



STATE OF OHIO
DEPARTMENT OF HEALTH

GUIDANCE ABOUT POSSESSION LICENSES FOR PRODUCTION OF RADIOACTIVE MATERIAL USING AN ACCELERATOR

NMS-LIC-21

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This consolidated guidance is based on the Nuclear Regulatory Commission's NUREG 1556, Volume 21, 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

AEA	Atomic Energy Act
ALARA	as low as is reasonably achievable
ALI	annual limit on intake
ANP	authorized nuclear pharmacist
ANSI	American National Standards Institute
bkg	background
BPR	Business Process Redesign
Bq	becquerel
CFR	Code of Federal Regulations
Ci	curie
cm	centimeter
cpm	counts per minute
DAC	derived air concentration
DFP	decommissioning funding plan
DIS	decay in storage
DOE	United States Department of Energy
DOT	United States Department of Transportation
dpm	disintegrations per minute
dpm/cm ²	disintegrations per minute per square centimeter
EPA	United States Environmental Protection Agency
EPAct	Energy Policy Act of 2005
FA	financial assurance
FDA	United States Food and Drug Administration
FSME	Office of Federal and State Management and Environmental Management Programs
GM	Geiger-Mueller
GPO	Government Printing Office
IN	Information Notice

IP	inspection procedure
LLW	low-level radioactive waste
LSC	liquid scintillation counter
LSA	low specific activity
MCA	multichannel analyzer
mCi	millicurie
mGy	milliGray
MDA	minimum detectable activity
MOU	Memorandum of Understanding
mR	milliroentgen
mrem	millirem
mrem/hr	millirem per hour
mSv	millisievert
mSv/hr	millisievert per hour
NARM	Naturally Occurring and Accelerator-produced Radioactive Material
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
NMSS	Office of Nuclear Materials Safety and Safeguards
NRC	Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program
OCFO	Office of the Chief Financial Officer
OMB	Office of Management and Budget
P&GD	Policy and Guidance Directive
PET	Positron Emission Tomography
QA	quality assurance
R	roentgen
Ra-226	radium-226
RG	Regulatory Guide
RQ	reportable quantity
RSO	radiation safety officer
SI	International System of Units (abbreviated SI from the French, Le Système

Internationale d'Unités)

SSDR	sealed source and device registry
std	standard
Sv	sievert
TAR	technical assistance request
TEDE	total effective dose equivalent
TI	transportation index
TLD	thermoluminescent dosimeters
USDA	United States Department of Agriculture
μCi	microcurie

PURPOSE OF REPORT

This report provides guidance to applicants that produce radioactive materials using an accelerator(s). It provides guidance to an applicant in preparing a license application as well as Ohio Administrative Code (OAC) criteria for evaluating the license application. The body of this document contains the standard requirements and guidance for the possession and distribution of radioactive material (e.g., radiochemicals) that is produced by an accelerator(s), which is located at the applicant's facility. This report also provides guidance to applicants in applying for authorization for the production and noncommercial distribution of PET radioactive drugs to medical use licensees in a consortium.

As a guidance document intended to assist a wide variety of applicants, this report contains a considerable amount of information about how licensees may choose to implement their programs to meet Ohio regulatory requirements. The information in this document is not intended to impose any conditions beyond those required by the OAC. This report provides specific guidance on what information should be submitted in an application to satisfy Ohio requirements.

Guidance and model procedures provided in this guidance document that are not required to be submitted are for illustrative purposes to guide licensees in developing their programs. Use of the word "should" implies "may" and is not intended to mean "must" or "shall," the procedures provided in this guidance are intended to serve only as examples.

Appendices D thru N contain additional information on various radiation safety topics.

In this document, dose or radiation dose means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent or total effective dose equivalent (TEDE). These terms are defined in Chapter 3701:1-38. Rem, and its SI equivalent Sievert (1 rem = 0.01 Sievert (Sv)), is used to describe units of radiation exposure or dose. This is done because 10 CFR Part 20 sets dose limits in terms of rem, not rad or roentgen (R). When the radioactive material emits beta and gamma rays, for practical reasons, we assume that 1 R = 1 rad = 1 rem. For alpha-emitting radioactive material, 1 rad is not equal to 1 rem. Determination of dose equivalent (rem) from an absorbed dose (rad) from alpha particles requires the use of an appropriate quality factor (Q) value. Q values are used to convert absorbed doses (rad) to dose equivalent (rem). Q values for alpha particles are addressed in rule 3701:1-38-11.

AGREEMENT STATES

In addition to Ohio, certain states have entered into agreements with the Nuclear Regulatory Commission (NRC) as authorized by section 274(b) of the “Atomic Energy Act of 1954” 68 Stat 919, 42 USC 2011, as amended that gives Agreement States 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, or through the Internet at <http://www.nrc.gov>. Any applicant other than a Federal agency that 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. 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.

Ohio Revised Code (ORC), Chapter 3748 “Radiation Control Program” provides the statutory basis for the regulatory control of radioactive materials and radiation-generating equipment in the State of Ohio.

Ohio became an Agreement State in August 1999 with the NRC in accordance with ORC 3748.03. The Department of Health (hereafter “department”) is designated the Ohio radiation control agency in ORC 3748.02.

The governor-appointed Public Health Council is granted authority in ORC 3748.04 including, but not limited to: adopt, amend or rescind rules; radiation standards; set fees; and other regulatory items.

The duties and authority of the director of health (hereafter “director”) are identified in ORC 3748.05.

Within the department, the Bureau of Radiation Protection (BRP) is the designated agency to handle day-to-day activities on behalf of the director and the ODH.

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 the Department of Energy and, under most circumstances, its prime contractors are exempt from licensing [10 CFR 30.12])	NRC
Non-Federal entity in non-Agreement State, District of Columbia, US territory, or possession, or in Offshore Federal Waters	NRC
Non-Federal entity in Agreement State at non-Federally controlled site	Agreement State
Non-Federal entity in Agreement State at Federally controlled site <i>not</i> subject to exclusive Federal jurisdiction	Agreement State
Non-Federal entity in Agreement State at Federally controlled site subject to exclusive Federal jurisdiction	NRC

Reference: A current list of Agreement States is available at the Office of Federal and State Materials and Environmental Management Programs’ (FSME) public Web site, which is located at <http://nrc-stp.ornl.gov>. As an alternative, request the list from an NRC Regional Office.

MANAGEMENT INVOLVMENT

The ODH recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. The ODH 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 ODH (OAC 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 qualified individuals to serve on the Radiation Safety Committee, if required, and to serve as radiation safety officer (RSO) for their licensed activities.
- Prohibition against discrimination of employees engaged in protected activities.
- Commitment to provide information to employees regarding the employee protection and deliberate misconduct provisions in OAC 3701:1-38-09.
- Obtaining the ODH’s prior written consent before transferring control of the license.
- Notifying the ODH in writing, within 10 business days following filing of petition for voluntary or involuntary bankruptcy.

For further discussion of management responsibilities, see section 7.7. 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.ohio.gov>, and look for “Nuclear Material Safety” under ODH Programs and the OAC under “Rules”.

5 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 HEA5133 (Appendix A) Items 1 through 4 and 12 through 15 on the form itself.
- Complete the 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.

All license applications will be available for review by the general public by contacting the ODH 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 ODH’s licensing process involves invoicing of the application fee. The ODH BRP has implemented a new database, named RADMAT, for entering and tracking all radioactive materials licensing and invoicing actions. One of the features of the new system is the ability to enter the necessary information for new licenses, renewals, and amendment requests directly into the database. **This will allow for electronic filing of license action requests by licensees.**

In order to allow for direct entry of information into the database, each licensee must designate one or more individuals as RADMAT user(s) for their license and these persons will be assigned a log-in ID and a unique password. This will allow access to the license record(s) for which the RADMAT user is authorized in order to originate licensing actions. The ODH protocol requires that the log-in ID and password be assigned to a trustworthy and reliable individual who will not disclose or share their log-in information with others. The log-in ID will be their first name, last name and the ODH Web site (e.g. Firstname.Lastname@odh.ohio.gov). The initial password will be assigned with the log-in ID, but must be changed by the RADMAT user upon their first log-in to the system.

There are several considerations that you need to be aware of when designating your RADMAT user(s):

¹In this document, dose or radiation dose is used as defined in 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.

1. If you designate your Radiation Safety Officer as a RADMAT user, and this person is a contracted individual with similar duties at other institutions, they may be named as a RADMAT user for those other licensees as well.
2. If a person is designated as a RADMAT user by more than one licensee, that individual will be provided with one log-in ID which will allow access to all licenses for which they have been designated, because the log-in ID is based on the user's first and last names, not the licensee's name or license number. Any information submitted via license applications and amendments, including trade secret and security information, will be visible to this individual.
3. If a designated RADMAT user leaves your employ, notify the BRP immediately so access to your facility's information may be removed from that user's account.

To receive access to the new database, you are requested to provide the BRP with the name(s) of the RADMAT user(s) for your radioactive materials license, using the attached form. If you are designating multiple individuals, please make copies of the form and submit one form for each person. Completed forms should be submitted to the BRP through one of the methods designated at the bottom of the form.

Designation of User for ODH RADMAT Computer System

The following individual has been designated as a RADMAT user for the Ohio Radioactive Materials License number listed below and should be provided access to the ODH RADMAT computer system on our behalf:

PLEASE PRINT or TYPE

RADMAT User's Name: _____

RADMAT User's Title: _____

RADMAT User's E-Mail Address: _____

Licensee Name: _____

Ohio Radioactive Materials License Number: _____

Certifying Official Designation:

The individual named above has been designated as a RADMAT user for the RADMAT computer system for the Ohio Radioactive Materials License number indicated above. I understand that I am to notify the Ohio Department of Health, Bureau of Radiation Protection in the event that the employment relationship with this individual is terminated.

Certifying Official's Signature: _____

Certifying Official's Printed Name: _____

Certifying Official's Title: _____ Date: _____

RADMAT User Statement of Understanding:

I have been designated as a RADMAT user for the ODH RADMAT computer system for the Ohio Radioactive Materials License number indicated above. I understand that I am to notify the Ohio Department of Health, Bureau of Radiation Protection in the event that I terminate my employment relationship with this licensee.

RADMAT User Signature: _____ Date: _____

Return the completed form to:

For Medical licenses

Ohio Department of Health
Bureau of Radiation Protection
Attn: Mark Light
246 North High Street
Columbus, Ohio 43215

For Non-Medical licenses

Substitute:
Attn: Stephen James

For Decommissioning licenses

Substitute:
Attn: Chuck McCracken

Or via e-mail to: Mark.Light@odh.ohio.gov

Stephen.James@odh.ohio.gov

Chuck.McCracken@odh.ohio.gov

Or to any of the above via fax to: 614-466-0381

For Bureau Use Only

Log-In ID Authorized By: _____ Date: _____

If you have any questions regarding this matter you may call the BRP at 614-644-2727 and ask to speak to Medical Licensing and Inspection supervisor for medical licenses, non-medical Licensing and Inspection supervisor for non-medical licenses, or the Decommissioning supervisor for decommissioning licenses. Submission of the signed application form, specifying that the amplifying information is in electronic form, is acceptable.

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 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 ODH at:

Ohio Department of Health
246 North High Street
Bureau of Radiation Protection
Columbus, Ohio 43215

In general, applicants wishing to possess or use licensed material in Ohio must file an application with ODH, not the NRC. However, if work will be conducted at federally controlled sites 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 the appropriate fee. Refer to Appendix A of Rule 3701:1-38-02 of the OAC, to determine the amount of the fee. Once technical review has begun, fees will not be refunded; application fees will be charged regardless of disposition of an application or the withdrawal of an application.

All licensees are also subject to annual fees; refer to OAC 3701:1-38-02 for these fees, and for additional information on reduced annual fees for licensees that qualify as “small entities.”

Direct all questions about fees or completion of Item 14 “Reduced Fees Certification” of the application form (Appendix A) to the Ohio Department of Health, Bureau of Radiation Protection, 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 application form (Appendix A).

7.1 TYPE OF APPLICATION

This is an application for: Initial License Renewal or Amendment of License Number:

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

Check “Amendment to License No.” if the application is for an amendment² to an existing general distribution license.

Check “Renewal of License No.” if the application is for the renewal² of an existing general distribution 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. Because of the significant authority given a broad scope licensee to oversee licensed activities, it is not appropriate for an individual to apply for a broad scope license. No individual other than the duly authorized applicant may, for any licensing matter, act on behalf of the applicant or provide information without written authorization of the applicant.

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

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 Transfer of Control

Regulations: OAC 3701:1-40-16(A).

Criteria: Licensees must provide full information and obtain director's prior written consent before transferring control of the license, also commonly referred to as "transferring the license."

Discussion: Transferring control may be the result of mergers, buyouts or majority stock transfers. Although it is not the director's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain prior written consent from the director. This ensures:

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

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

Notification of Bankruptcy Proceedings

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

Criteria: Within 10 business days of filing of a voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify ODH, in writing, identifying the bankruptcy court in which the petition was filed and the date of filing.

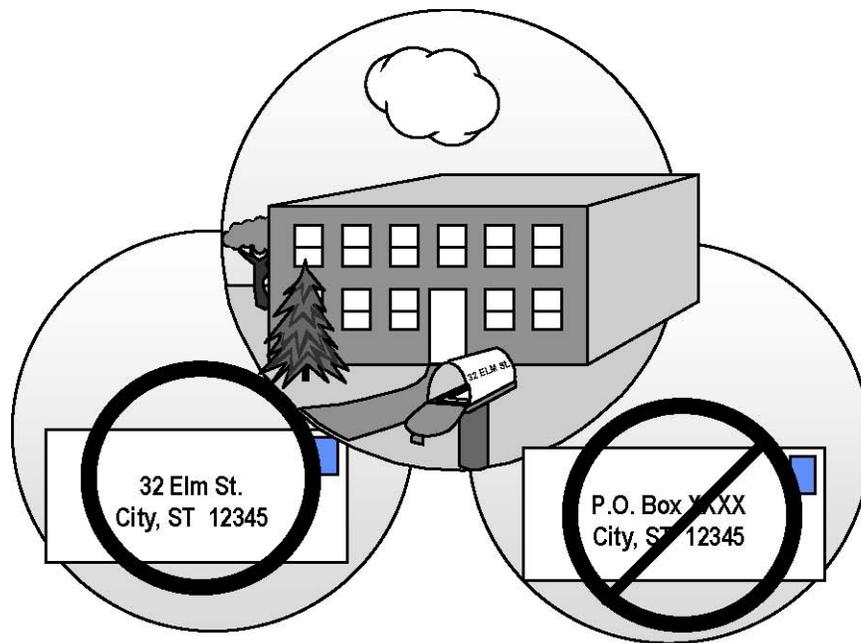
Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains responsible for all regulatory requirements. ODH needs to know when licensees are in bankruptcy proceedings in order to determine whether there are any public health and safety concerns (e.g., contaminated facility). ODH shares the results of its determinations with other involved entities (e.g., trustee) so health and safety issues can be resolved before bankruptcy actions are completed.

Response from Applicant: None required at the time of application for a new license. Licensees must notify ODH following the filing of a voluntary or involuntary petition for bankruptcy for or against the licensee.

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

An applicant for a specific license must be an organization with an address in the State of Ohio from which it will distribute the items. The applicant must specify the street address, city or other descriptive address (e.g. on State Route 7, five miles east of the intersection of State Route 7 and State Route 35, some city in Ohio) for each and every facility used as a location from which distribution will occur. A post office box address will not be accepted for the distribution address. Each point of distribution will be listed on the general distribution license.

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).



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Figure 8.1 Location of Possession and/or Use. *An acceptable location of possession and/or use specifies street address, city, state, and zip code and does not include a Post Office box number.*

Note: As discussed later under “Financial Assurance and Recordkeeping for Decommissioning,”

licensees must maintain permanent records of where licensed material was possessed, or possessed and 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). Acceptable records are sketches, written descriptions of the specific locations, or room numbers where licensed material is possessed and used or stored, and any records of spills or other unusual occurrences involving the spread of contamination in or around the licensee's facilities.

7.4 ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION

4. Licensee Contact Person			
If consultant or other non-employee, so indicate <input type="checkbox"/>			
Name:	Phone:	Fax:	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. ODH will contact this individual if there are questions about the application.

Notify ODH if the contact person or his or her telephone number changes so the ODH can contact the applicant or licensee in the future with questions, concerns or information.

The individual named in Item 4 of the application may or may not be the same individual who signs the application as the certifying official on behalf of the licensee and has the authority to make commitments to ODH (see Item 13 on Form HEA5133, Appendix A). Any commitments made by the applicant should be signed by the individual named in Item 13, because only that individual is considered by ODH to have the authority to make commitments on behalf of the applicant. ODH will not; therefore, accept license amendments or renewals signed by the individual identified in Item 4, if this person differs from the one named in Item 13.

ODH recognizes licensees may use a consultant or consultant group to help prepare the license application and provide support to the radiation protection program. Licensees are reminded that regardless of the role of the consultant in radiation protection program management, the licensee remains ultimately responsible for all aspects of the licensed program, including the services performed by the consultant. When selecting the person to be contacted, be aware that further important ODH and NRC communications will be directed to this person.

7.5 ITEM 5: RADIOACTIVE MATERIAL

7.5.1 UNSEALED AND/OR SEALED BYPRODUCT MATERIAL

Regulations: OAC rules 3701:1-40-01, 3701:1-40-04, 3701:1-40-14, 3701:1-40-15, 3701:1-40-16, 3701:1-40-18, 3701:1-46-21 and 3701:1-46-49

Criteria: A specific license is required, describing and authorizing the production and distribution of radioactive materials to persons specifically licensed. Applicants must submit information specifying each radionuclide that will be produced, the form of the radionuclide and the maximum activity to be possessed at any one time. The list of radionuclides should also include activation radionuclides that are produced during production of the primary radionuclide(s).

