uses of radioactive material.

1.2.3 RESEARCH INVOLVING HUMAN SUBJECTS

OAC rule 3701:1-58-01 defines “medical use” to include the administration of radioactive material or radiation therefrom to human research subjects. Furthermore, OAC rule 3701:1-58-04, “Provisions for the protection of human research subjects,” addresses the protection of the rights of human subjects involved in research by medical use licensees. For these licensees, prior ODH approval is not necessary if the research is conducted, funded, supported or regulated by another federal agency that has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, the licensee must apply for a specific amendment and receive approval for the amendment before conducting such research. Whether or not a license amendment is required, licensees must obtain informed consent from human subjects and prior review and approval of the research activities by an Institutional Review Board in accordance with the meaning of those terms under the federal policy. In accordance with OAC rule 3701:1-58-04, research involving human subjects shall be conducted only with radioactive materials listed in the license for the uses authorized in the license.

1.2.4 GENERAL *IN VITRO* LICENSE

In OAC rule 3701:1-46-11, “General License for Use of Radioactive Material for Certain *In Vitro* Clinical or Laboratory Testing,” ODH 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). OAC rule 3701:1-46-11 explains the requirements for using the materials listed. If the general license alone meets the applicant’s needs, only ODH HEA5518, Registration Certificate – *In Vitro* Testing With Radioactive Material Under General License, need be filed. Medical use licensees authorized pursuant to OAC Chapter 3701:1-58 do not need to file the form.

ODH limits possession to a total of 200 microcuries of photon-emitting materials listed in OAC rule 3701:1-46-11 at any one time, at any one location of storage or use. The use of materials listed in OAC rule 3701:1-46-11 within the inventory limits of that section is subject only to the requirements of that section and not to the requirements of OAC Chapter 3701:1-38, except as set forth in OAC rule 3701:1-46-11.

An applicant needing more than 200 microcuries of these materials must apply for a specific license and may request the increased inventory limit as a separate line item on Ohio License Application HEA 5133. This type of applicant generally requests an increased limit of three

millicuries. If requesting an increased inventory limit, the applicant will be subject to the requirements of OAC Chapter 3710:1-38, including the requirements for waste disposal.

1.3 OTHER REQUIREMENTS

1.3.1 THE “AS LOW AS IS REASONABLY ACHIEVABLE (ALARA)” CONCEPT

OAC rule 3701:1-38-11(E), “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 Radiation Safety Officer (RSO) is responsible for the day-to-day operation of the radiation protection program.

1.3.2 WRITTEN DIRECTIVE (WD) PROCEDURES

OAC rule 3701:1-58-16 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 R provides further information on developing these procedures.

2 AGREEMENT STATES

Certain states have entered into agreements with the NRC that give them the authority to license and inspect byproduct, source or special nuclear materials used or possessed within their borders. A current list of Agreement States (including names, addresses and telephone numbers of responsible officials) may be obtained upon request from the NRC's regional or field offices. Any applicant other than a federal agency who wishes to possess or use licensed material in one of these Agreement States needs to contact the responsible officials in that state for guidance on preparing an application; file these applications with state officials, not with the NRC.

In general, materials licensees who wish to conduct operations at temporary job sites in an Agreement State should contact that state's radiation control program office for information about state regulations. To ensure compliance with Agreement State reciprocity requirements, a licensee should request authorization well in advance of scheduled use.

Table 2.1 provides a quick way to check on which agency, if any, has regulatory authority.

Table 2.1, Who Regulates the Activity?

APPLICANT AND PROPOSED LOCATION OF WORK	REGULATORY AGENCY
Federal agency regardless of location (except that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [OAC rule 3701:1-40-06])	NRC
Non-federal entity in non-Agreement State, US territory or possession	NRC
Non-federal entity in Agreement State at non-federally controlled site	Agreement State
Non-federal entity in Agreement State at federally controlled site NOT subject to exclusive federal jurisdiction	Agreement State
Non-federal entity in Agreement State at federally-controlled site subject to exclusive federal jurisdiction	NRC

3 MANAGEMENT RESPONSIBILITY

The bureau recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. The bureau also believes consistent compliance with its regulations provides reasonable assurance licensed activities will be conducted safely. Ineffective management is frequently the underlying cause of safety and compliance problems. The term “management” refers to a senior-level manager who has responsibility for overseeing licensed activities.

To ensure adequate management involvement, a management representative must sign the submitted application acknowledging management's commitments 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 all information provided to the bureau (OAC rule 3701:1-40-05).
- Knowledge about the contents of the license and application.
- Committing adequate resources (including space, equipment, personnel, time and, if needed, contractors) to the radiation protection program to ensure public and worker safety is protected from radiation hazards and compliance with regulations is maintained.
- Selecting and assigning a qualified individual to serve as RSO for their licensed activities.

For information on inspection, investigation, enforcement and other compliance issues, contact the BRP at (614) 644-2727, or visit the ODH web site, at <http://www.odh.state.oh.us>.

As guidance documents are finalized, they will be added to the Web site.

4 HOW TO FILE

Applicants for a materials license should do the following:

- Be sure to use the most recent guidance in preparing an application.
- Complete the application form (Appendix A) Items 1 through 4, 12 and 13 on the form itself.
- Complete application form Items 5 through 11 on supplementary pages or use Appendix A.
- For each separate sheet other than Appendix A that is submitted with the application, identify and key 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.
- Avoid submitting proprietary information unless it is absolutely necessary. If necessary, mark all such pages prominently with the words, “Trade Secret,” along with a cover sheet for those pages also so marked. Do not include personal information such as individuals’ Social Security numbers, birth dates, etc., unless specifically requested.
- Submit an original, signed application and one copy.
- Retain one copy of the license application for future reference.

Deviations from the suggested wording of responses as shown in this guide or submission of alternative procedures may require a custom review.

All license applications will be available for review by the general public by contacting BRP. Employee personal information, i.e., home address, home telephone number, Social Security number, date of birth, radiation dose¹ information, should not be submitted unless specifically requested.

The bureau’s licensing process involves invoicing of all fees. Processing of electronic applications is currently possible. Please contact BRP for details.

¹ In this document, dose or radiation dose is used as defined in OAC rule 3701:1-38-01, 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 therein.

To ensure a smooth process, applicants are requested to follow these suggestions for attachments:

- Submit printed or typewritten text on smooth, crisp paper that will feed easily into a copier.
- Choose typeface designs that are sans serif, such as Arial, Helvetica, Futura, Univers; the text of this document is in a serif font called Times New Roman.
- Choose 12-point or larger font size.
- Avoid stylized characters such as script, italic, etc.
- Be sure the print is clear and sharp.
- Be sure there is high contrast between the ink and paper (black ink on white paper is best).

5 WHERE TO FILE

Applicants wishing to possess or use licensed material subject to ODH jurisdiction must file an application with the department at:

Ohio Department of Health
246 North High Street
Columbus, Ohio 43215

In general, applicants wishing to possess or use licensed material in Ohio must file an application with the director not the NRC. However, if work will be conducted at sites with exclusive federal jurisdiction in Ohio, applicants must first determine the jurisdictional status of the land in order to determine whether the NRC or the Agreement State has regulatory authority. See the section on “Agreement States” for additional information.

6 LICENSE FEES

Each application for which a fee is specified including applications for new licenses and license amendments, will be invoiced for the appropriate fee. Refer to Appendix A, Rule 3701:1-38-02 of the OAC to determine the amount of the fee. The bureau will not review the license application prior to fee receipt, except those designated full cost. Once technical review has begun, fees will generally not be refunded; application fees will be charged regardless of disposition of an application or the withdrawal of an application.

Most licensees are also subject to annual fees; refer to Rule 3701:1-38-02 for these fees, and for additional information on exemptions from annual fees and reduced annual fees for licensees that qualify as "small entities."

Direct all questions about fees or completion of 15 of the application form (Appendix A) to the Ohio Department of Health, 246 North High Street, Columbus, Ohio 43215. You may also call (614) 644-2727.

7 CONTENTS OF AN APPLICATION

The following comments apply to the indicated items on the application form (Appendix A).

7.1 TYPE OF APPLICATION

THIS IS AN APPLICATION FOR (Check appropriate item)

This is an application for: <input type="checkbox"/> Initial License <input type="checkbox"/> Renewal or <input type="checkbox"/> Amendment of License Number:
--

Check box “Initial License” if the application is for a new medical license.

Check “Amendment to License No.” if the application is for an amendment² to an existing medical license or if the application is to upgrade a medical license into a higher category of license, provide the license number.

Check “Renewal of License No.” if the application is for the renewal² of an existing medical license and provide the license number.

7.2 ITEMS 1 AND 2: APPLICANT’S NAME AND MAILING ADDRESS

1. Name of Licensee (Person or firm proposing to conduct the activities described below.)	2. Address of Licensee (Mailing address of licensee. This may be a PO Box.)
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List the legal name 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 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. Provide the mailing address where correspondence should be sent.

Note: The bureau (on behalf of the director and department) must be notified in the event of change of ownership or control and bankruptcy proceedings; see the next page for more details.
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² See “Amendments and Renewals to a License” later in this document. Licensees are required to request and obtain an amendment to the license before making changes in their radiation safety program. Examples of changes that require amendment are change of radiation safety officer (RSO) and increases in the license possession limit.

Timely Notification of Change of Ownership or Control:

Regulation/Rule: OAC rule 3701:1-40-16.

Criteria: Licensees must provide full information and obtain written concurrence from the bureau when transferring ownership or control of the license. A corporate ownership change is a major amendment.

Discussion: Changes in ownership may be the results of mergers, buyouts, or majority stock transfers. Although it is not the bureau's intent to interfere with the business decisions of licensees, it is necessary for licensees to notify the bureau promptly. This is to ensure the following:

- Radioactive materials are possessed, used or controlled only by persons who have a valid Ohio license unless it is on property which has been designated as exclusive federal jurisdiction specifically designated to the NRC or DOE.
- 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.
- Public health and safety are not compromised by the use of such materials.

Response from Applicant: None from an applicant for a new license; Appendix E identifies the information to be provided about changes of ownership or control.

Notification of Bankruptcy Proceedings

Regulation/Rule: OAC rule 3701:1-40-16(F).

Criteria: Within 10 business days following filing of voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify the bureau, 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.

7.3 ITEM 3: ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

3. Location(s) of Use or Storage (May not be a PO Box, an actual street address is required. Use additional pages if necessary.)
a. Address:
b. Address:
c. Address:

Specify the street address, city and state or other descriptive address (e.g., on Highway 10, five 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 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 OAC rule 3701:1-58-11 (B), the applicant should refer to Section 7.9.13 and Appendix U of this report for specific licensing guidance. ODH must be notified of mailing address changes.

Note: Being granted a radioactive materials license does not relieve a licensee from complying with other applicable federal, state or local regulations (e.g., local zoning requirements; a local ordinance requiring registration of radioactive material).

As discussed later under "Financial Assurance and Record Keeping for Decommissioning," licensees need to maintain permanent records on where licensed material was used or stored while the license was in force. This is 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.

7.4 ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION

4. Licensee Contact Person			
Name:	If consultant or other non-employee, so indicate <input type="checkbox"/>	Phone:	E-Mail:
()	()	()	()

Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed RSO, unless the applicant has named a different person as the contact. The bureau will contact this individual if there are questions about the application.

Notify the bureau if the contact person or their telephone number changes so the bureau 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 or a fee.

ODH recognizes that licensees may use a consultant or consultant group to help prepare the license application and provide support to the radiation protection program. However, ODH reminds licensees that regardless of the role of the consultant in radiation protection program management, the licensee remains responsible for all aspects of the licensed program, including the services performed by the consultant.

7.5 ITEM 5: RADIOACTIVE MATERIAL

5. Radioactive Material		
a. Element and Mass Number (e.g., Hydrogen-3)	b. Physical / Chemical Form (e.g., sealed source, liquid, metal foil)	c. Maximum Activity (in SI units)

Regulations: OAC rules 3701:1-40-14; 3701:1-46-48; 3701:1-58-26; 3701:1-58-32; 3701:1-58-34; 3701:1-58-37; 3701:1-58-43; 3701:1-58-53; 3701:1-58-55; 3701:1-58-72.

Criteria: OAC Chapter 3701:1-58 divides radioactive material for medical use into seven types of use (OAC rules 3701:1-58-32, 3701:1-58-34, 3701:1-58-37, 3701:1-58-43, 3701:1-58-53, 3701:1-58-55 and 3701:1-58-72).

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

OAC rules 3701:1-58-32 and 3701:1-58-34 Use: For OAC rules 3701:1-58-32 and 3701:1-58-34 use, the chemical/physical form may be “any” unsealed radioactive material permitted by OAC rules 3701:1-58-32 and 3701:1-58-34, as appropriate. For OAC rules 3701:1-58-32 and 3701:1-58-34 use, the total amount requested may be “as needed.” The following format may be used:

Radioactive Material	Chemical/Physical Form	Maximum Amount
Any radioactive material permitted by OAC rule 3701:1-58-32	Any	As needed
Any radioactive material permitted by OAC rule 3701:1-58-34	Any	As needed

OAC rule 3701:1-58-37 Use: For OAC rule 3701:1-58-37 use, the chemical/physical form may be “any” unsealed radioactive material permitted by OAC rule 3701:1-58-37. The total amount requested must be specified. The following format may be used:

Radioactive Material	Chemical/Physical Form	Maximum Amount
Any radioactive material permitted by OAC rule 3701:1-58-37	Any	300 millicuries

OAC rules 3701:1-58-37, 3701:1-58-43, 3701:1-58-53 and 3701:1-58-72 Use: For OAC rules 3701:1-58-37, 3701:1-58-43, 3701:1-58-53 and 3701:1-58-72 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.

The following format may be used:

Radioactive Material	Chemical/Physical Form	Maximum Amount
Iodine-125 (specific radiation therapy system liquid brachytherapy source)	Liquid source (Manufacturer Name, Model #XYZ)	2 curies total
Cesium 137 (i.e., specific brachytherapy radionuclide)	Sealed source or device (Manufacturer Name, Model #XYZ)	2 curies total
Gadolinium 153 (i.e., specific diagnostic sealed source radionuclide)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 500 millicuries per source and 1 curie total
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
Iridium 192 (i.e., specific afterloader sealed source radionuclide)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 12 curies per source and 21 curies total
Cobalt 60 (i.e., specific gamma stereotactic radiosurgery sealed source radionuclide)	Sealed source or device (Manufacturer Name, Model #XYZ)	Not to exceed 36 curies per source and 6,600 curies total

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

Calibration, Transmission and Reference Sources: For calibration, transmission and reference sources covered under OAC rule 3701:1-58-26, the specific sources do not need to be listed on the license as long as the licensee is authorized pursuant to OAC rule 3701:1-58-06 for medical use of radioactive material.

Shielding Material/Depleted Uranium: Some high activity radionuclide generators used to produce radioactive materials for OAC rules 3701:1-58-34 and 3701:1-58-37 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 Amount
Depleted uranium	Metal	999 kilograms

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 OAC rule 3701:1-46-11, survey meter calibration source, dosimetry system constancy check source, material for *in vitro*, animal or human research studies). The following format may be used:

Radioactive Material	Chemical/Physical Form	Maximum Amount
Any radioactive material permitted by OAC rule 3701:1-46-11	Prepackaged kits	50 millicuries

Sources that are authorized by OAC rule 3701:1-58-26, “Authorization for calibration, transmission, and reference sources,” do not have to be listed.

Applicants should number each line entry consecutively, following the OAC Chapter 3701:1-58 58 material.

Blood Irradiators: If the use of a device to irradiate blood is anticipated, the applicant should review NMS-LIC-05, “Program-Specific Guidance About Self-Shielded Irradiator Licensees.” 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.

Note: Certain quantities of radioactive material may require increased controls contact BRP for details.

7.5.1 SEALED SOURCES AND DEVICES

Regulations: OAC rules 3701:1-40-14(E); 3701:1-40-15(A)(2) 3701:1-46-48.

Criteria: In accordance with OAC rule 3701:1-40-14(E), 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 OAC rule 3701:1-58-26). Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by NRC, an Agreement State or NARM licensing state designated for product review.

Discussion: The director, 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 SSTR Certificate. Applicants must provide the manufacturer's name and model number for each requested sealed source and device so the director can verify they have been evaluated in an SSTR 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 requested sources and devices are compatible with each other and they conform to the SSTR designations registered with NRC or an Agreement State. Licensees may not make any changes to the sealed source, device or source-device combination that would alter the description or specifications from those indicated in the respective SSTR certificates without obtaining the director's prior permission in a license amendment. To ensure sealed sources and devices are used in ways that comply with the SSTR 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.

7.5.2 RECORD KEEPING FOR DECOMMISSIONING AND FINANCIAL ASSURANCE

Regulations: OAC rules 3701:1-40-16 (A) 3701:1-40-17

Criteria: All licensees are required to maintain records important to decommissioning. Licensees authorized to possess licensed material in excess of the limits specified in OAC rule 3701:1-40-17 must provide evidence of financial assurance for decommissioning.

Discussion: All licensees are required, under OAC rule 3701:1-40-17(I), 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. Pursuant to OAC rule 3701:1-40-17(I), licensees must transfer the records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with OAC rule 3701:1-40-16(A).

Licensees using sealed sources authorized by OAC Chapter 3701:1-58 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 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 ODH review of decommissioning procedures on a case-by-case basis.

Licensees authorized to possess radioactive material in excess of the limits specified in OAC rule 3701:1-40-17 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 OAC rule 3701:1-40-17 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 OAC rule 3701:1-40-17(A) 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. Appendix F to OAC rule 3701:1-40-17 contains acceptable wording for each mechanism authorized by the regulation to guarantee or secure funds.

The director will authorize sealed source possession exceeding the limits given in OAC rule 3701:1-40-17(C) 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 7.1 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 OAC rule 3701:1-40-17 for possession limits requiring financial assurance. The sum of the fractions procedure is also depicted in Table 7.1 and must be used to determine the need for financial assurance for both sealed and unsealed radioactive material.

Table 7.1 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	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 OAC rule 3701:1-40-17 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: If a decommissioning funding plan or certification of financial assurance is required, submit the required documents.

7.6 ITEM 6: PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

6. Purpose for which radioactive material will be used

Regulations: OAC rules 3701:1-40-15(A); 3701:1-58-32; 3701:1-58-34; 3701:1-58-37; 3701:1-58-43; 3701:1-58-53; 3701:1-58-55; 3701:1-58-53.

Rule Number	Title
3701:1-58-32 OAC	Medical Use of Unsealed Radioactive Material for Uptake, Dilution and Excretion Studies for Which a Written Directive is Not Required
3701:1-58-34 OAC	Medical Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required
3701:1-58-37 OAC	Medical Use of Unsealed Radioactive Material for Which a Written Directive is Required
3701:1-58-43 OAC	Medical Use of Sources for Manual Brachytherapy
3701:1-58-53 OAC	Medical Use of Sealed Sources for Diagnosis
3701:1-58-55 OAC	Medical Use of a Sealed Source(s) in a Device for Therapy-Teletherapy Unit
3701:1-58-55 OAC	Medical Use of a Sealed Source(s) in a Device for Therapy-Remote Afterloader Unit
3701:1-58-55 OAC	Medical Use of a Sealed Source(s) in a Device for Therapy-Gamma Stereotactic Radiosurgery Unit
3701:1-58-72 OAC	Other Medical Uses of Radioactive Material or Radiation from Radioactive Material

Discussion: OAC rules 3701:1-58-32, 3701:1-58-34, and 3701:1-58-37 Use: For OAC rules 3701:1-58-32, 3701:1-58-34, and 3701:1-58-37 use, the applicant should define the purpose of use by stating the applicable section of OAC Chapter 3701:1-58 (e.g., **OAC rules 3701:1-58-32, 3701:1-58-34, and 3701:1-58-37**) and the description of the applicable modality (e.g., any uptake, dilution and excretion procedure for which a written directive is not required).

The use of unsealed radioactive material in therapy (OAC rule 3701:1-58-37) 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. If an applicant's request is limited to I-131 under OAC rule 3701:1-58-37, the license will be limited to that radionuclide.

OAC rule 3701:1-58-43 Use: For OAC rule 3701:1-58-43 use, the applicant should define the purpose of use by stating the applicable section of OAC Chapter 3701:1-58 (i.e., OAC rule 3701:1-58-43). 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 5 of the radioactive materials license 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 sealed source and device evaluation on radiation safety issues, intraluminal use is considered analogous to intracavitary use.
- Topical (Surface) Applications.

OAC rule 3701:1-58-53 Use: For OAC rule 3701:1-58-53 use, the applicant should define the purpose of use by stating the applicable section of (i.e., OAC rule 3701:1-58-53) 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 5 of the radioactive material application 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 SSTR.

OAC rule 3701:1-58-55 Use: For OAC rule 3701:1-58-55 use, the applicant should define the purpose of use by stating the applicable section of OAC rule 3701:1-58-55 (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 5 of the radioactive material application with the device described in this item. If applicable, the applicant should state 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.

OAC rule 3701:1-58-72 Use: Applicants must apply for authorization to use radioactive material, or radiation therefrom, in medical applications under OAC rule 3701:1-58-72 when the type of use is not covered under OAC rules 3701:1-58-32 – 3701:1-58-55.

When applying for use under provisions of OAC rule 3701:1-58-72, applicants should describe the purpose of use and submit the information required under OAC rules 3701:1-58-07 (B) through (D), review regulatory requirements in other rules of OAC Chapter 3701:1-58 and use them as a guide on how to determine what should be included in an application that is required in OAC rule 3701:1-58-07. It is anticipated that many of the uses of radioactive material under the provisions of OAC rule 3701:1-58-72 may involve research or product development; thus, applicants should ensure review and compliance with OAC rule 3701:1-58-04, "Provisions for the Protection of Human Research Subjects," and OAC rule 3701:1-58-05, "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 investigational device exemption (IDE) or an investigational new drug exemption (IND) does not relieve individuals of the responsibility to

obtain a license to use the radioactive material in medicine under the provisions of OAC Chapter 3701:1-58. If the source for the type of use sought under OAC rule 3701:1-58-72 is a sealed source, Section 7.6 of this guide describes the information that must be provided at the time of application. Broad scope licensees are exempted under OAC rule 3701:1-58-10 (A) from requirements of OAC rule 3701:1-58-07 (A) (which relates to including certain information in an application about radiation safety aspects of medical use under OAC rule 3701:1-58-72). 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.

Non-Medical Uses: Applicants may also describe non-medical uses (e.g., survey meter calibrations with NIST traceable brachytherapy sources) and reference the applicable radioactive material provided in response to Item 5 of the radioactive material application.

Response from Applicant: The applicant must 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.

7.7 ITEMS 7 and 8: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

7. Radiation Safety Officer (Include training and experience.)
8. Training Program (Include topics to be covered, frequency of training, and recipients.)

Regulations: OAC rules 3701:1-40-15(A)(3); 3701:1-40-23; 3701:1-58-12; 3701:1-58-18; 3701:1-58-19; 3701:1-58-20; 3701:1-58-21; 3701:1-58-22; 3701:1-58-33; 3701:1-58-36; 3701:1-58-40; 3701:1-58-41; 3701:1-58-42; 3701:1-58-51; 3701:1-58-52; 3701:1-58-54; and 3701:1-58-71.

Criteria: The RSO, Authorized Users, Authorized Medical Physicists, and Authorized Nuclear Pharmacists must have adequate training and experience.

Discussion: OAC rule 3701:1-58-12 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 (if the licensee is required to establish a RSC). In OAC rule 3701:1-40-15(A)(3), the director 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. OAC Chapter 3701:1-58 gives 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 ODH purposes. Applicants should ensure they submit the specific training information required by ODH regulations in OAC Chapter 3701:1-58

Licensees are responsible for their radiation protection programs; it is essential that strong management control and oversight exist to ensure 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 ODH 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.

Licensees authorized for two or more different types of uses of radioactive material under OAC rules 3701:1-58-37 to 3701:1-58-52 and OAC rules 3701:1-58-55 to 3701:1-58-71 or two or more types of units under OAC rules 3701:1-58-55 to 3701:1-58-71, shall 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 RSO, a representative of the nursing service and a representative of management who is neither an authorized user nor the RSO. The committee may include other members the licensee considers appropriate.

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

Training for experienced RSO, teletherapy or medical physicist, authorized user or nuclear pharmacist; recentness of training. OAC rule 3701:1-58-21 provides that experienced individuals, who may be candidates to serve as RSO, AMP or ANP, are not required to meet the requirements of OAC rules 3701:1-58-18, 3701:1-58-19 or 3701:1-58-20 respectively, (are "grandfathered") under certain conditions, e.g., the individual is named on an NRC or Agreement State license. AUs are also not required to meet the requirements in OAC Chapter 3701:1-58 under certain conditions, e.g., if they are named on an NRC or Agreement State License. The individuals must have been named on a license or permit before the applicable date of Aug. 15, 2005. Regulations require that the training and experience specified in OAC Chapter 3701:1-58 must have been obtained within seven 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.

7.7.1 RADIATION SAFETY OFFICER (RSO)

Regulations: OAC rules 3701:1-40-15(A); 3701:1-58-02; 3701:1-58-09; 3701:1-58-12; 3701:1-58-18; 3701:1-58-21; 3701:1-58-22; 3701-39-02.1; 3701:1-58-73.