For activation radionuclides, the applicant could request authorization to possess and use byproduct material with atomic numbers from 1 through 83. The applicant should indicate the maximum quantity of each radionuclide to be possessed at any one time, and the total cumulative possession should be commensurate with the applicant's needs, facilities, procedures and demonstrated experience. If certain activation radionuclides will be produced in much larger quantities than described in the atomic number 1-83 request, the applicant should list these separately rather than increase the possession limit for all radionuclides. Similarly, if it is known that certain, relatively more hazardous activation radionuclides are produced in smaller quantities, they should also be listed separately.

Discussion: Each authorized radioisotope is listed on State of Ohio Radioactive Materials License by its element name, form and the maximum amount the licensee may possess at any one time (maximum possession limit).

Applicants and licensees should also determine whether they possess or will possess sealed sources or devices, which would include check, calibration, transmission and reference sources, or unsealed radioactive materials containing this new byproduct material. Applicants must request authorization for possession of these sealed source(s) or device(s).

The requirements regarding the application of a specific license for the use of sealed sources or devices containing naturally occurring or accelerator-produced radioactive material are provided in rule 3701:1-40-14 of the OAC.

A safety evaluation of sealed sources and devices is performed by NRC or an Agreement State before authorizing a manufacturer (or distributor) to distribute them to specific licensees. The safety evaluation is documented in an SDR Certificate.

Information on SDR certificates is available on NRC's Web site at <http://www.nrc.gov/materials/miau/ssd/obtain-reports.html> and may also be obtained by contacting the registration assistant by calling NRC's toll-free number, (800) 368-5642,

extension 415-7231. For additional guidance relating to sealed sources and devices, see also Ohio NMS-LIC-3 Rev 3, “Applications for Sealed Source and Device Evaluation and Registration.”

The applicant should list each requested radioisotope by its element name and its mass number in Item 5 on Form HEA5133. It is necessary to specify whether the material will be acquired and used in unsealed or sealed form. The name of the specific chemical compound that contains the radioisotope is not generally required. For listing activation radioisotopes, the location (e.g., target body or building materials) of the activated material should be indicated under the chemical and/or physical form column.

For unsealed radioactive material, applicants should specify whether radioisotopes that are produced will be in volatile or nonvolatile form, because additional safety precautions are required when handling material in a volatile form. Also, if the facility possesses discrete sources of radium-226, the discrete source should be described, because additional precautions may need to be taken if the source is compromised. Applicants requesting discrete sources of radium-226 and authorization to manipulate volatile radioactive material must describe appropriate facilities and engineering controls as described in Section 7.10, “Facilities and Equipment,” and radiation safety procedures for handling of such material in specific responses to Section 7.14, “Occupational Dose;” Section 7.15, “Public Dose;” Section 7.16, “Safe Handling of Radionuclides and Emergency Procedures;” and Section 7.17, “Surveys and Leak Tests.”

The applicant should also request authorization to possess depleted uranium if it will be used for shielding purposes. Depleted uranium is frequently used as shielding for molybdenum-99/technetium-99m generators when the molybdenum-99 activity is greater than 148 gigabecquerels (4 curies). 10 CFR 40.13(c)(6) exempts depleted uranium from the requirements for a license to the extent that the material is used as a shipping container, such as when molybdenum-99/technetium-99m generators are in transit from their manufacturer to the pharmacy; however, a specific license or authorization from Ohio is needed to possess and use the depleted uranium as a shield during the time that the applicant may use or store the generator at its facility. The applicant should specify the total amount of depleted uranium, in kilograms, that will be needed.

The anticipated possession limit in becquerel (Bq) or curie (Ci) for each radioisotope should also be specified. Possession limits must include the total anticipated inventory, including, licensed material in storage and waste, and should be commensurate with the applicant's needs and facilities for safe handling. Applicants should review the requirements for submitting a certification for financial assurance for decommissioning before specifying possession limits of any radioisotope with a half life greater than 120 days. These requirements are discussed in the Section on Financial Assurance and Decommissioning.

Response from Applicant:

For unsealed materials:

Provide an element name with mass number, chemical and/or physical form and a maximum requested possession limit for each radionuclide produced. For listing activation radioisotopes, the location (e.g., target body or target foil) of the activated material should be indicated under the chemical and/or physical form column.

Identify the largest quantity of each radionuclide to be possessed at one time under the license, including produced, stored and waste materials.

Note: For activation radionuclides, the applicant may request authorization to possess and use any form of byproduct material with atomic numbers 1 through 83. However, the applicant should indicate the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides.

For potentially volatile materials (e.g., I-123):

- Specify whether the material will be free (volatile) or bound (nonvolatile) and the requested possession limit for each form.

For sealed radioactive materials and discrete sources of radium-226:

- Identify each radionuclide (element name and mass number) that will be used in each source;
- Provide the manufacturer's (distributor's) name and model number for each sealed source and device and discrete source of radium-226 requested;
- Confirm that each sealed source, device, source/device combination and discrete source of radium-226 is registered as an approved sealed source, device or discrete source by NRC or an Agreement State.
- Confirm that the activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State.
- If the above information cannot be provided for the discrete source of radium-226, describe the discrete source.

Note:

- Licensees who request a possession limit in excess of the quantities specified in OAC rule 3701:1-40-14, must submit an emergency plan, as specified in OAC rule 3701:1-40-14. For depleted uranium, specify the total amount (in kilograms).

7.6 FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING

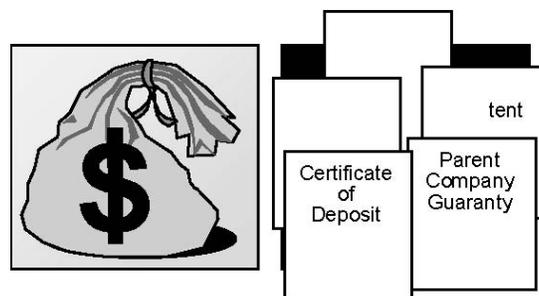
Regulations: OAC rules 3701:1-40-17, 3701:1-40-16.

Criteria: A licensee authorized to possess radioactive material in excess of the limits specified in OAC rule 3701:1-40-17 must submit a decommissioning funding plan (DFP) or provide a certification of financial assurance (FA) for decommissioning. Even if a DFP or FA is not required, licensees are required to maintain, in an identified location, decommissioning records related to structures and equipment where radioactive materials are used or stored and related to leaking sources. Pursuant to OAC rule 3701:1-40-17, licensees must transfer records important to decommissioning to either of the following:

- The new licensee before licensed activities are transferred or assigned according to OAC rule 3701:1-40-16 or,
- ODH before the license is terminated.

Discussion: The State of Ohio wants to ensure that decommissioning will be carried out with minimum impact on public and occupational health and safety and the environment. Most accelerator production facilities will be required to comply with the financial assurance requirements because of the activation materials that are produced during operation.

OAC rules requiring a DFP or FA are designed to provide reasonable assurance that the decommissioning of licensed facilities will be accomplished in a safe and timely manner and licensees will provide adequate funds to cover all costs associated with decommissioning. These requirements, if applicable, specify that a licensee either set aside funds for decommissioning activities or provide a guarantee, through a third party, that funds will be available. Applicants are required to submit a DFP or FA when the possession of radioactive material of half-life ($T_{1/2}$) greater than 120 days exceeds certain limits. Criteria for determining whether an applicant is required to submit a DFP or has an option of submitting either a DFP or FA (or neither) are stated in OAC 3701:1-40-17. A DFP contains a site-specific cost estimate and a certification of financial assurance. A Certification of Financial Assurance includes a certification that the licensee has provided the required financial assurance and an acceptable financial assurance instrument.



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Figure 8.2 Financial Assurance for Decommissioning. Most licensees that possess and operate an accelerator will need to provide financial assurance for decommissioning. Large

manufacturers may need one of several approved financial mechanisms.

The requirements for maintaining records important to decommissioning, including the type of information required, (see Figure 8.3) are stated in OAC 3701:1-40-17. All licensees are required to maintain these records in an identified location until the site is released for unrestricted use. In the event the licensed activities are transferred to another person or entity, these records shall be transferred to the new licensee prior to transfer of the licensed activities. The new licensee is responsible for maintaining these records until the license is terminated. Careful recordkeeping of radionuclides possessed and used, including form, amount and area used, will facilitate area release and license termination.

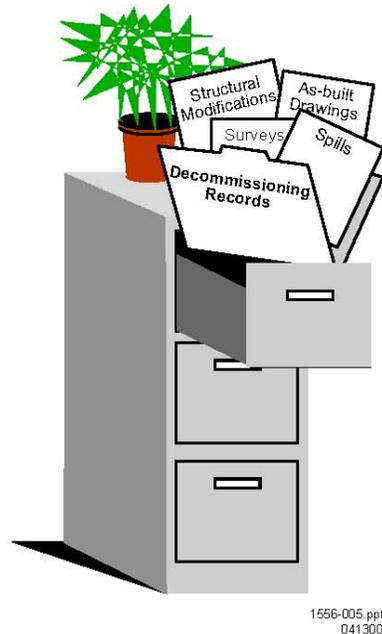


Figure 8.3 **Records Important to Decommissioning.** *All possession for production and distribution licensees must maintain records important to decommissioning, regardless of whether they need financial assurance for decommissioning.*

Response from Applicants: No response is needed from most applicants. If an F/A or a DFP is required, submit the required documents as described in OAC 3701:1-40-17.

7.7 ITEM 7: PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

Regulations: OAC 3701:1-40-15, OAC 3701:1-40-01.

Criteria: For this license, the materials will be produced by an accelerator and transferred or distributed to another license for use. The radioactive material produced will be possessed and possibly stored. Also, the activated products will be handled during maintenance, repair and disposal activities.

Discussion: Applicants should specify that the radioactive material requested in Item 5 will be possessed and/or stored incident to production by an accelerator in accordance with the regulations. Applicants may use the format given in Table 7.1 to provide the requested information. Once material is produced, it will be transferred internally to another license or it will be distributed to another licensee that will use the produced material to manufacture the final product. The produced radioactive material can be transferred or distributed to the following types of licenses:

- Manufacturing and distribution license;
- Commercial radiopharmacy license;
- Broad-scope license;
- Limited-scope license; and
- Medical use license (e.g., noncommercial radiopharmacy).

Table 7.1 Sample Format for Providing Information About Requested Radioisotopes.

Radioisotope	Chemical/ Physical Form	Maximum Possession Limit	Proposed Use
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Fluorine-18	Any	20 curies	Production and possession of a radiochemical for transfer or distribution to authorized licensees.
Indium-111	Any	1 curie	Production and possession of a radiochemical for transfer or distribution to authorized licensees.
Thallium-201	Any	1 curie	Production and possession of a radiochemical for transfer or distribution to authorized licensees.
Iodine-123	Unbound/volatile	100 millicuries	Production and possession of a radiochemical for transfer or distribution to authorized licensees.
Pd-103	Any	50 curies	Production and possession of a sealed source for transfer or distribution to authorized licensees.
Germanium-68	Sealed source, Mfg. name & model number	10 microcuries per source and 50 millicuries total	Calibration and check of instruments.
Cobalt-60	Target foils	50 millicuries	Possession and storage incident to production activities.
Maganese-54	Target body	100 millicuries	Possession and storage incident to production activities.
Cadmium-109	Target body	100 millicuries	Possession and storage incident to production activities.
Any byproduct material with atomic numbers 1 through 83	Activated components associated with equipment and/or shielding/building	Not to exceed 20 millicuries per radionuclide and 1 curie total, except as noted	Possession and storage incident to production activities.

Response from Applicant: For accelerator-produced radionuclides, applicants should state that radioactive materials will be possessed and stored incident to their production by an accelerator in accordance with the regulations. For sealed sources that are not produced, specify their

proposed use (e.g., calibration of instruments). Use of the format in Table 7.1 will facilitate the review of the application.

7.8 ITEM 8: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

Regulation: OAC 3701:1-40-15.

Criteria: Executive management, the RSO (and his/her staff, as necessary), and users work as a team to implement the Radiation Safety Program. Each individual plays a critical role within his or her area of responsibility. The roles and responsibilities of executive management, the RSO, the RSO's staff, users and others in restricted areas are discussed in the sections that follow. Refer to the subsequent sections specific to the RSO and individuals authorized to handle licensed material described below.

Discussion: Individuals must be qualified by training and experience to possess and use the material for the purpose(s) requested in a manner that will protect health and minimize danger to life or property before an application for a license is approved.

Each program in which radioactive materials are possessed and used under a State of Ohio Radioactive Materials License must have someone responsible for radiation safety and compliance with the OAC rules. The individual's training and experience must be commensurate with his or her duties and responsibilities. Supporting staff should be provided, as appropriate, for the size and scope of the program. A Radiation Safety Program for a production facility may consist of some or all of the following characteristics:

- The need for accurate detection, identification and measurement of radioactivity in various types of effluents (gas, liquid, solid) containing varying amounts of different radionuclides and for evaluation of these effluents against Ohio regulatory requirements and limitations;
- The need for radioactive effluent treatment by filtration, absorption, adsorption, holdup;
- The need for the selection, evaluation, design, maintenance and use of radioactive effluent- treatment systems;
- The need for the selection, evaluation and maintenance of radiation measurement and analysis equipment; and/or
- A potential for the contamination of facilities, equipment and personnel, accompanied by the need to control such contamination (including airborne contamination), decontaminate personnel and equipment and evaluate possible internal dose (including determination of the need for bioassays and interpretation of bioassay results).

The State of Ohio holds the licensee responsible for the Radiation Safety Program; therefore, it

is essential that strong management controls and oversight exist to ensure licensed activities are conducted safely. Management responsibility and liability are sometimes under-emphasized or not addressed in applications and are often poorly understood by licensee employees and managers. As discussed later in this guide, senior management will delegate to the RSO sufficient authority, organizational freedom and management prerogative to communicate with and direct personnel regarding OAC regulations and license provisions and to terminate unsafe activities involving byproduct material. Other responsibilities will be delegated to other individuals. Such delegations should be clearly communicated to all parties. While these delegations are important to the operation of the program, the licensee senior management maintains the ultimate responsibility for the safety of licensed activities.

Response from Applicant: Refer to the subsequent sections specific to the individuals described above. Applicants should submit an organizational chart describing the management structure, reporting paths and the flow of authority between executive management and the RSO.

7.8.1 RADIATION SAFETY OFFICER

Regulation: OAC 3701:1-40-15

Criteria: RSOs must have training and specific experience with the types and quantities of licensed material to be authorized on the license.

Discussion: The person responsible for implementing the Radiation Safety Program is the RSO. This individual may also be called the radiation protection officer. The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure radioactive materials are possessed and used in a safe manner.

The State of Ohio requires the name of the RSO to be listed on the license to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or designation as RSO.

To demonstrate adequate training and experience at a production facility, it is recommended that the RSO have: (1) at a minimum, a college degree at the bachelor level or equivalent training and experience in physical, chemical, biological sciences or engineering; and (2) training and experience commensurate with the scope of proposed activities. Training should include the following subjects:

- Radiation Protection Principles;
- Characteristics of Ionizing Radiation;
- Units of Radiation Dose and Quantities;
- Radiation Detection Instrumentation;
- Biological Hazards of Exposure to Radiation (appropriate to types and forms of licensed material to be possessed and used);

- State of Ohio Regulatory Requirements and Standards; and
- Handling of Radioactive Materials in Relation to Production Activities (e.g., maintenance and repair of the accelerator).

The amount of training and experience will depend on the type, form, quantity and proposed use of the licensed material requested. For instance, in addition to a college degree, RSOs at accelerator facilities where workers may handle curie quantities of radioactive material should be specialists in the field of radiation protection and may need at least 40 hours of radiation safety training specific to their job duties as well as a year of experience with similar types, forms, quantities and uses of radioactive material before the individual is qualified to be RSO. The proposed RSO's training and experience must be sufficient to identify and control the anticipated radiation hazards. For example, the RSO should have experience planning and training and experience commensurate with the scope of proposed activities conducting evaluations, surveys, and measurements similar to those required by the licensee's Radiation Safety Program. In addition, the RSO designee should have obtained the above training in a formal course designed for RSOs, presented by an academic institution, commercial radiation safety consulting company or a professional organization of radiation professional experts.

Response from Applicant: Provide the following:

- Name of the proposed RSO; and
 - Information demonstrating the proposed RSO is qualified by training and experience.
- Applicants should provide information about the proposed RSO's training and experience relative to the licensed material and uses requested in the application. Do not include private, personal information (e.g., home address, home telephone number, Social Security number, date of birth and radiation dose information).
- Applicants should not submit extraneous information such as unrelated lists of publications, research grants, committee and society memberships and personal, private information. Submittal of unrelated material may delay the review process.

Note: It is important to notify the State of Ohio, as soon as possible, of changes in the designation of the RSO. The name and qualifications of the replacement RSO should be submitted to the State of Ohio as part of an amendment request.

7.8.2 INDIVIDUALS AUTHORIZED TO HANDLE LICENSED MATERIAL

Regulations: OAC rules 3701:1-38-10, 3701:1-38-11, 3701:1-40-15.

Criteria: Individuals authorized to handle licensed material must have adequate training and experience with the types and quantities of licensed material that they propose to possess and handle.

Discussion: Applicants must name at least one individual who is qualified to handle the

requested licensed materials. For a production license, handling of licensed materials includes, for example, the processing of radiochemicals and the handling or manipulation of activated targets and/or components. An individual who is authorized to handle licensed material is a person whose training and experience have been reviewed and approved by director, who is named on the license and who uses or directly supervises the use of licensed material. This individual's primary responsibility is to ensure that radioactive materials are handled safely and according to regulatory requirements. The individual is also responsible for ensuring that procedures and engineering controls are used to keep occupational doses and doses to members of the public ALARA.

Individuals authorized to handle licensed material must have adequate and appropriate training to provide reasonable assurance they will handle licensed material safely, including maintaining security of, and access to, licensed material and respond appropriately to events or accidents involving licensed material to prevent the spread of contamination.

To demonstrate adequate training and experience at an accelerator facility, the authorized individual should have: (1) a college degree at the bachelor level, or equivalent training and experience in physical, chemical or biological sciences or in engineering; and (2) training and experience commensurate with the scope of proposed activities such as handling of activated targets and activated products associated with accelerator activities. Training should include the following subjects:

- Radiation Protection Principles;
- Characteristics of Ionizing Radiation;
- Units of Radiation Dose and Quantities;
- Radiation Detection Instrumentation;
- Biological Hazards of Exposure to Radiation (appropriate to the types and forms of byproduct material to be used); and
- Handling of Radioactive Materials Relevant to Accelerator Activities.

The amount of training and experience will depend on the type, form, quantity, and proposed use of the licensed material requested. For instance, in addition to a college degree or equivalent experience, an authorized individual at a production facility who may handle Curie quantities of radioactive material should have at least 40 hours of radiation safety training specific to his or her job duties as well as a minimum of six months of experience with similar types, forms, quantities, and uses of radioactive material before the individual is qualified to be authorized to handle licensed material. In general, authorized individuals should demonstrate training and experience with the type and quantity of material they propose to handle. For example, an individual with training and experience only with sealed radioactive sources might not be qualified to use or supervise the use of unsealed licensed material. In addition, someone with experience using only trace quantities of radioactive materials may not understand the risks of working with much larger (e.g., 10 or 100 times larger) quantities of the same substance. Applicants should pay particular attention to the type of radiation involved. For example, someone experienced with low-energy beta emitters may not have appropriate experience for high-energy gamma emitters.

An individual who is authorized to handle licensed material is considered to be supervising the handling of radioactive materials when he or she directs personnel in activities involving licensed material. Although the authorized individual may delegate specific tasks to supervised users (e.g., conducting surveys, keeping records), the authorized individual is responsible for the safe handling of radioactive material to assure that areas are not contaminated.

Note that accelerator manufacturers or companies that provide repair and/or maintenance service to licensed accelerator facilities may need to possess an NRC service provider license or equivalent Agreement State license. In particular, this would be required when individuals (e.g., service engineers) perform certain maintenance and repair activities that involve the handling of radioactive materials (e.g., activated targets or components) during the accelerator maintenance and repair activities.

Response from Applicant: Provide the following:

Name of each proposed individual with the types and quantities of licensed material to be possessed and handled; and information demonstrating that each proposed individual is qualified by training and experience to possess and handle the requested licensed materials. Applicants should provide information about the proposed authorized individual's training and experience relative to the licensed material and uses requested in the application.

Do not include private, personal information (e.g., home address, home telephone number, Social Security number, date of birth and radiation dose information). Applicants should not submit extraneous information such as unrelated lists of publications, research grants, committee and society memberships, and personal privacy information. Submittal of unrelated material may delay the review process.

7.9 ITEM 9: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

Regulations: OAC rules 3701:1-38-10, and 3701:1-40-15.

Criteria: Individuals whose assigned duties involve exposure to radiation and/or radioactive material (from both licensed and unlicensed sources), and in the course of their employment are likely to receive in a year an occupational dose of radiation greater than 1 mSv (100 mrem), whether from all external sources, all internal sources or any combination, must receive instruction commensurate with potential radiological health protection problems present in the work place, as required by OAC rule 3701:1-38-10.

Discussion: Before beginning work with licensed material, individuals should receive radiation safety training commensurate with their assigned duties and specific to the licensee's Radiation Safety Program. Each individual should also receive periodic refresher training at no more than 12-month intervals. Training should also be performed whenever there is a significant change in hazards, duties, procedures, regulations or terms of the license.

Licensees should not assume that safety instruction has been adequately covered by prior employment or academic training. Site-specific training should be provided for all individuals. Ancillary personnel (e.g., clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material (whether escorted or not) need to be informed about radiation hazards and the appropriate precautions. The licensee should assess each individual's involvement with licensed material and cover each applicable subject appropriately.

Training may be in the form of lecture, demonstrations, videotape or self-study, and it should emphasize practical subjects important to the safe possession and use of licensed material. If training is not conducted by an instructor, a method should be adopted whereby a trainee can ask questions and discuss topics relating to occupational radiation exposure. The guidance in Appendix F, "Radiation Safety Training Topics," may be used to develop a training program. The program should consider all topics pertinent for each group of workers as well as the method and frequency of training.

The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary.

This assessment may be performed by a written test or observation of the individual in the performance of assigned duties. Remedial training for missed test questions or other areas of apparent weakness should be conducted or additional formal training planned to cover deficient areas. The person conducting the training should be a qualified individual (e.g., a person who meets the qualifications for RSO or authorized user on the license and is familiar with the licensee's program).

Response from Applicant: Submit a description of the radiation safety training program, including topics covered, groups of workers, assessment of training, qualifications of instructors and the method and frequency of training.

7.10 ITEM 10: FACILITIES AND EQUIPMENT

Regulations: OAC rules 3701:1-38-11, 3701:1-38-22, 3701:1-40-03, 3701:1-40-15, and 3701:1-40-17.

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property. Licensee must minimize the possibility of contamination and keep exposures to workers and the public ALARA.

Discussion: Applicants must demonstrate that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and their employees, keep exposures to radiation and radioactive materials ALARA and minimize the danger to life and property from the uses of the types and quantities of radioactive materials to be used.

Applicants may delay completing facilities and acquiring equipment until after the application

review is completed, in case changes are required as a result of the application review. This also ensures the adequacy of the facilities and equipment before the applicant makes a significant financial commitment. In all cases, the applicant may not possess or use licensed material until after the facilities are approved, equipment is procured and the license is issued.

Applicants are reminded that records important to decommissioning include the following:

- As-built drawings and modifications of structures and equipment in restricted areas;
- As-built drawings and modifications of locations of possible inaccessible contamination such as buried pipes or transfer lines that may be subject to contamination; and
- Records of spills and unusual occurrences that may result in contamination of the facility or site.

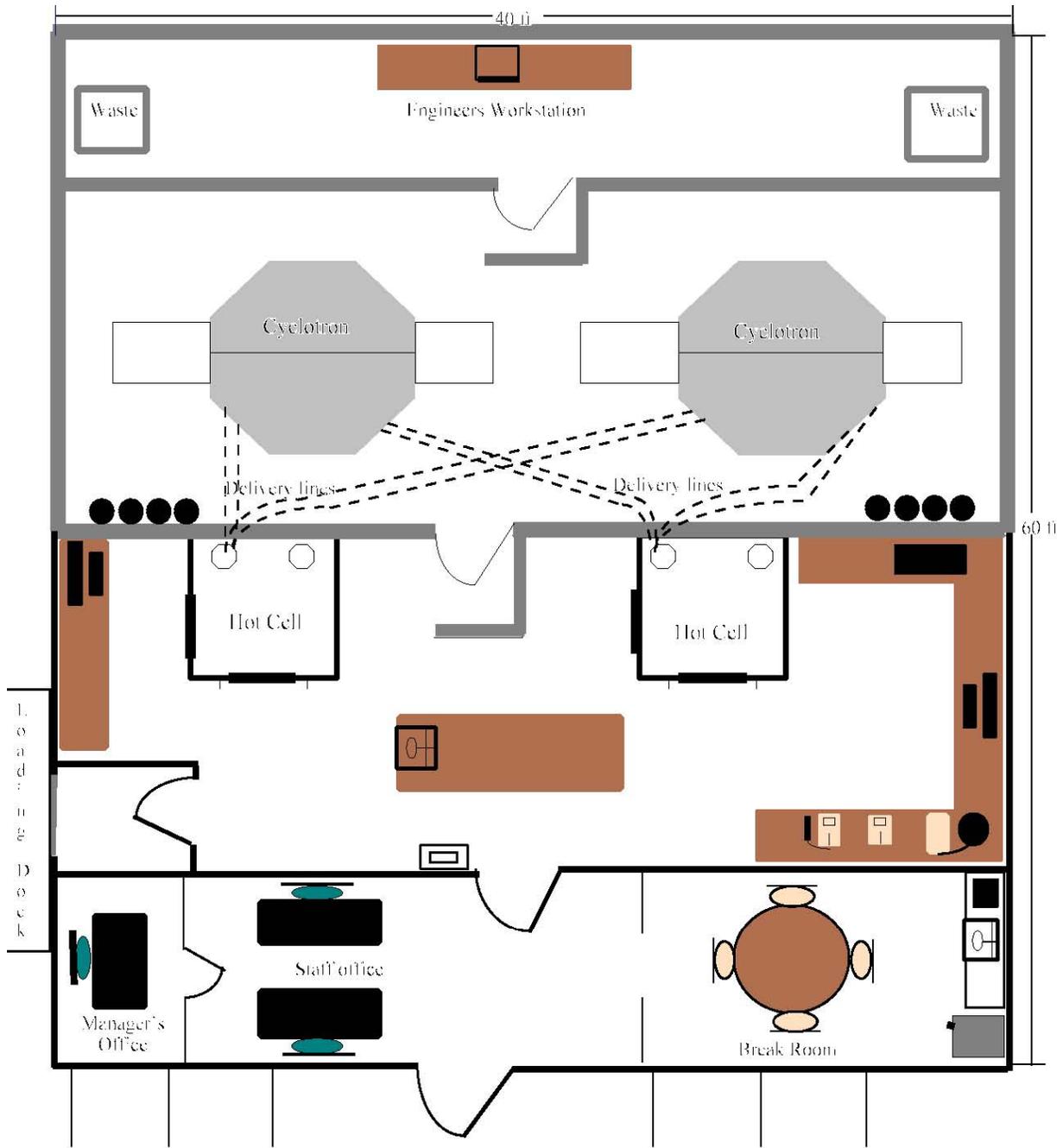
These records are required to be maintained in an identifiable location. Facilities are required to meet Ohio criteria prior to release.

Therefore, careful facility design is important to prevent contamination, or facilitate decontamination, reducing the costs needed for decommissioning. For further information, see Section 8.5.2, “Financial Assurance and Recordkeeping for Decommissioning.” For additional guidance regarding facilities and equipment, refer to Appendix G, Facilities and Equipment.

Response from Applicant: Describe the facilities and equipment to be made available at each location where radioactive material will be produced, possessed and/or used (see Appendix G for topics to consider). Include the following information:

- A description of the accelerator, which includes the name of the manufacturer, model accelerator energy, maximum current, type of targets and type of shielding materials. Note that this information will assist the license reviewer in understanding the types of materials and activation products that could be produced and the maximum quantity of radioactive material that could be produced and will not be incorporated into the license as a license condition;
- A description of the areas assigned for the production, which includes transfer of produced material, storage, preparation, shipping, security and measurement of radioactive materials;
- A description and diagrams that show the locations of delivery lines, shielded areas and equipment (e.g., hot cells, waste), the proximity of radiation sources to unrestricted areas and other items related to radiation safety (see Figures 8.5 and 8.6);
- A diagram and a description of the ventilation system, including representative equipment such as hot cells, glove boxes or fume hoods. Pertinent airflow rates, differential pressures, filtration equipment and monitoring systems should be described in terms of the minimum performance to be achieved. Confirm that such systems will be employed for the use or storage of radioactive materials that have the probability of becoming airborne; and

- Verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of OAC rule 3701:1-38-13 and are within the ALARA constraints for air emissions established under OAC rule 3701:1-38-11.



SECURITY-RELATED INFORMATION - WITHHOLD UNDER 10CFR 2.390*

* For the purposes of this NUREG, this diagram is marked appropriately for an application. This particular diagram does not contain real security-related information.

Figure 8.5 Facility Diagram for a Radioactive Materials Production Facility.

SECURITY-RELATED INFORMATION - WITHHOLD UNDER 10CFR 2.390*

* For the purposes of this Guide, this diagram is marked appropriately for an application. This particular diagram does not contain real security-related information.

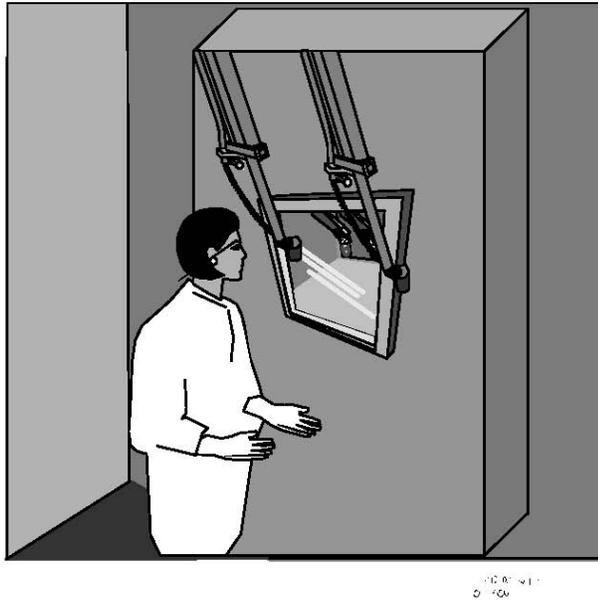


Figure 8.6 Shielded Protective Enclosure (Hot Cell) With Remote Manipulators.

RADIATION SAFETY PROGRAM

7.11 ITEM 11 AUDIT PROGRAM

Regulations: OAC rules 3701:1-38-10, 3701:1-38-11, 3701:1-38-13, 3701:1-38-14, 3701:1-38-18, 3701:1-38-20, 3701:1-38-21, 3701:1-38-23, 3701:1-40-17, 3701:1-40-19, 3701:1-40-21.

Criteria: Licensees must review the content and implementation of their Radiation Safety Programs at least annually.

Discussion: It is in the best interest of licensees to have a strong audit program to ensure:

- Compliance with Ohio rules and DOT regulations and the terms and conditions of the license;
- Occupational doses and doses to members of the public are ALARA (3701:1-38-11) and dose reduction efforts have been considered; and
- Operating procedures are in place for activities that could potentially affect radioactive material or occupational dose (3701:1-38-11).

An audit program that promptly identifies potential violations of regulatory requirements and takes prompt, comprehensive steps to correct them, meets director's expectations. Elements of an effective audit program are described below.

Audit Objectives. The director holds the licensee responsible for the Radiation Safety Program. It is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Audits may be used by licensees to self-assess the adequacy of the licensed program, identify program weaknesses, and allow licensees to take early corrective actions (before an NRC inspection).

The objectives of the audit should include an evaluation of the licensees':

- (1) Efforts to maintain doses ALARA;
- (2) Compliance with NRC requirements;
- (3) Ability to identify and correct deficiencies in their Radiation Safety Program;
- (4) Management of the Radiation Safety Program including the role of senior management and the RSO; and
- (5) Implementation of the Radiation Survey Program.

Scope of Audit. Audits should cover both the management of the Radiation Safety Program and the details of its implementation in the areas chosen for review. Mechanisms used by senior management to ensure that adequate oversight of the program is exercised should be included in the scope of the audit.

Auditor Qualifications. Auditors should have training and experience similar to that of an individual authorized for the types, forms, uses and quantities of radioactive material used in the areas audited. Auditors should not be selected from the staff of areas to be audited, nor their management. Ideally, auditors are third parties, from independent organizations.

Audit Frequency. Audits should be conducted at least once every 12 months. However, it is recommended that program audits be conducted more frequently than annually if the licensee's activities involve the use of high-activity materials or frequent handling of intermediate activity materials. Applicants should consider developing survey and audit schedules based on activity and use (e.g., high-use/activity areas may be audited monthly, moderate-use/activity areas may be audited quarterly). More frequent audits should be considered if the potential for overexposures exists.

Audit Techniques. While documentation should be reviewed during any audit of a Radiation Safety Program, emphasis should be placed on actual observations of work in progress. Applicants should consider performing unannounced audits of radioactive material users to observe work in progress and determine if, for example, operating and emergency procedures are

available and are being followed. Radiation safety audits should include activities conducted during all shifts. Some details of typical audit techniques follow:

Audit History. Note the date of the last audit, whether any deficiencies were identified and whether actions were taken to correct the deficiencies.

Organization and Scope of Program Area Audited. Give a brief description of the organizational structure, noting any changes in personnel. Describe the scope of licensed activities at the audited location. Check whether the RSO is the person identified in the license and fulfills the duties specified in the license.

Training, Retraining, and Instructions to Workers. Ensure workers have received the training required by OAC rule 3701:1-38-10. Be sure that, before being permitted to use byproduct material, the user has received training and has a copy of the licensee's operating and emergency procedures. Note whether refresher training is conducted in accordance with licensee commitments and all shift workers are included. By interview and/or observation of selected workers, ensure each has a copy of the licensee's procedures and can implement them properly. Special attention should be directed to the adequacy of training and observation of new employees performing their radioactive material duties.

Facilities. Verify the facilities are as described in the license documents.

Materials. Verify the license authorizes the quantities and types of byproduct material that the licensee possesses.

Leak Tests. Verify all sealed sources are tested for leakage at the prescribed frequency and in accordance with licensee commitments. Records of results should be maintained.

Inventories. Verify inventories are conducted at least once every six months to account for all sources; inventory records should be maintained.

Radiation Surveys. Verify the licensee has appropriate, operable and calibrated survey instruments available, the instruments are calibrated (at the required frequency) in accordance with license conditions and survey records are in accordance with OAC rule 3701:1-38-20. Calibration records must be retained for three years after the record is made. Check that radiation levels in areas adjacent to use areas are within regulatory limits. Verify compliance with OAC rule 3701:1-38-13 for dose limits to the public. Records of surveys must be retained for three years after the record is made.

Production Activities. Verify used accelerator parts (e.g., targets, o-rings) and other activated products are properly stored and shielded. Also, verify maintenance/repair logs are maintained and accurate.

Transfer of Radioactive Material (Includes Waste Disposal). Ensure transfers are performed in accordance with OAC rule 3701:1-40-19. Records of surveys, receipt and transfer must be

maintained in accordance with OAC rule 3701:1-38-21, and OAC rule 3701:1-40-21.

Transportation. Determine compliance with DOT requirements. Verify radioactive packages are prepared, marked and labeled in accordance with 49 CFR Parts 172 and 173 requirements. Verify that shipping papers are prepared, contain all needed information and are readily accessible during transport (49 CFR 172.200-204 and 177.718).