Criteria: RSOs must have adequate training and experience. The training and experience requirements for the RSO are described in OAC rule 3701:1-58-18 and allow for the following training pathways:

- Identification as a RSO, a teletherapy or medical physicist or a nuclear pharmacist as provided in OAC rule 3701:1-58-21, on an NRC or Agreement State license or permit issued by a NRC or agreement state broad scope licensee or by a master license permittee of broad scope before the effective date of this rule (Aug. 15, 2005).
- Certification as provided in OAC rule 3701:1-58-18(A) by a specialty board whose certification process has been recognized by the NRC or an Agreement State.

or

- Completion of classroom and laboratory training (200 hours) and 1 year of full time radiation safety experience as described in OAC rule 3701:1-58-18(B) plus written certification, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements of paragraph (B)(1) and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.

or

- Identification as provided in OAC rule 3701:1-58-18(3) on the licensee's license as an AU, AMP, or ANP with experience in the radiation safety aspects of similar types of radioactive material use for which the individual has RSO responsibilities.

The licensee must also establish, in writing, the authority, duties, and responsibilities of the RSO as required by OAC rule 3701:1-58-12(B).

Discussion: The RSO is responsible for day-to-day oversight of the radiation protection program. In accordance with OAC rule 3701:1-58-12, 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 OAC rule 3701:1-58-12 to ensure radioactive materials are used in a safe manner. The director requires the name of the RSO on the license and an agreement in writing from the RSO, to ensure 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 director 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 OAC Chapter 3701:1-58.

Appendix H contains a model RSO Delegation of Authority. Appendix B contains a form which can be used to document the RSO's training and experience.

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 the director.
- Timely and accurate reporting and maintenance of appropriate records.
- Annual program audits.
- Proper use and routine maintenance.
- Personnel training.
- Investigation of incidents involving radioactive material (e.g., medical events).

Appendix H contains a detailed list of typical duties and responsibilities of the RSO.

Applicants are reminded of recentness of training requirements described in OAC rule 3701:1-58-22. Specifically, RSO applicants must have successfully completed the applicable training and experience criteria described in OAC Chapter 3701:1-58 within seven 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 the following:

- Name of the proposed RSO.

AND

For an individual previously identified as an RSO on an NRC or Agreement State license or permit:

- Previous license number and a copy of the license (NRC or 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 that authorized the uses requested and on which the individual was named as the RSO.

For an individual qualifying under OAC rule 3701:1-58-18(A):

- Copy of certification by a specialty board whose certification process has been recognized³ the NRC or an Agreement State under *OAC rule 3701:1-58-18(A)*.

For an individual qualifying under OAC rule 3701:1-58-18(B):

- Description of the training and experience specified in OAC rule 3701:1-58-18(B) demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.

AND

Written certification, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements of paragraph (B)(1) the rule named above and has achieved a level of radiation safety knowledge sufficient to function independently as RSO.

For an individual qualifying under OAC rule 3701:1-58-18(3):

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

Notes:

- The licensee must notify ODH within 30 days if an RSO permanently discontinues his or her duties under the license or has a name change under OAC rule 3701:1-58-09 and to request an amendment to change an RSO under OAC rule 3701:1-58-08.
- An AU, AMP or ANP may be designated as the RSO on the license if the individual has experience with the radiation safety aspects of similar types of radioactive material use for which he or she has RSO responsibilities (see OAC rule 3701:1-58-18(3)) and, as required by OAC rule 3701:1-58-12(G), has sufficient time, authority, organizational freedom, resources, and management prerogative to perform the duties.
- The training and experience for the RSO of a medical use broad scope license will be reviewed using the above criteria as well as criteria in OAC rule 3701:1-40.

7.7.2 AUTHORIZED USERS (AUs)

Regulations: OAC rules 3701:1-40-15(A); 3701:1-58-01; 3701:1-58-06; 3701:1-58-09; 3701:1-58-14; 3701:1-58-21; 3701:1-58-22; 3701:1-58-33; 3701:1-58-36; 3701:1-58-40; 3701:1-58-41; 3701:1-58-42; 3701:1-58-51; 3701:1-58-52; 3701:1-58-54; 3701:1-58-71.

Criteria: Training and experience requirements for AUs are described in OAC rules 3701:1-58-33, 3701:1-58-36, 3701:1-58-40, 3701:1-58-41, 3701:1-58-42, 3701:1-58-51, 3701:1-58-52, 3701:1-58-54, 3701:1-58-71.

³ 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.html>.

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 WDs, if required.

Applicants must meet recentness-of-training requirements described in OAC rule 3701:1-58-22. AU applicants must have successfully completed the applicable training and experience criteria described in OAC Chapter 3710:1-58 within seven 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.

OAC rule 3701:1-58-21 provides that experienced AUs who are named on a license or permit are not required to comply with the training requirements in OAC rules 3701:1-58-32 through 3701:1-58-71 to continue performing those medical uses for which they were authorized before the effective date of changes to the regulations in OAC rule 3701:1-58-21 (Aug. 15, 2005). 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 OAC rule 3701:1-58-15), 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 OAC rule 3701:1-58-14, "Supervision," and in compliance with applicable FDA, other federal and state requirements (OAC rule 3701:1-58-05). Examples include FDA requirements for conduct of certain types of clinical research after submission of applications for investigational new drugs (INDs) and under the auspices of a Radioactive Drug Research Committee.

There is no ODH requirement that an AU must render an interpretation of a diagnostic image or results of a therapeutic procedure. The director recognizes the AU may or may not be the physician who interprets such studies. Additionally, ODH 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.

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

An applicant should note which user will be involved with a particular use by referring to Items 5 and 6 of the application and providing information about the user's training and experience. Authorized non-medical use or uses that do not involve the intentional exposure of humans (e.g., *in vitro* and animal research, calibration, dosimetry research) will be reviewed on a case-by-case basis.

Response from Applicant: Provide the following:

- Name of the proposed AU and uses requested.

AND

For an individual previously identified as an AU on a NRC or Agreement State license or permit under OAC rule 3701:1-58-21:

- Physicians, dentists or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the director, the NRC or Agreement State, a permit issued by a NRC master material licensee, a permit issued by a NRC or agreement state broad scope licensee or a permit issued by a NRC master material license broad scope permittee before the effective date of this rule (Aug. 15, 2005) who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of OAC rules 3701:1-58-33, 3701:1-58-36, 3701:1-58-40, 3701:1-58-41, 3701:1-58-42 , 3701:1-58-51, 3701:1-58-52, 3701:1-58-54 or 3701:1-58-71.

For an individual qualifying under OAC rules 3701:1-58-32 through 3701:1-58-54 and/or 3701:1-58-55 through 3701:1-58-71 who is board certified:

- Copy of the certification(s) by a specialty board(s) whose certification process has been recognized⁴ by the Director, NRC, an agreement state, or NARM licensing state for NARM, applicable to the use requested.

AND

- If applicable, description of recent related continuing education and experience as required by OAC rule 3701:1-58-22.

For an individual qualifying under OAC rules 3701:1-58-32 through 3701:1-58-54 and/or 3701:1-58-55 through 3701:1-58-71, who is not board certified:

- A description of the training and experience identified in OAC rules 3701:1-58-32 through 3701:1-58-54 and/ or 3701:1-58-55 through 3701:1-58-71 demonstrating that the proposed AU is qualified by training and experience for the use requested.

AND

- Written certification, signed by a preceptor AU, that the individual has satisfactorily completed the requirements and has achieved a level of competency sufficient to function independently as an AU for the medical uses authorized.

AND

⁴ 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.html>.

- If applicable, description of recent related continuing education and experience as required by OAC rule 3701:1-58-22.

Notes:

- Licensees must notify the director within 30 days if an AU permanently discontinues his or her duties under the license or has a name change under OAC rule 3701:1-58-09.
- Descriptions of training and experience will be reviewed using the criteria listed above. The director will review the documentation to determine if the applicable criteria in OAC Chapter 3701:1-58 are met. If the training and experience do not appear to meet the OAC Chapter 3701:1-58 criteria, the director may request additional information from the applicant.

Note to reviewers: Licenses will reflect any limitations on use for listed authorized users (e.g., whether administrations in excess of 33 mCi of iodine-131 are allowed and specific uses under OAC rule 3701:1-58-55, etc.).

7.7.3 AUTHORIZED NUCLEAR PHARMACIST (ANP)

Regulations: OAC rules 3701:1-40-15(A); 3701:1-46-43(B)(2); 3701:1-58-01; 3701:1-58-06; 3701:1-58-09; 3701:1-58-14; 3701:1-38-20; 3701:1-58-21; 3701:1-58-22.

Criteria: Training and experience requirements for ANPs are described in OAC rule 3701:1-38-20.

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 OAC rule 3701:1-58-14, "Supervision," and in compliance with applicable FDA, other federal and state requirements (OAC rule 3701:1-58-05). (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 OAC rule 3701:1-58-22. Specifically, nuclear pharmacist applicants must have successfully completed the applicable training and experience criteria described in OAC Chapter 3701:1-58 within seven 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 proposed ANP.

AND

For an individual previously identified as an ANP on a NRC or Agreement State license or permit under OAC rule 3701:1-58-21(A):

- Copy of the licensee (if issued by the NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master material licensee, a permit issued by a NRC or Agreement State broad scope licensee or a permit issued by an 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, prior to Aug. 15, 2005.

For an individual qualifying under OAC rule 3701:1-58-20:

- Copy of the certification(s) of the specialty board whose certification process has been recognized⁵ under OAC rule 3701:1-58-20(A).

OR

- Description of the training and experience specified in OAC rule 3701:1-58-20(B) demonstrating the proposed ANP is qualified by training and experience.

AND

- Written certification signed by a preceptor ANP that the individual has satisfactorily completed the requirements in paragraph (B) (1) of this rule and had achieved a level of competency sufficient to function independently as an ANP.

AND

- If applicable, description of recent, related continuing education and experience as required by OAC rule 3701:1-58-22.

Note:

- Licensees must notify the director within 30 days if an ANP permanently discontinues his or her duties under the license or has a name change under OAC rule 3701:1-58-09.

7.7.4 AUTHORIZED MEDICAL PHYSICIST (AMP)

Regulations: OAC rules 3701:1-40-15(A); 3701:1-58-01; 3701:1-58-09; 3701:1-58-19; 3701:1-58-21; 3701:1-58-22; 3701:1-58-49.

Criteria: Training and experience requirements for AMPs are described in OAC rule 3701:1-58-19.

⁵ 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.html>>

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 OAC rule 3701:1-58-22. Specifically, medical physicist applicants must have successfully completed the applicable training and experience criteria described in OAC Chapter 3701:1-58 within seven 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 NRC or Agreement State license or permit under OAC rule 3701:1-58-21(A):

- Copy of the licensee (if issued by the NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master material licensee, a permit issued by a NRC or Agreement State broad scope licensee or a permit issued by an NRC master material license broad scope permittee on which the individual was named an AMP, prior to Aug. 15, 2005.

For an individual qualifying under OAC rule 3701:1-58-19:

- Copy of the certification(s) of the specialty board(s) whose certification process has been recognized⁶ under OAC rule 3701:1-58-19(A).

OR

- Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in OAC rule 3701:1-58-19(B) for the uses requested.

AND

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

AND

- If applicable, description of recent, related continuing education and experience as required by OAC rule 3701:1-58-22.

⁶ 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.html>.

Note:

- Licensees must notify the director within 30 days if an AMP permanently discontinues his or her duties under the license or has a name change under OAC rule 3701:1-58-08.

7.8 ITEM 9: FACILITIES AND EQUIPMENT

9. Facilities and Equipment (attach documentation and diagram of locations of use and storage.)

Regulations: OAC rules 3701:1-40-15(A)(2); 3701:1-58-07(B)(1); 3701:1-58-11(A).

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

Discussion: Requirements to provide information about the design and construction of facilities and safety equipment are contained in OAC rules 3701:1-40-15(A)(2), 3701:1-58-07(B)(1) and 3701:1-58-11(A).

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.

7.8.1 FACILITY DIAGRAM

Regulations: OAC rules 3701:1-38-01; 3701:1-38-11(E); 3701:1-38-12(A); 3701:1-38-13; 3701:1-38-13(E); 3701:1-38-15; 3701:1-38-15; 3701:1-38-18(A); 3701:1-38-18(A)(4); 3701:1-38-20(B); 3701:1-40-15(A)(2); 3701:1-58-07; 3701:1-40-09; 3701:1-58-11(A)(3); 3701:1-58-30; 3701:1-58-39(A); 3701:1-58-47; 3701:1-58-59.

Criteria: In order to issue a license, the bureau must find the facilities and equipment adequate to protect health and minimize danger to life or property as required under OAC rule 3701:1-40-15(A) and/or OAC rule 3701:1-58-11(A).

Discussion: Applicants must describe the proposed facilities and equipment as required by OAC rule 3701:1-58-07. 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 OAC rule 3701:1-58-32 and OAC rule 3701:1-58-34, applicants should provide room numbers for areas in which radioactive materials are used or prepared for

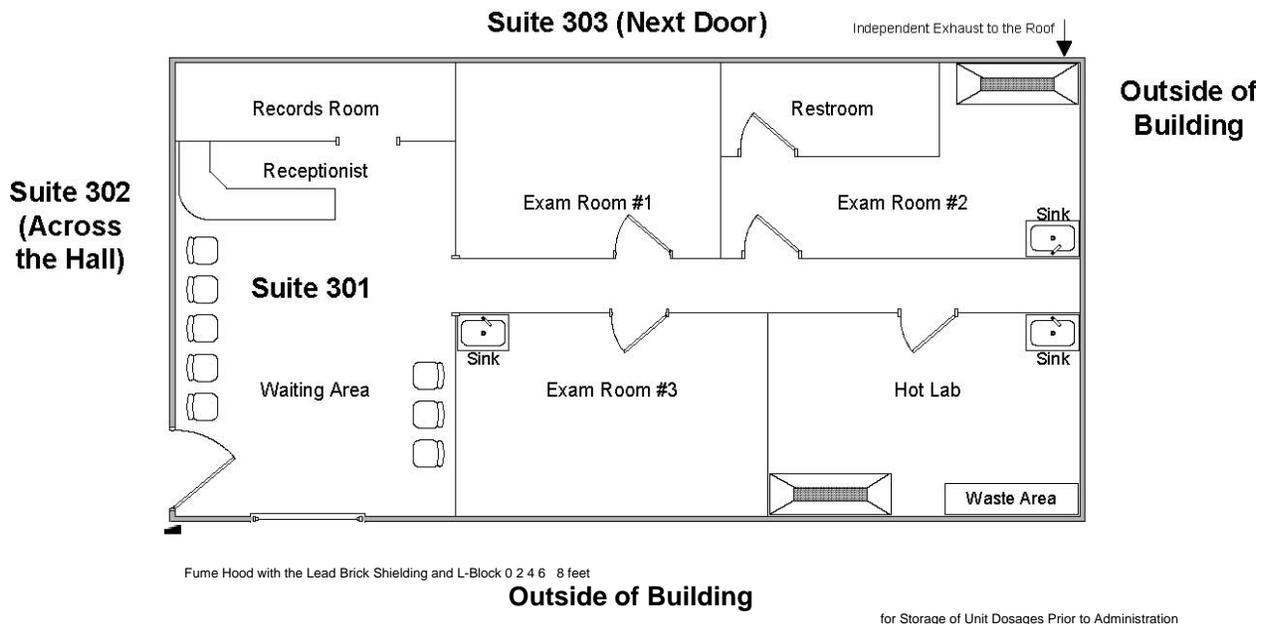
use (i.e., “hot labs”). When information regarding an area or room is provided, adjacent areas and rooms, including those above and below, should be described. For types of use permitted by OAC rule 3701:1-58-37 and OAC rule 3701:1-58-43, applicants should provide the above information and in addition they should provide the locations where sources are stored. Describe the rooms where patients will be housed if they cannot be released under OAC rule 3701:1-58-30. The discussion should include a description of shielding, if applicable. For types of use permitted by OAC rule 3701:1-58-53, the applicant should provide the room numbers of use.

For types of use permitted by OAC rule 3701:1-58-55, 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 OAC rule 3701:1-58-72, applicants should review the above to determine the type of information appropriate to evaluate the adequacy of the facilities.

Licensees are required by OAC rule 3701:1-58-08 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 OAC rule 3701:1-58-32 or OAC rule 3701:1-58-34.

Licensees are required by OAC rule 3701:1-58-09 to notify ODH within 30 days following changes in areas of use for OAC rule 3701:1-58-32 and OAC rule 3701:1-58-34 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.



- Suite 301 is on the top floor.
- Suite 301 is located at a corner of the building.
- Suite 302 is occupied by an accounting firm.
- Suite 303 is occupied by a law firm.
- Directly below Suite 301 is an insurance company.

Figure 7.1 Facility Diagram for Nuclear Medicine Suite

The applicant should demonstrate the limits specified in OAC rule 3701:1-38- 13(A) will not be exceeded. If the calculations demonstrate 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 authorization from the director to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem) and demonstrating the requirements of OAC rule 3701:1-38-13 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 OAC rule 3701:1-38- 13(A). 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 (OAC rule 3701:1-38-11(E)) must be developed (see OAC rule 3701:1-38- 13(D)(1)).

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 the director. 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.”

or

- “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, 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 on the facility diagrams:

- 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 OAC rule 3701:1-38-01(A)(135)(165).
- 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.

7.8.2 RADIATION MONITORING INSTRUMENTS

Regulations: OAC rules 3701:1-38-11(E); 3701:1-38-14(A); 3701:1-38-20(B); 3701:1-38-12(A); 3701:1-40-15(A)(2); 3701:1-58-14; 3701:1-58-24; and 3701:1-58-78.

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 OAC rule 3701:1-38-11(E) must include provisions for survey instrument calibration (OAC rule 3701:1-38-14(A)). 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 because it is not expected 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 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 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 J provides guidance regarding appropriate instrumentation and model survey instrument calibration procedures to meet the requirements detailed in OAC rule 3701:1-58-24.

Response from Applicant: Provide the following:

- A statement that: “Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations.”

AND/OR

- A statement that: “We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in OAC rule 3701:1-38-14(A) and that meet the requirements of OAC rule 3701:1-58-24.”

AND

- 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.

AND

- A statement that: “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.”

Note: If calibrations will not be performed by the licensee or by a person qualified to perform survey meter calibration, the applicant should propose an alternate method of calibration for review by the director.

7.8.3 DOSE CALIBRATOR AND OTHER EQUIPMENT USED TO MEASURE DOSAGES OF UNSEALED RADIOACTIVE MATERIAL

Regulations: OAC rules 3701:1-40-03; 3701:1-40-15; 3701:1-58-14; 3701:1-58-392; 3701:1-58-23; 3701:1-58-25; 3701:1-58-77; 3701:1-58-79.

Criteria: In OAC rules 3701:1-58-23 and 3701:1-58-25, ODH describes requirements for the use, possession, calibration and check of instruments (e.g., dose calibrators) used to measure patient dosages.

Discussion: As described in OAC rule 3701:1-58-25, 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 OAC rule 3701:1-46-43, (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 OAC rule 3701:1-58-25 (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 ODH-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 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:

- A statement that: “Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer’s instructions.”

7.8.4 THERAPY UNIT — CALIBRATION AND USE

Regulations: OAC rules 3701:1-40-15(A)(2); 3701:1-58-14; 3701:1-58-48; 3701:1-58-60; 3701:1-58-61; 3701:1-58-62; 3701:1-58-63; 3701:1-58-64; 3701:1-58-65; 3701:1-58-66; 3701:1-58-89; 3701:1-58-93; 3701:1-58-94; 3701:1-58-95; 3701:1-58-96; and 3701:1-58-97.

Criteria: The above regulations contain requirements including record keeping 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 brachytherapy sources and LDR remote afterloader sources, licensees may use source activity or output determined by the manufacturer, provided the manufacturer’s measurements meet applicable requirements.

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 accordance with OAC Chapter 3701:1-58, the applicant must possess a calibrated dosimetry system (e.g., Farmer chamber, electrometer, well-type ionization chamber) that will be used to perform calibration measurements of sealed sources to be used for patient therapy. Dosimetry systems and/or sealed sources used to calibrate the licensee’s dosimetry systems must be traceable to NIST or to a laboratory accredited by AAPM, pursuant to OAC rule 3701:1-58-60. 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 (OAC rules 3701:1-58-64, 3701:1-58-65, and 3701:1-58-66).

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, whenever spot-check measurements (if required) indicate the output differs by more than five percent 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 OAC rules 3701:1-58-61, 3701:1-58-62, and 3701:1-58-63. 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.

Response from Applicant: Provide the following:

- The applicant must provide the procedures required by OAC rules 3701:1-58-64, 3701:1-58-65, and 3701:1-58-66, if applicable to the license application.

7.8.5 OTHER EQUIPMENT AND FACILITIES

Regulations: OAC rules 3701:1-38-11(E); 3701:1-38-17; 3701:1-38-15(A)(2); 3701:1-40-16; 3701:1-58-07; 3701:1-58-39; 3701:1-58-47; 3701:1-58-50; 3701:1-58-59; 3701:1-58-67; 3701:1-58-70.

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

Discussion: The applicant should describe in Item 9 of the application other equipment and facilities available for safe use and storage of radioactive material listed in Item 5 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 radioiodine, 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, radiation levels have returned to ambient levels. One method of meeting the requirements of OAC rule 3701:1-58-59(C) 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.

OAC rule 3701:1-58-59(D) 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 (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. OAC rule 3701:1-58-59(B), in part, requires each door leading into the treatment room to 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) exists.
 - 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.
- 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 one minute. Controls that disable this alarm circuit or provide for silencing the alarm for periods in excess of one 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 the shielding will remain in place during the course of patient's 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: For manual brachytherapy facilities, provide a description of the emergency response equipment. For teletherapy, GSR and remote afterloader facilities, provide a description of the following:

- Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room.
- Area radiation monitoring equipment.
- Viewing and intercom systems (except for LDR units).
- Steps that will be taken to ensure 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 whenever the device is not in use or is unattended. The console keys will be inaccessible to unauthorized persons.
- Emergency response equipment.

7.9 ITEM 10: RADIATION PROTECTION PROGRAM

10. Radiation Protection Program (Include personnel monitoring, instrumentation, and procedures.)
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Regulations: OAC rules 3701:1-38-11(E); 3701:1-38-20(B); 3701:1-40-15; 3701:1-40-16(C); 3701:1-58-12; 3701:1-58-13; 3701:1-58-58; 3701:1-58-73; 3701:1-58-74.

Criteria: OAC rule 3701:1-38-11(E) 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 OAC Chapter 3701:1-38 regulations. The licensee is responsible for the conduct of all licensed activities and the acts and omissions of individuals handling licensed material. OAC rule 3701:1-40-16(C) provides the director 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. OAC rule 3701:1-58-12 describes the licensee management's authorities and responsibilities for the radiation protection program. OAC rule 3701:1-58-13 sets forth four circumstances in which the licensee may revise its radiation protection program without the director's approval. For example, no director's 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. Tables C.1 and C.2 in Appendix C may be helpful in determining what information should be provided when requesting a license.

7.9.1 SAFETY PROCEDURES AND INSTRUCTIONS

Regulations: OAC rules 3701:1-58-(C)(2); 3701:1-58-58; 3701:1-58-64; 3701:1-58-65; and 3701:1-58-66.

Criteria: Before using materials under OAC rule 3701:1-58-55, the applicant must develop, document, submit and implement written safety procedures for emergency response. OAC rule 3701:1-58-58 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 OAC rule 3701:1-58-58 must include:

- Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions.
- The process for restricting access and posting the treatment area to minimize the risk of inadvertent exposure.
- 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.

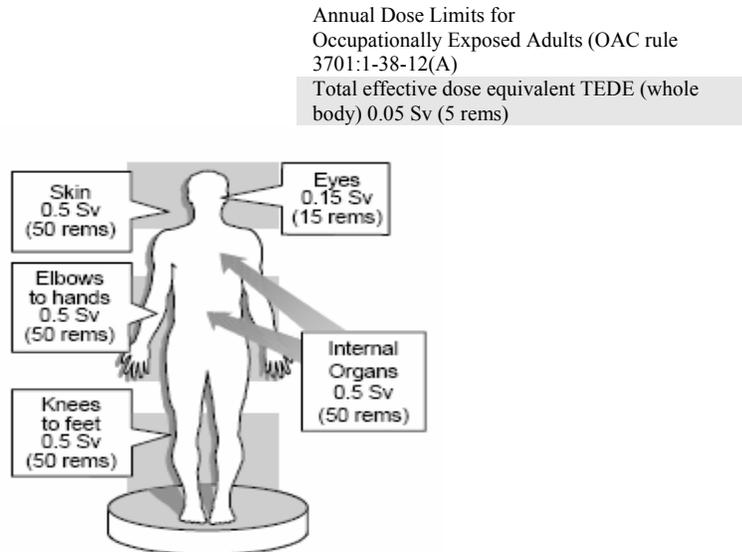
Response from Applicant: Provide procedures required by OAC rule 3701:1-58-58.

7.9.2 OCCUPATIONAL DOSE

Regulations: OAC rules 3701:1-38-01, 3701:1-38-11(E) ; 3701:1-38-12(A); 3701:1-38-12(B); 3701:1-38-12(D)(3); 3701:1-38-12(G); 3701:1-38-12(H); 3701:1-38-14; 3701:1-38-14(B); 3701:1-38-20(B); and 3701:1-38-20(G).

Criteria: Applicants must do either of the following:

- Demonstrate that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of ten percent of the allowable limits as shown in Figure 7.2.



**Figure 7.2 Annual Occupational Dose Limits for Adults
OR**

- Monitor external and/or internal occupational radiation exposure, if required by OAC rule 3701:1-38-14(B).

Discussion: The radiation protection program that licensees are required to develop, document and implement in accordance with OAC rule 3701:1-38-11(E), 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 Chapter 38 of the OAC. 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 Chapter 38 of the OAC 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 Chapter 38 of the OAC limits.

Appendix L 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 (OSLs) 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 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 (OAC rule 3701:1-38-14(A)).

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 OAC rule 3701:1-38-14, licensees must verify 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 OAC rule 3701:1-38-12(D) and OAC rule 3701:1-38-14(B). 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 bioassay 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 the service is licensed by an NRC (or an equivalent Agreement State) license or provide another alternative for ODH to review.

Response from Applicant: If personnel monitoring is required, provide the following:

- A statement that: “Either 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 Chapter 58 of the Ohio Administrative Code or we will provide dosimetry that meets the requirements listed under “Criteria” in “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees.”

OR

- A description of an alternative method for demonstrating compliance with the referenced regulations.

7.9.3 AREA SURVEYS

Regulations: OAC rules 3701:1-38-01; 3701:1-38-11(E); 3701:1-38-12(A); 3701:1-38-13; 3701:1-38-13(E); 3701:1-38-14; 3701:1-38-17; 3701:1-38-17(B); 3701:1-38-20(B); 3701:1-38-20(C); 3701:1-38-20(I); 3701:1-58-29; 3701:1-38-39; 3701:1-38-44; 3701:1-38-56; and 3701:1-38-81.

Criteria: Licensees are required to make surveys of potential radiological hazards in their workplace. OAC rule 3701:1-58-29 requires area surveys to be performed at the end of the day in areas where radiopharmaceuticals have been used. For example, licensees must perform surveys to:

- Ensure 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 one hour from licensed operations.
- Ensure licensed material will be used, transported and stored in such a way that occupational doses to individuals will not exceed the limits specified in OAC rule 3701:1-38-12(A).
- Control and maintain constant surveillance over licensed material that is not in storage and secure licensed material from unauthorized access or removal.
- Ensure licensed material will be used, transported and stored in such a way the air emissions do not exceed the constraint value in OAC rule 3701:1-38-11(E).

Discussion: The radiation protection program that licensees are required to develop, document and implement in accordance with OAC rule 3701:1-38-11(E) 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 surveys accurately assess radiological conditions.

- Contamination:
 - Fixed.
 - Removable.
- Air effluent.
- Water effluent.
- Leak test.
- Bioassays.
- Air sample.
- Restricted areas.
- Unrestricted areas.
- 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.
- Surveys of radiopharmaceutical packages entering (e.g., from suppliers) and departing (e.g., returned radiopharmaceuticals to the supplier).

Licensees are required to perform daily surveys in all areas used for the preparation and administration of all radiopharmaceuticals. Appendix Q contains model procedures that represent one acceptable method of establishing surveys for ambient radiation level and contamination surveys.

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.
- 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.
- Areas of public access in and around the patient's room.

Response from Applicant: Provide the following statement:

“We have developed and will implement and maintain written procedures for area surveys in accordance with OAC rule 3701:1-38-11(E) that meet the requirements of OAC rules 3701:1-38-14 and 3701:1-58-29.”

7.9.4 SAFE USE OF UNSEALED LICENSED MATERIAL

Regulations: OAC rules 3701:1-38-11(E); 3701:1-38-13; 3701:1-38-13(E); 3701:1-38-20(B); 3701:1-38-20(C); 3701:1-40-15(A)(2); 3701:1-40-16(C); 3701:1-58-14; 3701:1-58-28; 3701:1-58-29; and 3701:1-58-38.

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 OAC rule 3701:1-38-11(E) 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.
- Monitoring hands after handling unsealed radioactive material.

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

Response from Applicant: Provide the following statement:

“We have developed and will implement and maintain procedures for safe use of unsealed radioactive material that meet the requirements of OAC rule 3701:1-38-11(E) and OAC rule 3701:1-38-13.”

7.9.5 SPILL PROCEDURES

Regulations: OAC rules 3701:1-38-10(A); 3701:1-38-11(E); 3701:1-38-22(F); 3701:1-38-19(C); 3701:1-38-21(C); 3701:1-40-14; 3701:1-40-17(I); 3701:1-40-20; 3701:1-40-21; and 3701:1-58-14.

Criteria: Before using licensed material, the licensee must develop, document and implement a radiation protection program that includes proper response to spills of licensed material.

Discussion: The radiation protection program that licensees are required to develop, document and implement in accordance with OAC rule 3701:1-38-11(E) must include provisions for responding to spills or other contamination events in order to prevent the spread of radioactive material. Appendix M 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 ODH 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).

Response from Applicant: Provide the following statement:

“We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with rule 3701:1-38-11(E).”

7.9.6 INSTALLATION, MAINTENANCE, ADJUSTMENT, REPAIR, AND INSPECTION OF THERAPY DEVICES CONTAINING SEALED SOURCES

Regulations: OAC rules 3701:1-38-11(E); 3701:1-40-14; 3701:1-40-16; 3701:1-58-57; 3701:1-58-69; 3701:1-58-91; and 3701:1-58-100.

Criteria: In accordance with OAC rule 3701:1-58-57 and OAC rule 3701:1-58-69, 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, OAC rule 3701:1-58-69 requires teletherapy and GSR units be fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to ensure the source exposure mechanism functions properly. Maintenance is necessary to ensure 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 director requires maintenance and repair (as defined above) to be performed only by persons specifically licensed by 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 OAC rule 3701:1-58-57 before responding to this item. OAC rule 3701:1-58-57 allows for an AMP to perform certain service activities with regard to LDR remote afterloader units.

Response from Applicant: No response is necessary if the licensee contracts with personnel who are licensed by NRC or an Agreement State to install, maintain, adjust, repair and inspect the specific therapy device possessed by the licensee. However, if the applicant requests that an employee who is trained by the manufacturer be authorized to perform the aforementioned activities, the applicant must provide sufficient information to allow the director to evaluate and approve such authorization (see OAC rules 3701:1-58-57 and 701:1-58-69).

This should include the following:

- Name of the proposed employee and types of activities requested.

AND

- Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested.

AND

- Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.

Note: The applicant should specify only that installation, maintenance, inspection, adjustment and repair functions described in a certificate or letter from the manufacturer of the device that documents the employee's training in the requested function(s).

7.9.7 MINIMIZATION OF CONTAMINATION

Regulations: OAC rules 3701:1-38-22(F); 3701:1-58-27.

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 7.9.5, “Spill 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 Q, Tables Q.2 and Q.3.

Sealed sources and devices that are approved by NRC or an Agreement State and located and used according to their SSDR Certificates usually pose little risk of contamination. Leak tests performed as specified in the SSDR Certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and stored, repaired or disposed of according to ODH requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts.

Response from Applicant: A response from applicants is not required under the following condition: the director will consider that the above criteria have been met if the information provided in applicant’s responses satisfy the criteria in Sections 7.8, 7.8.1, 7.9, 7.9.4, 7.9.6 and 7.10, on the topics: Facility and Equipment; Facility Diagram; Radiation Protection Program; Safety Program; and Waste Management.

7.9.8 SAFETY INSTRUCTIONS FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Regulations: OAC rules 3701:1-38-10(B); 3701:1-58-14; 3701:1-58-38; 3701:1-58-46; 3701:1-58-58; and 3701:1-58-86.

Criteria: Individuals working with or in the vicinity of licensed material must have adequate safety instruction as required by Chapters 3701:1-38 and 3701:1-58 of the OAC. For individuals who, in the course of employment, are likely to receive in a year an occupational dose of radiation more than 1 millisievert (mSv) [100 millirem (mrem)], the licensee must provide safety instructions as required by OAC rule 3701:1-38-10(B). Additional requirements for training in radiation safety for individuals involved with therapeutic treatment of patients are described in OAC rules 3701:1-58-38, 3701:1-58-46 and 3701:1-58-58. OAC rule 3701:1-58-14 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 OAC rule 3701:1-38-10(B). For example, a licensee might determine 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 OAC rule 3701:1-38-10(B) and in accordance with OAC rules 3701:1-58-38, 3701:1-58-46 and 3701:1-58-58, 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 OAC rule 3701:1-58-58-30. 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.

In accordance with OAC rule 3701:1-58-14, 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 ODH regulations and license conditions with respect to the use of radioactive material.

In accordance with OAC rule 3701:1-58-14(B), 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 OAC rule 3701:1-58-06(B), 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 ODH regulations. OAC rule 3701:1-58-14(C) states a licensee that permits supervised activities, under paragraph OAC rule 3701:1-58-14(A) and (B), is responsible for the acts and omissions of the supervised individuals.

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

Response from Applicant: No response is necessary.

7.9.9 PUBLIC DOSE

Regulations: OAC rules 3701:1-38-13(A), 3701:1-38-13; 3701:1-38-13(C); 3701:1-38-17; 3701:1-38-17(B); and 3701:1-38-20(J).

Criteria: Licensees must do the following:

- Ensure 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 one 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. These include 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 OAC rule 3701:1-38-13(A) does not include doses received due to exposure to patients released in accordance with OAC rule 3701:1-58-30. The provisions of OAC rule 3701:1-38-13 should not be applied to radiation received by a member of the general public from patients released under OAC rule 3701:1-58-30. If a patient is released pursuant to OAC rule 3701:1-58-30, 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 OAC rule 3701:1-58-30.

OAC rule 3701:1-38-13(C) allows licensees to permit visitors to a patient who cannot be released under OAC rule 3701:1-58-30 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 7.8.1 and may find confirmatory surveys to be useful in assuring compliance with OAC rule 3701:1-38-13.

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 OAC rule 3701:1-38-21(C), and take prompt actions to ensure against recurrence.

Response from Applicant: No response required.

7.9.10 OPENING PACKAGES

Regulations: OAC rules 3701:1-38-18(F)(G)(H) and 3701:1-38-20(C).

Criteria: Licensees must ensure packages are opened safely and the requirements of OAC rule 3701:1-38-18(F)(G)(H) are met. Licensees must retain records of package surveys in accordance with OAC rule 3701:1-38-20(C).

Discussion: Licensees must establish, maintain and retain written procedures for safely opening packages to ensure that the monitoring requirements of OAC rule 3701:1-38-18(F)(G)(H) are met and that radiation exposure to personnel coming near or in contact with the packages containing radioactive material are ALARA.

Appendix O contains model procedures that represent one method for safely opening packages containing radioactive materials.

Response from Applicant: No response required.

7.9.11 PROCEDURES FOR ADMINISTRATIONS WHEN A WRITTEN DIRECTIVE IS REQUIRED

Regulations: OAC rules 3701:1-58-14; 3701:1-58-15; 3701:1-58-16; 3701:1-58-73; and 3701:1-58-76.

Criteria: OAC rule 3701:1-58-15 sets forth the requirements for WDs. OAC rule 3701:1-58-16 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 do not need to be submitted to the director. This gives licensees the flexibility to revise the procedures to enhance effectiveness without obtaining the director’s approval. Appendix R provides guidance on developing the procedures.

Response from Applicant: No response required.

7.9.12 RELEASE OF PATIENTS OR HUMAN RESEARCH SUBJECTS

Regulations: OAC rules 3701:1-58-30 and 3701:1-58-82.

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 with OAC rule 3701:1-58-30(B).

Discussion: OAC rule 3701:1-58-30 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 breastfeeding infant or a child could exceed 1 mSv (0.1 rem), assuming there was no interruption of breastfeeding; the instructions also shall include:

- Guidance on the interruption or discontinuation of breastfeeding.
- Information on the potential consequences of failure to follow the guidance.

Appendix T 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 (Section 1).
- Instructions to the patient are required by OAC rule 3701:1-58-30(B).
- Appendix T 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 OAC rule 3701:1-58-30.

Response from Applicant: No response required.

7.9.13 MOBILE MEDICAL SERVICE

Regulations: OAC rules 3701:1-58-01; 3701:1-58-07; 3701:1-58-11; 3701:1-58-31; 3701:1-58-67; 3701:1-58-83; 3701:1-58-98; 3701:1-50-05; 3701:1-50-07; 3701:1-50-08; 3701:1-50-09; 3701:1-58-30; and of 3701:1-50-24;

Criteria: In addition to the requirements in OAC rules 3701:1-58-31 and 3701:1-58-67 as applicable, mobile medical service licensees must comply with all other applicable regulations.

Discussion: This section contains additional guidance for applicants requesting licensure of mobile medical services. “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 Chapter 3701:1-58 of the OAC. 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 the criteria in OAC rule 3701:1-58-30 are met before releasing patients treated in their facilities.

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

Response from Applicant: No response required.

7.9.14 AUDIT PROGRAM

Regulations: OAC rules 3701:1-38-11(E) and 3701:1-38-20(B).

Criteria: Under OAC rule 3701:1-38-11(E), all licensees must annually review the content and implementation of the radiation protection program. The review should ensure the following:

- Compliance with ODH and applicable DOT regulations and the terms and conditions of the license.
- Occupational doses and doses to members of the public are ALARA (OAC rule 3701:1-38-11(E)).

Discussion: The applicant should develop and implement procedures for the required review or audit of the radiation protection program's content and implementation. Appendix K contains model procedures that are only a suggested guide and are one way to meet this requirement. Some sections of Appendix K 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.

ODH 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 director's goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies.

Response from Applicant: No response is necessary.

7.9.15 OPERATING AND EMERGENCY PROCEDURES

Regulations: OAC rules 3701:1-38-10(A)(1)(c); 3701:1-38-11(E); 3701:1-38-15; 3701:1-38-17; 3701:1-38-17(B); 3701:1-38-18(F,G,H); 3701:1-38-20(B); 3701:1-38-21 (A)-(C); 3701:1-38-23(H,I); 3701:1-40-20; 3701:1-58-07; 3701:1-58-16; 3701:1-58-30; 3701:1-58-38; 3701:1-58-39; 3701:1-58-44; 3701:1-58-45; 3701:1-58-46; 3701:1-58-47; 3701:1-58-58; 3701:1-58-59; 3701:1-58-101; 3701:1-58-102; and 3701:1-58-103.

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 7.9.10).
 - 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 7.9.6).
 - Instructions for conducting area radiation level and contamination surveys (see Section 7.9.3).
 - Instructions for administering licensed material in accordance with the WD (see Section 7.9.11).
 - Steps to ensure that patient release is in accordance with OAC rule 3701:1-58-30 (see Section 7.9.12).
 - Instructions for calibration of survey and dosage measuring instruments (see Sections 7.8.2 and 7.8.3).

- Periodic spot checks of therapy device units, sources and treatment facilities (see Section 7.8.4).
- Instructions for radioactive waste management (see Section 7.10).
- 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 Sections 7.9.5 and 7.9.21).
- Steps for source retrieval and access control of damaged sealed source(s) and/or malfunctioning devices containing sealed source(s) (see Section 7.9.1).
- Steps to take if a therapy patient undergoes emergency surgery or dies.

AND

The licensee should consider the following:

- 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 OAC rule 3701:1-38-11(E)(2) 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. OAC rules 3701:1-38-15 and 3701:1-38-17(B) 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."

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, ODH must be notified when an incident involving licensed material occurs. Refer to the regulations (OAC rules 3701:1-38-21 (A)-(C), 3701:1-40-20, 3701:1-38-23(H, I), 3701:1-58-101, 3701:1-58-102, and 3701:1-58-103) for a description of when notifications are required.

Appendix M provides model procedures that are one method for responding to some types of emergencies.

Response from Applicant: No response is necessary.

7.9.16 MATERIAL RECEIPT AND ACCOUNTABILITY

Regulations: OAC rules 3701:1-38-17; 3701:1-38-17(B); 3701:1-38-18(F, G, H); 3701:1-38-21(A); 3701:1-40-17(I); 3701:1-40-19; 3701:1-40-21; 3701:1-58-27; and 3701:1-58-45.

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

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

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

Response from Applicant: No response is necessary.

7.9.17 ORDERING AND RECEIVING

Regulations: OAC rules 3701:1-38-17; 3701:1-38-17(B); 3701:1-38-18(F, G, H); and 3701:1-40-21.

Criteria: OAC rule 3701:1-38-18(F, G, H) contains the requirements for receiving packages containing licensed material. Additionally, the security of licensed material, required by OAC rules 3701:1-38-17 and 3701:1-38-17(B), must be considered for all receiving areas. OAC rule 3701:1-40-21 requires licensees, in part, to maintain records showing the receipt of radioactive material.

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

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

7.9.18 SEALED SOURCE INVENTORY

Regulations: OAC rules 3701:1-38-17; 3701:1-38-17(B); 3701:1-40-21; 3701:1-58-27; 3701:1-58-45; 3701:1-58-80; and 3701:1-58-88.

Criteria: The bureau requires the licensee in possession of a sealed source or brachytherapy source to conduct a semiannual physical inventory of all such sources in its possession.

Discussion: According to OAC rule 3701:1-58-27, the licensee must conduct a semiannual 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 OAC rule 3701:1-58-27(G). However, the licensee must maintain records of GSR source receipt, transfer and disposal, under OAC rule 3701:1-40-21, to indicate the current inventory of sources at the licensee's facility.

Response from Applicant: No response is necessary.

7.9.19 RECORDS OF DOSAGES AND USE OF BRACHYTHERAPY SOURCE

Regulations: OAC rules 3701:1-40-21; 3701:1-58-25; 3701:1-58-79; 3701:1-58-85; and 3701:1-58-88.

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

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 μ Ci).
- Date and time of dosage determination.
- 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 OAC rule 3701:1-46-43 or equivalent NRC or Agreement State requirements.

If molybdenum concentration is measured under OAC rule 3701:1-58-35, records of molybdenum concentration must be made under OAC rule 3701:1-58-85 and must include, for each measured elution of technetium-99m:

- Ratio of the measurements expressed as kBq (μ Ci) of molybdenum-99 per MBq (mCi) of technetium-99m.

- Date and time of the measurement.
- 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.

7.9.20 RECORD KEEPING

Regulations: OAC rules 3701:1-38-20; 3701:1-40-21; and 3701:1-58-73 through 100.

Criteria: Licensees must maintain records as provided in OAC rules 3701:1-38-20; 3701:1-40-21; and 3701:1-58-73 through 100.

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

A table of record keeping requirements appears in Appendix W.

Response from Applicant: No response is necessary.

7.9.21 REPORTING

Regulations: OAC rules 3701:1-38-21; 3701:1-38-23(H, I); 3701:1-58-101 through 103.

Criteria: Licensees are required to report to ODH 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 OAC rules 3701:1-58-101 through 103, 3701:1-38-21; and in 3701:1-38-23(H, I). The timing and type of report are specified within these parts.

Discussion: The director requires licensees to report incidents that might compromise the health and safety of patients, health care providers or the public. Therefore, Chapters 3701:1-38, 3701:1-40 and 3701:1-58 of the Ohio Administrative Code include provisions that describe reporting requirements associated with the medical use of radioactive material.

A table of reporting requirements appears in Appendix X.

Response from Applicant: No response is necessary.

7.9.22 LEAK TESTS

Regulations: OAC rules 3701:1-38-14(A); 3701:1-38-20(C); 3701:1-58-27; 3701:1-58-80; and 3701:1-58-103.

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

Discussion: Licensees must perform leak testing of sealed sources, e.g., calibration, transmission and reference sources, or brachytherapy sources in accordance with OAC rule 3701:1-58-27. Appendix P provides model procedures that are one way to perform leak testing. OAC rule 3701:1-58-27 requires licensees to perform leak tests at six-month intervals or at other intervals approved by the director, the 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 six 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 μ Ci) 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 director, the 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 μ Ci) or less of beta-emitting or gamma-emitting material, or 0.37 MBq (10 μ Ci) or less of alpha-emitting material.
- Sources contain Ir-192 seeds in nylon ribbon.
- 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: No response is necessary.

7.9.23 SAFETY PROCEDURES FOR TREATMENTS WHEN PATIENTS ARE HOSPITALIZED

Regulations: OAC rules 3701:1-38-11(E); 3701:1-38-13; 3701:1-38-14(A); 3701:1-38-17(A); 3701:1-38-20(C); 3701:1-58-39; 3701:1-58-44; 3701:1-58-46; 3701:1-58-47; 3701:1-58-56; 3701:1-58-58; 3701:1-58-59; and 3701:1-58-87.

Criteria: Applicants must develop and implement procedures to ensure 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: OAC rules 3701:1-58-39, 3701:1-58-47 and 3701:1-58-59 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 OAC rule 3701:1-58-30. 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 Chapter 3701:1-38 of the OAC.

OAC rules 3701:1-58-44(B) and 3701:1-58-56(A) 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. OAC rule 3701:1-58-59(E) 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 OAC rule 3701:1-58-30:

- Provide a room with a private sanitary facility for patients treated with a radiopharmaceutical therapy dosage (Note: OAC rule 3701:1-58-39(A) allows for a room shared with another radiopharmaceutical therapy patient).
- Provide a private room for patients implanted with brachytherapy sources (Note: OAC rule 3701:1-58-47 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 (OAC rules 3701:1-58-39 and 3701:1-58-47).
- 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 (OAC rules 3701:1-58-39 and 3701:1-38-14(A)).

- Notify the RSO, or his/her designee and AU as soon as possible if the patient has a medical emergency or dies (OAC rules 3701:1-58-39, 3701:1-58-47 and 3701:1-58-59).

OAC rule 3701:1-38-14(A) 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 OAC rule 3701:1-58-30 following the dosage administration or implant (e.g., measured exposure rates, combination of measured and calculated exposure rates).

OAC rule 3701:1-38-17(A) 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 Chapter 38 of the OAC, 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.

7.9.24 TRANSPORTATION

Regulations: OAC rules 3701:1-38-11(E); 3701:1-40-19; 3701:1-40-21; 3701:1-50-05; 3701:1-50-26; 3701:1-50-07; 3701:1-50-08; and 3701:1-50-09.

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 ODH 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 OAC rule 3701:1-50-07 provides the authorization used by most licensees to transport, or offer for transport, packages of radioactive material and specifies certain conditions. OAC rule 3701:1-50-05 sets forth the requirements for transportation of licensed material. OAC rule 3701:1-50-26 exempts any physician licensed by a state to dispense drugs in the practice of medicine, who is also licensed under Chapter 3701:1-58 of the OAC or the equivalent Agreement State regulations from the requirements in OAC rule 3701:1-50-05. 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. OAC rule 3701:1-50-07 or OAC rule 3701:1-50-09 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 OAC rule 3701:1-58-07 or OAC rule 3701:1-58-09, as appropriate, then becomes responsible for proper packaging of the radioactive materials and compliance with the bureau and DOT regulations. Licensees who do this must ensure the manufacturer (or service licensee):

- Is authorized to possess the licensed material (see OAC rule 3701:1-40-19).
- Actually takes possession of the licensed material under its license.

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

During an inspection, BRP uses the provisions of OAC rule 3701:1-50-05 to examine and enforce various DOT requirements applicable to medical use licensees.

Appendix Y 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.

7.10 ITEM 11: WASTE MANAGEMENT

Regulations: OAC rules 3701:1-38-11(E); 3701:1-38-13; 3701:1-38-13(E); 3701:1-38-14; 3701:1-38-18(C); 3701:1-38-19; 3701:1-38-20(B); 3701:1-38-20(C); 3701:1-38-20(I); 3701:1-38-20(J); 3701:1-40-15(A)(2); 3701:1-40-19; 3701:1-40-21; 3701:1-46-11; and 3701:1-50.

Criteria: Licensed materials must be disposed of in accordance with the director's requirements by:

- Transfer to an authorized recipient (OAC rule 3701:1-40-19(B)).
- Decay-in-storage.
- Release in effluents within the limits in OAC rule 3701:1-38-13.
- As authorized under OAC rule 3701:1-38-19 (C, D, E, F, and G).

Discussion: The radiation protection program that licensees are required to develop, document and implement in accordance with OAC rule 3701:1-38-11(E) must include provisions for waste

disposal of licensed material. Appendix V 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 OAC rule 3701:1-38-19(B) or in applicable regulations. Follow the packaging instructions received from the transfer agent and the burial site operator. Keep the consignment sheet from the transfer agent as the record of disposal.
- When setting up a program for decay-in-storage, consider short-term and long-term storage. Consider designing long-term storage to allow for segregation of wastes with different half-lives (e.g., the use of multiple shielded containers) and use of containers with shielded covers to maintain occupational exposure at ALARA levels. Storage areas must be in a secure location.
- Waste from *in vitro* kits (except mock iodine-125), which are generally licensed under OAC rule 3701:1-46-11 is exempt from waste disposal regulations in Chapter 3701:1-38 of the OAC, as set forth in OAC rule 3701:1-46-11(F). 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 OAC rules 3701:1-38-13(E) and 3701:1-38-19(D), respectively.
 - Regulations for disposal in the sanitary sewer appear in OAC rule 3701:1-38-19(D). 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 OAC rule 3701:1-38-19(D)).
 - Limits on permissible concentrations in effluents to unrestricted areas are enumerated in Table II of Appendix C to OAC rule 3701:1-38-12. These limits apply at the boundary of the restricted area.
 - Liquid scintillation-counting media containing 1.85 kBq (0.05 μ Ci) per gram of H-3 or C-14 may be disposed of without regard to its radioactivity (OAC rule 3701:1-38-19(G)).
- If applicants/licensees propose to treat or dispose of licensed material by incineration, they must comply with OAC rule 3701:1-38-19(F).
- 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 Section 7.8.1 (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 air-borne 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 ODH and attempt to contact the hospital where the pacemaker was implanted to arrange for explanation. The licensee who implanted the device is responsible for the follow-up, explanation and return of the pacemaker to the manufacturer for proper disposal.