Personnel Radiation Protection. Evaluate the licensee's determination that unmonitored personnel are not likely to receive more than 10 percent of the allowable limits. Alternatively, if personnel dosimetry is provided and required, verify that it complies with OAC rule 3701:1-38-14 and licensee commitments. Review personnel monitoring records; compare exposures of individuals doing similar work; determine reasons for significant differences in exposures. The licensee is also responsible for ensuring dosimetry results are assigned accurately and should consider the assigned deep-dose equivalent and shallow-dose equivalent must be for the part of the body receiving the highest exposure. Therefore, if possible, whole body and extremity dosimeters should be placed in the areas that receive the highest exposure. An evaluation should be performed to determine if the maximum dose to a part of the whole body or an extremity may be substantially higher than the dose measured by the dosimeter. If the evaluation indicates that the maximum dose to a part of the whole body or extremity is higher than that measured by the dosimeter, the higher dose will be used as the dose of record (see Section 8.10.4). If any worker declared her pregnancy in writing, evaluate compliance with OAC rule 3701:1-38-12. Check whether records are maintained as required by OAC rule 3701:1-38-20.

Auditor's Independent Measurements. The auditor should make independent survey measurements and compare the results with those made or used by the licensee. Survey measurements should include engineer's workstation, waste/storage locations and other shielded locations/equipment.

Notification and Reports. Check for compliance with the notification and reporting requirements in OAC Chapters 3701:1-38 and 3701:1-40. Ensure the licensee is aware of the telephone number for Ohio Department of Health, Bureau of Radiation Protection, 614-644-2727.

Posting and Labeling. Check for compliance with the posting and labeling requirements of OAC rules 3701:1-38-10, 3701:1-38-18 and 3701:1-38-23.

Recordkeeping for Decommissioning. Check to determine compliance with OAC rule 3701:1-40-17.

Bulletins and Information Notices. Check to determine if such notifications as bulletins, information notices and newsletters are received from Ohio. Check whether appropriate actions were taken in response to Ohio mailings.

Special License Conditions or Issues. Verify compliance with any special conditions in the license. If there are any unusual aspects of work, review and evaluate compliance with regulatory requirements.

Recommendations. List any recommendations to improve the overall efficiency and effectiveness of the audit and Radiation Safety Program.

Evaluation of Other Factors. Evaluate management's involvement with the Radiation Safety Program, whether the RSO has sufficient time to perform his/her duties and whether there is sufficient staff to handle the workload and maintain compliance with regulatory requirements.

Problems or Deficiencies Noted. The licensee should have a process for correcting violations and deficiencies during and after the audit. The licensee should identify the safety significance of each violation to set priorities and identify resources to correct these violations. Results of the audit program reviews should be reported to senior management to allow for timely and aggressive remedial actions sufficient in scope to ensure compliance with Ohio rules and licensee conditions. Certain identified problems or potential violations may require notification or a report to the BRP. Licensees are encouraged to contact the BRP for guidance if they are uncertain about a reporting requirement. All audit findings and corresponding corrective actions, whether from internal, state or federal audit findings, should be communicated to the staff for review and added to new and refresher radiation safety training sessions. If the findings represent a significant safety impact to the staff, special training sessions may be appropriate.

Records to be Maintained: Licensees must maintain records of audits and other reviews of program content and implementation for three years from the date of the record. Audit records should contain the following information: date of audit, name of person(s) who conducted the audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up. These records must be maintained for inspection by the BRP.

Response from Applicant: No response is required. The licensee's program for auditing its Radiation Safety Program will be reviewed during inspection.

7.12 ITEM 12 RADIATION MONITORING

Regulations: OAC rules 3701:1-38-14, 3701:1-38-20, 3701:1-40-15.

Criteria: Licensees must possess radiation monitoring instruments to evaluate possible radiation hazards that may be present. Instruments used for quantitative radiation measurements must be calibrated periodically for the radiation measured.

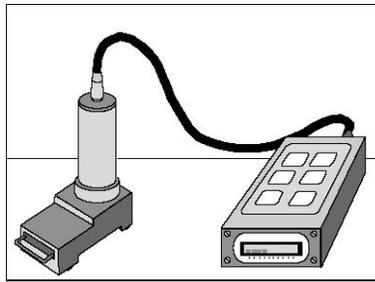
Discussion: Licensees must possess calibrated radiation detection/measurement instruments to perform, as necessary, the following:

- Dose rate surveys;
- Personnel and facility contamination measurements;
- Area monitoring;
- Sealed source leak tests;
- Air sampling measurements;
- Bioassay measurements;
- Effluent release measurements; and
- Package surveys.

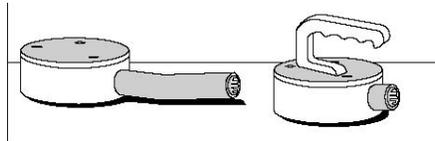
For the purposes of this document, radiation monitoring instruments are defined as any device used to measure the radiological conditions, which include licensed and non-licensed (e.g., accelerator operation) activities, at a licensed facility. Some of the instruments that may be used to perform the above functions include:

- Portable or stationary count rate meters;
- Portable or stationary dose rate or exposure rate meters;
- Area monitors;
- Single or multichannel analyzers (MCA);
- Liquid scintillation counters (LSC);
- Gamma counters;
- Proportional counters;
- Stack monitors;
- Solid state detectors;
- Neutron detectors; and
- Hand and foot contamination monitors.

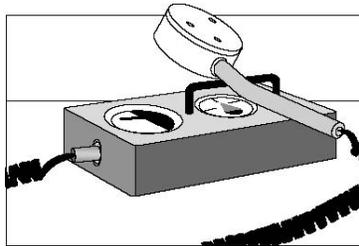
The choice of instrument should be appropriate for the type of radiation to be measured, and for the type of measurement to be taken (count rate, dose rate, etc.). Figure 8.7 illustrates some common survey instruments used for contamination surveys. Applications should include descriptions of the instrumentation available for use and the instrumentation that applicants intend to purchase prior to starting licensed activities. The description should include type of instrument and probe, and the instrument's intended purpose.



Beta/gamma Probes



Survey Meter and Attached Beta/gamma Probe



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Figure 8.7 Examples of Portable Instruments Used in Laboratory Settings.

Instruments used for qualitative surveys are intended only to detect contamination in the laboratory. Such instruments should be checked for operational response with an appropriate check source containing radioactive material and can be calibrated with an electronic pulser instead of a radioactive source. However, these instruments cannot be used for measurement of surface contamination or radiation levels without performing a calibration with appropriate radioactive sources, as described in Appendix G, “Radiation Monitoring Instrument Specifications and Model Survey Instrument and Air Sampler Calibration Program.”

Instrument calibrations should be performed by the instrument manufacturer or a person specifically authorized by NRC or an Agreement State, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey instrument calibrations should submit procedures for review.

Appendix G provides information about instrument specifications and model calibration procedures. Applicants should be aware that calibrations often require possession and use of a calibration source or device. Instruments for counting smear wipes to detect contamination and/or leakage need calibration sources that may be listed on the production license.

Response from Applicant: Provide one of the following:

A description of the instrumentation (as described above) that will be used to perform required surveys, and a statement that: “We will use instruments that meet the radiation monitoring instrument specifications published in Appendix G to NMS-LIC-21, ‘Program-Specific Guidance About Possession License for Production of Radioactive Materials Using an Accelerator,’

OR

A description of alternative equipment and/or procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration and calibration frequency of survey equipment will be performed. Calibrations may be performed by licensees specifically authorized to provide this service. It is not necessary to have a copy of the instrument manufacturer’s license, but calibration vendors other than the instrument manufacturer should be verified to ensure they have authorization to calibrate instruments for others;

AND

A description of the instruments used to quantitatively measure the radioactivity in the products and process, and the procedures followed to ensure accuracy of those measurements.

Note: Alternative responses will be reviewed using the criteria listed above.

7.13 ITEM 13 MATERIAL ACCOUNTABILITY

Regulations: OAC rules 3701:1-38-17, 3701:1-38-18, 3701:1-38-19, 3701:1-38-23, 3701:1-38-21, 3701:1-40-19, 3701:1-40-21.

Criteria: Licensees must ensure the security and accountability of licensed material.

Discussion: As illustrated in Figure 8.6, licensed materials must be tracked from production to disposal in order to ensure accountability; identify when licensed material could be lost, stolen or misplaced; and ensure possession limits listed on the license are not exceeded. Licensees may exercise control over licensed material accountability by including the following items:

- Physical inventories of sealed sources at intervals not to exceed six months;
- Maintaining material inventory within license possession limits;
- Maintaining records of transferred and distributed materials; and
- Maintaining records of disposed material (e.g., waste records).

Licensees must secure and control licensed material and should have a means of promptly detecting losses of licensed material. OAC rule 3701:1-38-17 requires licensees to secure radioactive materials from unauthorized removal or access while in storage and to control and maintain constant surveillance over licensed material that is not in storage.

Licenses will normally contain specific conditions requiring the licensee to perform inventories and leak tests of sealed sources every six months. Because the leak tests require an individual to locate and work with the sealed source, records of leak tests may be used as part of an inventory and accountability program. Sources in storage that are used infrequently may not require leak testing; however, the inventory must still be performed at the specified interval.

With regard to unsealed licensed material, licensees use various methods (e.g., computer programs, manual ledgers, log books) to account for production, use, transfer, disposal and radioactive decay. These methods help to ensure that possession limits are not exceeded.

Table 8.2 list the types and retention times for the records the applicant must maintain of production, use, transfer and disposal (as waste) of all licensed material. Other records such as transfer records could be linked to radioactive material inventory records.

Table 8.2 Record Maintenance

Type of Record	How Long Record Must be Maintained
Production	For as long as the material is possessed until 3 years after transfer or disposal
Transfer	For 3 years after transfer
Disposal	Until NRC terminates the license
Important to decommissioning	Until the site is released for unrestricted use

Material accountability records typically contain the following information:

- Radionuclide and activity (in units of becquerels or curies), and date of measurement of byproduct material;
- For each sealed source, manufacturer, model number, location and, if needed for identification, serial number and as appropriate, manufacturer and model number of device containing the sealed source;
- Date of the transfer and name and license number of the recipient, and description of the radioactive material (e.g., radionuclide, activity, manufacturer’s name and model number, serial number); and
- For licensed materials disposed of as waste, the radionuclide, activity, date of disposal, and method of disposal (decay, sewer, etc.)

See the section on “Waste Disposal” for additional information. Information about locations where licensed material is used or stored are among the records important to decommissioning and required by OAC rule 3701:1-40-17. See also the section on “Financial Assurance and

Recordkeeping for Decommissioning.”

Response from Applicant: Provide the following statements:

“We have developed, and will implement and maintain written procedures for licensed material accountability and control to ensure that:

- license possession limits are not exceeded;
- licensed material in storage is secured from unauthorized access or removal;
- licensed material not in storage is maintained under constant surveillance and control; and
- records of production, transfer and disposal of licensed material are maintained;

AND

“We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed six months.”

7.14 ITEM 14 OCCUPATIONAL DOSE

Regulations: OAC rules 3701:1-38-14, 3701:1-38-12, 3701:1-38-20.

Criteria: Each licensee shall evaluate the potential occupational exposures of all workers and monitor occupational exposure to radiation when required.

Discussion: The licensee should perform an evaluation of the dose, which may be received from licensed and nonlicensed (e.g., accelerator operation) activities, the individual is likely to receive prior to allowing the individual to receive the dose (prospective evaluation). When performing the prospective evaluation, only a dose that could be received at the facilities of the applicant or licensee performing the evaluation needs to be considered. These estimates can be based on any combination of work location, radiation monitoring, survey results, monitoring results of individuals in similar work situations or other estimates to produce a “best estimate” of the actual dose received. For individuals who have received doses at other facilities in the current year, the previous dose need not be considered in the prospective evaluation if monitoring was not required at the other facilities.

This evaluation need not be made for every individual; evaluations can be made for employees with similar job functions or work areas.

If the prospective evaluation shows that an individual's dose is not likely to exceed 10 percent of any applicable regulatory limit, the individual is not required to be monitored for radiation exposure and there are no recordkeeping or reporting requirements for doses received by that individual. If the prospective dose evaluation shows that the individual is likely to exceed 10 percent of an applicable limit, monitoring is required.

Licensees shall monitor worker exposures for:

Adults who are likely to receive an annual dose in excess of any of the following:

- 5 mSv (0.5 rem) deep-dose equivalent;
- 15 mSv (1.5 rems) eye dose equivalent;
- 50 mSv (5 rems) shallow-dose equivalent to the skin; and
- 50 mSv (5 rems) shallow-dose equivalent to any extremity.

Minors who are likely to receive an annual dose in excess of any of the following:

- 1mSv (0.1 rem) deep-dose equivalent;
 - 1.5 mSv (0.15 rem) eye dose equivalent;
 - 5 mSv (0.5 rem) shallow-dose equivalent to the skin; and
 - 5 mSv (0.5 rem) shallow-dose equivalent to any extremity.
- Declared pregnant women who are likely to receive an annual dose from occupational exposures in excess of 1.0 mSv (0.1 rem) deep-dose equivalent, although the dose limit applies to the entire gestation period.

Internal exposure monitoring is required for:

- Adults likely to receive in one year an intake in excess of 10 percent of the applicable annual limit on intake (ALI) for ingestion and inhalation; and
- Minors and declared pregnant women likely to receive in one year a committed effective dose equivalent in excess of 1.0 mSv (0.1 rem).

If an individual is likely to receive in one year a dose greater than 10 percent of any applicable limit (see Figure 8.8 for annual dose limits for adults), monitoring for occupational exposure is required. An occupational dose includes the dose received by individuals in the course of their employment (see OAC rule 3701:1-38-01), including exposure to radiation and to radioactive material from licensed and "unlicensed" sources of radiation, whether in the possession of the licensee or other person.

Therefore, authorized individuals and other radiation workers at a production facility are generally likely to receive 10 percent of the limits for an occupational dose.

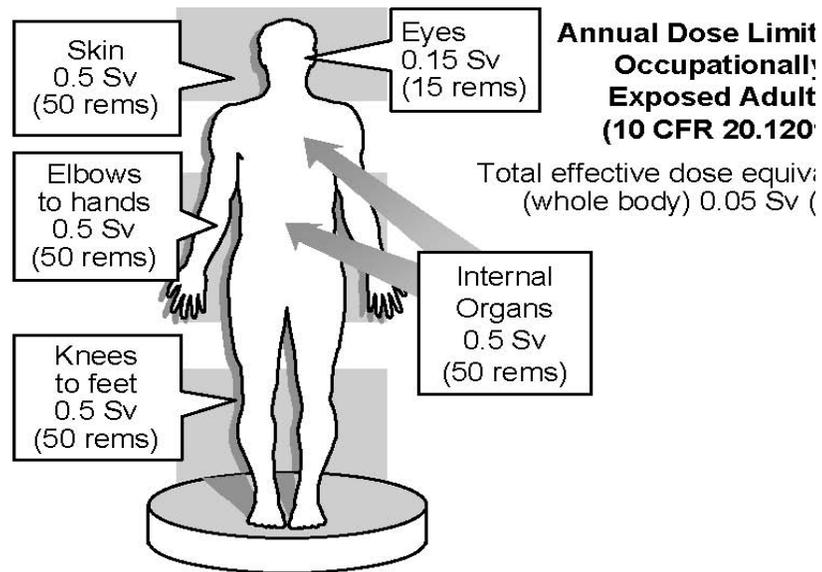


Figure 8.8 Annual Dose Limits for Occupationally Exposed Adults.

Annual Dose Limits for Occupationally Exposed Adults(OAC rule 3701:1-38-12)

Total effective dose equivalent TEDE (whole body) 0.05 Sv (5 rem)

$$\text{TOTAL EFFECTIVE DOSE EQUIVALENT (TEDE)} = \text{DEEP DOSE FROM EXTERNAL EXPOSURE} + \text{DOSE FROM INTERNALLY DEPOSITED RADIONUCLIDES}$$

Most licensees use either film badges, thermoluminescent dosimeters (TLDs), or Optically-Stimulated Luminescence (OSL) dosimeters that are supplied by a processor approved by the National Voluntary Laboratory Accreditation Program (NVLAP) to monitor for external exposure. Applicants should verify the processor is NVLAP-approved. Consult the NVLAP-approved processor for its recommendations for exchange frequency and proper use. If monitoring is required, then the licensee must maintain records of the monitoring regardless of the actual dose received. For individuals who handle licensed material at production facilities, extremity and whole body dosimeters should be worn. It is recommended that extremity and whole body dosimeters be exchanged at least monthly. Also, for individuals who will handle PET radionuclides or other radionuclides that emit high energy gammas/photons, it is recommended that extremity dosimeters be exchanged at least biweekly and a pocket or alarming dosimeter, which provides a real-time dose estimate, be used in addition to the individual's

personal whole body dosimeter. Workers are typically monitored for a year or more to determine an actual annual dose.

The monitoring results are then used to determine the need to continue monitoring workers. The dose to workers may need to be re-evaluated if there are changes to the licensee's program, such as procedures, frequency of use, quantity of licensed material used or isotopes used. The licensee should also consider a more frequent exchange of dosimeters when employees start a new job function, so their doses can be closely monitored when they are performing unfamiliar tasks.

In addition, see Appendix K, "Radiation Safety Survey Topics" for information on bioassay monitoring for internal exposure assessment. Routine bioassays should be performed when volatile radioactive material (e.g., I-123) is produced and/or handled.

Response from Applicant: Provide the following statement:

"We have developed and will implement and maintain written procedures for monitoring occupational doses that meet the requirements in OAC rules 3701:1-38-14, 3701:1-38-12, 3701:1-38-20, as applicable."

Note:

- Alternative responses will be evaluated using the criteria listed above.
- Some licensees choose to monitor their workers for reasons other than compliance with NRC requirements (e.g., in response to worker requests).

7.15 ITEM 15 PUBLIC DOSE

Regulations: OAC rules 3701:1-38-01, 3701:1-38-11, 3701:1-38-13, 3701:1-38-17, 3701:1-38-20, 3701:1-38-21.

Criteria: Licensees must do the following:

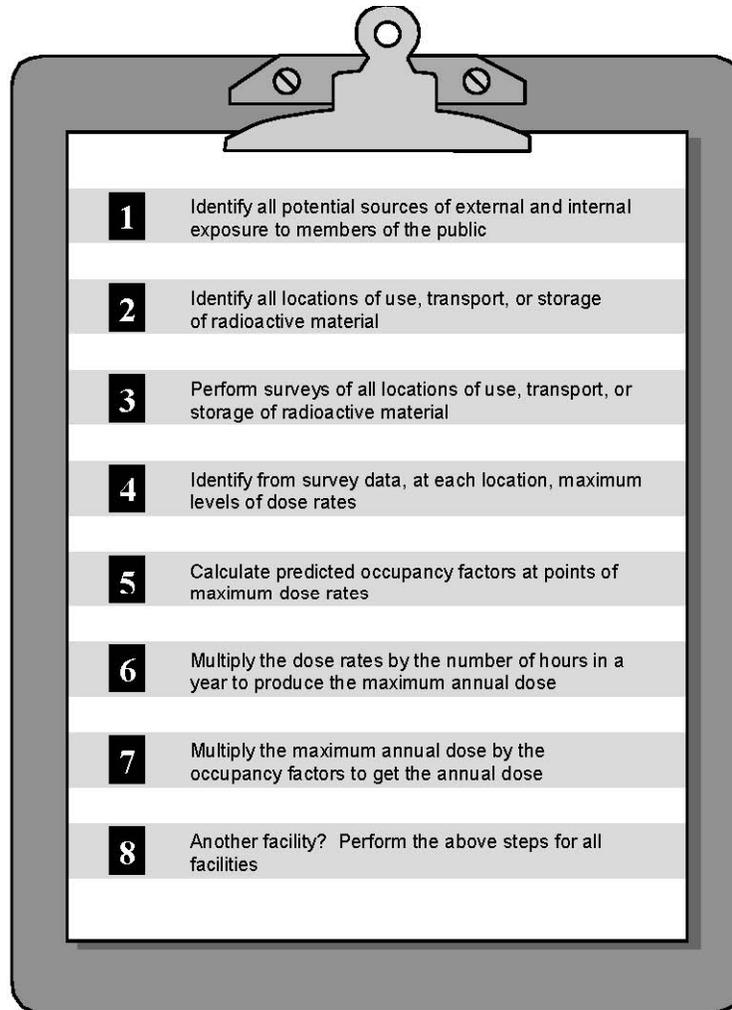
- Ensure licensed material will be used, transported, stored, and disposed of in such a way that members of the public will not receive more than 1 mSv (100 mrem) (TEDE) in one year from licensed activities;
- Ensure air emissions of radioactive material to the environment will not result in

exposures to individual members of the public in excess of 0.1 mSv (10 mrem) (TEDE) in one year from those emissions;

- Ensure the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour, from licensed operations; and
- Prevent unauthorized access, removal or use of licensed material.

Discussion: “Member of the public” is defined in Chapter 3701:1-38 of the OAC as “any individual except when that individual is receiving an occupational dose.” “Public dose” is defined in Chapter 3701:1-38 of the OAC as “the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee.” Public dose excludes doses received from background radiation, sanitary sewerage discharges from licensees and medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individual’s assigned duties. It does not depend on the area (restricted, controlled or unrestricted) the individual is in when the dose is received. For guidance about accepted methodologies for determining dose to members of the public, refer to Appendix H, “Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits.”

Figure 8.9 shows the steps to calculate the annual dose to an individual member of the public.



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Figure 8.9 Calculating Public Dose. *Steps to calculate the annual dose to an individual member of the public (see Appendix I for more information about occupancy factors).*

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There are many possible internal dose pathways that contribute to the TEDE. The TEDE can, however, be broken down into three major dose pathway groups:

- 1 Airborne radioactive material;
- 2 Waterborne radioactive material; and
- 3 External radiation exposure.

The licensee should review these major pathways and decide which are applicable to its operations. The licensee must ensure the TEDE from all exposure pathways arising from licensed activities does not exceed 1.0 mSv (100 mrem) to the maximally exposed member of the public. In addition, the licensee must control air emissions, such that the individual member of the public likely to receive the highest TEDE does not exceed the constraint level of 0.1 mSv (10 mrem) per year from those emissions. If exceeded, the licensee must report this, in accordance with OAC rule 3701:1-38-21, and take prompt actions to ensure against recurrence.

Licensees should design a monitoring program to ensure compliance with OAC rules 3701:1-38-11 and 3701:1-38-13. The extent and frequency of monitoring will depend upon each licensee's needs. For additional guidance regarding monitoring of effluents, refer to the section entitled, "Radiation Safety Program - Surveys."

During State of Ohio inspections, licensees must be able to provide documentation demonstrating, by measurement or calculation, the TEDE to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit and the dose constraint.

Response from Applicant: Initially, the applicant need not provide a response. The application will be evaluated and the license reviewer will determine if enough information is present to assure compliance with the limiting exposure to a member of the public. A response may be required when there is insufficient information to assure a member of the public will not receive a total exposure exceeding 0.1 mSv (100 mrem). When no response is required, compliance will be examined during inspection. During State of Ohio inspections, licensees must be able to demonstrate, by measurement or calculation, the TEDE to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public. See Appendix H for examples of methods to demonstrate compliance.

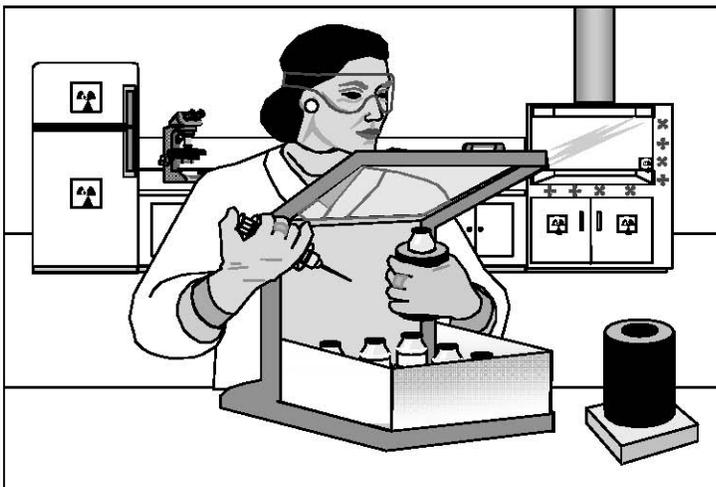
7.16 ITEM 16 SAFE HANDLING OF RADIONUCLIDES AND EMERGENCY PROCEDURES

Regulations: OAC rules 3701:1-38-10, 3701:1-38-11, 3701:1-38-17, 3701:1-38-18, 3701:1-38-21, 3701:1-38-23, 3701:1-40-14, 3701:1-40-20.

Criteria: Operating procedures for activities that can potentially impact radioactive material or occupational dose must be developed, documented, implemented and maintained to comply with OAC rule 3701:1-38-11, Radiation Safety Programs.

Discussion: Licensees are responsible for the security and safe possession and use of all licensed material from the time it is produced at the facility until it is used, transferred/delivered and/or disposed. Licensees must develop written procedures to ensure safe possession and use of licensed material, and the procedures should also include operational and administrative guidelines.

The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to workers or members of



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the public. **Figure 8.10 Use of Appropriate Shielding.**

General Safety Procedures

The written procedures should include the following elements:

- Contamination controls;
- Waste disposal practices;
- Personnel and area monitoring (including limits);
- Use of protective clothing and equipment;
- Recordkeeping requirements;
- Reporting requirements; and
- Responsibilities.

These procedures should include policies for:

- Frequency of personnel monitoring;
- Use of appropriate shielding (see Figure 8.10); and
- Frequent change of gloves to minimize exposure to the individual and to avoid spread of contamination in the laboratory.

Applicants should also develop product- and radioisotope-specific procedures based on the respective hazards associated with the products and radioisotopes. General safety guidelines are described in Appendix I, “General Topics for Safe Possession and Use of Radioactive Materials and Model Emergency Procedures” and Appendix K, “Radiation Safety Survey Topics.”

Applicants should use these guidelines to develop procedures for the safe use of radioisotopes.

Licensees should determine if they have areas that require posting in accordance with OAC rule 3701:1-38-18, unless they meet the exemptions listed in OAC rule 3701:1-38-18. Also, containers of licensed material (including radioactive waste) must be labeled in accordance with OAC rule 3701:1-38-18, unless they meet the exemptions in OAC rule 3701:1-38-18.

Security Procedures

All licensed materials that are stored in controlled or unrestricted areas must be secured from unauthorized access or removal, so individuals who are not knowledgeable about radioactive materials cannot be exposed to or contaminated by the material and cannot take the material. When any licensed material is handled in controlled or unrestricted areas, it must be under constant surveillance to prevent others from becoming contaminated by or exposed to the material, or to prevent persons from removing the material from the area. Acceptable methods for securing material will vary from one facility to another. Some alternatives used by licensees include: storage and use of licensed materials only in restricted areas; limiting access to an entire facility or building or portion of the building only to radiation workers; providing storage areas that can be locked to prevent access to the material; and implementing procedures that require a radiation worker to be within “line of sight” of the materials whenever licensed materials are in use. Applicants should develop procedures that clearly state acceptable methods to secure licensed material at their facility. Particular attention may need to be paid to security procedures at facilities that may have unusual needs due to the activities performed, such as hot cells, animal care facilities and waste processing facilities.

Emergency Procedures

Accidents and emergencies can happen during any operation with radioisotopes, including their transportation, use, production processes, transfer and disposal. Such incidents can result in contamination or release of material to the environment, and unintended radiation exposure to workers and members of the public. In addition, such incidents as loss or theft of licensed material, sabotage, fires and floods can jeopardize the safety of personnel and members of the public. It may therefore be necessary to develop written procedures to minimize, as much as possible, the impact of these incidents on personnel, members of the public and the environment. Applicants who plan to possess quantities of material in excess of the applicable amounts listed in OAC rule 3701:1-40-14 may also be required to submit an “Emergency Response Plan for Responding to a Release.”

Applicants should establish written procedures to handle events ranging from a minor spill (see Figure 8.11) to a major accident that may require intervention by outside emergency response personnel. For accelerator facilities, written procedures should be included for specific accident

scenarios such as target failures, spills or releases outside a containment enclosure, delivery line failures, malfunction of air supply or exhaust systems and high radiation levels in exhaust monitors or systems. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment and the appropriate roles of users and the radiation safety staff.

Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, the licensee staff should have a clear understanding of their limitations in an emergency, along with step-by-step instructions and clear guidelines for whom to contact. Licensees should have a sufficient number of appropriate and calibrated survey instruments readily available. Emergency spill kits should be strategically placed in well-marked locations for use by all users and the radiation safety staff. All equipment should be periodically inspected for proper operation and replenished as necessary. Appendix I includes model emergency procedures. Applicants may adopt these procedures or develop their own, incorporating the safety features included in these model procedures.



Figure 8.11 Proper Handling of Incident. Panels 1 and 2 indicate how contamination can be spread if the incident is not handled properly as in panels 3 and 4.

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Response from Applicant: The applicant should state that procedures for safe handling of radionuclides and emergencies will be developed and documented before production of licensed material. In addition, the applicant should state that operating and emergency procedures will be

implemented and maintained. The applicant should submit a statement that “Procedures will be revised only if: (1) the changes are reviewed and approved by the licensee management and the RSO in writing; (2) the licensee staff is provided training in the revised procedures prior to implementation; (3) the changes are in compliance with NRC regulations and the license; and (4) the changes do not degrade the effectiveness of the program.”

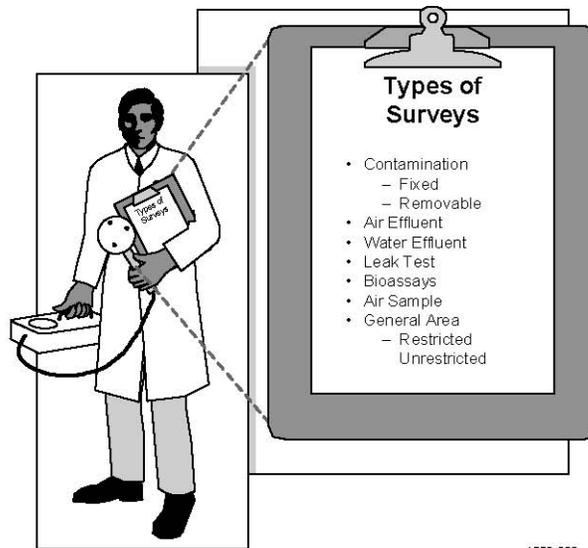
If an “Emergency Response Plan” is required for a license pursuant to OAC rule 3701:1-40-14, the applicant should submit it as a separate part of the application.

7.17 ITEM 17 SURVEYS AND LEAK TESTS

Regulations: OAC rules 3701:1-38-14, 3701:1-38-20, 3701:1-46-39, 3701:1-46-46.

Criteria: Licensees are required by OAC rule 3701:1-38-14 to make surveys of potential radiological hazards in their workplace. The director requires testing to determine whether there is any radioactive leakage from sealed sources. Records of surveys and leak tests results must be maintained.

Discussion: Surveys are evaluations of radiological conditions and potential hazards (see Figure 8.12). These evaluations may be measurements (e.g., radiation levels measured with survey instruments or results of wipe tests for contamination), calculation 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 the radiological conditions for both licensed and non-licensed (e.g., accelerator operation) activities and the licensed facility. In order to meet regulatory requirements for surveying, measurements of radiological quantities should be understood in terms of their properties (i.e., alpha, beta, gamma) and compared to the appropriate limits.



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Figure 8.12 Types of Surveys. *There are many different types of surveys performed by manufacturer and distribution licensees.*

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Radiation surveys are used to detect and evaluate contamination of:

- Facilities;
- Equipment;
- Personnel (during production, use, possession, transfer, or disposal of licensed material, see Figure 8.13);
- Restricted and unrestricted areas;
- Packages; and
- Products produced.

Surveys are also used to plan work in areas where licensed material or radiation exists and to evaluate doses to workers and individual members of the public.

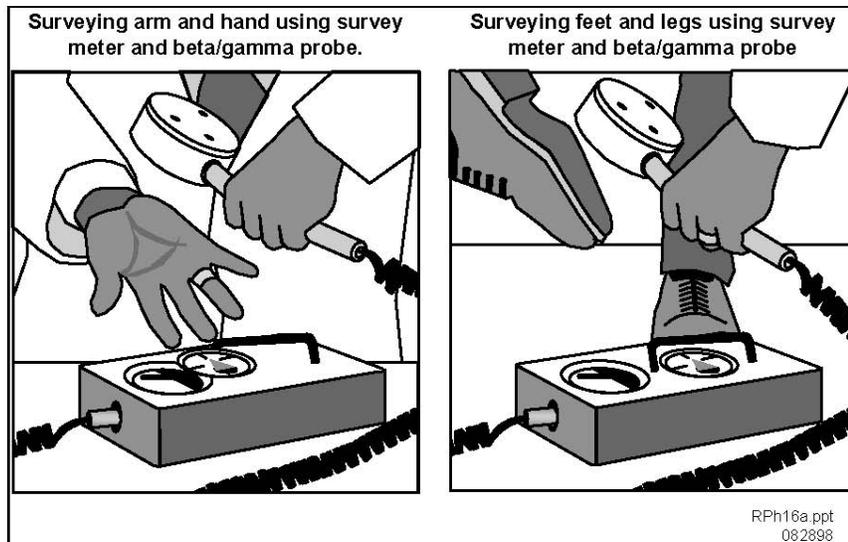


Figure 8.13 Personnel Surveys. *Users of unsealed licensed material should check themselves for contamination (frisk) before leaving the restricted area(s) of the facility.*

OAC rule 3701:1-38-14 states that 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 regulations. Many different types of surveys may need to be performed due to the particular use of licensed materials. The most important are as follows:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, workstations and equipment;
- Measurements of radioactive material concentrations in air for areas where radioactive materials are handled or processed in unsealed form, and where operations could expose workers to the inhalation of radioactive material, or where licensed material is or could be, released to unrestricted areas;
- Measurements of radioactive material concentrations in water that is released to the environment or to the sanitary sewer;
- Bioassays to determine the kinds, quantities or concentration, and in some cases, the location of radioactive material in the human body. A bioassay can be made by direct measurement (in vivo counting), or by analysis and evaluation of material excreted or removed from the human body (in vitro counting); and
- Surveys of external radiation exposure levels in both restricted and unrestricted areas.

The frequency of routine surveys depends on the nature, quantity and use of radioactive

materials, as well as the specific protective facilities, equipment and procedures that are designed to protect the worker from external and internal exposure. Also, the frequency of the survey depends on the type of survey, such as those listed above (see Appendix K, “Radiation Safety Survey Topics”).

Not all instruments can measure a given type of radiation. The presence of other radiation may interfere with a detector’s ability to measure the radiation of interest. Correct use of radiation detection and measurements is an important aspect of any Radiation Safety Program. Table H.1 in Appendix G contains radiation monitoring and survey instruments and calibration programs that are acceptable to director.

Chapter 3701:1-38 does not specify limits for surface contamination. Each applicant should propose and justify what removable surface contamination limits will be allowable before decontamination will be performed in each work area. Contamination checks are required before distributing licensed material. Table L.5 in Appendix K contains contamination limits that are acceptable to the director.

Sealed Source and Plated Foil Leak Tests

When issued, a license will require performance of leak tests of sealed/plated foil sources at intervals as approved by NRC or an Agreement State and specified by the SDDR certificate. 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 microcuries) of radioactivity.

Manufacturers, consultants and other organizations may be authorized by NRC or an Agreement State either to perform the entire leak test sequence for other licensees or provide leak test kits to licensees. In the latter case, the licensee should take the leak test sample according to the sealed source or plated foil manufacturer’s (distributor’s) and the kit supplier’s instructions and return it to the kit supplier for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. Licensees may also be authorized to conduct the entire leak test sequence themselves.