Response from Applicant: Provide the following statement:

“We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with OAC rule 3701:1-38-11(E) that also meet the requirements of the applicable OAC rule 3701:1-38-19.”

7.11 ITEM 12: DOMESTIC/FOREIGN CORPORATION

12. Indicate whether licensee is a <input type="checkbox"/> Domestic (in-state) or <input type="checkbox"/> Foreign (out-of-state) corporation <small>If a Foreign corporation, show the Designated Agent</small>		
Name:	Address:	Phone: ()

Applicants should indicate their corporate designation. Section 1701.01 of the Ohio Revised Code (ORC) provides the following definitions:

- “Corporation” or “domestic corporation” means a corporation for profit formed under the laws of this state.
- “Foreign corporation” means a corporation for profit formed under the laws of another state.

Applicants that meet the definition of “foreign corporation” should provide the name, address and phone number of their designated agent within Ohio. A designated agent is required by Section 1703.041 of the ORC.

7.12 ITEM 13: CERTIFICATION

13. Application Certification		
The applicant stated herein, or any official executing this application on behalf of the applicant, certifies that:		
a. This application is prepared in conformity with Chapter 3748 of the Revised Code and rules adopted thereunder.		
b. All information contained herein, including supplements and attachments is true and correct to the best of our knowledge and belief.		
Printed name and title of applicant/official executing this application	Signature	Date

Individuals acting in a private capacity are required to date and sign the application form. Otherwise, representatives of the corporation or legal entity filing the application should date and sign the application form. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. As discussed previously in “Management Responsibility,” signing the application acknowledges management’s commitment and responsibilities for the radiation protection program. The department will return all unsigned applications for proper signature.

NOTES:
<ul style="list-style-type: none">It is a criminal offense to make a willful false statement or representation on applications or correspondence.
When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

7.13 ITEM 14: TAX ID NUMBER

14. Licensee Federal Tax ID number (If no Tax ID number, then Social Security Number):

The bureau needs this number in order to process any adjustments to fees, which favor the licensee, such as refunds of overpayments. If the applicant is an individual and does not have a tax ID number, include the Social Security number.

7.14 ITEM 15: REDUCED FEES CERTIFICATION

15. License Reduced Fees Certification (Attach financial documentation to indicate qualifications for reduced fees.)		
The applicant stated herein, or any official executing this application on behalf of the applicant, certifies that:		
a. This License Reduced Fees Certification is prepared in conformity with Chapter 3748 of the Revised Code and rules adopted thereunder.		
b. All information contained herein, including supplements and attachments is true and correct to the best of our knowledge and belief.		
c. The qualifications for reduced fees is based on OAC 3701:1-38-02, paragraph (J), subparagraph ()		
Printed name and title of applicant/official executing this application	Signature	Date

Applicants should review and determine if the facility to be licensed for radioactive material meets the definitions for reduced license fees as delineated in paragraph (J) of rule 3701:1-38-02 of the OAC. Applicants shall sign the certification and attach all required supporting documentation if the applicant desires a reduction in fees as provided for in the OAC.

Appendix A

State of Ohio Application for a License for Radioactive Material

Ohio Department of Health Application for a License for Radioactive Material

This is an application for: <input type="checkbox"/> Initial License <input type="checkbox"/> Renewal or <input type="checkbox"/> Amendment of License Number:			
1. Name of Licensee (Person or firm proposing to conduct the activities described below.)		2. Address of Licensee (Mailing address of licensee. This may be a PO Box.)	
3. Location(s) of Use or Storage (May not be a PO Box, an actual street address is required. Use additional pages if necessary.)			
a. Address:			
b. Address:			
c. Address:			
4. Licensee Contact Person If consultant or other non-employee, so indicate <input type="checkbox"/>			
Name:	Phone: ()	Fax: ()	E-Mail:

Submit detailed information for items 5 through 11 on separate 8-1/2" x 11" plain paper.
See examples and instructions provided for type and scope of information requested.

5. Radioactive Material		
a. Element and Mass Number (e.g., Hydrogen-3)	b. Physical / Chemical Form (e.g., sealed source, liquid, metal foil)	c. Maximum Activity (in SI units)
6. Purpose for which radioactive material will be used		
7. Radiation Safety Officer (Include training and experience.)		
8. Training Program (Include topics to be covered, frequency of training, and recipients.)		
9. Facilities and Equipment (attach documentation and diagram of locations of use and storage.)		
10. Radiation Protection Program (Include personnel monitoring, instrumentation, and procedures.)		
11. Waste Disposal / Waste Management (List methods to be used by name or reference.)		
12. Indicate whether licensee is a <input type="checkbox"/> Domestic (in-state) or <input type="checkbox"/> Foreign (out-of-state) corporation If a Foreign corporation, show the Designated Agent		
Name:	Address:	Phone: ()
13. Application Certification		
The applicant stated herein, or any official executing this application on behalf of the applicant, certifies that:		
a. This application is prepared in conformity with Chapter 3748 of the Revised Code and rules adopted thereunder.		
b. All information contained herein, including supplements and attachments is true and correct to the best of our knowledge and belief.		
Printed name and title of applicant/official executing this application	Signature	Date
14. Licensee Federal Tax ID number (If no Tax ID number, then Social Security Number):		
15. License Reduced Fees Certification (Attach financial documentation to indicate qualifications for reduced fees.)		
The applicant stated herein, or any official executing this application on behalf of the applicant, certifies that:		
a. This License Reduced Fees Certification is prepared in conformity with Chapter 3748 of the Revised Code and rules adopted thereunder.		
b. All information contained herein, including supplements and attachments is true and correct to the best of our knowledge and belief.		
c. The qualifications for reduced fees is based on OAC 3701:1-38-02, paragraph (J), subparagraph ()		
Printed name and title of applicant/official executing this application	Signature	Date
Return completed application to: Ohio Department of Health Radiation Protection 246 North High Street Columbus, Ohio 43215	Make payment instrument payable to: Treasurer, State of Ohio Ohio Department of Health Accounts Receivable Unit P.O. Box 15278 Columbus, Ohio 43215	

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Appendix B

**Training and Experience and
Preceptor Statement**

TRAINING, EXPERIENCE AND PRECEPTOR STATEMENT

The Ohio Department of Health, Bureau of Radiation Protection is requesting disclosure of all information on this statement for the purpose of authorizing an individual to work with radioactive material. Failure to provide any information may result in denial or delay of authorizing an individual to work with radioactive material.

Instructions: Complete all applicable items. Use supplementary sheets where necessary. Retain one copy and submit original of the document to the Ohio Department of Health, 246 North High Street, Bureau of Radiation Protection, Columbus, Ohio 43215.

PART I TRAINING AND EXPERIENCE

Describe training and experience in sufficient detail to match the training and experience criteria in applicable regulations (Chapter 58 of the Ohio Administrative Code).

1. Name of Individual, Proposed Authorization and Applicable Training Requirements
2. Physician, Podiatrist, Dentist or Pharmacist – State or Territory Where Licensed

3. CERTIFICATION

Specialty Board	Category	Month and Year Certified

4. Didactic or Classroom and Laboratory Training (optional for Medical Physicists)

The following does not need to be completed when using Board Certification to meet Chapter 58 of the Ohio Administrative training and experience requirements.

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation			
Radiation Protection			
Mathematics Pertaining to Use and Measurement of Radioactivity			
Chemistry of Radioactive Material for Medical Use			
Other			

6. Formal Training (applies to Medical Physicist and Therapy Physicians)

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Number	Dates	Name of Organization that Approved the Program and applicable Regulation OAC 3701:1-58-51

7. Radiation Safety Officer – One Year Full-Time Work Experience (in areas identified in number 5a and 5b)

- Yes** Completed one year of full time radiation safety experience (in all areas identified in number 5a) under the supervision of _____ the RSO for License No. _____ .
- N/A**

8. Medical Physicist – One Year Full-Time Training/Work Experience

- Yes** A. Completed one year of full-time training in therapeutic radiological physics (OAC 3701:1-58-19) under the supervision of _____ who meets the requirements for Authorized Medical Physicist
- N/A** the supervision of _____ who meets the requirements for Authorized Medical Physicist
- and**
- Yes** B. Completed one year of full-time work experience (for areas in number 5a) for (specify use or device) _____ under the supervision of _____ who is a medical physicist that meets requirements for Authorized Medical Physicists (OAC 3701:1-58-19)
- N/A** (specify user or device) _____ .

9. Supervised 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 Chapter 58, provide the following information for each):

Name of Supervisor	Supervisor is:
	<input type="checkbox"/> Authorized user <input type="checkbox"/> Authorized medical physicist <input type="checkbox"/> Radiation safety officer <input type="checkbox"/> Authorized nuclear pharmacist

Supervisor meets requirements of Chapter 58, Section(s) _____

for medical use in Chapter 58, Section(s) _____

Address of Supervising Individual	Materials License Number (Indicate which state or if NRC)

PART II PRECEPTOR STATEMENT

NOTE: This part must be completed by the individual’s preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet the training requirements in OAC 3701:1-58-54.

Yes **10.a.** The individual named in number 1 has satisfactorily completed the training requirements in
 N/A Chapter 58 of the Ohio Administrative Code, Section(s) and Paragraph(s) _____
_____.

Yes **10.b.** The individual named in number 1 is competent to independently function as an authorized __
 N/A _____ for Chapter 58 Ohio Administrative Code _____
_____ uses.

11. Preceptor Approval and Certification

I certify the approval of number 10a and 10b, and certify that I am an Authorized Nuclear Pharmacist;
or

I certify the approval of number 10a and 10b, and certify that I meet the ODH requirements of _____
_____ section(s) Chapter 58 Administrative Code or equivalent Agreement State requirements to be
preceptor:

- Authorized User Radiation Safety Officer Medical Physicist

For the following uses of radioactive material(s) under Chapter 58 _____

Address of Preceptor

Materials License Number (Indicate which state or if NRC)

Print Name of Preceptor

Signature – Preceptor

Date Signed

Appendix C
License Application Checklists

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

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., rule 3701:1-58-37, rule 3701:1-58-43, 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 ODH regulations that apply to the given category apply to your type of license. If any “P” beside an item is highlighted, you should provide a commitment as described in the section referenced in the body of this document. If any “G” beside an item is highlighted, see subsequent sections for required responses. “APP” indicates that this document contains an appendix that addresses the item.

Table C.1 Applicability Table								
Item #	Topic	OAC Rules						APP
		3701:1-58-32/34	3701:1-58-37	3701:1-58-43	3701:1-58-53	3701:1-58-55	3701:1-58-72	
7.5	Unsealed Radioactive Material – Uptake, Dilution, Excretion, Imaging and Localization Studies	Y						
7.5	Unsealed Radioactive Material – Written Directive Required		Y					
7.5	Manual Brachytherapy			Y				
7.5	Sealed Sources for Diagnosis				Y			
7.5	Teletherapy Units					Y		
7.5	Remote Afterloader Units					Y		
7.5	Gamma Stereotactic Radiosurgery Units					Y		
7.5	Other Medical Uses						Y	
7.5.1	Sealed Sources and Devices	N	N	Y	Y	Y	Y	
7.5.2	Financial Assurance Determination	Y	Y	Y	Y	Y	Y	
7.6	Purpose(s) for Which Licensed Material Will be Used	Y	Y	Y	Y	Y	Y	
7.7	Training and Experience	G	G	G	G	G	G	
7.7.1	Radiation Safety Officer	Y	Y	Y	Y	Y	Y	H,D
7.7.2	Authorized User(s) (AUs)	Y	Y	Y	Y	Y	Y	D
7.7.3	Authorized Nuclear Pharmacist (ANP)	Y	Y	N/A	N/A	N/A	Y	D
7.7.4	Authorized Medical Physicist (AMP)	N/A	N/A	Y*	N/A	Y	Y	D
7.8	Facilities and Equipment	G	G	G	G	G	G	
7.8.1	Facility Diagram	Y	Y	Y	Y	Y	Y	
7.8.2	Radiation Monitoring Instruments	Y,P	Y,P	Y,P	Y,P	Y,P	Y,P	J
7.8.3	Dose Calibrator and Other Equipment	P	P	N/A	N/A	N/A	P	
7.8.4	Therapy Unit - Calibration and Use	N/A	N/A	N	N/A	Y	N	
7.8.5	Other Equipment and Facilities	N	N	N	N	Y	N	
7.9	Radiation Protection Program	G	G	G	G	G	G	
7.9.1	Safety Procedures and Instructions	N/A	N/A	N/A	N/A	Y	N/A	
7.9.2	Occupational Dose	P	P	P	P	P	P	L
7.9.3	Area Surveys	P	P	P	P	P	P	Q
7.9.4	Safe Use of Unsealed Licensed Material	P	P	N/A	N/A	N/A	P	S

7.9.5	Spill Procedures	P	P	P	N/A	N/A	P	M
7.9.6	Service of Therapy Devices Containing Sealed Sources	N/A	N/A	N/A	N/A	Y	Y	
7.9.7	Minimization of Contamination	N	N	N	N	N	N	
7.10	Waste Management	P	P	P	P	P	P	V
7.12	Certification	Y	Y	Y	Y	Y	Y	
7.14	Fees	Y	Y	Y	Y	Y	Y	
7.9.8	Safety Instruction for Individuals in Restricted Areas	N	N	N	N	N	N	I
7.9.9	Public Dose	N	N	N	N	N	N	
7.9.10	Opening Packages	N	N	N	N	N	N	
7.9.11	Written Directive Procedures	N/A	N	N	N/A	N	N	R
7.9.12	Release of Patients or Human Research Subjects	N	N	N	N/A	N/A	N	T
7.9.13	Mobile Medical Service	N	N	N	N	N	N	U
7.9.14	Audit Program	N	N	N	N	N	N	K
7.9.15	Operating and Emergency Procedure	N	N	N	N	N	N	M
7.9.16	Material Receipt and Accountability	N	N	N	N	N	N	
7.9.17	Ordering and Receiving	N	N	N	N	N	N	N
7.9.18	Sealed Source Inventory	N	N	N	N	N	N	
7.9.19	Records of Dosages and Use of Brachytherapy Source	N	N	N	N	N	N	
7.9.20	Record keeping	N	N	N	N	N	N	W
7.9.21	Reporting	N	N	N	N	N	N	X
7.9.22	Leak Tests	N	N	N	N	N	N	P
7.9.23	Safety Procedures for Treatments when Patients are Hospitalized	N/A	N	N	N/A	N**	N	
7.9.24	Transportation	N	N	N	N	N	N	Y
* Y beside item 8.13 for use under rule 3701:1-58-43 applies to Sr-90 only.								
** N/A for teletherapy and gamma stereotactic radiosurgery outpatient treatments.								

Table C.2 outlines the detailed responses that may be made to Items 5 and 6 of the application for the 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 OAC rule 3701:1-58-32 or OAC rule 3701:1-58-34, then the applicant should check the “yes” column next to OAC rule 3701:1-58-32 and OAC rule 3701:1-58-34 in table C.2. The table then indicates appropriate responses for that type of use. An applicant may copy the checklist and include it in the license application.

TABLE C.2 ITEMS 5 AND 6 ON THE ODH APPLICATION: RADIOACTIVE MATERIAL AND USE*(If Using This Checklist, Check Applicable Rows And Fill In Details, And Attach Copy Of Checklist To The Application.)*

Yes	Radionuclide	Form Or Manufacturer/ Model No.	Maximum Quantity	Purpose Of Use
	Any radioactive material permitted by OAC rule 3701:1-58-32	Any	As needed	Any uptake, dilution and excretion study permitted by OAC rule 3701:1-58-32.
	Any radioactive permitted by OAC rule 3701:1-58-34	Any	As needed	Any imaging and localization study permitted by OAC rule 3701:1-58-34.
	Any radioactive material permitted by OAC rule 3701:1-58-37	Any	___ millicuries	Any radiopharmaceutical therapy procedure permitted by OAC rule 3701:1-58-37.
	Iodine-131	Any	___ millicuries	Administration of I-131 sodium iodide.
	Radioactive material permitted by OAC rule 3701:1-58-43 (Radionuclide _____)	Sealed source or device (manufacturer _____, Model No. _____)	___ millicuries	Any brachytherapy procedure permitted by OAC rule 3701:1-58-43.
	Radioactive material permitted by OAC rule 3701:1-58-43 (Radionuclide _____)	Sealed source or device (manufacturer _____, Model No. _____)	___ millicuries	Any brachytherapy procedure permitted by OAC rule 3701:1-58-43.
	Radioactive material permitted by OAC rule 3701:1-58-43 (Radionuclide _____)	Sealed source or device (manufacturer _____, Model No. _____)	___ millicuries	Any brachytherapy procedure permitted by OAC rule 3701:1-58-43.
	Strontium-90	Sealed source or device (manufacturer _____, Model No. _____)	___ millicuries	Treatment of superficial eye conditions using an applicator distributed pursuant to OAC rule 3701:1-46-44 and permitted by OAC rule 3701:1-58-43.
	Radioactive material permitted by OAC rule 3701:1-58-53 Check all that apply: <input type="checkbox"/> Gd-153; <input type="checkbox"/> I-125; <input type="checkbox"/> Other, describe	Sealed source or device (manufacturer _____, Model No. _____)	___ curies per source and ___ curies total	Diagnostic medical use of sealed sources permitted by OAC rule 3701:1-58-53 incompatible devices registered pursuant to OAC rule 3701:1-40-14(E).

Note: Certain quantities of radioactive material may require increased controls contact BRP for details.

TABLE C.2 ITEMS 5 AND 6 ON THE ODH APPLICATION: RADIOACTIVE MATERIAL AND USE

(If Using This Checklist, Check Applicable Rows And Fill In Details, And Attach Copy Of Checklist To The Application.)

Yes	Radionuclide	Form Or Manufacturer/ Model No.	Maximum Quantity	Purpose Of Use
	Iridium-192	Sealed source or device (manufacturer _____, Model No. _____)	___ curies per source and ___ curies total	One source for medical use permitted by OAC rule 3701:1-58-55, in 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.
	Cobalt-60	Sealed source or device (manufacturer _____, Model No. _____)	___ curies per source and ___ curies total	One source for medical use permitted by OAC rule 3701:1-58-55, in manufacturer _____ Model No. _____ teletherapy unit.
	Cobalt-60	Sealed source or device (manufacturer _____, Model No. _____)	___ curies per source and ___ curies total	For medical use permitted by OAC rule 3701:1-58-55, in manufacturer _____ Model No. _____ stereotactic radiosurgery device. Sources in the shipping container as necessary for replacement of the sources in the stereotactic radiosurgery device.
	Any radioactive material permitted by OAC rule 3701:1-46-11	Prepackaged kits	___ millicuries	<i>In vitro</i> studies.
	Depleted uranium	Metal	___ kilograms	Shielding in a teletherapy unit.
	Depleted uranium	Metal	___ kilograms	Shielding in a linear accelerator.

TABLE C.2 ITEMS 5 AND 6 ON THE ODH APPLICATION: RADIOACTIVE MATERIAL AND USE <i>(If Using This Checklist, Check Applicable Rows And Fill In Details, And Attach Copy Of Checklist To The Application.)</i>				
Yes	Radionuclide	Form Or Manufacturer/ Model No.	Maximum Quantity	Purpose Of Use
	Any radionuclide in excess of 30 millicuries 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. _____ for calibration 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 a component of manufacturer _____ Model No. _____, nuclear-powered cardiac pacemakers for clinical evaluation in accordance with manufacturer's protocol dated _____. This authorization includes: follow-up, explantation, recovery, disposal, and implantation.
	Other	Form or manufacturer/ Model No. _____	___ millicuries	Purpose of use _____

Table C.3 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 fill in the name(s) of RSO in Table C.3 and then check the boxes indicating which documents pertaining to the RSO are being included in the license application. An applicant may copy the checklist and include it in the license application.

Table C.3 Items 7 through 11 on ODH Application: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(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 material included in application
Item 7: Radiation Safety Officer _____	<i>For an individual previously identified as an RSO on an NRC or Agreement State license or permit under OAC rule 3701:1-58-21:</i>	<input type="checkbox"/>
	Previous license number (if issued by ODH/BRP) or a copy of the a license or a permit (if issued by an NRC or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope) that authorized the uses requested and on which the individual was named as the RSO, <i>prior to Aug. 15, 2005.</i>	
	<i>For an individual qualifying under OAC rule 3701:1-58-18(A):</i>	<input type="checkbox"/>
	Copy of certification by a specialty board whose certification process has been recognized ¹ by the NRC or an Agreement State under OAC rule 3701:1-58-18(A).	
	<i>For an individual qualifying under OAC rule 3701:1-58-18(B):</i>	<input type="checkbox"/>
	Description of the training and experience specified in OAC rule 3701:1-58-18(B) demonstrating the proposed RSO is qualified by training and experience as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO. AND	
	Written certification, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements of paragraph (B)(1) of this OAC rule and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.	<input type="checkbox"/>
	<i>For an individual qualifying under OAC rule 3701:1-58-18(C):</i>	<input type="checkbox"/>
	Copy of the licensee’s license indicating that the individual is an authorized user, authorized medical physicist or authorized nuclear pharmacist identified on the licensee’s license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has radiation safety officer responsibilities. AND	
	If applicable, description of recent related continuing education and experience as required by OAC rule 3701:1-58-22.	<input type="checkbox"/>

¹ 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.html>.

Item Number and Title	Suggested Response	Check box to indicate material included in application
7: Authorized Users Name(s), and, Requested Uses for Each Individual	<p><i>For an individual previously identified as an AU on an NRC or Agreement State license or permit under OAC rule 3701:1-58-21:</i></p> <p>Previous license number (if issued by ODH/BRP) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master material licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC master material license broad scope permittee on which the physician, dentist, or podiatrist was specifically named as an AU for the uses requested, <i>prior to Aug. 15, 2005.</i></p>	<input type="checkbox"/>
	<p><i>For an individual qualifying under OAC Chapter 3701:1-58 rules 33, 36, 40, 41, 42, 51, 52, 54, and 71:</i></p> <p>Copy of the certification(s) by a specialty board(s) whose certification process has been recognized² by the director, NRC, an Agreement State or NARM licensing state for NARM.</p> <p style="text-align: center;">OR</p>	<input type="checkbox"/>
	<p>Description of the training and/or experience specified in the OAC rule demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is sought.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>Written certification, signed by a preceptor physician AU, that the training and experience specified for certification has been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized.</p> <p style="text-align: center;">AND</p>	<input type="checkbox"/>
	<p>If applicable, description of recent related continuing education and experience as required by OAC rule 3701:1-58-22.</p>	<input type="checkbox"/>
Item 7: Authorized Nuclear Pharmacists Name(s):	<p><i>For an individual previously identified as an ANP on an NRC or Agreement State license or permit under OAC rule 3701:1-58-21:</i></p> <p>Previous license number (if issued by ODH/BRP) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master material licensee, a permit issued by an NRC or Agreement State broad scope licensee or a permit issued by an NRC master material license broad scope permittee on which the individual was specifically named an ANP for the uses requested, <i>prior to Aug. 15, 2005.</i></p>	<input type="checkbox"/>
	<p><i>For an individual qualifying under OAC rule 3701:1-58-20 (A):</i></p> <p>Copy of the certification(s) of the specialty board(s) whose certification process has been recognized³ under OAC rule 3701:1-58-20(A).</p>	<input type="checkbox"/>

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.html>>

³ 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.html>>

	<i>For an individual qualifying under OAC rule 3701:1-58-20 (B):</i>	
	Description of the training and experience specified in OAC rule 3701:1-58-20(B) demonstrating that the proposed ANP is qualified by training and experience. AND	<input type="checkbox"/>
	Written certification, signed by a preceptor ANP, that the required training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved. AND	<input type="checkbox"/>
	If applicable, description of recent, related continuing education and experience as required by OAC rule 3701:1-58-22.	<input type="checkbox"/>
Item 7: Authorized Medical Physicists	<i>For an individual previously identified as an AMP on an NRC or Agreement State license or permit under OAC rule 3701:1-58-21:</i>	<input type="checkbox"/>
	Previous license number (if issued by the ODH) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master material licensee, a permit issued by an NRC or Agreement State broad scope licensee or a permit issued by an NRC master material license broad scope permittee on which the individual was specifically named an AMP for the uses requested, prior to Aug. 15, 2005.	
	<i>For an individual qualifying under OAC rule 3701:1-58-19(A):</i>	
	Copy of the certification(s) of the specialty board(s) whose certification process has been recognized ⁴ under OAC rule 3701:1-58-19(A).	<input type="checkbox"/>
	<i>For an individual qualifying under OAC rule 3701:1-58-19(B):</i>	<input type="checkbox"/>
	Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics or health physics. AND	
	Complete one year of full-time training in therapeutic radiological physics. AND	<input type="checkbox"/>
	Complete an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist at a medical institution. AND	<input type="checkbox"/>
	Written certification, signed by a preceptor AMP, that training and experience required for certification has been satisfactorily completed and that a level of competency sufficient to function independently as an AMP for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. AND	<input type="checkbox"/>
	If applicable, description of recent related continuing education and experience as required by OAC rule 3701:1-58-22.	<input type="checkbox"/>

⁴ 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.html>>

Table C.3 Items 7 through 11 on ODH Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(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 material included in application
Item 9: 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:	<input type="checkbox"/>
	<ul style="list-style-type: none"> • 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." 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • 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 OAC rule 3701:1-38-01. 	<input type="checkbox"/>
	<ul style="list-style-type: none"> • 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.). 	<input type="checkbox"/>
	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.	<input type="checkbox"/>
Item 9: Radiation Monitoring Instruments	A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations."	<input type="checkbox"/>
	<p align="center">AND/OR</p> <p>A statement that: "We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in OAC rule 3701:1-38-14 and that meet the requirements of OAC rule 3701:1-58-24.</p> <p align="center">AND</p>	<input type="checkbox"/>
	<p>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.</p> <p align="center">AND</p>	<input type="checkbox"/>
	A statement that: "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."	<input type="checkbox"/>