Leak tests are not required if:

- Sources contain only licensed material with a half-life of less than 30 days;
- Sources contain only a radioactive gas;
- Sources contain 3.7 MBq (100 microcuries) or less of beta-emitting or gamma-emitting material or 370 kBq (10 microcuries) or less of alpha-emitting material; or
- Sources are stored and are not being used (must be leak tested before use or transfer).

For more information regarding leak tests, see Appendix L, Model Leak Test Program.

Response from Applicant: Do one of the following:

- State: “We will survey our facility and maintain contamination levels in accordance with

the survey frequencies and contamination levels published in Appendix L NMS-LIC-21.” If applicable, state: “We will perform contamination checks on all manufactured sealed sources prior to distribution. Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSDR certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer’s (distributor’s) and kit supplier’s instructions. As an alternative, we will implement the model leak test program published in Appendix L to NMS-LIC-21;”

OR

- Submit a description of alternative equipment and/or procedures to evaluate a radiological hazard and for determining whether there is radioactive leakage from sealed sources or plated foils.

Note:

- Alternative responses will be reviewed using the criteria listed above;
- If a sealed source or plated foil is added to an existing license, that license might already authorize the licensee to perform the entire leak test sequence. In this case, the licensee may perform the leak testing on the sealed source or plated foil according to the procedures previously approved on its license.

7.18 ITEM 18 MAINTENANCE

Regulation: OAC rule 3701:1-38-11.

Criteria: Maintenance of equipment and facilities for the production and use of radioactive materials (e.g., accelerators and chemistry synthesis units) is necessary. Maintenance should be planned and carried out as frequently as needed, using ALARA principles. Individuals performing maintenance should be trained in the procedures they implement.

Procedures should be written to account for the skills of the implementing personnel. Ordinarily, individuals handling unshielded materials should have up to 40 hours of classroom and on-the-job training in radiation safety. Instructors should be more extensively qualified than the staff they teach.

Discussion: Maintenance of equipment and facilities is necessary in order to produce a quality product safely and efficiently and to ensure a safe environment for staff and the public.

Producing radioactive materials is an additional hazard, requiring attention to detail when incorporating maintenance information into procedures. Licensee staff should ensure that materials in the process stream are properly shielded/located/protected to minimize the hazard to maintenance staff. Maintenance staff should be aware of the hazards and the procedures to minimize their exposure to radioactive materials that are possessed and used to control the production process. As examples: (1) the staff should survey the accelerator working area prior to entry into the accelerator vault or opening of accelerator self-shields; and (2) a maintenance procedure should direct the shutdown and lockout of the accelerator before beginning work in the area. Maintenance procedures should be prepared with the use of engineering controls first, using ALARA principles and administrative controls, as needed.

Response from Applicant: No response is required in the application process. The results of actions taken in the maintenance and repair of facilities and equipment process will be reviewed during inspection.

7.19 ITEM 19 TRANSPORTATION

Regulations: OAC rules 3701:1-40-19, 3701:1-40-19, 3701:1-50-05, 3701:1-50-06, 3701:1-50-07, 3701:1-50-09, 3701:1-50-17, 49 CFR 107, 49 CFR 171-180, 49 CFR 390-397.

Criteria: A licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of DOT regulations in 49 CFR Parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport. Therefore, applicants who will package, transport or ship licensed material, including radioactive waste, must develop, implement and maintain safety programs for transport of radioactive material to ensure compliance with Ohio and DOT regulations.

Discussion: In accordance with a Memorandum of Understanding between the DOT and NRC, NRC inspects and enforces DOT's regulations governing the transport of radioactive materials by NRC's licensees.

Licensees should consider the safety of all individuals who may handle or come into contact with the packages containing licensed material.

Therefore, the primary considerations in packaging licensed material should be to ensure package integrity is not compromised during transport and that radiation levels (including removable contamination levels) at the package surfaces not only meet the regulatory requirements of OAC Chapter 3701:1-40, but are ALARA.

DOT regulations require individuals who perform functions related to the packaging and shipment of radioactive material packages receive training specific to those functions. The training must include a general awareness of DOT requirements, function-specific training for

the individuals' duties, safety training and security awareness training. DOT also specifies the frequency of the training and a record retention requirement for training.

The types and quantities of radioactive materials shipped by production licensees generally meet the criteria for shipment in a "Type A" package, as defined by DOT. The requirements for these packages include the provisions for shipping papers, packaging design standards, package marking and labeling and radiation and contamination level limits. For licensees who transport their own packages, the packages must be blocked and braced, and shipping papers must be stored in the driver's compartment as described in 49 CFR 177.817.

All domestic shipping paper and label information must be stated in the International System of Units (SI) only;

OR

Must be in SI units first, with English units in parenthesis.

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. Transporting licensed materials originating at some facilities involves quantities of radioactive material that require a Type B package. The manufacturer (or service licensee) who is subject to the provisions of OAC rule 3701:1-50-07 is responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations.

If a licensee plans to make shipments of licensed materials in Type B packages on its own, the licensee must be registered as a user of the package and have an NRC-approved quality assurance (QA) plan, two of the requirements under the OAC rule 3701:1-50-07 general license. For information about QA plans, see Revision 2 of Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," dated March 2005.

Licensees should also develop and maintain their own radiation safety procedures for transporting licensed material within their own facilities if it does not involve the use of public highways.

Response from Applicant: No response is needed from applicants during the licensing phase. Transportation activities will be reviewed during inspection.

7.20 ITEM 20 MINIMIZATION OF CONTAMINATION

Regulation: OAC rule 3701:1-38-22

Criteria: Applicants for new licenses must describe 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 fullest extent practicable, the generation of radioactive waste.

Discussion: When designing facilities and developing procedures for their safe use, applicants should think ahead and consider how to minimize radioactive contamination/decontamination during operation and during decommissioning efforts, and how to minimize radioactive waste generation during all phases of facility life cycle.

For accelerator production facilities, it is important to consider the types of materials used for the construction of the facility and for the shielding of the accelerator. Due to the neutron activation that generally takes place during the operation of the accelerator, it is important to carefully characterize all of the materials used in the accelerator (e.g., target material), the shielding of the accelerator and the accelerator facility to minimize the amount of activated products that are produced.

Customers may also request the licensee of the production facility to provide recovery and shipping services for unwanted, damaged and replacement materials/sources. As such, the licensee should consider the designs of shipping and recovery containers to meet transportation requirements. Procedures should be developed to enable these activities to be carried out with small impact on the radiological condition of the facility, decommissioning in the future and employee external and internal radiation exposure.

When submitting new applications, applicants should also consider the following:

- Implementation of, and adherence to, good health physics practices in operations;
- Minimization of areas, to the extent practicable, where licensed materials are used and stored;
- Maximization of the frequency of surveys, within reason, to minimize spread of contamination in the event of a spill;
- Choice of isotope to be used, whenever practical, in consideration of half-life and chemical composition;
- Appropriate filtration of effluent streams;
- Use of nonporous materials for such areas as laboratory bench tops and flooring;
- Ventilation stacks and duct work with minimal lengths and minimal abrupt changes in direction;
- Air flows appropriate to the work being conducted;
- Use of appropriate plumbing materials with minimal pipe lengths and traps; and
- Minimization of the number of disposal sites (sinks) where liquid waste is disposed if there is a sanitary sewer system.

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 should be immediately withdrawn from use and decontaminated, repaired or disposed of according to NRC requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts. Other efforts to minimize radioactive waste do not apply to programs using only sealed sources and devices that have not leaked.

Response from Applicant: The applicant does not need to provide a response to this item under the following condition: NRC will consider that the above criteria have been met if the applicant's responses meet the criteria in the following sections: Section 8.5.1, "Radioactive Material – Unsealed and/or Sealed Byproduct Material;" Section 8.9, "Facilities and Equipment;" Section 8.10.6, "Radiation Safety Program – Safe Handling of Radionuclides and Emergency Procedures;" Section 8.10.7, "Radiation Safety Program – Surveys and Leak Tests;" and Section 8.11, "Waste Management."

7.21 ITEM 21: WASTE MANAGEMENT

Regulations: OAC rules 3701:1-38-11, 3701:1-38-13, 3701:1-38-18, 3701:1-38-19, 3701:1-38-20, 3701:1-40-21, OAC Chapter 3701:1-54

Criteria: Radioactive waste generated as part of the production and distribution process must be disposed of in accordance with regulatory requirements and license conditions. Appropriate records of waste disposal must be maintained. Waste materials (such as glove, rags, tools) may not be received from others unless recipients are specifically licensed to receive such waste. Licensed materials that were distributed (such as decayed sources or devices at end of useful life) may be received from others and sent for proper disposal.

Discussion: The applicant should discuss the methods for management and disposal of radioactive waste. The program should include procedures for handling of waste, safe and secure storage, waste characterization, waste minimization and disposal of radioactive waste. Appropriate training should be provided to waste handlers.

The following methods of waste disposal may be considered and should be addressed in the application, as appropriate.

Transfer to an Authorized Recipient

Waste may be transferred to a recipient (usually a waste disposal service company or the original supplier) who is properly licensed to receive such waste in accordance with OAC rule 3701:1-38-19. Each shipment must comply with all applicable NRC and DOT requirements.

Licensees should implement procedures to reduce the volume of radioactive waste for final disposal in an authorized low-level radioactive waste (LLRW) disposal facility. These procedures include volume reduction by segregating, consolidating, compacting or allowing

certain waste to decay in storage. Waste compaction or other treatments can reduce the volume of radioactive waste, but such processes may pose additional radiological hazards (e.g., airborne radioactivity) to workers, members of the public and the environment. Safety procedures to address these concerns should be implemented.

Decay-in-Storage

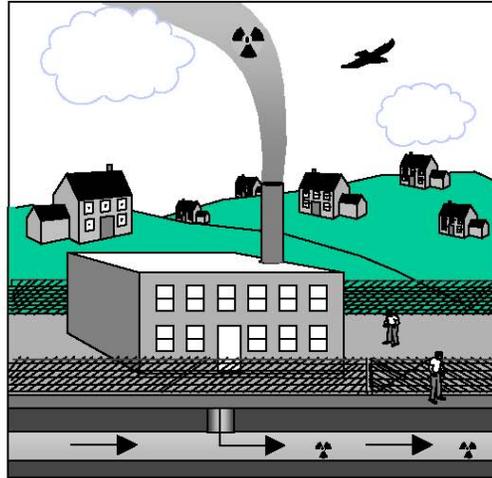
Storage of radioactive materials with half-lives of greater than 120 days should be characterized regarding volume and anticipated time in residence at the licensee's facility prior to disposal. The director permits licensed materials with half-lives of less than or equal to 120 days to be disposed of by decay-in-storage (DIS). Waste should be held in storage until the radiation exposure rate cannot be distinguished from background radiation levels. Applicants should assure that adequate space and facilities are available for the storage of such waste and care should be taken to ensure the waste form does not degrade or adversely interact with the waste container. Procedures for management of waste by DIS should include methods of segregation, surveys prior to disposal and maintenance of records of disposal.

Licenseses can minimize the need for storage space, if radioactive waste is segregated according to physical half-life. Segregation of waste is accomplished by depositing radioisotopes of shorter physical half-lives in containers separate from those used to store radioactive waste with longer physical half-lives. Radioactive waste with shorter half-lives will take less time to decay and thus may be disposed in shorter periods of time, freeing storage space.

The director does not consider storage as a substitute for final disposal of radioactive wastes. Other than storage for radioactive decay, LLRW should be stored only when disposal capacity is unavailable, and for no longer than is necessary.

A model procedure for DIS is contained in Appendix N, "Waste Disposal."

Release into Air and Water



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Figure 8.14 Air and Water Effluents from a Production Facility. Also note the fence, creating a “controlled area.”

Release of radioactive material into air and water must conform to the requirements described in OAC rule 3701:1-38-13. The applicant should discuss the monitoring and control mechanisms in place to ensure compliance with the requirements. Applicants are reminded of the “constraint” on air emissions of radioactive material required by 3701:1-38-11 which effectively reduces the limits specified in 3701:1-38-13 for release of gaseous effluents by a factor of 10.

Licenses considering disposal by release to the sanitary sewerage system must comply with the requirements of OAC rule 3701:1-38-19. Licensees are responsible for demonstrating licensed materials discharged into the sewerage system are readily soluble or biologically readily dispersible in water. Liquid scintillation media and ash are examples of material that may or may not be readily dispersible. Licensees should carefully consider the possibility of reconcentration of radioisotopes that are released into the sewerage system.

Applicants should provide procedures that will ensure all releases of radioactive waste into the sanitary sewerage system meet the criteria stated in OAC rule 3701:1-38-19 and do not exceed the monthly and annual limits specified in the regulations. Licensees are required to maintain accurate records of all releases of licensed material into the sanitary sewerage system. A model procedure for disposal of radioactive waste via a sanitary sewer is described in Appendix N.

If liquid releases are made to a private sewerage treatment system, septic system or leach field, the sludges or other solids from these systems may become contaminated with radioactive material.

Applicants should describe the monitoring planned for these systems in Item 8.10.7 of the application. Contaminated sludges should be disposed of as radioactive waste using one of the methods described in this section. Applicants may obtain approval of alternative disposal methods through application to the director as described in OAC rule 3701:1-38-19.

Incineration

Applicants who wish to treat or dispose of licensed material by incineration must comply with the requirements of OAC rule 3701:1-38-19. A model procedure for incineration of waste is described in Appendix N.

Waste Volume Reduction

Waste volume reduction operations (e.g., compaction) that could create a radiological hazard to licensee employees or the general public should be described in detail in the application. A model procedure for waste compaction is described in Appendix N.

Other Methods Specifically Approved by the Director Pursuant to OAC Rule 3701:1-38-19

Applicants may also request alternate methods for the disposal of radioactive waste generated at their facilities. Such requests must describe the waste-containing licensed material, including the physical and chemical properties that may be important to assess risks associated with the waste, and the proposed manner and conditions of waste disposal. Additionally, the applicant must submit its analysis and evaluation of pertinent information on the nature of the environment, nature and location of other affected facilities, and procedures to ensure radiation doses are maintained ALARA and within regulatory limits.

Some licensees do not have an LLRW disposal facility available to them and therefore may wish to use on-site interim storage until such time that a facility becomes available. Licensees should exhaust all possible alternatives for disposal of radioactive waste and rely upon on-site extended interim storage of radioactive waste only as a last resort, because protection of workers and the public is enhanced by disposal rather than storage of waste. Licensees may also find it more economical to dispose of radioactive waste than to store it on site because as the available capacity decreases, the cost of disposal of radioactive waste may continue to increase. LLRW should be stored only when disposal capacity is unavailable and for no longer than is necessary.

Additional Considerations

The application should describe the ALARA considerations taken before disposal of radioactive materials.

Discuss the potential for unmonitored or unanticipated release of radioactive materials to work areas and from release points (i.e., hoods and incinerator stacks). To be in compliance with the ALARA philosophy stated in OAC rule 3701:1-38-11, radioactive material waste stream concentrations should be a fraction (generally 10 percent to 20 percent) of the limits specified in

OAC rule 3701:1-38-11 Appendix B. Furthermore, due to the variability of inventory control programs for monitoring disposal and releases of licensed material possessed or possessed and in use, a program for physically measuring releases should be in place whenever releases exceed the specified ALARA action point. Because of the difficulties and costs associated with disposal of sealed sources, applicants should pre-plan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement. Sealed source manufacturers and suppliers that accept return of sealed sources should consider this when developing their waste management programs.

Response from Applicant: Provide procedures for waste collection, storage, and disposal by any of the authorized methods described in this section. Applicants should contact the Ohio Department of Health, Bureau of Radiation Protection for guidance and obtain advance approval of any method(s) of waste disposal other than those discussed in this section.

Note: Alternative responses will be reviewed using the criteria listed above.

7.22 ITEM 22: 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 of Rule 3701:1-38-02 of the OAC, to determine the amount of the fee. ODH will not review the license application prior to fee receipt, except those designated full cost. Once technical review has begun, fees will 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 OAC 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 Item 14 “Reduced Fees Certification” of the application form (Appendix A) to the Ohio Department of Health, Bureau of Radiation Protection, 246 North High Street, Columbus, Ohio 43215. You may also call (614) 644-2727.

7.23 Item 23 CERTIFICATION

7.23 ITEM 23: DOMESTIC/FOREIGN CORPORATION

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: ()

Applicants should indicate their corporate designation. Section 1701.01 of the Revised Code 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. A designated agent is required by Section 1703.041 of the ORC.

7.23 ITEM 24: 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. ODH 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.

7.2
3 ITEM 25: T

14. Licensee Federal Tax

OD

H 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.

7.23 ITEM 26: 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.

8 AMENDMENTS AND RENEWALS TO A LICENSE

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 180 days before the expiration date (OAC 3701:1-40-18(A)).

Applications for license amendment, in addition to the following, must provide the appropriate fee. For renewal and amendment requests applicants must do the following:

- Be sure to use the most recent guidance in preparing an amendment or renewal request;
- Submit either the application form or a letter requesting amendment or renewal;
- Provide the license number; and
- For renewals, provide a complete and up-to-date application if many outdated documents are referenced or there have been significant changes in regulatory requirements, ODH's guidance, the licensee's organization or radiation protection program. Alternatively, describe clearly the exact nature of the changes, additions and deletions.

Licenses wishing to renew their licenses should submit a complete application according to NMS-LIC-11. ODH staff's action will be similar to that described for amendments, but will include an extension of the license's expiration 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.

9 TERMINATION OF ACTIVITIES

Regulations: OAC 3701:1-40-16(A); OAC 3701:1-40-17(I); OAC 3701:1-40-18(C); OAC 3701:1-40-18(G); OAC 3701:1-40-18(I); OAC 3701:1-40-18(K); OAC 3701:1-40-21(F); OAC 3701:1-38-22(A); OAC 3701:1-38-22(B); OAC 3701:1-38-22(D); OAC 3701:1-38-22(D)(4); and OAC 3701:1-38-22(G).