Table C.3 Items 7 through 11 on ODH Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(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 material included in application
Item 9: Dose Calibrator and Other Dosage Measuring Equipment	A statement that: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."	<input type="checkbox"/>
Item 9: Therapy Unit Calibration and Use	We are providing the procedures required by OAC rules 3701:1-58-64, 3701:1-58-65 and 3701:1-58-66, if applicable to the license application.	<input type="checkbox"/>
Item 9: Other Equipment and Facilities	Attached is a description identified as Attachment 9.4, of additional facilities and equipment.	<input type="checkbox"/>
	For manual brachytherapy facilities, we are providing a description of the emergency response equipment.	<input type="checkbox"/>
	For teletherapy, GSR and remote afterloader facilities, we are providing a description of the following:	<input type="checkbox"/>
	Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room;	<input type="checkbox"/>
	Area radiation monitoring equipment;	<input type="checkbox"/>
	Viewing and intercom systems (except for LDR units);	<input type="checkbox"/>
	Steps that will be taken to ensure no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) are in the treatment room;	<input type="checkbox"/>
	Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons;	<input type="checkbox"/>
	Emergency response equipment.	<input type="checkbox"/>
Item 10: Safety Procedures and Instructions	Attached procedures required by OAC rule 3701:1-58-58.	<input type="checkbox"/>
Item 10: Occupational Dose	A statement that: "Either 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 Chapter 3701:1-38 of the OAC or we will provide dosimetry that meets the requirements listed under "Criteria" in NMS-LIC-09, "Guidance About OAC Chapter 3701:1-58 Medical Use Licensees."	<input type="checkbox"/>
	OR A description of an alternative method for demonstrating compliance with the referenced regulations.	<input type="checkbox"/>

Table C.3 Items 7 through 11 on ODH Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(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 material included in application
Item 10: Area Surveys	A statement that: "We have developed and will implement and maintain written procedures for area surveys in accordance with OAC rule 3701:1-38-11 that meet the requirements of OAC rules 3701:1-38-14 and 3701:1-58-29."	<input type="checkbox"/>
Item 10: Safe Use of Unsealed Licensed Material	A statement that: "We have developed and will implement and maintain procedures for safe use of unsealed radioactive material that meet the requirements of OAC rules 3701:1-38-11 and 3701:1-38-13."	<input type="checkbox"/>
Item 10: Spill Procedures	A statement that: "We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with OAC rule 3701:1-38-11."	<input type="checkbox"/>
Item 10: Installation, Maintenance, Adjustment, Repair and Inspection of Therapy Devices Containing Sealed Sources	Name of the proposed employee and types of activities requested: <hr style="width: 50%; margin: auto;"/> <p align="center">AND</p>	<input type="checkbox"/>
	Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested. <p align="center">AND</p>	<input type="checkbox"/>
	Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.	<input type="checkbox"/>
Item 10: Minimization of Contamination	A response is not required under the following condition: ODH will consider that the above criteria have been met if the information provided in applicant's responses satisfy the criteria in Sections 7.8, 7.8.1, 7.9, 7.9.4 and 7.10, on the topics: Facility and Equipment; Facility Diagram; Radiation Protection Program; Safety Program; and Waste Management.	<input type="checkbox"/>
Item 11: Waste Management	A statement that: "We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with OAC rule 3701:1-38-11, that also meet the requirements of OAC rule 3701:1-38-19."	<input type="checkbox"/>

Appendix D

**Documentation of Training and
Experience to Identify Individuals on a
License as
Authorized User (AU),
Radiation Safety Officer (RSO),
Authorized Medical Physicist (AMP) or
Authorized Nuclear Pharmacist (ANP)**

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

An applicant or licensee that is adding an experienced authorized user, authorized medical physicist, authorized nuclear pharmacist or radiation safety officer to its medical use license needs to provide evidence the individual is listed on a medical use license issued by the NRC, Agreement State, a permit issued by an NRC master material licensee, a permit issued by an Agreement State, an NRC or Agreement State broad scope licensee or a permit issued by an NRC master material broad scope permittee before the effective date of rule 3701:1-58-21 of the Ohio Administrative Code (Aug. 15, 2005) provided the individual is authorized for the same types of use(s) requested in the application under review, and the individual meets the recentness-of-training criteria described in OAC rule 3701:1-58-22.

When adding an experienced authorized nuclear pharmacist to the license, the applicant also may provide evidence that the individual is listed on an NRC or Agreement State commercial nuclear pharmacy license or identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy authorized to identify authorized nuclear pharmacists. For individuals who have been previously authorized by, but not listed on, the commercial nuclear pharmacy license, medical broad scope license or master materials license medical broad scope permit, the applicant should submit either verification of previous authorizations granted or evidence of acceptable training and experience.

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

Applicants should complete the appropriate sections on the training and experience and preceptor statement in Appendix B of this guidance to show the individuals meet the appropriate training and experience criteria in OAC rules 3701:1-58-12 through 3701:1-58-22 or OAC rules 3701:1-58-32 through 3701:1-58-71. The training and experience and preceptor statement were developed to provide a single location where six different professional groups (physicians, dentists, podiatrists, medical physicists, pharmacists, and radiation safety officers) and 10 different medical sub-specialties could document completion of appropriate training and experience requirements. Therefore, some of the sections will not be applicable for each group.

There are two different training and experience routes to qualify an individual as an authorized user, authorized medical physicist, authorized nuclear pharmacist or radiation safety officer. The first is by means of certification by a board recognized by the director as provided in OAC rules 3701:1-58-18, 3701:1-58-19(A), 3701:1-58-20(A), 3701:1-58-33(A), 3701:1-58-36(A), 3701:1-58-40(A), 3701:1-58-41(A), 3701:1-58-42(A), 3701:1-58-51(A), 3701:1-58-54(A) or 3701:1-58-71(A).

The second route is by meeting the structured educational program, supervised work experience and preceptor certification requirements in OAC rules 3701:1-58-12 through 3701:1-58-22 or OAC rules 3701:1-58-32 through 3701:1-58-71.

III. Recentness of Training

The required training and experience described in OAC Chapter 3701:1-58 must be obtained within the seven years preceding the date of the application, or the individual must document having had related continuing education, retraining and experience since obtaining the required training and experience. Examples of acceptable continuing education and experience include the following:

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

IV. Instructions and Guidance for Filling Out the ‘*Training, Experience and Preceptor Statement*’

Note: Individuals who have been certified by boards recognized by the director need only complete **items 1, 2 and 3** of Training and Experience and Preceptor Statement. Information for all other individuals to be listed on the license as an authorized user, authorized medical physicist, authorized nuclear pharmacist or radiation safety officer must be provided in subsequent sections of Training and Experience and Preceptor Statement.

Part I. Training and Experience

Provide information for each individual for whom authorization is sought.

Item 1 Name of Individual, Proposed Authorization and Applicable Training Requirements.

Provide the individual’s complete name so ODH can distinguish the training and experience received from that received by others with a similar name, specify the type authorization being requested (radiation safety officer, authorized user, authorized medical physicist, and authorized nuclear pharmacist), and applicable training requirements.

Note: Do not include personal or private information (e.g., date of birth, Social Security number) as part of your qualification documentation.

Item 2 State or Territory Where Licensed

ODH requires physicians, dentists, podiatrists, and pharmacists to be licensed by the State of Ohio to prescribe drugs in the practice of medicine, practice dentistry, practice podiatry or practice pharmacy, respectively.

Item 3 Certification

The applicant should provide a copy of the board certification or provide the complete name of the specialty board and the category (or subspecialty) if the board recognizes more than one certification specialty. Data provided about the month and year certified is used to establish recentness of training, to confirm ODH recognizes that board's certifications and to verify that the applicant meets the training requirements.

If an individual to be listed on the license as an authorized user, authorized medical physicist, authorized nuclear pharmacist, or radiation safety officer cannot meet the Specialty Board certification route, the applicant must fill out the appropriate remaining sections of ODH Form "Training and Experience and Preceptor Statement."

Items 4, 5a, and 5b "Didactic or Classroom and Laboratory Training"; 5a, "Work Experience with Radiation," and 5b. "Supervised Clinical Case Experience."

Applicants with individuals needing Authorized User and Authorized Nuclear Pharmacist recognition should consider the completion of Items 4 and 5 as a unit because the hours required for training and supervised work experience are usually added together to meet the requirement. Because the applicant is not required to receive the training described in Item 4 at one location or at one time, space is provided to identify each location and date of training. The clock hours must be indicated for those individuals who must meet a minimum number of training and work experience hours. The specific number of hours needed for each training element will depend upon that individual's needs. Item 4 is optional for the medical physicist applicant because OAC Chapter 3701:1-58, "Medical Use of Radioactive Material," does not specify the specific training elements needed to be an authorized medical physicist.

Most applicants will complete only Item 5a because most individuals are required to have supervised work experience but are not required to have specific clinical case experience. Those individuals who have to document clinical case experiences (e.g., the Strontium-90 eye applicator users) may also have specific work experience elements that need to be documented in Item 5b, as part of the clinical case experience.

Note: Classroom and Laboratory Training or Didactic Training may be provided at medical teaching/university institutions. In some cases, a course may be provided for that particular need and taught in consecutive days; in others, the period may be a semester or quarter as part of the formal curriculum.

The required "structural educational programs" or "training" may be obtained in any number of settings, locations and educational situations.

If the applicant is seeking authorization under the requirements of OAC rules 3701:1-58-12 through 3701:1-58-22 and OAC rules 3701:1-58-32 through 3701:1-58-71, the preceptor is responsible for the initial determination of the adequacy of the training (and work experience) to permit the individual to function independently.

Item 6 Formal Training

This item is completed for individuals qualified to be medical physicists or physicians meeting the requirements in OAC rules 3701:1-58-51 or 3701:1-58-71.

Item 7 Radiation Safety Officer – One Year Full-time Work Experience

This item is used to document that the applicant meets the regulatory requirement of one full year of full-time work experience in the areas which are listed in Item 5a.

Item 8 Medical Physicist – One Year Full-time Training and Experience

This section is used to document the medical physicist has received one full year of full time training and one full year of work experience. Both are required to be under the supervision of an authorized medical physicist but they do not have to be under the same medical physicist.

Item 9 Supervising Individual

Item 9 need only be completed by an applicant seeking to have an individual listed on the license as an AU, RSO or AMP under OAC rules 3701:1-58-24 through 3701:1-58-52 or OAC rules 3701:1-58-55 through 3701:1-58-71. In addition, the use of Item 9 is also dependent on whether information on the identity, qualifications and location (license number) of the supervising individual has already been provided elsewhere on the Training and Experience and Preceptor Statement Form (e.g., in Items 7, 8 or 12).

Note: If the individual had more than one supervisor, all supervising individual names must be listed in Items 5a and 5b and Item 9 filled out for each.

Note: The authorized nuclear pharmacist applicant is required to have supervised practical experience in a nuclear pharmacy but the individual(s) providing the supervision are not specified. Therefore the applicant does not need to identify a supervising individual in Item 5a or complete Item 9.

Part II Preceptor Statement

The director defines the term “preceptor” in OAC rule 3701:1-58-01, “Definitions,” to mean “an individual who provides, directs, or verifies training and experience required for an individual to become an Authorized User, an Authorized Medical Physicist, an Authorized Nuclear Pharmacist, or a Radiation Safety Officer.” While the supervising individual for the work experience may also be the preceptor, the preceptor does not have to be the supervising individual as long as the preceptor directs or verifies the training and experience required. The preceptor must certify in writing regarding the training and experience of any individual to serve as an authorized user, authorized nuclear pharmacist, authorized medical physicist or radiation safety officer (pursuant to OAC rules 3701:1-58-12 through 3701:1-58-52 or OAC rules 3701:1-58-55 through 3701:1-58-71) and certify that the individual has satisfactorily completed the appropriate training and experience criteria and has achieved a level of competency or a level of radiation safety knowledge sufficient to function independently. This preceptor also has to meet specific requirements.

The director recognizes supervised work experience, such as that described in OAC rule 3701:1-58-36(C), conducted under the supervision of an authorized user in a licensed material use program. A supervisor is an AU who provides frequent direction, instruction and direct oversight of the student as the student completes the required work experience in the use of radioactive material. Supervision may occur at various licensed facilities, from a large teaching university hospital to a small private practice. However, work experience for sealed source therapy, as described in OAC rules 3701:1-58-51, 3701:1-58-52(B)(2) and 3701:1-58-71(B)(1), must have been gained at a medical institution. When the supervised work experience is complete, the applicant should provide documentation of it using training and experience and preceptor statement or equivalent as attachments to the State of Ohio Radioactive Materials License Form (Appendix A) or a letter from the preceptor that indicates that the applicant has obtained all required experience elements.

Item 10a and 10b For AU, RSO, ANP or AMP under

Item 10 has two components: The information in 10a certifies that the applicant has satisfactorily completed the training and supervised work experience requirements and 10b certifies that the applicant has the competency to function independently.

Item 11 ‘Preceptor Approval and Certification’

Item 11 requires the preceptor to certify they are an authorized nuclear pharmacist or radiation safety officer or meets the requirements to be a preceptor AU, AMP and requires the preceptor’s signature.

Note: OAC rule 3701:1-58-53 ‘Sealed Sources for Diagnosis’ does not require a preceptor statement.

Note: See Appendix B for ‘Training and Experience and Preceptor Statement’

Appendix E
Information Needed for Transfer of
Control Application

Licensees must provide full information and obtain the bureau's prior written consent before transferring ownership or control of the license; some licensees refer to this as "transferring the license." Call the BRP Decommissioning section at 614-644-2727 for further information.

Appendix F

Guidance on Decommissioning Funding Plan and Financial Assurance

See Ohio Administrative Code rule 3701:1-40-17 for guidance.

Appendix G
“Certificate of Disposition of Materials”

Ohio Department Of Health Certificate of Disposition of Materials

1. Instructions:

- A. Print or type and attach all required documentation.
- B. Submit this form to:
Ohio Department of Health
Bureau of Radiation Protection
246 North High Street
Columbus, Ohio 43216-0118

2. Licensee Information

A. Name			
Mailing address	City	State	ZIP
B. License Number		C. License Expiration Date	
D. Location(s): If address is different than mailing address, list address(es). If partial release, list areas to be released. If line item or authorization, list items to be deleted from license.			

3. Requested Action

- License Termination Full Facility Close Out Partial Facility Close Out - Attach floor plan or maps of the area
- Line Item removal Other

4. Disposition of Radioactive Materials

- No materials have ever been procured or possessed by the licensee at this location
- All activities by this license at the specified location(s) or area(s) have ceased. All materials procured and/or possessed under this license at this location(s) or area(s) have been removed.
- N/A Yes Describe specific material transfer actions. Provide all documentation.
- N/A Yes If radioactive wastes were generated in the course of this license action, describe all radioactive material disposal actions.
- N/A Yes If materials were disposed directly by the licensee rather than transferred to another licensee, licensed disposal site, or waste contractor, describe the specific disposal procedure (e.g. methods delineated in OAC 3701:1-38-19).
- N/A Yes If materials were transferred to another licensee, provide recipient's name and address, recipient's NRC or Agreement State license number, and date of the transfer. Include a copy of correspondence verifying the recipient has taken possession of the material. The disposing licensee is responsible for assuring that the recipient is licensed to receive the materials being transferred.

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5. Surveys for Contamination and Radiation Levels

Did the licensee conduct a radiation survey to confirm the absence of licensed radioactive materials and to determine whether any contamination remains at this location covered by the licensee?

Yes The results are attached were forwarded to the Ohio Department of Health on _____(date).

No Only sealed sources were present, the most recent leak tests for each source indicates no leakage, AND there is no past incident of a leaking source at this location.

No Other. Provide explanation of why surveys are not necessary.

6. Contact Information

A. Name		B. Title		
C. Address		City	State	ZIP
D. Telephone ()	E. FAX ()		F. E-mail	

7. Certification

I hereby certify that:

A. All information in this form is true and complete.

B. Printed name	Title
C. Signature	D. Date

Warning: False statements in this certificate may be subject to civil and/or criminal penalties. Ohio Department of Health regulations require that submissions to the Ohio Department of Health be complete and accurate in all material respects.

Appendix H

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 ODH 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 OAC rule 3701:1-58-12. 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 SSTR 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 NRC or Agreement State license.
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed material.
- Documentation is maintained to demonstrate individuals are not likely to receive, in one year, a radiation dose in excess of 10 percentage 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, 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 the director, 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.
- 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 Ohio Department of Health 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 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 the trainee routinely uses. Applicants may either adopt these model procedures or develop an alternative program to meet ODH requirements. Guidance on requirements for training and experience for AMPs and AUs who engage in certain specialized practices is also included.

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

Personnel will receive instruction before assuming duties with, or in the vicinity of, radioactive materials during annual refresher training, and whenever there is a significant change in duties, regulations, terms of the license or type of radioactive material or therapy device used. Records of worker training will be maintained for at least three 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 OAC rule 3701:1-38-11(E).
- Risk estimates including comparison with other health risks.
- Posting requirements OAC rule 3701:1-38-18(A)(4).
- Proper use of personnel dosimetry (when applicable).
- Access control procedures OAC rules 3701:1-38-15 and 3701:1-38-17(B).
- Proper use of radiation shielding, if used.
- Patient release procedures OAC rule 3701:1-58-30.
- 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 OAC rules 3701:1-38-10(B), 3701:1-58-38, 3701:1-58-46, 3701:1-58-58.

- Occupational dose limits and their significance OAC rule 3701:1-38-12(A).
- Dose limits to the embryo/fetus, including instruction on declaration of pregnancy OAC rule 3701:1-38-12(H).
- Worker's right to be informed of occupational radiation exposure OAC rule 3701:1-38-10(C).
- Each individual's obligation to report unsafe conditions to the RSO OAC rule 3701:1-38-10(B).
- Applicable regulations, license conditions, information notices, bulletins, etc. OAC rule 3701:1-38-10(B).
- Where copies of the applicable regulations, the Ohio radioactive materials license and its application are posted or made available for examination OAC rule 3701:1-38-10(A).
- Proper record keeping required by ODH regulations OAC rule 3701:1-38-10(B).
- Appropriate surveys to be conducted OAC rule 3701:1-38-14(A).
- Proper calibration of required survey instruments OAC rule 3701:1-38-14(A)(2).
- Emergency procedures.
- Decontamination and release of facilities and equipment (OAC rule 3701:1-38-22(F), 3701:1-40-18).
- Dose to individual members of the public (OAC rule 3701:1-38-13).
- Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste management, sealed source leak testing) (OAC rule 3701:1-58-14).

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 OAC rule 3701:1-58-27.
- Emergency procedures including emergency response drills OAC rules 3701:1-58-38, 3701:1-58-46 and 3701:1-58-58.
- Operating instructions OAC rules 3701:1-58-14 and 3701:1-58-58.
- Computerized treatment planning system OAC rule 3701:1-58-70.
- Dosimetry protocol OAC rule 3701:1-58-60.
- Detailed pretreatment quality assurance checks OAC rules 3701:1-58-14 and 3701:1-58-58.

- 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 OAC rules 3701:1-58-38 and 3701:1-58-46.
- Patient control procedures OAC rules 3701:1-58-38, 3701:1-58-46, and 3701:1-58-58.
- Visitor control procedures such as visitors’ stay times and safe lines in radiation control areas (patient’s room) OAC rules 3701:1-58-38, 3701:1-58-46 and 3701:1-58-58.
- Licensee’s WD Procedures, to ensure 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 treatment is to the correct site (or, for GSR, correct positioning of the helmet) OAC rule 3701:1-58-16.
- 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) OAC rules 3701:1-58-46 and 3701:1-58-58.
- Size and appearance of different types of sources and applicators OAC rules 3701:1-58-46 and 3701:1-58-58.
- Previous incidents, events, and/or accidents.
- 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 OAC rule 3701:1-58-19(B). 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 ophthalmic treatments OAC rule 3701:1-58-49. 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 OAC rule 3701:1-58-19(B).

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 OAC rules 3701:1-58-40, 3701:1-58-42, 3701:1-58-51, 3701:1-58-52 and 3701:1-58-71, 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 OAC rules 3701:1-58-40, 3701:1-58-51, 3701:1-58-52 and 3701:1-58-71.

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. The training program for ancillary staff that performs 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 OAC rule 3701:1-58-10(B).
- 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) OAC rule 3701:1-38-10(B).
- The applicable provisions of ODH regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material (e.g., posting and labeling of radioactive material) OAC rule 3701:1-38-10(B).
- Responsibility to report promptly to the licensee any condition that may lead to or cause a violation of ODH regulations and licenses or unnecessary exposure to radiation and/or radioactive material (e.g., notification of the RSO regarding radiation protection issues) OAC rule 3701:1-38-10(B).
- Appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material OAC rule 3701:1-38-10(B).
- Radiation exposure reports that workers may request, as per OAC rule 3701:1-38-10(C).

Appendix J
Radiation Monitoring Instrument
Specifications and Model Survey
Instrument Calibration Program

Model procedures for describing the specifications for monitoring instruments and a program for calibration of survey instruments appear below. Applicants may either adopt these model procedures or adopt alternative procedures.

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 percent 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 percent to 40 percent, 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 percent. If a pancake or thin-end window GM probe is used, the detection efficiency is significantly lower and care should be taken to ensure that the GM probe is capable of detecting the trigger levels.
- Medium- to high-energy gamma emitters such as I-131 can be detected with either GM or sodium iodide probes, depending on the required sensitivity. In general, the sensitivity of GM probes is much lower than for sodium iodide probes.
- The following table (except for items marked with an asterisk (*), extracted from “The Health Physics & Radiological Health Handbook,” Revised Edition, 1992, may be helpful in selecting instruments.

Table J.1 Typical Survey Instruments

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

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

Model Procedure for Calibrating Survey Instruments

This model provides acceptable procedures for survey instrument calibrations. You may either adopt these model procedures or develop your own procedures to meet the requirements of Chapter 38 and OAC rule 3701-58-24. (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>).

- Radiation survey instruments will be calibrated with a radioactive source in accordance with OAC rule 3701-58-24. Electronic calibrations alone are not acceptable. Survey meters must be calibrated at least annually, before first use and after servicing or repairs that affect calibration. (Battery changes are not considered "servicing.") Instruments used to monitor higher energies are most easily calibrated in known radiation fields produced by sources of gamma rays of approximately the same energies as those to be measured. An ideal calibration source would emit the applicable radiation (e.g., alpha, beta or gamma) with an energy spectrum similar to that to be measured and have a suitably long half-life.
- Use radioactive sealed source(s) that:
 - Approximates a point source.
 - Is certified, NIST-traceable, standard source that has an activity or exposure rate accurate to within 5 percent; if the activity or exposure rate is determined by measurement, document the method used to make the determination and traceability to NIST.
 - Emit the type of radiation measured.
 - Approximate the same energy (e.g., Cs-137, Co-60) as the environment in which the calibrated device will be employed.
 - Provide a radiation dose rate sufficient to reach the full scale (<1000 mR/hr) of the instrument calibrated.
- Use the inverse square and radioactive decay laws, as appropriate, to correct for changes in exposure rate due to changes in distance or source decay.
- A record must be made of each survey meter calibration and retained for three years after each record is made (OAC rules 3701-38-20(C) and 3701-58-78).
- Before use, perform daily check (with a dedicated check source) and battery checks.
- Instrument readings should be within ± 10 percent of known radiation values at calibration points; however, readings within ± 20 percent are acceptable if a calibration chart or graph is prepared and made available with the instrument.
- The kinds of scales frequently used on radiation survey meters should be calibrated as follows:
 - Calibrate Linear-Readout Instruments at no fewer than two points on each scale. Calibration will be checked near the ends of each scale (at approximately 20 percent and 80 percent).

- Calibrate Logarithmic-Readout Instruments at two points on each decade.
- Calibrate Digital-Readout Instruments with either manual or automatic scale switching for indicating exposure rates at no fewer than two points on each scale. Check calibrations near the ends of each scale (at approximately 20 percent and 80 percent of each scale).
- Calibrate Digital-Readout Instruments without scale switching for indicating exposure rates at two points on each decade.
- Calibrate Integrating instruments at two dose rates (at approximately 20 percent and 80 percent of the dose rate range).
- Readings above 1000 mR/hr (250 microcoulomb/kilogram of air per hour) need not be calibrated; however, such scales may be checked for operation and approximately correct response.
- Include in survey meter calibration records the procedure used and the data obtained. Record the following:
 - A description of the instrument including the manufacturer's name, model number, serial number and type of detector.
 - A description of the NIST-traceable calibration source including the calibration procedure, exposure rate, distance at which it was measured and date of measurement.
 - For each calibration point, the calculated exposure rate, the indicated exposure rate, the calculated correction factor (the calculated exposure rate divided by the indicated exposure rate) and the scale selected on the instrument.
 - The exposure reading indicated with the instrument in the "battery check" mode (if available on the instrument).
 - For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular).
 - For instruments with internal detectors, the angle between the radiation flux field and a specified surface of the instrument.
 - For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure.
 - The exposure rate from a check source, if used.
 - The name of the person who performed the calibration and the date it was performed.
 - The following information should be attached to the instrument as a calibration sticker or tag:
 - The source that was used to calibrate the instrument.
 - The proper deflection in the battery check mode (unless this is clearly indicated on the instrument).
 - Special use conditions (e.g., an indication that a scale or decade was checked only for function but not calibrated).

- The date of calibration and the next calibration due date.
- The apparent exposure rate from the check source, if used.

Determining the Efficiency of NaI(Tl) Uptake Probes

Sodium iodide (thallium doped) [NaI(Tl)] uptake probes are commonly used for bioassays of personnel administering I-131 radionuclides in the form of sodium iodide. Refer to Appendix C to Chapter 38 of the OAC for the Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) for occupational exposure to radionuclides. Convert count rates (e.g., in cpm) to units of activity (dpm, μ Ci) when performing bioassays to determine thyroid burdens of radioiodines. Use the following procedure to calibrate probe for uptake measurements:

- Frequency: perform calibrations annually, before first use and after repairs that affect calibrations.
- 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 will be within ± 5 percent stated value and traceable to a primary radiation standard such as those maintained by NIST.
- Calculate efficiency of the instrument.

For example:

$$Eff_a = \frac{[(cpm \text{ from } std) - (cpm \text{ from } bkg)]}{(activity \text{ of } std \text{ in } microcurie)}$$

where:

Eff_a = efficiency, in cpm / microcurie

cpm = counts per minute

std = standard

bkg = background

The absolute efficiency is dependent on the counting geometry. Applicants may elect to use the intrinsic efficiency, which no longer includes the solid angle subtended by the detector and has much less of a dependence on the counting geometry.

Operational and calibration checks, using a dedicated check source, should be conducted on each day the instrument is used.

The date of the efficiency test should be attached to the instrument as a calibration sticker or tag and the following information should be included:

- The date of the next efficiency due.
- Results of efficiency calculation(s).

Calculating the Gamma Well Efficiency of Counting Equipment

Gamma well counting equipment is often used for assaying the wipe testing of packages, sealed sources and areas where unsealed radioactive material is prepared, administered or stored.

Converting cpm to dpm using smear wipes is required when dealing with radiation surveys of sealed and unsealed radioactive materials. Calculate the efficiency of all instruments used for

assaying wipe tests on an annual basis, before first use and/or after repair, using the following procedure:

- 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 will be within ± 5 percent of the stated value and traceable to a primary radiation standard such as those maintained by NIST.
- Calculate efficiency of the instrument.

For example,

$$Eff_a = \frac{[(cpm \text{ from } std) - (cpm \text{ from } bkg)]}{(\text{activity of } std \text{ in microcurie})}$$

where:

Eff_a = efficiency, in cpm / microcurie

cpm = counts per minute

std = standard

bkg = background

Operational and calibration checks, using a dedicated check source, should be conducted on each day the instrument is used.

The date of the efficiency test should be attached to the instrument as a calibration sticker or tag and the following information should be included:

- The date of the next efficiency due.
- Results of efficiency calculation(s).

Reference: NUREG-1556 Vol. 18, 'Program Guidance About Service Provider Licenses' dated May 2005.

Appendix K
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: _____
(Signature)

Date: _____

Management Review: _____
(Signature)

Date: _____

Audit History

- A. Were previous audits conducted annually [OAC rule 3701:1-38-11(E)]?
- B. Were records of previous audits maintained [OAC rule 3701:1-38-20(B)]?
- 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 [OAC rule 3701:1-58-08]?
 - 2) Does new RSO meet NRC training requirements [OAC rules 3701:1-58-18, 3701:1-58-21 and 3701:1-58-22]?
 - 3) Is RSO fulfilling all duties [OAC rule 3701:1-58-12]?
 - 4) Is the written agreement in place for a new RSO [3701:1-58-12(B)]?
- 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 [OAC rule 3701:1-40-17]? If so, is financial assurance adequate?
- 3) Calibration, transmission and reference sources [OAC rule 3701:1-58-26]?
 - a. Sealed sources manufactured and distributed by a person licensed pursuant to OAC rule 3701:1-46-44, equivalent Agreement State regulations, or redistributed by a licensee authorized to redistribute sealed sources, and sources do not exceed 30 millicurie each [OAC rule 3701:1-58-26(A) and (B)]?
 - b. Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 15 millicurie [OAC rule 3701:1-58-26(C)]?
 - 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 A of Chapter 40 [OAC rule 3701:1-58-26(D)]?
 - d. Technetium-99m in individual amounts as needed [OAC rule 3701:1-58-26(D)]?
- 4) Unsealed materials used under OAC rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 are:
 - a. Obtained from a manufacturer or preparer licensed under OAC rule 3701:1-46-43?

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 OAC rule 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37, as applicable?
- G. Are the sealed sources possessed and used as described in the Sealed Source and Device Registration (SSDR) Certificate [OAC rules 3701:1-46-49, 3701:1-58-43, 3701:1-58-53, and 3701:1-58-55]? 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 [OAC rule 3701:1-58-08(E)]?
- J. If control of license was transferred or bankruptcy filed, was ODH prior consent obtained or notification made, respectively [OAC rules 3701:1-40-16(A) and 3701:1-40-16(F)]?

Radiation Safety Program

- A. Minor changes to program [OAC rule 3701:1-58-13]?

- B. Records of changes maintained for five years [OAC rule 3701:1-58-74].
- C. Content and implementation reviewed annually by the licensee [OAC rule 3701:1-38-11(E)]?
- D. Records of reviews maintained [OAC rule 3701:1-38-20(B)]?

Use by Authorized Individuals

- A. Authorized nuclear pharmacist [OAC rules 3701:1-58-20, 3701:1-58-21 and 3701:1-58-22]
(Note: Does not apply to facilities that are registered/licensed by FDA/State Agency as a drug manufacturer with distribution regulated under OAC Chapter 3701:1-46):
 - _____ 1) Certified by specialty board
 - _____ 2) Identified on 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 [OAC rules 3701:1-58-21, 3701:1-58-22, and 3701:1-58-33, 3701:1-58-36, 3701:1-58-40, 3701:1-58-41, 3701:1-58-42, 3701:1-58-51, 3701:1-58-52, 3701:1-58-54 and 3701:1-58-71]:
 - _____ 1) Certified by specialty board
 - _____ 2) Identified on 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 [OAC rules 3701:1-58-19, 3701:1-58-21 and 3701:1-58-22]:
 - _____ 1) Certified by specialty board
 - _____ 2) Identified on 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 OAC rules 3701:1-58-31 and 3701:1-58-67?
- B. Compliance with OAC rule 3701:1-38-13 evaluated and met?
- C. Letter signed by management of each client [OAC rule 3701:1-58-31(A)(1)]?
- D. Licensed material was not delivered to client's address (unless client was authorized) [OAC rule 3701:1-58-31(B)]?
- E. Dosage measuring instruments checked for proper function before used at each address of use or on each day of use, if more frequent [OAC rule 3701:1-58-31(A)(2)]?
- F. Survey instruments checked for proper operation before used at each address of use [OAC rule 3701:1-58-31(A)(3)]?

- G. Survey of all areas of use prior to leaving each client address [OAC rule 3701:1-58-31(A)(4)]?
- H. Additional technical requirements for mobile remote afterloaders per [OAC rule 3701:1-58-67]?

Amendments Since Last Audit [OAC rule 3701:1-58-08]

- A. Any amendments since last audit [OAC rule 3701:1-58-08]?

Notifications Since Last Audit [OAC rule 3701:1-58-09]

- A. Any notifications since last audit [OAC rule 3701:1-58-09]?
- B. Appropriate documentation provided to ODH for authorized nuclear pharmacist, authorized medical physicists or authorized user no later than 30 days after the individual starts work [OAC rule 3701:1-58-09(A)]?
- C. ODH 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 OAC rules 3701:1-58-32 or 3701:1-58-34 use [3701:1-58-09(B)]?

Training, Retraining and Instructions to Workers

- A. Have workers been provided with required instructions [OAC rules 3701:1-38-10(B), 3701:1-58-14, 3701:1-58-38, 3701:1-58-46 and 3701:1-58-58]?
- B. Is the individual's understanding of current procedures and regulations adequate?
- C. Training program implemented?
 - 1) Operating procedures [OAC rule 3701:1-58-14, 3701:1-58-38, 3701:1-58-46 and 3701:1-58-58]?
 - 2) Emergency procedures [OAC rules 3701:1-58-14, 3701:1-58-38, 3701:1-58-46 and 3701:1-58-58]?
 - 3) Periodic training required and implemented [OAC rules 3701:1-58-38, 3701:1-58-46 and 3701:1-58-58]?
 - 4) Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed and was refresher training provided, as needed [OAC rule 3701:1-38-10(B)]?
 - 5) Was each supervised user instructed in the licensee's written radiation protection procedures and administration of written directives, as appropriate [OAC rule 3701:1-58-14]?
 - 6) Are initial and periodic training records maintained for each individual [OAC rule 3701:1-58-86]?
 - 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 [OAC rule 3701:1-58-58]?
- E. Chapter 38 – Workers cognizant of requirements for:
- 1) Radiation safety program [OAC rules 3701:1-58-12, 3701:1-58-13 and 3701:1-38-11(E)]?
 - 2) Annual dose limits [OAC Rules 3701:1-38-12(A), 3701:1-38-13 and 3701:1-38-13(E)]?
 - 3) ODH Forms: HEA5101 “*Lifetime Occupational Exposure History*” and HEA 5102 “*Occupational Exposure Record for Monitoring Period*” 10 percent monitoring threshold [OAC rule 3701:1-38-14(B)]?
 - 4) Dose limits to embryo/fetus and declared pregnant worker [OAC rule 3701:1-38-12(H)]?
 - 5) Grave Danger Posting [OAC rule 3701:1-58-18(A)(4)]?
 - 6) Procedures for opening packages [OAC rule 3701:1-38-18(F,G, and H)]?
 - 7) Additional therapy device instructions/training:
- F. Supervision of individuals by authorized user and/or authorized nuclear pharmacist in accordance with 3701:1-58-14?

Training for Manual Brachytherapy and Use of Unsealed Radioactive Material for Which A Written Directive is Required

- A. Safety instruction to personnel provided include [OAC rules 3701:1-58-38 and 3701:1-58-46]:
- 1) Control of patient and visitors?
 - 2) Routine visitation to patients in accordance with OAC rule 3701:1-38-13?
 - 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 [OAC rule 3701:1-58-86]?

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 [OAC rules 3701:1-58-47 and 3701:1-58-59]?
- D. Storage areas:

- 1) Materials secured from unauthorized removal or access [OAC rule 3701:1-38-17(A)]?
- 2) Licensee controls and maintains constant surveillance of licensed material not in storage [OAC rule 3701:1-38-17(B)]?

E. Therapy unit operation:

- 1) Unit, console, console keys and treatment room controlled adequately [OAC rules 3701:1-38-17(A) and 3701:1-58-58(A)(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 [OAC rule 3701:1-58-58(A)(3)]?

Dose or Dosage Measuring Equipment

A. Possession, use and calibration of instruments to measure activities of unsealed radionuclides [OAC rule 3701:1-58-23]:

- 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 percent)?
- 5) Records maintained and include required information [OAC rule 3701:1-58-77]?

B. Determination of dosages of unsealed radioactive material [OAC rule 3701:1-58-25]

- 1) Each dosage determined and recorded prior to medical use [OAC rule 3701:1-58-25(A)]?
- 2) Measurement of unit dosages made either by direct measurement or by decay correction [OAC rule 3701:1-58-25(B)]?
- 3) For other than unit dosages, measurement made by direct measurement of radioactivity or by combination of radioactivity or volumetric measurement and calculation [OAC rule 3701:1-58-25(C)]?

C. Licensee uses generators?

- 1) First eluate after receipt tested for Mo-99 breakthrough [OAC rule 3701:1-58-35(B)]?
- 2) No radiopharmaceuticals administered with Mo-99 concentrations over 0.15 μCi per mCi of Tc-99m [OAC rule 3701:1-58-35(A)]?
- 3) Records maintained [OAC rule 3701:1-58-85]?

D. Dosimetry Equipment [OAC rule 3701:1-58-60]:

- 1) Calibrated system available for use [OAC rule 3701:1-58-60(A)]?

- 2) Calibrated by NIST or an AAPM-accredited lab within previous two years and after servicing [OAC rule 3701:1-58-60(A)(1)] OR calibrated by intercomparison per OAC rule 3701:1-58-60(A)(2)?
- 3) Calibrated within the previous four years [OAC rule 3701:1-58-60(A)(2)]?
- 4) Licensee has available for use a dosimetry system for spot-check measurements [OAC rule 3701:1-58-60(B)]?
- 5) Record of each calibration, intercomparison and comparison maintained [OAC rule 3701:1-58-93]?

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 [OAC rule 3701:1-58-27(B)(1)]?
- 2) Inventory of sealed sources and brachytherapy sources performed semiannually [OAC rule 3701:1-58-27(G)]?
- 3) Records maintained [OAC rule 3701:1-58-80]?

Radiation Survey Instruments

A. Survey instruments used to show compliance with OAC Chapter 3701:1-38 and OAC rule 3701:1-40-15(A)(2):

- 1) Appropriate operable survey instruments possessed or available [OAC rule 3701:1-38-14]?
- 2) Calibrations [OAC rule 3701:1-58-24 (A) and (B)]:
 - a. Before first use, annually and after repairs?
 - b. Within 20 percent on each scale or decade of interest?
- 3) Records maintained [OAC rule 3701:1-58-78]?

B. Radiation surveys performed in accordance with the licensee's procedures and the regulatory requirements [OAC rules 3701:1-38-14(A) and 3701:1-58-29]?

- 1) Daily in all areas where radiopharmaceuticals are prepared or administered (except patient rooms) [OAC rule 3701:1-58-29]?
- 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 the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry [OAC rule 3701:1-58-68(A)] and records maintained [OAC rule 3701:1-58-81 and OAC rule 3701:1-58-99]?
 - 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 [OAC rule 3701:1-38-13]?
- B. Has a survey or evaluation been performed per OAC rule 3701:1-38-14(A)?
- 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 [OAC rule 3701:1-38-13]?
- E. Is licensed material used or stored in a manner that would prevent unauthorized access or removal [OAC rules 3701:1-38-17 and 3701:1-38-17(B)]?
- F. Records maintained [OAC rules 3701:1-38-20(C) and 3701:1-38-20(I)]?

Patient Release

- A. Individuals released when TEDE less than 0.5 rem [OAC rule 3701:1-58-30(A)]?
- B. Instructions to the released individual, including breastfeeding women, include required information [OAC rule 3701:1-58-30(B)]?
- C. Release records maintained [OAC rule 3701:1-58-82(A)]?
- D. Records of instructions given to breastfeeding women maintained, if required [OAC rule 3701:1-58-82(B)]?

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 [OAC rule 3701:1-58-39(A)]?
- B. RSO and AU promptly notified if patient died or had a medical emergency [OAC rule 3701:1-58-39(B)]?

Brachytherapy

- A. Safety precautions implemented to include patient facilities, posting, stay times and emergency response equipment [OAC rule 3701:1-58-47]?
- B. Survey immediately after implant [OAC rule 3701:1-58-44(A)]?
- C. Patients surveyed immediately after removing the last temporary implant source [OAC rule 3701:1-58-44(B)]?
- D. RSO and AU promptly notified if patient died or had a medical emergency [OAC rule 3701:1-58-47(C)]?
- E. Records maintained [OAC rule 3701:1-58-87]?

Radioactive Waste

- A. Disposal:
 - 1) Decay-in-storage [OAC rule 3701:1-38-19(E)]?
 - 2) Procedures followed?
 - 3) Labels removed or defaced [OAC rules 3701:1-38-18(C) and 3701:1-38-19(E)]?
- B. Special procedures performed as required?
- C. Authorized disposals [OAC rule 3701:1-38-19(A,B)]?
- D. Records maintained [OAC rules 3701:1-38-20 and 3701:1-58-84]?
- E. Effluents:
 - 1) Release to sanitary sewer [OAC rule 3701:1-38-19(D)]?
 - a. Material is readily soluble or readily dispersible [OAC rule 3701:1-38-19(D)]?
 - b. Monthly average release concentrations do not exceed OAC rule 3701:1-38-12 App. C, Table III 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 [OAC rule 3701:1-38-19(D)]?
 - d. Procedures to ensure representative sampling and analysis implemented [OAC rule 3701:1-38-14(A)]?
 - 2) Release to septic tanks [OAC rule 3701:1-38-19(D)]?
 - a. Within unrestricted limits [OAC rule 3701:1-38-12 App. C, Table III]?

- 3) Waste incinerated?
 - a. License authorizes [OAC rule 3701:1-38-19F]?
 - b. Directly monitor exhaust?
 - c. Air-borne releases evaluated and controlled [OAC rules 3701:1-38-13(E) and 3701:1-38-14]?
- 4) Air effluents and ashes controlled [OAC rules 3701:1-38-11, 3701:1-38-12, 3701:1-38-13, 3701:1-38-14 and 3701:1-38-19(A,B)]?
 - a. Air effluent less than 10 mrem constraint limit [OAC rule 3701-38-11(E)]?
 - b. If no, reported appropriate information to ODH.
 - i. Corrective actions implemented and on schedule?
 - c. Description of effluent program:
 - i. Monitoring system hardware adequate?
 - ii. Equipment calibrated as appropriate?
 - iii. Air samples/sampling technique (i.e., charcoal, HEPA, etc.) analyzed with appropriate instrumentation?
- F. Waste storage protection from elements and fire?
 - 1) Control of waste maintained [OAC rule 3701:1-38-17]?
 - 2) Containers properly labeled and area properly posted [OAC rules 3701:1-38-18(A)(4) and 3701:1-38-18(C)]?
 - 3) Package integrity adequately maintained?
- G. Waste disposal:
 - 1) Sources transferred to authorized individuals [OAC rule 3701:1-38-19(I) and 3701:1-38-19(A,B)]?
 - 2) Name of organization: _____
- H. Records of surveys and material accountability are maintained [OAC rules 3701:1-38-20(C), 3701:1-38-20(J) and 3701:1-58-84]?

Receipt and Transfer of Radioactive Material

- A. Describe how packages are received and by whom.
- B. Written package opening procedures established and followed?
- C. All incoming packages with a DOT label monitored for radioactive contamination, unless exempted (gases and special form) [OAC rule 3701:1-38-11(E)]?
- D. Incoming packages surveyed [OAC rule 3701:1-38-18(F)(2)]?
- E. Monitoring in (C) and (D) performed within time specified [OAC rule 3701:1-38-18(F)(5)]?
- F. Transfer(s) performed per [OAC rule 3701:1-40-19]?

- G. All sources surveyed before shipment and transfer [OAC rule 3701:1-38-14(A)]?
- H. Records of surveys and receipt/transfer maintained [OAC rules 3701:1-38-20(C) and 3701:1-40-21]?
- I. Package receipt/distribution activities evaluated for compliance with OAC rule 3701:1-38-13?

Transportation (OAC rule 3701:1-50-05(A) and 49 CFR 171-189)

- A. Shipments are:
 - 1) Delivered to common carriers.
 - 2) Transported in own private vehicle.
 - 3) Both.
 - 4) No shipments since last audit.
- B. Return radiopharmacy doses or sealed sources?
 - 1) Licensee assumes shipping responsibility?
 - 2) If NO, describe arrangements made between licensee and radiopharmacy for shipping responsibilities:
- C. Packages:
 - 1) Authorized packages used?
 - 2) Performance test records on file?
 - 3) Two labels (White-I, Yellow-II, Yellow-III) with TI, Nuclide, Activity and Hazard Class?
 - a. DOT-7A packages
 - b. Special form sources
 - 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 five years [OAC rule 3701:1-58-69 (A)]?

- B. Needed service arranged for as identified during the inspection?
- C. Service performed by persons specifically authorized to do so [OAC rule 3701:1-58-69 (B)]?

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 [OAC rules 3701:1-58-61(A)(1), 3701:1-58-62(A)(1), and 3701:1-58-63(A)(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 [OAC rules 3701:1-58-61(A)(3)], 3701:1-58-62(A)(3) and (4) and 3701:1-58-63(A)(3)]?
- D. Whenever spot-checks indicate output differs from expected by ± 5 percent [OAC rules 3701:1-58-61(A)(2)(a) and 3701:1-58-63(A)(2)(a)]?
- E. After source exchange, relocation, and major repair or modification [OAC rules 3701:1-61(A)(2), 3701:1-58-62(A)(2), and 3701:1-58-63(A)(2)]?
- F. Performed with properly calibrated instrument [OAC rules 3701:1-58-61(C), 3701:1-58-62(C), and 3701:1-58-63(C)]?
- G. Includes:
 - 1) For teletherapy:
 - a. Output measured within ± 3 percent of expected for the range of field sizes, range of distances [OAC rule 3701:1-58-61(B)(1)]?
 - b. Coincidence of radiation field and field light localizer [OAC rule 3701:1-58-61(B)(2)]?
 - c. Uniformity of radiation field and beam angle dependence [OAC rule 3701:1-58-61(B)(3)]?
 - d. Timer accuracy and linearity over the range of use [OAC rule 3701:1-58-61(B)(4)]?
 - e. On-off error [OAC rule 3701:1-58-61(B)(5)]?
 - f. Accuracy of all measuring and localization devices [OAC rule 3701:1-58-61(B)(6)]?
 - 2) For remote afterloaders:
 - a. Output measured within $\pm 5\%$ of expected [OAC rule 3701:1-58-62(B)(1)]?
 - b. Source positioning accuracy within ± 1 millimeter [OAC rule 3701:1-58-62(B)(2)]?
 - c. Source retraction with backup battery upon power failure [OAC rule 3701:1-58-62(B)(3)]?
 - d. Length of source transfer tubes [OAC rule 3701:1-58-62(B)(4)]?

- e. Timer accuracy and linearity over the typical range of use [OAC rule 3701:1-58-62(B)(5)]?
 - f. Length of the applicators [OAC rule 3701:1-58-62(B)(6)]?
 - g. Function of source transfer tubes, applicators and transfer tube-applicator interfaces [OAC rule 3701:1-58-62(B)(7)]?
 - h. Autoradiograph quarterly of the LDR source(s) to verify source(s) arrangement and inventory [OAC rule 3701:1-58-62(E)]?
- 3) For gamma stereotactic radiosurgery:
- a. Output measured within ± 3 percent of expected [OAC rule 3701:1-58-63(B)(1)]?
 - b. Helmet factors [OAC rule 3701:1-58-63(B)(2)]?
 - c. Isocenter coincidence [OAC rule 3701:1-58-63(B)(3)]?
 - d. Timer accuracy and linearity over the range of use [OAC rule 3701:1-58-63(B)(4)]?
 - e. On-off error [OAC rule 3701:1-58-63(B)(5)]?
 - f. Trunnion centricity [OAC rule 3701:1-58-63(B)(6)]?
 - g. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off [OAC rule 3701:1-58-63(B)(7)]?
 - h. Helmet microswitches [OAC rule 3701:1-58-63(B)(8)]?
 - i. Emergency timing circuit [OAC rule 3701:1-58-63(B)(9)]?
 - j. Stereotactic frames and localizing devices (trunnions) [OAC rule 3701:1-58-63(B)(10)]?
- H. Output corrected mathematically for decay [OAC rules 3701:1-58-61(E), 3701:1-58-62(G), and 3701:1-58-63(E)]?
- I. Records maintained [OAC rule 3701:1-58-94]?

Periodic Spot Checks For Therapeutic Devices

- A. Performed at required frequency [OAC rules 3701:1-58-64(A), 3701:1-58-65(A) and 3701:1-58-66(A)]?
- B. Procedures established by authorized medical physicist [OAC rules 3701:1-58-64(B), 3701:1-58-65(B) and OAC rule 3701:1-58-66(B)]?
- C. Procedures followed?
- D. Medical physicist reviews results within 15 days [OAC rules 3701:1-58-64(C), 3701:1-58-65(C) and 3701:1-58-66(B)]?
- E. Performed with properly calibrated instrument [OAC rules 3701:1-58-64(A)(5) and 3701:1-58-66(C)(2)(a)]?
- F. Output and safety spot checks include:
 - 1) For teletherapy:

- a. Timer accuracy and linearity over the range of use [OAC rule 3701:1-58-64(A)(1)]?
 - b. On-off error [OAC rule 3701:1-58-64(A)(2)]?
 - c. Coincidence of radiation field and field light localizer [OAC rule 3701:1-58-64(A)(3)]?
 - d. Accuracy of all measuring and localization devices [OAC rule 3701:1-58-64(A)(4)]?
 - e. The output for one typical set of operating conditions [OAC rule 3701:1-58-64(A)(5)]?
 - f. Difference between measured and expected output [OAC rule 3701:1-58-64(A)(6)]?
 - g. Interlock systems [OAC rule 3701:1-58-64(D)(1)]?
 - h. Beam stops [OAC rule 3701:1-58-64(D)(2)]?
 - i. Source exposure indicator lights [OAC rule 3701:1-58-64(D)(3)]?
 - j. Viewing and intercom systems [OAC rule 3701:1-58-64(D)(4)]?
 - k. Treatment room doors, inside and out [OAC rule 3701:1-58-64(D)(5)]?
 - l. Electrical treatment doors with power shut off [OAC rule 3701:1-58-64(D)(6)]?
- 2) For remote afterloaders:
- a. Interlock systems [OAC rule 3701:1-58-65(D)(1)]?
 - b. Source exposure indicator lights [OAC rule 3701:1-58-65(D)(2)]?
 - c. Viewing and intercom systems except for LDR [OAC rule 3701:1-58-65(D)(3)]?
 - d. Emergency response equipment [OAC rule 3701:1-58-65(D)(4)]?
 - e. Radiation monitors used to indicate source position [OAC rule 3701:1-58-65(D)(5)]?
 - f. Timer accuracy [OAC rule 3701:1-58-65(D)(6)]?
 - g. Clock (date and time) in the unit's computer [OAC rule 3701:1-58-65(D)(7)]?
 - h. Decayed source(s) activity in the unit's computer [OAC rule 3701:1-58-65(D)(8)]?
- 3) For gamma stereotactic radiosurgery:
- a. Treatment table retraction mechanism [OAC rule 3701:1-58-66(C)(1)(a)]?
 - b. Helmet microswitches [OAC rule 3701:1-58-66(C)(1)(b)]?
 - c. Emergency timing circuits [OAC rule 3701:1-58-66(C)(1)(c)]?
 - d. Stereotactic frames and localizing devices [OAC rule 3701:1-58-66(C)(1)(d)]?
 - e. The output for one typical set of operating conditions [OAC rule 3701:1-58-66(C)(2)(a)]?