Criteria: The licensee must do the following:

Notify the BRP, as the director's designee, in writing, within 60 days, of:

- The expiration of its license;
- A decision to permanently cease licensed activities at the entire site (regardless of contamination levels);
- A decision to permanently cease licensed activities in any separate building or outdoor area if they contain residual radioactivity making them unsuitable for unrestricted activity in accordance with OAC 3701:1-40-18(C)(2) (regardless of contamination levels);
- No principal activities have been conducted at the entire site under the license for a period of 24 months;
- No principal activities have been conducted for a period of 24 months in any separate building or outdoor area if they contain residual radioactivity making them unsuitable for unrestricted activity in accordance with OAC 3701:1-40-18(C)(4) (regardless of contamination levels);
- Submit a decommissioning plan if required by OAC 3701:1-40-18(G);
- Conduct decommissioning as required by OAC 3701:1-40-18(I) and (K);
- Submit to BRP, a completed "Certificate of Disposition of Materials" (or equivalent information) and a demonstration that the premises are suitable for release for unrestricted use (e.g., results of final survey); and
- Before a license is terminated, send the records important to decommissioning (as required by OAC 3701:1-40-17(I)) to BRP. If licensed activities are transferred or assigned in accordance with OAC 3701:1-40-16(A), transfer records important to decommissioning to the new licensee.

Discussion: As noted in several instances discussed in "Criteria," before a licensee can decide whether it must notify the BRP, the licensee must determine whether residual radioactivity is present and if so, whether the levels make the building or outdoor area unsuitable for release according to BRP requirements. A licensee's determination that a facility is not contaminated is subject to verification by inspection.

The permanent cessation of principal activities in an individual room or laboratory may require

the licensee to notify BRP if no other licensed activities are being performed in the building. This also applies to buildings that were approved by the broad scope licensee as locations of use but not specifically named on the broad scope license.

Table 9.1 Acceptable License Termination Screening Values of Common Radionuclides for Building Surface Contamination

Radionuclide	Symbol	Acceptable Screening Levels*
hydrogen-3 (tritium)	³ H	1.2 x 10 ⁸
carbon-14	¹⁴ C	3.7 x 10 ⁶
sodium-22	²² Na	9.5 x 10 ³
sulfur-35	³⁵ S	1.3 x 10 ⁷
chlorine-36	³⁶ Cl	5.0 x 10 ⁵
manganese-54	⁵⁴ Mn	3.2 x 10 ⁴
iron-55	⁵⁵ Fe	4.5 x 10 ⁶
cobalt-60	⁶⁰ Co	7.1 x 10 ³
nickel-63	⁶³ Ni	1.8 x 10 ⁶
strontium-90	⁹⁰ Sr	8.7 x 10 ⁶
technetium-99	⁹⁹ Tc	1.3 x 10 ⁶
iodine-129	¹²⁹ I	3.5 x 10 ⁴
cesium-137	¹³⁷ Cs	2.8 x 10 ⁴
iridium-192	¹⁹² Ir	7.4 x 10 ⁴

* Screening levels are based on the assumption that the fraction of removable surface contamination is equal to 0.1. For cases when the fraction of removable contamination is undetermined or higher than 0.1, users may assume, for screening purposes, that 100 percent of surface contamination is removable; and therefore the screening levels should be decreased by a factor of 10. Alternatively, users having site-specific data on the fraction of removable contamination (e.g., within 10 percent to 100 percent range) may calculate site-specific screening levels using D and D Version 1, based on site-specific resuspension factor. For unrestricted release (dpm/100 cm²) units are disintegrations per minute per 100 square centimeters (dpm/100 cm²). 1 dpm is equivalent to 0.0167 becquerel (Bq). The screening values represent surface concentrations of individual radionuclides that would be deemed in compliance with the 0.25 mSv/yr (25 mrem/yr) unrestricted release dose limit in OAC 3701:1-38-22(B). For radionuclides in a mixture, the “sum of fractions” rule applies; see OAC 3701:1-38-12, Appendix C, Note 4.

Response from Applicant: The applicant is not required to submit a response to the BRP during the initial application. However, when the license expires or at the time the licensee ceases operations, then any necessary decommissioning activities must be undertaken and the

certificate of disposition of materials or equivalent information must be submitted and other actions must be taken as summarized in criteria above.

Reference: The Certificate of Disposition of Materials may be obtained from the BRP (Decommissioning Section) upon request.

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	

Appendix B

Suggested Format for Providing Information Requested in Items 5 through 11 of the Application

The table below is designed to help applicants develop their applications. It may also be used as a License Reviewer Checklist for applications for a production and distribution license. A box (in a column) indicates the licensee may agree to use a model procedure, or if not using a model procedure, the licensee should describe its program or submit its procedures for the particular item.

Item No.	Suggested Response	Agree to Use	Description Attached
5.	<p>RADIOACTIVE MATERIAL Unsealed and/or Sealed Sources</p> <ul style="list-style-type: none"> • For unsealed materials: – Provide radionuclide (element name and mass number), chemical and/or physical form and maximum requested possession limit for each radionuclide produced. For listing activation radionuclides, the location (e.g., target body or concrete) of the activated material should be indicated under the chemical and/or physical form column (Item 5.b); and – Identify the largest quantity of each radionuclide to be possessed at one time under the license, including produced, stored and waste materials. <p>Note: For activation radionuclides, the applicant could request authorization to possess and use any form of byproduct material with atomic numbers 1 through 83. However, the applicant should indicate the maximum quantity of each radionuclide to be possessed at any one time and the total cumulative quantity for all radionuclides.</p> <ul style="list-style-type: none"> • For potentially volatile materials (e.g., I-123): – Specify whether the material will be free (volatile) or bound (nonvolatile) and the requested possession limit for each form. • For sealed radioactive materials and discrete sources of radium-226: – Identify each radionuclide (element name and mass number) that will be used in each source; – Provide the manufacturer’s (distributor’s) name and model number for each sealed source and device and discrete source of radium-226 requested; – Confirm each sealed source, device, and source/device combination is registered as an approved sealed source or device by NRC or an Agreement State; – Confirm that the activity per source and maximum activity in each device will not exceed the maximum activity on the approved certificate of registration issued by NRC or by an Agreement State; and – If the above information cannot be provided for the discrete source of radium-226, describe the discrete source. 		

Item No.	Suggested Response	Agree to Use	Description Attached
5.	<p>RADIOACTIVE MATERIAL (Cont.) Financial Assurance and Recordkeeping for Decommissioning If a DFP or FA is required, please contact the BRP Decommissioning Section at 614-644-2727</p>		
6.	<p>PURPOSE FOR WHICH LICENSED MATERIAL WILL BE USED List the specific use or purpose of each radioisotope that will be possessed and used.</p>		
7.	<p>INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE Applicants should submit an organizational chart describing the management structure, reporting paths and flow of authority between executive management and the RSO. RSO Provide the name of the proposed RSO and information demonstrating that the proposed RSO is qualified by training and experience.</p> <p>Individuals Authorized to Handle Licensed Material Provide the name of each proposed individual, with the types and quantities of licensed material to be possessed and/or handled. Also provide information demonstrating that each proposed individual is qualified by training and experience to possess and handle the requested licensed materials.</p>		
9.	<p>FACILITIES AND EQUIPMENT Describe the facilities and equipment to be made available at each location where radioactive material will be produced, possessed and/or used. Include the following information:</p> <ul style="list-style-type: none"> • Provide a description of the accelerator, which includes the name of the manufacturer, model, accelerator energy, maximum current, type of targets and type of shielding materials; 		

Item No.	Suggested Response	Agree to Use	Description Attached
9.	<p>FACILITIES AND EQUIPMENT (Cont.) Note: This information about the accelerator will assist the license reviewer in understanding the types of materials and activation products that could be produced and the maximum quantity of radioactive material that could be produced and will not be incorporated into the license as a license condition;</p> <ul style="list-style-type: none"> • Provide a description of the areas assigned for the production, which includes transfer of produced material, storage, preparation, shipping, security and measurement of radioactive materials; • Provide a description and diagrams showing the locations of delivery lines, shielded areas and equipment (e.g., hot cells, waste), the proximity of radiation sources to unrestricted areas and other items related to radiation safety (see Figures 8.6 and 8.7); • Provide a diagram and a description of the ventilation system, including representative equipment such as hot cells, glove boxes, or fume hoods. Pertinent airflow rates, differential pressures, filtration equipment and monitoring systems should be described in terms of the minimum performance to be achieved. Confirm that such systems will be employed for the use or storage of radioactive materials that have the probability of becoming airborne; and • Provide verification that ventilation systems ensure effluents are within the dose limits of OAC rule 3701:1-38-13, and the ALARA constraints for air emissions established under OAC rule 3701:1-38-11 are ALARA. 		
10.	<p>RADIATION SAFETY PROGRAM</p> <p>Audit Program No response is required. The licensee’s program for auditing its Radiation Safety Program will be reviewed during inspection.</p> <p>Radiation Monitoring Instruments Describe the instrumentation that will be used to perform required surveys, and state that: “We will use instruments that meet the radiation monitoring instrument specifications published in Appendix G to NMS-LIC-21, ‘Program-Specific Guidance About Possession Licenses for Production of Radioactive Materials Using an Accelerator;’ OR</p>		

Item No.	Suggested Response	Agree to Use	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont.) Describe the alternative equipment and/or procedures for ensuring appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration and calibration frequency of survey equipment will be performed. Calibrations may be performed by licensees specifically authorized to provide this service. It is not necessary to have a copy of the instrument manufacturer’s license, but calibration vendors other than the instrument manufacturer should be verified to ensure they have authorization to calibrate instruments for others;</p> <p>AND</p> <p>Describe the instruments used to quantitatively measure the radioactivity in the products and process, and the procedures followed to ensure accuracy of those measurements.</p> <p>Material Accountability • “We have developed, and will implement and maintain written procedures for licensed material accountability and control to ensure that: – license possession limits are not exceeded; – licensed material in storage is secured from unauthorized access or removal; – licensed material not in storage is maintained under constant surveillance and control; and – records of production, transfer, and disposal of licensed material are maintained;”</p> <p>AND • “We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed six months.”</p> <p>Occupational Dose “We have developed and will implement and maintain written procedures for monitoring occupational dose that meet the requirements in OAC rule 3701:1-38-14 and OAC rule 3701:1-38-12, as applicable.”</p> <p>Public Dose Initially, a response is not required from the applicant.</p>		

Item No.	Suggested Response	Agree to Use	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont.)</p> <p>Safe Handling of Radionuclides and Emergency Procedures Develop and maintain procedures for safe handling of radionuclides and emergencies. State that such procedures will be developed and documented before production of licensed material. The applicant should state that procedures will be revised only if: • The changes are reviewed and approved by licensee management and the RSO; • Licensee staff is trained in the revised procedures before they are implemented; • The changes are in compliance with NRC regulations and the license; and • The changes do not degrade the effectiveness of the program. If an emergency response plan is needed, submit it as a separate part of the application.</p> <p>Surveys “We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix K NMS-LIC-21. Leak tests of sealed sources will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State, to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer’s (distributor’s) and kit supplier’s instructions. As an alternative, we will implement the model leak test program published in Appendix L to NMS-LIC-21.”</p> <p>OR Submit a description of alternative equipment and/or procedures to evaluate a radiological hazard and for determining whether there is radioactive leakage from sealed sources or plated foils.</p> <p>Maintenance No response is required in the application process.</p>		

Item No.	Suggested Response	Agree to Use	Description Attached
10.	<p>RADIATION SAFETY PROGRAM (Cont.)</p> <p>Transportation No response is needed from applicants during the licensing phase.</p> <p>Minimization of Contamination The applicant does not need to provide a response to this item under the following condition: NRC will consider that the above criteria have been met if the applicant's responses meet the criteria in the following sections: Section 7.5.1, "Radioactive Material – Sealed Sources and Devices or Unsealed Radioactive Material;" Section 7.10, "Facilities and Equipment;" Section 7.16, "Radiation Safety Program – Safe Handling of Radionuclides and Emergency Procedures;" Section 7.17, "Radiation Safety Program – Surveys and Leak Tests;" and Section 7.21, "Waste Management."</p>		
11.	<p>WASTE MANAGEMENT Provide procedures for waste collection, storage, and disposal by any of the authorized methods described in this section. Applicants should contact the appropriate NRC Regional Office for guidance and obtain advance approval of any method(s) of waste disposal other than those discussed in this section.</p>		

Appendix C

SAMPLE LICENSE

LICENSEE	LICENSE NUMBER
1. PET DRUGS, Inc.	3. 0250025xxxx
2. 1 Woody Hayes Drive Sub-basement Columbus, Ohio 43213	EXPIRATION DATE
	4. July 1, 2008
	BUREAU DOCKET NUMBER
	5.

6. RADIOACTIVE MATERIAL	7. CHEMICAL AND/OR PHYSICAL FORM	8. MAXIMUM QUANTITY THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE
A. Flourine-18	A. Any form	A. 370 GBq (10 Curies)
B. Carbon-11	B. Any form	B. 370 GBQ (10 Curies)
C. Oxygen-15	C. Any form	C. 370 GBq (10 Curies)
D. Nitrogen-13	D. Any form	D. 370 GBQ (10 Curies)
E. Activation Products	E. Activated foils, cyclotron components, and concrete	E. 7.40 GBq (200 mCi)
F. Cobalt-57	F. Sealed source, Isotope Products Model RV-057-5M or equivalent	F. 222 MBq (6 mCi)
G. Cesium-137	G. Sealed source, Isotope Products Model RV-137-200U or equivalent	G. 11.1 MBq (300 µCi)

9. Authorized Use

- A - D. **Distribution of radioactive drugs to authorized recipients per 3701:1-46-43 of the Ohio Administrative Code.**
- E. **Activated foils and components removed from the cyclotron that was made radioactive incident to the production of Flourine-18, Carbon-11, Oxygen-15, and /or Nitrogen-13 being held for radioactive decay, and any incidental neutron activation products in the cyclotron vault concrete.**
- F - G. **Sealed sources for instrument calibration and check sources.**

CONDITIONS

10. Licensed material may only be used at the licensee's facilities located at:

1 Woody Hayes Drive
Sub-basement
Columbus, Ohio 43213

11. The Radiation Safety Officer for this license is: **Woody Hayes, R. Ph.**
12. Licensed material shall be limited by the procedures outlined in Sections 6, 7, and 8 of this license. Materials may only be used by, or under the supervision of, the below listed individual(s) designated in writing:

Authorized Nuclear Pharmacists

- A. **Woody Hayes R.Ph.**

13. **An Authorized Nuclear Pharmacist shall be physically present at the place of authorized use whenever licensed material is used.**
14. **Conditions for the use of sealed sources**
 - A. **Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six (6) months.**
 - B. **Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three (3) months.**
 - C. **In the absence of a certificate from a transferor indicating that a leak test has been made within the required leak test interval, a sealed source shall not be put into service until tested.**
 - D. **Sealed sources need not be tested if**
 1. **They contain only a radioactive gas; or**
 2. **The half-life of the radioisotope is 30 days or less; or**
 3. **They contain 3.7 MBq (100 µCi) or less of beta or gamma emitting material or 370 kBq (10 µCi) or less of alpha-emitting material; or**
 4. **They are in storage and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than ten years without being tested for leakage and/or contamination.**
 - E. **The leak test shall be capable of detecting the presence of 185 (5nCi) Bq of radioactive material on the test sample. If the test reveals the presence of 185 Bq (5 nCi) or more of removable contamination, a report shall be filed with the Ohio Department of Health, and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Ohio Department of Health regulations. The report shall be filed within 5 days of the date the leak test result is known with the Bureau of Radiation Protection - Ohio Department of Health, 246 N. High St., P.O. Box 118, Columbus, Ohio 43266-0118. The report shall specify the source involved, the test results, and corrective action taken.**
 - F. **Tests for leakage and/or contamination shall be performed by the licensee or other persons specifically licensed by the Director, the NRC, or an Agreement State, to perform such services.**
15. **All sealed sources that are used or obtained shall have been evaluated and approved under the provisions of rule 3701:1-46-49 of the Ohio Administrative Code or by equivalent NRC, Agreement State, or NARM licensing state regulation.**
16. **The licensee shall conduct a physical inventory every 6 months, or at another interval approved by the Director, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for at least three (3) years from the date of each inventory, and shall include: the quantities and kinds of licensed material, manufacturer's name and model numbers, location of the sources and/or devices, and the date of the inventory.**
17. **The licensee is authorized to transport licensed radioactive material in accordance with Chapter 3701:1-50 of the Ohio Administrative Code.**
18. **The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay in storage before disposal in ordinary trash, provided:**
 - A. **Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.**

Authorized Nuclear Pharmacists

- B. **Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.**

APPENDIX D

Radiation Safety Officer Duties and Responsibilities

The RSO's duties and responsibilities include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license (see Figure 8.5). Typically, these duties and responsibilities include the following:

- Ensure licensed material possessed by the licensee is limited to the types and quantities of licensed material listed on the license;
- Maintain documentation that demonstrates the dose to individual members of the public does not exceed the limit specified in OAC rule 3701:1-38-13;
- Ensure security of radioactive material;
- Post documents as required by OAC rule 3701:1-38-10;
- Ensure licensed material is transported in accordance with applicable Ohio, NRC and DOT requirements;
- Ensure that radiation exposures are ALARA;
- Oversee all activities (licensed and nonlicensed) involving radioactive material, including monitoring and surveys of all areas in which radioactive material is possessed or possessed and used;
- Act as liaison with the BRP and other regulatory authorities;
- Provide necessary information on all aspects of radiation protection to personnel at all levels of responsibility, pursuant to OAC Chapter 3701:1-38, and any other applicable regulations;
- Oversee proper transfer and delivery of radioactive material, and conduct radiation surveys for all shipments of radioactive material arriving at or leaving from the institution, as well as packaging and labeling all radioactive material leaving the institution;
- Distribute and process personnel radiation monitoring equipment, determine the need for and evaluate bioassays, monitor personnel radiation exposure and bioassay records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching established limits and recommend appropriate remedial action;
- Conduct training programs and otherwise instruct personnel in the proper procedures for handling radioactive material prior to possession or possession and use, both at periodic intervals (refresher training) and as required by changes in procedures, equipment or regulations;
- Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal records;
- Oversee the storage of radioactive material not in current use, including waste;
- Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments;

- Maintain an inventory of all radioisotopes possessed under the license and limit the quantity to the amounts authorized by the license;
- Immediately terminate any unsafe condition or activity that is found to be a threat to public health and safety or property;
- Supervise decontamination and recovery operations;
- Maintain other records not specifically designated above (e.g., records of production, transfers and surveys as required by OAC rule 3701:1-40-21 and OAC Chapter 3701:1-38, "Records");
- Hold periodic meetings with, and provide reports to, licensee management;
- Ensure all users are properly trained;
- Perform periodic audits of the Radiation Safety Program to ensure the licensee is complying with all applicable Ohio regulations, the terms and conditions of the license (e.g., leak tests, inventories, possession or possession and use limited to trained, approved users), the content and implementation of the Radiation Safety Program to achieve occupational doses and doses to members of the public that are ALARA in accordance with OAC rule 3701:1-38-11 and the requirement that all records be properly maintained;
- Ensure the results of audits, identification of deficiencies and recommendations for change are documented (and maintained for at least three years) and provided to management for review and ensure prompt action is taken to correct deficiencies;
- Ensure the audit results and corrective actions are communicated to all personnel who possess or possess and use licensed material;
- Ensure all incidents, accidents and personnel exposure to radiation in excess of ALARA or Chapter 3701:1-38 limits are investigated and reported to the BRP and other appropriate authorities, if required, within the required time limits; and
- Maintain an understanding of, and up-to-date copies of, Ohio regulations, the license and revised licensee procedures, and ensure the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to the BRP during the licensing process.