- f. Difference between measured and expected output [OAC rule 3701:1-58-66(C)(2)(b)]?
 - g. Source output compared against computer calculation of output [OAC rule 3701:1-58-66(C)(1)(c)]?
 - h. Timer accuracy and linearity over the range of use [OAC rule 3701:1-58-66(C)(1)(d)]?
 - i. On-off error [OAC rule 3701:1-58-66(C)(1)(e)]?
 - j. Trunnion centricity [OAC rule 3701:1-58-66(C)(1)(f)]?
 - k. Interlock systems [OAC rule 3701:1-58-66(D)(1)]?
 - l. Source exposure indicator lights [OAC rule 3701:1-58-66(D)(2)]?
 - m. Viewing and intercom systems [OAC rule 3701:1-58-66(D)(3)]?
 - n. Timer termination [OAC rule 3701:1-58-66(D)(4)]?
 - o. Radiation monitors used to indicate room exposures [OAC rule 3701:1-58-66(D)(5)]?
 - p. Emergency off buttons [OAC rule 3701:1-58-66(D)(6)]?
- G. Licensee promptly repaired items found to be not operating properly and did not use unit until repaired, if required [OAC rules 3701:1-58-64(E) 3701:1-58-65(E), and 3701:1-58-66(E, F)]?
- H. Records maintained [OAC rules 3701:1-58-95, 3701:1-58-96 and 3701:1-58-97]?

Installation, Maintenance and Repair of Therapy Devices

- A. Only authorized individuals perform installation, maintenance, adjustment, repair and inspection [OAC rules 3701:1-58-57 and 3701:1-58-69]?

Name of organization/individual: _____

- B. Records maintained [OAC rules 3701:1-58-91 and 3701:1-58-100]?

Operating Procedures For Therapy Devices

- A. Instructions on location of emergency procedures and emergency response telephone numbers are posted at the device console [OAC rule 3701:1-58-58(C)]?
- B. Copy of the entire procedures physically located at the device console [OAC rule 3701:1-58-58(B)]?
- C. Procedures include:
- 1) 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 [OAC rule 3701:1-58-58(A)(4)]?
- D. Radiation survey of patient is performed to ensure source is returned to shielded position [OAC rule 3701:1-58-56(A)]?
- E. Records of radiation surveys maintained for three years [OAC rule 3701:1-58-87]?

- 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) [OAC rule 3701:1-58-59(F)(1) and (2)]?
 - 2) Physically present throughout all patient treatments with a gamma stereotactic radiosurgery device [OAC rule 3701:1-58-59(F)(3)]?

Personnel Radiation Protection

- A. Exposure evaluation performed [OAC rule 3701:1-38-14(A)]?
- B. ALARA program implemented [OAC rule 3701:1-38-11(E)]?
- C. External Dosimetry:
- 1) Monitors workers per [OAC rule 3701:1-38-14(B)(1)]?
 - 2) External exposures account for contributions from air-borne activity [OAC rule 3701:1-38-12(C)]?
 - 3) Supplier frequency?
 - 4) Supplier is NVLAP-approved [OAC rule 3701:1-38-14(A)(3)(a)]?
 - 5) Dosimeters exchanged at required frequency?
- D. Internal Dosimetry
- 1) Monitors workers per OAC rule 3701:1-38-14(B)?
 - 2) Briefly describe program for monitoring and controlling internal exposures [OAC rule 3701:1-38-16(A)].
 - 3) Monitoring/controlling program implemented (includes bioassays)?
 - 4) Respiratory protection equipment [OAC rule 3701:1-38-16 C and D]?
- 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 [OAC rule 3701:1-38-12(E)]?
 - 4) Maximum exposures TEDE: _____ Other: _____
 - 5) Maximum CDEs: _____ Organs _____
 - 6) Maximum CEDE _____
 - 7) Internal and external summed [OAC rule 3701:1-38-12(B)]?
 - 8) Were occupational limits met [OAC rule 3701:1-38-12(A)]?
 - 9) ODH forms or equivalent [OAC rules 3701:1-38-12(E) and 3701:1-38-20(G)]?
 - a. HEA 5101 “*Lifetime Occupational Exposure History*”

b. HEA 5102 “*Occupational Exposure Record for Monitoring Period*”

- 10) If a worker declared her pregnancy during the audit period, then was the dose in compliance [OAC rule 3701:1-38-12(H)] and were the records maintained [OAC rule 3701:1-38-20(I)]?
- F. Who performed any planned special exposures at this facility (number of people involved and doses received) [OAC rules 3701:1-38-12(F), 3701:1-38-12(E), 3701:1-38-20(F) and 3701:1-38-21(D)]?
- G. Records of exposures, surveys, monitoring and evaluations maintained [OAC rules 3701:1-38-20(B), 3701:1-38-20(C) and 3701:1-38-20(G)]?

Confirmatory Measurements

- A. Detail location and results of confirmatory measurements.

Medical Events

- A. If medical events [criteria in OAC rule 3701:1-58-101] 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
- Ohio Department of Health Bureau of Radiation Protection
 - The referring physician patient
 - The patient
 - In writing/by telephone
 - If notification did not occur, why not?
- 3) Written Reports [OAC rule 3701:1-58-101]:
- a. Submitted to Ohio Department of Health Bureau of Radiation Protection within 15 days?

Notification and Reports

- A. In compliance with OAC rules 3701:1-38-10(C) and 3701:1-40-20 (reports to individuals, public and occupational, monitored to show compliance with OAC Chapter 3701:1-38)?
- B. In compliance with OAC rules 3701:1-38-21(A) and 3701:1-40-20 (theft or loss)?
- C. In compliance with OAC rules 3701:1-38-21(B) and 3701:1-40-20 (incidents)?
- D. In compliance with OAC rules 3701:1-38-21(C) and 3701:1-40-20 (overexposures and high radiation levels)?
- E. Aware of the Ohio Department of Health Bureau of Radiation Protection phone number (614-644-2727)?
- F. In compliance with OAC rule 3701:1-40-20 (Constraint on air emissions)?

Posting and Labeling

- A. ODH Form “Notice to Workers” is posted [OAC rule 3701:1-38-10(A)]?
- B. Chapter 3701:1-38 of the OAC, and license documents are posted, or a notice indicating where documents can be examined is posted [OAC rule 3701:1-38-10(A)]?
- C. Other posting and labeling per OAC rules 3701:1-38-18(A)(4) and 3701:1-38-18(C); and not exempted by OAC rules 3701:1-38-18(B) and 3701:1-38-18(E)?

Record keeping 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 [OAC rule 3701:1-38-20]?
- B. Records include all information outlined in OAC rule 3701:1-38-20?

Bulletins and Information Notices

- A. Bulletins, information notices, 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 L

Model Procedures for an Occupational Dose Program

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 OAC rules 3701:1-38-11(E), 3701:1-38-12(A-H) and 3701:1-38-14(A,B,C). 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 OAC rule 3701:1-38-14(B)(1). OAC rule 3701:1-38-12(A) provide the occupational dose limits for adults. OAC rules 3701:1-38-14(B) and (C) 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 OAC rule 3701:1-38-01, “Definitions.” In addition, if monitoring is required pursuant to OAC rules 3701:1-38-14(B) and (C), each licensee shall maintain records of doses received (see OAC rule 3701:1-38-20(H)) and individuals must be informed on at least an annual basis of their doses (see OAC rule 3701:1-38-10(C)(2)).

If an individual is likely to receive more than 10 percent of the annual dose limits, the Director 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

OAC rule 3701:1-38-11(E) states that “each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities...” and “the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).” Additionally, OAC rule 3701:1-38-11(E) 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 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 OAC rule 3701:1-38-12(A) 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 OAC rule 3701:1-38-01, the DDE to the whole body is considered to be at a tissue depth of 1 cm (1000 mg/cm²), shallow-dose equivalent to the skin or extremities at 0.007 cm (7 mg/cm²) and eye dose equivalent at 0.3 cm (300 mg/cm²). In evaluating the eye dose equivalent, it is acceptable to take credit for the shielding provided by protective lenses.

- 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 OAC rule 3701:1-38-12(A). 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 monitoring of occupational exposure is not necessary for a group of radiation workers, it must be demonstrated that doses will not exceed 10 percent of the applicable limits. In these cases, the director does not require licensees to monitor radiation doses for this class of worker.

The following methods may be used to demonstrate doses are expected to be within 10 percent 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 individual monitoring devices such as film badges, optically stimulated luminescence dosimeters (OSLs) or TLDs. These devices must be evaluated by a processor that is National Voluntary Laboratory Accreditation Program (NVLAP)-approved, as required by OAC rule 3701:1-38-14(A).

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 (OAC rule 3701:1-

38-12(4)). 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 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.

OAC rule 3701:1-38-20(H) requires the recording for individual monitoring be done on ODH Form HEA 5102 or equivalent. ODH Form HEA 5102 is used to record 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 OAC rule 3701:1-38-12(A), 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 performs 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 director 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 L.1 (i.e., 10 percent 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 L.1 (i.e., 30 percent 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 L.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 on ODH Form HEA 5102, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring. Take the actions listed below when the investigation levels listed in Table L.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 M.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 or 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 L.1.

Declared Pregnancy and Dose to Embryo/Fetus

OAC rule 3701:1-38-12(H) 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.
- 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 NRC 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 personnel will receive greater than 10 percent of the annual limit on intake (ALI) from intakes in 1 year (OAC rule 3701:1-38-14(B)). Chapter 3701:1-38 of the OAC 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 air-borne radioactivity in $\mu\text{Ci/ml}$ that, if an occupational worker were to be continuously exposed to for 2,000 hours (1 year), would result in either a CEDE of 5 rem (0.05 Sv) to the whole body or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue, with no consideration for the contribution of external dose. The ALI and DAC for each radionuclide in a specific chemical form are listed in OAC rule 3701:1-38-12 Appendix C.

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 OAC rule 3701:1-38-12 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." Per OAC rule 3701:1-38-12 Appendix C, 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:

- Adequate equipment to perform bioassay measurements.
- Procedures for calibrating the equipment including factors necessary to convert counts per minute into becquerel or microcurie units.
- The technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue).
- The interval between bioassays.
- Action levels.
- 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.

Record Keeping

Records of measurement data, calculations of intakes and methods for calculating dose must be maintained as required by OAC rules 3701:1-38-20(H). For additional information on record keeping and reporting occupational exposure data, including intakes, refer to Revision 1 of NRC Regulatory Guide 8.7, "Instructions for Recording and Reporting Occupational Radiation Exposure Data."

Summation of External and Internal Doses

Pursuant to OAC rule 3701:1-38-12(B), the external and internal doses must be summed if required to monitor both under OAC rule 3701:1-38-14(B).

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."
- NRC Regulatory Issue Summary 2002-10, "Revision of Skin Dose Unit in 10CFR 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 M
Model Emergency Procedures

Model Spill, Emergency Surgery and Autopsy Procedures

Model Spill Procedures – Low- and High-dose Unsealed Sources

This model provides acceptable procedures for responding to emergencies. Applicants may either adopt this model or develop alternative procedures to meet the requirements of OAC rule 3701:1-38-11(E).

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 the director may be required pursuant to OAC rule 3701:1-40-20.

Use Table M.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 M.1 Relative Hazards of Common Radionuclides			
Radionuclide	Millicurie	Radionuclide	Millicurie
P-32	1	Tc-99m	100
Cr-51	100	In-111	10
Co-57	10	I-123	10
Co-58	10	I-125	1
Fe-59	1	I-131	1
Co-60	1	Sm-153	10
Ga-67	10	Yb-169	10
Se-75	1	Hg-197	10
Sr-85	10	Au-198	10
Sr-89	1	Tl-201	100

Spill Kit

Assemble a spill kit that may contain the following items:

- Disposable gloves and housekeeping gloves.
- Disposable lab coats.
- Disposable head coverings.
- Disposable shoe covers.
- Roll of absorbent paper with plastic backing.
- Masking tape.
- Plastic trash bags with twist ties.
- “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.
- 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.

Appendix N

**Model Procedures for
Ordering and Receiving Packages**

Model Procedures for Ordering and Receiving Packages

This model provides acceptable procedures for ordering and receiving packages containing licensed material. Applicants may either adopt this model or develop alternative procedures.

Model Guidance

- 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 on following page. 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 O

Model Procedure for Safely Opening Packages Containing Radioactive Material

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 OAC rule 3701:1-38-18(F, G, H, I).

Special requirements must be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits specified in Table A.1 of OAC rule 3701:1-50-25 (e.g., 13.5 curies of Mo-99 [20 curies for domestic use], Cs-137, Ir-192; 54.1 curies of I-125; 541 curies of Xe-133 or 216 curies of Tc-99m). 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 three hours of receipt (if received during working hours) or no later than three hours from the beginning of the next working day (if received after working hours), in accordance with the requirements of OAC rule 3701:1-38-18(F)(5). The Ohio Department of Health Bureau of Radiation Protection and the final delivery carrier must be notified if the following conditions apply:

- Removable radioactive surface contamination exceeds the limits of OAC rule 3710:1-50-17(I)
- External radiation levels exceed the limits of OAC rule 3701:1-50-17.

Model Procedure

1. Put on gloves to prevent hand contamination.
2. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO or the designee of the RSO if the RSO is not present immediately.
3. Monitor the external surfaces of a labeled¹ package for radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form, as defined in 10CFR 71.4 and OAC rule 3701:1-50-01.
4. Monitor the external surfaces of a labeled¹ package for radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10CFR 71.4 and Appendix A to 10CFR Part 71.
5. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels, if there is evidence of degradation of package integrity such as packages that are crushed, wet or damaged.
6. Remove the packing slip.
7. Open the outer package, following any instructions that may be provided by the supplier.
8. Open the inner package and verify the contents agree with the packing slip.

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

9. Check the integrity of the final source container. Notify the RSO (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(Tl) crystal and rate meter, a liquid scintillation counter or a proportional flow counter may be used for these assays. The detection efficiency will be determined to convert wipe sample counts per minute to disintegrations per minute. *Note: a dose calibrator is not sufficiently sensitive for this measurement.* Take precautions against the potential spread of contamination.
11. Check the user request to ensure 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 OAC rule 3701:1-46-11, 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 the material received is the material that was ordered.

Appendix P
Model Leak Test Program

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 μ Ci) 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 percent of the stated value and traceable to a primary radiation standard, such as those maintained by NIST.

Calculate efficiency of the instrument.

For example,

$$Eff = \frac{[(cpm \text{ from } std) - (cpm \text{ from } bkg)]}{(activity \text{ of } std \text{ in } microcurie)}$$

where:

Eff = efficiency, in cpm / microcurie

cpm = counts per minute

std = standard

bkg = background

- Analyze each wipe sample to determine net count rate.
- For each sample, calculate the activity in microcurie and record.
- The activity on the wipe sample is given by:

$$\frac{[(cpm \text{ from } wipe \text{ sample}) - (cpm \text{ from } bkg)]}{(Eff \text{ in } cpm/microcurie)}$$

= activity on wipe sample in microcurie

- Leak test records will be retained in accordance with OAC rule 3701:1-58-80 for three 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.
 - The name of the individual who performed the test.
- If the wipe test reveals 185 Bq (0.005 μ Ci) or greater:
 - Immediately withdraw the sealed source from use and store, dispose or cause it to be repaired in accordance with the requirements in OAC Chapters 3701:1-38 and 3701:1-40, and [OAC rule 3701:1-58-27].
 - File a report within five days of the leak test in accordance with OAC rule 3701:1-58-103.

Appendix Q
Model Procedure for Area Surveys

This model provides acceptable procedures for area surveys. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of OAC rules 3701:1-38-11(E), 3701:1-38-14(A) and 3701:1-58-29. 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 OAC rules 3701:1-38-11(E), 3701:1-38-14(A), and 3701:1-58-29):

- Perform surveys of dose rates in locations where:
 - Workers are exposed to radiation levels that might result in radiation doses in excess of 10 percent of the occupational dose limits.
 - 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).
- OAC rule 3701:1-38-13 requires the TEDE to an individual member of the public from the licensed operation not to exceed 1 mSv (0.1 rem) in a year, and 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 the requirements of OAC rule 3701:1-38-13 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 for all radiopharmaceutical elution, preparation, assay and administration areas for diagnostic and therapeutic uses.
 - 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 Q.1.

Table Q.1 Ambient Dose Rate Trigger Levels		
Type of Survey	Area Surveyed	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 J-1 titled “Stationary Instruments Used to Measure Wipe, Bioassay, and Effluent Samples” in Appendix J 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 Q.2 for restricted areas and Q.3 for unrestricted areas (e.g., 200 dpm/100 cm² 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 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 Q.2. Contamination found in unrestricted areas and on personal clothing will be immediately decontaminated to background levels.

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, Hg197, Tl-201
Restricted areas, protective clothing used only in restricted areas	2000	20000

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 one 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 cm².
- ⁵ The amount of removable radioactive material per 100 cm² of surface area should be determined by wiping that area with filter or soft absorbent paper, applying moderate pressure and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

- 6 The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 millirad/hour at one centimeter and 1.0 millirad/hour at one centimeter, respectively, measured through not more than seven 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 Q.1 and Q.2:

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

- Acceptable unrestricted area trigger levels are implemented (e.g., Tables Q.1 and Q.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 are used in the hot laboratory, the survey frequency for the hot laboratory would be daily; because 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 Q.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	Co-60 Sr-90 I-125 I-126 I-131 I-133 Cs-134 Cs-137 Eu-152 (13 y) Eu-154 Ir-192 Tl-204
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 O-15 Rb-87 Tc-99m Rh-103m In-113m Xe-133 Cs-134m

Table Q.5 Classification of Laboratories for Alternate Survey Frequency			
Survey Frequency Category			
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 Q.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 R

Model Procedures for Developing, Maintaining and Implementing Written Directives

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 OAC rules 3710:1-58-15 and 3701:1-58-16.

Written Directive Procedures

This model provides guidance to licensees and applicants for developing, maintaining and implementing procedures for administrations that require written directives (WDs). 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 OAC rule 3701:1-58-16 will be met.

The WD must be prepared for any administration of I-131 sodium iodide greater than 1.11 MBq (30 μ Ci), any therapeutic dosage of a radiopharmaceutical and any therapeutic dose of radiation from radioactive material. The WD must contain the information described in OAC rule 3710:1-58-15 and be retained in accordance with OAC rule 3710:1-58-75.

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 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 OAC rule 3710:1-58-15 requires, or would require, a WD (as defined in OAC rule 3710:1-58-01), the licensee should develop, implement and maintain written procedures for WDs to meet the requirements and/or objectives of OAC rules 3710:1-58-15, 3710:1-58-16, and 3710:1-58-25, outlined below:

- Have an authorized user date and sign a WD prior to the administration that includes the information in OAC rule 3701:1-58-15(B), including the patient or human research subject's name.
- Verify the patient's or human research subject's identity prior to each administration.
- Verify 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.
- 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 OAC rules 3710:1-58-15 and 3710:1-58-16:

- 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 OAC rules 3710:1-58-15 and 3710:1-58-16 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 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 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).
 - 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 OAC rule 3710:1-58-15(B)(6). 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 percent 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 OAC rule 3701:1-58-19) using a dosimetry system other than the one that was used during the full calibration (the dosimetry system will meet the requirements specified in OAC rule 3710:1-58-60).
 - 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 percent.
- 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 OAC rule 3710:1-58-16, 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 Ohio Department of Health no later than the next calendar day after discovery of a medical event and submit a written report to the Ohio Department of Health, Bureau of Radiation Protection within 15 days after the discovery of the medical event, as required by OAC rule 3701:1-58-101. Also notify the referring physician and the patient as required by OAC rule 3701:1-58-101. (**Note:** The telephone number for ODH/BRP is 614 644-2727.)

Appendix S
Model Procedures for Safe Use of
Unsealed Licensed Material

This model provides acceptable procedures for safe use of unsealed licensed material. You may either adopt this model procedure or develop your own procedure. (Some of the health physics practices listed below may also apply to sealed sources.)

- 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.
- 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 byproduct 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 quantities of radiopharmaceuticals must be surveyed daily in accordance with OAC rule 3701:1-58-29 (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 OAC rules 3701:1-58-28 and 3701:1-38-18(C).
- Syringes and unit dosages must be labeled in accordance with OAC rules 3701:1-58-28 and 3701:1-38-18(C). 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 A to OAC rule 3701:1-38-18(E), the syringe or vial need only be labeled to identify the radioactive drug (OAC rule 3701:1-58-28). 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 (OAC rule 3701:1-58-25).
- Do not use a dosage if it does not fall within the prescribed dosage range or if it varies more than ± 20 percent 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 WD (OAC rule 3701:1-58-16).
- 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 ODH license (or such individual's designee).

Appendix T
Model Procedure for Release of Patients
or Human Research Subjects
Administered Radioactive Materials

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

OAC rule 3701:1-58-30, "Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material," of OAC Chapter 3701:1-58, "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 T1:

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

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 T.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, $(1 - e^{-0.693 t / T_p})$ 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 T.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 one day and no consideration of biological elimination, it is assumed the individual likely to receive the highest dose from exposure to the patient would receive a dose of 25 percent of the dose to total decay (0.25 in Equation T.2), at a distance of 1 meter. Selection of 25 percent of the dose to total decay at one meter for estimating the dose is based on measurements discussed in the supporting regulatory analysis that indicates the dose calculated using an occupancy factor, E , of 25 percent at one meter is conservative in most normal situations.
- For radionuclides with a physical half-life less than or equal to one 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 one day:

Equation T.2:

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

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

Equation T.3:

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

Equations T.2 and T.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 breastfeeding infants or children who continue to breastfeed. Patients who are breastfeeding an infant or child must be considered separately, as discussed in Item T.1.1, “Release of Patients Based on Administered Activity.”

T.1 Release Criteria

Licenses 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.

T.1.1 Release of Patients Based on Administered Activity

In compliance with the dose limit in OAC rule 3701:1-58-30(A), licensees may release patients from licensee control if the activity administered is no greater than the activity in Column 1 of Table T.1. The activities in Table T.1 are based on a total effective dose equivalent of 5 millisieverts (0.5 rem) to an individual using the following conservative assumptions:

- Administered activity.
- Physical half-life.
- Occupancy factor of 0.25 at one meter for physical half-lives greater than one day and, to be conservative, an occupancy factor of 1 at one meter for physical half-lives less than or equal to one day.
- 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 breastfeeding an infant or child, as discussed in Item T.3.2, “Records of Instructions for Breastfeeding Patients.” The licensee may demonstrate compliance by using the records of activity that are already required by OAC rules 3701:1-58-15 and 3701:1-58-25.

If the activity administered exceeds the activity in Column 1 of Table T.1, the licensee may release the patient when the activity has decayed to the activity in Column 1 of Table T.1. In this case, OAC rule 3701:1-58-30 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 T.1 were calculated using either Equation T.2 or T.3, depending on the physical half-life of the radionuclide.

If a radionuclide that is not listed in Table T.1 is administered, the licensee can demonstrate compliance with the regulation by maintaining, for ODH inspection, calculation of the release activity that corresponds to the dose limit of 5 millisievert (0.5 rem). Equation T.2 or T.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 T.1 do not include consideration of the dose to a breastfeeding infant or child from ingestion of radiopharmaceuticals contained in the patient’s breast milk. When the patient is breastfeeding an infant or child, the activities in Column 1 of Table T.1 are not applicable to the infant or child. In this case, it may be necessary to give instructions as described in Items T.2.2 and T.2.3 as a condition for release. If failure to interrupt or discontinue could result in a dose to the breastfeeding infant or child in excess of 5 millisieverts (0.5 rem), a record that instructions were provided is required by OAC rule 3701:1-58-30.

T.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 T.1, provided the measured dose rate at one meter (from the surface of the patient) is no greater than the value in Column 2 of Table T.1 for that radionuclide. In this case, however, OAC rule 3701:1-58-30 requires a record because the release is based on considering shielding by tissue.

If a radionuclide not listed in Table T.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 one meter is no greater than the calculated dose rate, the patient may be released. A record of the release is required by OAC rule 3701:1-58-30. The dose rate at one meter may be calculated from Equation T.2 or T.3, as appropriate, because the dose rate at one meter is equal to $\Gamma Q / 10,000 \text{ cm}^2$.

T.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 OAC rule 3701:1-58-30(A), 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 T.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 OAC rule 3701:1-58-30. 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 OAC rule 3701:1-58-30.

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

Table T.1 Activities and Dose Rates for Authorizing Patient Release†

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

Footnotes for Table T-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 one meter in Column 2, the licensee must maintain a record as required by OAC rule 3701:1-58-30(C), because the measurement includes shielding by tissue. See Item T.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 T.2 or T.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.

T.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 OAC rule 3701:1-58-30.

T.2.1 Activities and Dose Rates Requiring Instructions

Based on OAC rule 3701:1-58-30, 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. Column 1 of Table T.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 T.2 may be used for determining when instructions must be given. If the patient is breastfeeding an infant or child, additional instructions may be necessary (see Item T.2.2, “Additional Instructions for Release of Patients Who Could be Breastfeeding 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 T.2 is administered, the licensee may calculate the activity or dose rate that corresponds to 1 millisievert (0.1 rem). Equation T.2 or T.3, as appropriate, may be used.

T.2.2 Additional Instructions for Release of Patients Who Could Be Breastfeeding After Release

The requirement in OAC rule 3701:1-58-30 that a licensee provide instructions on the discontinuation or the interruption period of breastfeeding, and the consequences of failing to follow the recommendation, presumes the licensee will inquire, as appropriate, regarding the breastfeeding status of the patient. The purpose of the instructions (e.g., on interruption or discontinuation) is to permit licensees to release a patient who could be breastfeeding 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 breastfeeding.

If the patient could be breastfeeding an infant or child after release, and if a radiopharmaceutical with an activity above the value stated in Column 1 of Table T.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 breastfeeding infant or child. Table T.3 also provides recommendations for interrupting or discontinuing breastfeeding to minimize the dose to below 1 millisievert (0.1 rem) if the patient has received certain radiopharmaceutical doses.

The radiopharmaceuticals listed in Table T.3 are commonly used in medical diagnosis and treatment.

If a radiopharmaceutical not listed in Table T.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 50 percent 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.

T.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 T.2.3.1 and T.2.3.2).

Table T.2 Activities and Dose Rates Above Which Instructions Should Be Given When Authorizing Patient Release*				
Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required		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

Table T.2 Activities and Dose Rates Above Which Instructions Should Be Given When Authorizing Patient Release*

Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required		COLUMN 2 Dose Rate at 1 Meter Above Which Instructions Are Required	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
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 T.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.

Notes: The values for activity were calculated using Equations T.2 or T.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.

Table T.3 Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who are Breastfeeding an Infant or Child

Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required		COLUMN 2 Activity Above Which a Record is Required		COLUMN 3 Examples of Recommended Duration of Interruption of Breast- feeding
	(MBq)	(mCi)	(MBq)		(mCi)
I-131 NaI	0.01	0.0004	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 for 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 hours 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	30	6000	150	
Tc-99m PYP	900	25	4000	120	
Tc-99m Red Blood Cell <i>In Vivo</i> Labeling	400	10	2000	50	6 hours for 740 MBq (20 mCi)
Tc-99m Red Blood Cell <i>In Vitro</i> Labeling	1000	30	6000	150	
Tc-99m Sulphur Colloid	300	7	1000	35	6 hours for 440 MBq (12 mCi)
Tc-99m DTPA Aerosol	1000	30	6000	150	

Table T.3 Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who are Breastfeeding an Infant or Child

Radionuclide	COLUMN 1 Activity Above Which Instructions Are Required		COLUMN 2 Activity Above Which a Record is Required		COLUMN 3 Examples of Recommended Duration of Interruption of Breast- feeding
	(MBq)	(mCi)	(MBq)		(mCi)
Tc-99m MAG3	1000	30	6000	150	
Tc-99m White Blood 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	0.2	1 month for 150 MBq (4 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 T.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.

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 breastfeeding.

T.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, ODH still considers the instructions in this pamphlet to be an acceptable method for meeting the requirements of OAC rule 3701:1-58-30, 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 breastfeeding, the instructions should include appropriate recommendations on whether to interrupt breastfeeding, the length of time to interrupt breastfeeding, or, if necessary, the discontinuation of breastfeeding. The instructions should include information on the consequences of failure to follow the recommendation to interrupt or discontinue breastfeeding. The consequences should be explained so the patient will understand, in some cases, breastfeeding after an administration of certain radionuclides should be avoided. For example, a consequence of procedures involving iodine-131 is that continued breastfeeding 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 breastfeeding. If the Society of Nuclear Medicine's pamphlet is given at release to a patient who is breastfeeding an infant or child, the pamphlet should be supplemented with information specified in OAC rule 3701:1-58-30.

The requirement of OAC rule 3701:1-58-30 regarding written instructions to patients who could be breastfeeding 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.

T.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 _____.

T.3 Records

T.3.1 Records of Release

There is no requirement for record keeping on the release of patients who were released in accordance with Column 1 of Table T.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 OAC rule 3701:1-58-30(C). This record should include the patient identifier (in a way that ensures 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 OAC rule 3701:1-58-30, should be kept in a manner that ensures the patient's confidentiality, meaning the records should not contain the patient's name or any other information that could lead to identification of the patient. These record keeping requirements may also be used to verify 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.

T.3.2 Records of Instructions for Breastfeeding Patients

If failure to interrupt or discontinue breastfeeding 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 OAC rule 3701:1-58-30. Column 2 of Table T.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 breastfeeding.

The record should include the patient's identifier (in a way that ensures 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 breastfeeding an infant or child.

T.4 Summary Table

Table T.4 summarizes the criteria for releasing patients and the requirements for providing instructions and maintaining records.

Table T.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 T.1	Yes, if administered activity > Column 1 of Table T.2	No
Table T.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 T.1	Yes, if administered activity > Column 1 of Table T.2
No	Table T.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 T.1

Implementation

The purpose of this section is to provide information to licensees and applicants regarding ODH staff's plans for using this appendix. Except in those cases in which a licensee proposes an acceptable alternative method for complying with OAC rule 3701:1-58-30, the methods described in this appendix will be used in the evaluation of a licensee's compliance with OAC rule 3701:1-58-30.

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 T.5 Half-lives and Exposure Rate Constants of Radionuclides Used in Medicine		
Radionuclide	Physical Half-life (days)¹	Exposure Rate Constant² (R/mCi-h at 1 cm)
Ag-111	7.45	0.15
Au-198	2.696	2.3
Cr-51	27.704	0.16
Cu-64	0.529	1.2
Cu-67	2.578	0.58
Ga-67	3.261	0.753
I-123	0.55	1.61
I-125	60.14	1.42
I-125 implant	60.14	1.11 ³
I-131	8.04	2.2
In-111	2.83	3.21
Ir-192 implant	74.02	4.59 ³
P-32	14.29	N/A ⁵
Pd-103 implant	16.96	0.86 ⁴
Re-186	3.777	0.2
Re-188	0.708	0.26
Sc-47	3.351	0.56
Se-75	119.8	2
Sm-153	1.946	0.425
Sn-117m	13.61	1.48
Sr-89	50.5	N/A ⁵
Tc-99m	0.251	0.756
Tl-201	3.044	0.447
Yb-169	32.01	1.83
Y-90	2.67	N/A ⁶
Yb-169	32.01	1.83

Footnotes for Table T.5

1. K.F. Eckerman, A.B. Wolbarst, and A.C.B. Richardson, "Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Report No. EPA-520/1-88-020, Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, DC, 1988.

2. Values for the exposure rate constant for Au-198, Cr-51, Cu-64, I-131, Sc-47, and Se-75 were taken from the *Radiological Health Handbook*, U.S. Department of Health, Education, and Welfare, pp. 135, 1970. For Cu-67, I-123, In-111, Re-186, and Re-188, the values for the exposure rate constant were taken from D.E. Barber, J.W. Baum, and C.B. Meinhold, "Radiation Safety Issues Related to Radiolabeled Antibodies," NUREG/CR-4444, U.S. NRC, Washington, DC, 1991. For Ag-111, Ga-67, I-125, Sm-153, Sn-117m, Tc-99m, Tl-201, and Yb-169, the exposure rate constants were calculated because the published values for these radionuclides were an approximation, presented as a range, or varied from one reference to another. Details of the calculation of the exposure rate constants are shown in Table A.2 of Appendix A to NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," U.S. NRC, February 1997.
3. R. Nath, A.S. Meigooni, and J.A. Meli, "Dosimetry on Transverse Axes of ¹²⁵I and ¹⁹²Ir Interstitial Brachytherapy Sources," *Medical Physics*, Volume 17, Number 6, November/December 1990. The exposure rate constant given is a measured value averaged for several source models and takes into account the attenuation of gamma rays within the implant capsule itself.
4. A.S. Meigooni, S. Sabnis, R. Nath, "Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants," *Endocurietherapy Hyperthermia Oncology*, Volume 6, April 1990. The exposure rate constant given is an "apparent" value (i.e., with respect to an apparent source activity) and takes into account the attenuation of gamma rays within the implant capsule itself.
5. Not applicable (N/A) because the release activity is not based on beta emissions.

Supplement B

Procedures for Calculating Doses Based on Patient-specific Factors

A licensee may release a patient to whom an activity with a value higher than the values listed in Column 1 of Table T.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 one meter, biological or effective half-life or shielding by tissue, a record of the basis of the release is required by OAC rule 3701:1-58-30. The following equation can be used to calculate doses:

Equation B-1:

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

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.

t = Exposure time in days.

B.1 Occupancy Factor

B.1.1 Rationale for Occupancy Factors Used to Derive Table T.1

In Table T.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 one 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 one day). The basis for the occupancy factor of 0.25 at one 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 an occupancy factor of 0.25 at one 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 one 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 one 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 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 T.1 were based on an occupancy factor of 1 at one meter when the half-life is less than or equal to one 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 one 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 one day.
- $E = 0.25$ when an effective half-life is greater than one day, if the patient has been given instructions such as:
 - Maintain a prudent distance from others for at least the first two 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 two days.
 - Have sole use of a bathroom for at least the first two days.
 - Drink plenty of fluids for at least the first two days.
- $E = 0.125$ when an effective half-life is greater than one 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 two days.
 - Have few visits by family or friends for at least the first two 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 ($t = \infty$) is calculated based on the physical half-life using Equation B-1. (This calculation illustrates the use of physical half-life. To account for biological elimination, calculations described in the next section should be used.)

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

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 one meter may be used.

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

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

Because the dose is less than 5 millisievert (0.5 rem), the patient may be released, but OAC rule 3701:1-58-30(B) requires that instructions be given to the patient on maintaining doses to others ALARA. A record of the calculation must be maintained, pursuant to OAC rule 3701:1-58-30(C), because an occupancy factor of less than 0.25 at one 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 OAC rule 3701:1-58-30. 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.

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:

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

Equation B-4:

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

Where:

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

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

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, during the first eight hours after the administration, about 80 percent 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 eight hours (0.33 day) after administration. This component comes directly from Equation B-1, using the physical half-life and a factor of 80 percent. Second is the dose from the extrathyroidal component from eight 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 eight 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:

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

Where:

F_1 = Extrathyroidal uptake fraction.

F_2 = Thyroidal uptake fraction.

E_1 = Occupancy factor for the first eight hours.

E_2 = Occupancy factor from eight hours to total decay.

All the other parameters are as defined in Equations B-1, B-3 and B-4. Acceptable values for F_1 , $T_{1\text{eff}}$, F_2 and $T_{2\text{eff}}$ are shown in Table T.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 OAC rule 3701:1-58-30(C) is described in Item T.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 T.5. The uptake fractions and effective half-lives are from Table T.6. An occupancy factor, E , of 0.75 at one meter, will be used for the first component because the time period under consideration is less than one 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 one 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).

	Extrathyroidal Component		Thyroidal Component	
Medical Condition	Uptake Fraction F_1	Effective Half-Life $T_{1\text{eff}}$ (day)	Uptake Fraction F_2	Effective Half-Life $T_{2\text{eff}}$ (day)
Hyperthyroidism	0.201	0.32 ²	0.80 ¹	5.21
Post Thyroidectomy for Thyroid Cancer	0.953	0.32 ²	0.05 ³	7.32

Footnotes for Table T.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 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:

$$D(\infty) = \frac{(34.6)(2.2)(150)}{(100 \text{ cm})^2} \left\{ (0.75)(8.04)(0.8) \left(1 - e^{-0.639 (0.33)/8.04} \right) \right. \\ \left. + e^{-0.639 (0.33)/8.04} (0.25)(0.95)(0.32) \right. \\ \left. + e^{-0.639 (0.33)/8.04} (0.25)(0.05)(7.3) \right. \\ \left. D(\infty) = 3.40 \text{ mSv (0.340 rem)} \right.$$

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 OAC rule 3701:1-58-30, assuming the foregoing assumptions can be justified for the individual patient's case and 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 T.5, and Table T.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:

$$D(\infty) = \frac{(34.6)(2.2)(55)}{(100 \text{ cm})^2} \left\{ (0.75)(8.04)(0.8) \left(1 - e^{-0.639 (0.33)/8.04} \right) \right. \\ \left. + e^{-0.639 (0.33)/8.04} (0.25)(0.20)(0.32) \right. \\ \left. + e^{-0.639 (0.33)/8.04} (0.25)(0.80)(5.2) \right. \\ \left. D(\infty) = 4.86 \text{ mSv (0.486 rem)} \right.$$

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 OAC rule 3701:1-58-30 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.
- 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 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:

$$D_i = (33 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$
$$D_i = 0.17 \text{ mSv (0.017 rem)}$$

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 percent 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 percent of the external dose because the internal dose due to this source is small in comparison to the magnitude of uncertainty in the external dose.

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

$$D_i = (150 \text{ mCi})(10^{-5})(53 \text{ rem/mCi})$$
$$D_i = 0.80 \text{ mSv (0.08 rem)}$$

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

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

Regulatory Analysis

"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.

Appendix U
Guidance for Mobile Medical Services

Mobile medical service providers must comply with all applicable sections of OAC Chapter 3701:1-58 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 OAC rules 3701:1-58-55 through 3701:1-58-71.

Type and Location of Use

In general, there are two types of mobile medical service. One type is transportation and use of radioactive material within a transport vehicle (e.g., in-van use). A second type is transportation of radioactive material to a client's facility for use within a client's facility by the mobile medical service's employees (i.e., transport and use).

For the first and second types, which include use by the service provider, the service provider should apply for full-service authorization. Service providers who only transport and store a therapy device need only apply for authorization for possession and transport of the radioactive material. In this case, when the service provider is only transporting the therapy device for use, the client must possess a license for medical use of the radioactive material. Additionally, in this case, the client is authorized to provide the patient treatments and is responsible for all aspects of the radioactive material use and patient treatments upon transfer of the radioactive material to their possession.

For all types, licensed activities must be conducted in accordance with the regulations for compliance with OAC rule 3701:1-58-31, which states the licensee will obtain a letter signed by the management of each of its clients for which services are rendered. The letter will permit the use of radioactive material at the client's address and will clearly delineate the authority and responsibility of each entity. This agreement must be applicable for the entire period of time over which the service is to be provided. The letter will be retained for three years after the last provision of service, as required by OAC rules 3701:1-58-31 and 3701:1-58-83. Additionally, as required by OAC rule 3701:1-58-31, the licensee must survey to ensure compliance with the requirements in OAC Chapter 3701:1-38 (e.g., ensure all radioactive material including radiopharmaceuticals, sealed sources and all associated wastes have been removed) before leaving a client's address.

The location of use for mobile medical services is of two basic types. One type of location is the base location where licensed material is received, stored and sometimes used. The other type of location is the temporary job site at client facilities. The following two sections describe the type of information necessary for base locations and temporary job sites.

Base Location

The base location (e.g., central radiopharmaceutical laboratory or storage location for the remote afterloader) for the mobile medical service must be specified. The base facility may be located in a medical institution, non-institutional medical practice, commercial facility or mobile van. 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 OAC rules 3701:1-40-15 and 3701:1-58-07, you must

submit a description and diagram(s) of the proposed base facility and associated equipment in accordance with Items 8.14 through 8.19 of this report. The description and diagram of the proposed facility should demonstrate 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 radiation levels in unrestricted areas are in compliance with OAC rule 3701:1-38-13. 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 OAC rule 3701:1-38-12, "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.
 - 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 OAC rule 3701:1-38-13, "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 OAC rule 3701:1-58-31, that location of the device/vehicle will be on client-owned or client-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 8.14 through 8.19 of this report. The description and diagram of the proposed use facility must demonstrate 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 radiation levels in unrestricted areas are in compliance with OAC rule 3701:1-38-13. 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 OAC rule 3701:1-58-31, 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 OAC rules 3701:1-58-62, 3701:1-58-65 and 3701:1-58-67.

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 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 OAC rule 3701:1-58-14, 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 OAC rule 3701:1-40-21, 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 three years.
- 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 OAC rule 3701:1-40-21, 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 three years.

Supervision

In addition to the requirements in OAC rules 3701:1-38-10 and 3701:1-58-14 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 OAC rule 3701:1-58-14, 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.
- Comply with the provisions of Chapter 58, [e.g., OAC rules 3701:1-58-31 and 3701:1-58-67 (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 OAC rules 3701:1-38-10, 3701:1-58-14, 3701:1-58-38, 3701:1-58-46 and 3701:1-58-58 (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 OAC rule 3701:1-58-31, 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 OAC rule 3701:1-38-11. 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 NRC's Operation Center and all appropriate state radiological protection agencies.
- 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.
- Procedures to ensure 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 OAC rule 3701:1-40-20, 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 three hours) to events such as a medical event or lost radioactive material.

Transportation

Develop, document and implement procedures to assure 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.
 - 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 the van will be secured against unauthorized access and 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 8.28 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 OAC rule 3701:1-38-19. 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 ODH 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 OAC rule 3701:1-38-12 and 3701:1-38-13, 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 OAC rule 3701:1-58-65 and the additional spot checks required by OAC rule 3701:1-58-67 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 OAC rules 3701:1-58-98 and 3701:1-58-96, showing the results of the above safety checks for ODH inspection and review for a period of three years.
- Perform surveys of the source housing and areas adjacent to the treatment room following relocation of an 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 V

Model Procedure for Waste Disposal by Decay-in-storage, Generator Return and Licensed Material Return

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 alternative procedures to meet the requirements of OAC rules 3701:1-38-19, 3701:1-38-11 and 3701:1-58-19.

Model Procedure for Decay-in-storage

(OAC rule 3701:1-58-19(E) 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 OAC rule 3701:1-38-19(E)).
 - 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. OAC Chapter 3701:1-58 does not relieve licensees from the requirement to comply with OAC Chapter 3701:1-50 and DOT regulations. Perform the following actions when returning generators:

- Retain the records needed to demonstrate 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 OAC rule 3701:1-40-21.

Model Procedure for Return of Licensed Material to Authorized Recipients

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

- In accordance with OAC rule 3701:1-40-19, confirm that persons are authorized to receive radioactive material prior to transfer (e.g., obtain a copy of the transferee's ODH 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's instructions.
- Retain records of receipts and transfers in accordance with OAC rule 3701:1-40-21.

Appendix W

Record Keeping Requirements

Table W.1 Typical Records and Retention Times

Record	Survey Requirement (OAC rule)	Record Keeping Requirement (OAC rule)	Retention Period
Results of surveys and calibrations	3701:1-38-14; 3701:1-38-18	3701:1-38-20	3 years
Results of surveys to determine dose from external sources		3701:1-38-20	Duration of license
Results of measurements and calculations used to determine individual intakes		3701:1-38-20	Duration of license
Results of air samplings, surveys and bioassays	3701:1-38-16; 3701:1-38-16	3701:1-38-20	Duration of license
Results of measurements and calculations used to evaluate the release of radioactive effluents to the environment		3701:1-38-20	Duration of license
Determination of prior occupational dose		3701:1-38-12	Duration of license
Planned special exposure	3701:1-38-12	3701:1-38-20	Duration of license
Individual monitoring results	3701:1-38-14	3701:1-38-20	Duration of license
Dose to individual members of the public	3701:1-38-13	3701:1-38-20	Duration of license
Waste disposal	3701:1-38-19; 3701:1-38-19; 3701:1-38-19; 3701:1-38-19	3701:1-38-20	Duration of license
Records of receipt of radioactive material		3701:1-40-21	Duration of possession and 3 years after transfer
Records of transfer of radioactive material		3701:1-40-21	3 years after transfer
Records of disposal of radioactive material		3701:1-40-21	Duration of license
Authority and responsibilities of radiation protection program	3701:1-58-12	3701:1-58-73	5 years
Radiation protection program changes	3701:1-58-13	3701:1-58-74	5 years
Written directives	3701:1-58-15	3701:1-58-75	3 years
Procedures for administrations requiring a written directive	3701:1-58-16	3701:1-58-76	Duration of license
Calibrations of instruments used to measure activity of unsealed byproduct material	3701:1-58-23	3701:1-58-77	3 years

Table W.1 Typical Records and Retention Times

Record	Survey Requirement (OAC rule)	Recordkeeping Requirement (OAC rule)	Retention Period
Radiation survey instrument calibrations	3701:1-58-24	3701:1-58-78	3 years
Dosages of unsealed radioactive material for medical use	3701:1-58-25	3701:1-58-79	3 years
Leak tests and inventory of sealed sources and brachytherapy sources	3701:1-58-27	3701:1-58-80	3 years
Surveys for ambient radiation exposure rate	3701:1-58-29	3701:1-58-81	3 years
Release of individuals containing unsealed radioactive material or implants containing radioactive material	3701:1-58-30	3701:1-58-82	3 years
Mobile medical services	3701:1-58-31	3701:1-58-83	3 years
Decay-in-storage	3701:1-38-19	3701:1-58-84	3 years
Molybdenum-99 concentrations	3701:1-58-35	3701:1-58-85	3 years
Safety instruction	3701:1-58-38; 3701:1-58-46 3701:1-58-58	3701:1-58-86	3 years
Surveys after source implant and removal	3701:1-58-44; 3701:1-58-56	3701:1-58-87	3 years
Brachytherapy source accountability	3701:1-58-45	3701:1-58-88	3 years
Calibration measurements of brachytherapy sources	3701:1-58-48	3701:1-58-89	3 years
Decay of strontium-90 sources for ophthalmic treatments	3701:1-58-49	3701:1-58-90	Life of source
Installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	3701:1-58-56	3701:1-58-91	3 years
Safety procedures	3701:1-58-58; 3701:1-58-58	3701:1-58-92	Duration of possession of specified equipment
Dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	3701:1-58-60	3701:1-58-93	Duration of license
Teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations	3701:1-58-61; 3701:1-58-62; 3701:1-58-63	3701:1-58-94	3 years
Periodic spot-checks of teletherapy units	3701:1-58-64	3701:1-58-95	3 years

Table W.1 Typical Records and Retention Times

Record	Survey Requirement (OAC rule)	Recordkeeping Requirement (OAC rule)	Retention Period
Periodic spot-checks of remote afterloader units	3701:1-58-65	3701:1-58-96	3 years
Periodic spot-checks of gamma stereotactic radiosurgery units	3701:1-58-66	3701:1-58-97	3 years
Additional technical requirements for mobile remote afterloader units	3701:1-58-67	3701:1-58-98	3 years
Surveys of therapeutic treatment units	3701:1-58-68	3701:1-58-99	Duration of use of unit
5-year inspection for teletherapy and gamma stereotactic radiosurgery units	3701:1-58-69	3701:1-58-100	Duration of use of unit

Appendix X

Reporting Requirements

Table X.1 Typical ODH Notifications and/or Reports

Event	Telephone Notification	Written Report	Regulatory Requirement (OAC rule)
Reports to individual workers	None	Annually	3701:1-38-10
Reports to former individual workers	None	Upon request	3701:1-38-10
Notification of special circumstances to individuals	None	30 days	3701:1-38-10
Reports to worker terminating employment	None	upon request	3701:1-38-10
Theft or loss of material	Immediate	30 days	3701:1-38-21
Whole body dose greater than 0.25 Sv (25 rems)	Immediate	30 days	3701:1-38-21; 3701:1-38-21
Extremity dose greater than 2.5 Sv (250 rems)	Immediate	30 days	3701:1-38-21; 3701:1-38-21
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	3701:1-38-21; 3701:1-38-21
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	3701:1-38-21; 3701:1-38-21
Doses in excess of specified criteria	None	30 days	3701:1-38-21
Levels of radiation or concentrations of radioactive material in excess of specified criteria	None	30 days	3701:1-38-21
Planned special exposures	None	30 days	3701:1-38-21
Report to individuals of exceeding dose limits	None	30 days	3701:1-38-21
Report of individual monitoring	None	Annually	3701:1-38-21
Defect in equipment that could create a substantial safety hazard	2 days	30 days	3701:1-38-23
Event that prevents Immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	Immediate	30 days	3701:1-40-20

Table X.1 Typical ODH Notifications and/or Reports			
Event	Telephone Notification	Written Report	Regulatory Requirement (OAC rule)
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	3701:1-40-20
Unplanned fire or explosion that affects the integrity of any licensed material or device, container or equipment with licensed material	24 hours	30 days	3701:1-40-20
Licensee permits individual to work as AU, ANP or AMP	None	30 days	3701:1-58-09
AU, ANP or AMP discontinues performance of duties under license or has a name change	None	30 days	3701:1-58-09
Licensee's mailing address changes	None	30 days	3701:1-58-09
Licensee's name changes without constituting a transfer of control	None	30 days	3701:1-58-09
Licensee adds or changes areas of OAC 3701:1-58-32 or OAC 3701:1-58-34 use of radioactive material identified in application or license	None	30 days	3701:1-58-09
Medical event	1 day	15 days	3701:1-58-101
Dose to embryo or nursing child	1 day	15 days	3701:1-58-102
Leaking source	None	5 days	3701:1-58-103

Note: Telephone notifications shall be made to the Bureau of Radiation Protection at 614-644-2727.

Appendix Y
Summary of DOT Requirements for
Transportation of Type A or Type B
Quantities of Licensed Material

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 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.
- 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>.