APPENDIX E

Radiation Safety Training

This appendix is intended only as a guide for developing a training program. Individuals working with radioisotopes may not require training on every topic provided. For example, housekeeping staff may need to know only what symbols to look for, which waste cans to empty or which areas to enter or avoid. Conversely, laboratory technicians may require detailed information on particular topics. As a result, instruction for some individuals may be accomplished by providing a simple handout whereas others may require extensive training, including a written exam to assess retention of the topics presented.

The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary. This assessment may be performed by a written test or observation of the individual in the performance of assigned duties. Remedial training for missed test questions or other areas of apparent weakness should be conducted or additional formal training planned to cover deficient areas.

Frequency of Training

- A. Before assuming duties with, or in the vicinity of, radioactive materials;
- B. Whenever there is a significant change in duties, regulations or the terms of the license; and
- C. Annually (refresher training).

General Information

- A. Radiation safety:
 - 1 radiation vs. contamination;
 - 2 internal vs. external exposure;
 - 3 biological effects of radiation;
 - 4 ALARA concept;
 - 5 use of time, distance, and shielding to minimize exposure;
 - 6 contact dose rates and dose rates at a distance from high-activity sources; and
 - 7 dose reduction responsibilities.

- B. Regulatory requirements:
 - 1 RSO;
 - 2 material control and accountability;
 - 3 personnel dosimetry;
 - 4 Radiation Safety Program audits;
 - 5 transfer and disposal;
 - 6 recordkeeping;
 - 7 surveys;
 - 8 postings;
 - 9 labeling of containers;
 - 10 handling and reporting of incidents or events;
 - 11 licensing and inspection by Ohio;
 - 12 need for complete and accurate information;
 - 13 employee protection;
 - 14 deliberate misconduct.

Licensee-specific Program Elements

- A. Authorized individuals and supervised individuals;
- B. Worker-specific production activities (e.g., maintenance of the accelerator);
- C. Shipping;
- D. Moving/transferring radioisotopes to different areas or licensees;
- E. Applicable regulations and license conditions;
- F. Areas where radioactive material is used or stored;
- G. Potential hazards associated with radioactive material in each area where the individuals will work;
- H. Appropriate radiation safety procedures;
- I. Licensee's in-house work rules (for instructions on laboratory safety and uses of radioisotopes, see Appendix I);
- J. Each individual's obligation to report unsafe conditions to the RSO;
- K. Appropriate response to spills, emergencies, or other unsafe conditions;
- L. Worker's right to be informed of occupational radiation exposure and bioassay results, if applicable; and
- M. Locations where the licensee has posted or made available: notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by OAC Chapter 3701:1-38.

N. Emergency procedures:

- 1 RSO name and telephone number;
- 2 immediate steps to prevent or control spread of contamination;
- 3 clean-up instructions, decontamination.

O. Survey program:

- 1 survey instrument accessibility;
- 2 who is responsible;
- 3 types, contamination and areas;
- 4 frequency;
- 5 levels of contamination;
- 6 personnel, hands, shoes;
- 7 records.

P. Waste:

- 1 liquid;
- 2 solids;
- 3 sanitary sewer;
- 4 burial (transfer to low-level waste repository);
- 5 storage;
- 6 decay-in-storage;
- 7 waste storage surveys;
- 8 incineration;
- 9 records.

Q. Dosimetry:

- 1 whole body;
- 2 extremities;
- 3 lost or replacement badges and dose assessment;
- 4 bioassay procedures;
- 5 records.

R. Instrumentation:

- 1 survey meters – use, calibration frequency, use of check sources;
- 2 analytical instruments – gas flow counters, liquid scintillation counters;

S. Procedures for receiving packages containing radioactive materials (if applicable):

- 1 normal;

- 2 off-duty;
- 3 notification of user and RSO;
- 4 security;
- 5 exposure levels;
- 6 possession limit;
- 7 receipt of damaged packages.

T. Sealed sources:

- 1 leak-test requirements;
- 2 inventory requirements;
- 3 exempt quantities;
- 4 records.

U. State/Licensee audit findings.

V. Other topics.

W. Question and answer period.

For Laboratory Safety and Use of Radioisotopes

- A. Control procedures for obtaining permission to possess or possess and use radioactive materials at the facility; give limitations on quantity to be handled per user, or allowed per experiment;
- B. Protective clothing and what laboratory apparel to wear and what equipment to use;
- C. Limitations and conditions relative to handling unsealed licensed material and what laboratory equipment to use when working with such material. For example, discuss which licensed materials and what procedures should be confined to radiochemical fume hoods or glove boxes. Explain what shielding or remote handling equipment is to be used when beta and/or gamma-emitting licensed materials are handled;
- D. Routine survey and monitoring procedures to be followed for contamination control. Include where and how contaminated articles and glassware are to be handled and stored;
- E. Emergency procedures concerning spills, fires, release of material and/or accidental contamination of personnel;
- F. Decontamination procedures to use and whom to contact in case of an emergency;
- G. Instructions concerning transfer of licensed materials between rooms, halls or corridors, if applicable;
- H. Requirements for storage, labeling of containers and identification of areas where licensed materials are possessed or possessed and used;

- I. Personnel monitoring devices to use, where to obtain them and exchange procedures and exposure results;
- J. Waste disposal procedures to follow, limitations for disposal of liquid or solid wastes and procedures to use for waste storage. If the program involves experiments with animals, procedures for cleaning animal quarters and handling animal excreta and carcasses for disposal;
- K. Records to be maintained on possession, use and disposal of licensed materials; and

- L. Prohibitions of pipetting by mouth, eating, smoking and drinking in areas where licensed materials are possessed or possessed and used.

APPENDIX F

Facilities and Equipment

Below is a list of topics that should be considered when developing a description of the facilities and equipment that a licensee will use or otherwise have available. Not every applicant will need to address each of these topics in its application.

- Restricted areas are defined as areas to which access is limited by the licensee to protect individuals against undue risks from exposure to radiation and radioactive materials. Restricted areas do not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area. Refer to OAC Chapter 3701:1-38 for more information regarding restricted area controls. The application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. Scaled drawings and sketches should be submitted showing the relationship between restricted areas and unrestricted areas and the location of all pertinent safety-related equipment. Drawings should show the uses of adjacent areas, including those beside, above and below, and a recitation of the various shielding materials in the separating surfaces.
- A site diagram should indicate buildings and areas and their uses such as research, production or waste storage.
- Bench top or open work areas may be used for sealed sources, for small quantities of solid materials in a form not likely to become airborne or dispersed and for small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Trays and/or absorbent surface covers to catch and retain spilled liquids should be used on these open work surfaces and inside the closed systems discussed below. Surfaces should be smooth and nonporous, to facilitate decontamination.
- Radioactive materials that are handled or used in unsealed forms should be confined to control the release of material and to prevent the spread of contamination. Gaseous, volatile and fine particulate solid materials should be handled in closed or isolated systems such as fume hoods, glove boxes or hot cells with controlled, and possibly filtered, exhaust systems.
- Chemical-type fume hoods provide a working area with controlled inward airflow from the room to the hood exhaust system. Hoods are used for gases, for unsealed volatile licensed materials and

for processes such as evaporation that may release gases and vapors. Fume hoods provide emergency ventilation and exhaust for unplanned releases, such as accidental spills and ruptures, as well as routine exhaust of effluents. Filters may be necessary for the exhaust stream unless monitoring and/or calculations demonstrate that any planned or likely effluent will be in accordance with the limits found in OAC Chapter 3701:1-38.

- Glove boxes are sealed boxes with transparent viewing windows, sealable ports and/or doors for transferring materials and equipment, and gloves sealed to the box through which licensed materials are handled. Glove boxes are used for the containment during storage and use of liquids and solids that can become airborne particulates or aerosols. Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.
- Hot cells are generally sealed, shielded compartments with transparent viewing windows, sealable ports and/or doors for handling high gamma/photon emitting radioactive materials. Generally, remote manipulator arms are used within the hot cell to manipulate/handle license materials. Also, hot cells can be used for gases, for unsealed volatile licensed materials and for processes such as evaporation that may release gases, fine particulates and vapors. Hot cells can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.
- Sink faucets should be designed, where possible, for operation by foot, knee or elbow rather than by hand.
- Plumbing and duct work should be designed to avoid radioactive contamination build-up. This build-up of contamination can create external radiation exposure hazards and problems for decommissioning.
- Shielding consisting of lead or other high-density material in the form of bricks, panels, L-shields, storage containers or other shapes may be used on bench tops, in fume hoods or in glove boxes to reduce radiation exposure from gamma-emitting radioactive materials. Shielded shipping containers are frequently used for continued storage after receipt of materials. Other shielding used may consist of high-density plastic for beta-emitting radioactive materials.
- Optimal shielding requirements will depend on the intensity and energy of the radiation; the type, quality and configuration of the local shielding in place; and the duration of personnel exposure in conducting the operation.
- The proper ventilation system is very important at production facilities. Systems should be designed to ensure adequate performance for each area in terms of flow rates and directions. When describing ventilation systems, applicants should provide a detailed description of the ventilation system, which includes location of air intakes for the building and any surrounding buildings, airflow rates, pressures and any filtration equipment that is used within the system.
- Particular sinks should be designated for disposal of liquid radioactive waste to the sanitary sewerage system. In some cases, depending on the number of users and the distance between areas

of use, more than one sink may need to be designated.

- Labeled waste containers should be used. These containers may be shielded as necessary, placed near the waste-generating areas, placed away from areas frequently occupied by personnel and secured from unauthorized removal. Additionally, these containers should be effectively enclosed to prevent airborne contamination from deposited radioactive materials.
- Remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials (ALARA). In addition, shielded handling devices, such as shielded syringes, can be used to protect workers from materials that cannot be handled remotely. Pipetting should be done using appropriate devices. Pipetting by mouth should be strictly forbidden.
- Where appropriate, ventilation systems should be designed such that, in the event of an accident, they can be shut down and isolated to contain radioactivity. For an accelerator facility, generally the ventilation system should be designed so the accelerator(s) has the most negative pressure and a higher air flow within the restricted areas of the facility. This is done to help avoid airborne contamination from possible high activity releases such as target ruptures or other failures within the accelerator during operation.
- Designated areas should be provided for coats and personal belongings, to avoid contamination.
- Areas with low background radiation levels should be designated for personnel dosimetry storage when not in use.
- Areas of use should be well-lighted to avoid spills and other accidents that could result in contamination buildup.
- Observation of activities conducted behind shielding with remote tools (or with extended arms and hands, within limits consistent with permissible occupational exposures) can be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields or by remote video monitoring.
- The combination of containment, shielding and handling devices proposed for any use of radioactive materials should be appropriate to the type and quantity of materials to be used and to the type and duration of the operations to be conducted.
- If respiratory protective equipment will be used to limit inhalation of airborne licensed material, follow the provisions of OAC Chapter 3701:1-38.
- If compaction of waste is performed, ensure the facilities are adequate for the ventilation of the area where the waste is compacted. In addition, also ensure air sampling for internal exposures is available, if needed per OAC rule 3701:1-38-12.

APPENDIX G

Radiation Monitoring Instrument Specifications and Model Survey Instrument and Air Sampler Calibration Program

The specifications in Table H.1 will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facility(ies).

Table H.1 Typical Survey Instruments¹ (Instruments used to measure radiological conditions at licensed facilities).

Portable Instruments Used for Contamination and Ambient Radiation Surveys

Detectors	Radiation	Energy Range/Range	Efficiency
REM Meter	Neutron	mrem – rem	Low
Exposure Rate Meters (e.g., ion chambers)	Gamma, X-ray	μR-R	N/A
Count Rate Meters			
Zinc Sulfide*	Alpha	All energies	Moderate
GM	Beta	All energies (dependent on window thickness)	Moderate
	Gamma	All energies	< 1%
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Gas Flow Proportional	Alpha	All energies	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
LSC*	Alpha	All energies	High
	Beta	All energies	High

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

Table from The Health Physics & Radiological Health Handbook, Revised Edition, Edited by Bernard Shleien, 1992 (except for * items).

Model Instrument Calibration Program

Training

Before allowing an individual to perform survey instrument calibrations, the RSO should ensure that he or she has sufficient training and experience to perform independent survey instrument calibrations.

Classroom training may be in the form of lecture, videotape or self-study and should cover the following subject areas:

- Principles and practices of radiation protection;
- Radioactivity measurements, monitoring techniques and using instruments;
- Mathematics and calculations basic to using and measuring radioactivity; and
- Biological effects of radiation.

Appropriate on-the-job-training should consist of the following:

- Observing authorized personnel performing survey instrument calibration; and
- Conducting survey meter calibrations under the supervision and in the physical presence of an individual authorized to perform calibrations.

Facilities and Equipment for Calibration of Dose Rate or Exposure Rate Instruments

- 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; and

- Individuals conducting calibrations will use a calibrated and operable survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Model Procedure for Calibrating Survey Instruments

A radioactive sealed source(s) used for calibrating survey instruments should:

- Approximate a point source;
- Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified to be within ± 5 percent accuracy by the National Institute of Standards and Technology (NIST);
- Approximate the same energy and type of radiation as the environment in which the calibrated device will be employed; and
- For dose rate and exposure rate instruments, the source should be strong enough to give an exposure rate of at least about 7.7×10^6 coulombs/kilogram/hour (30 mR/hr) at 100 cm [e.g., 3.1 gigabecquerels (85 mCi) of cesium-137 or 7.8×10^7 megabecquerels (21 mCi) of cobalt-60].

ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration" provides the following:

The three kinds of scales frequently used on dose or dose rate survey meters are calibrated as follows:

- Linear readout instruments with a single calibration control for all scales shall be adjusted at the point recommended by the manufacturer or at a point within the normal range of use. Instruments with calibration controls for each scale shall be adjusted on each scale. After adjustment, the response of the instrument shall be checked at approximately 20 percent and 80 percent of full scale. The instrument's readings shall be within ± 15 percent of the conventionally true values for the lower point and ± 10 percent for the upper point;
- Logarithmic readout instruments, which commonly have a single readout scale spanning several decades, normally have two or more adjustments. The instrument shall be adjusted for each scale according to site specifications or the manufacturer's specifications. After adjustment, calibration shall be checked at a minimum of one point on each decade. Instrument readings shall have a maximum deviation from the conventionally true value of no more than 10 percent of the full decade value; and
- Meters with a digital display device shall be calibrated the same as meters with a linear scale.

Note:

- Readings above 2.58×10^4 coulomb/kilogram/hour (1 R/hr) need not be calibrated, but such scales should be checked for operation and response to radiation; and
- The inverse square and radioactive decay law should be used to correct changes in exposure rate

due to changes in distance or source decay.

Surface Contamination Measurement Instruments²

- The efficiency of survey meters must be determined by using radiation sources with energies and types of radiation that are similar to those the survey instrument will measure.
- If each scale has a calibration potentiometer, the reading shall be adjusted to read the conventionally true value at approximately 80 percent of full scale, and the reading at approximately 20 percent of full scale shall be observed. If only one calibration potentiometer is available, the reading shall be adjusted at mid-scale on one of the scales, and readings on the other scales shall be observed. Readings shall be within 20 percent of the conventionally true value.

Model Procedures for Calibrating, Liquid Scintillation Counters, Gamma Counters, Gas Flow Proportional Counters and Multichannel Analyzers

A radioactive sealed source used for calibrating instruments should do the following:

- Approximate the geometry of the samples to be analyzed;
- Have its apparent source activity traceable by documented measurements to a standard certified to be within ± 5 percent accuracy by NIST; and
- Approximate the same energy and type of radiation as the samples that the calibrated device will be used to measure.

Calibration

- Calibration should produce readings within ± 20 percent of the actual values over the range of the instrument.
- Calibration of liquid scintillation counters should include quench correction.

Calibration Records

Calibration reports, for all survey instruments, should indicate the procedure used and the data obtained. The description of the calibration will include:

- The owner or user of the instrument;
- A description of the instrument, including the manufacturer's name, model number, serial number and type of detector;
- A description of the calibration source, including the exposure rate at a specified distance or

activity on a specified date;

- For each calibration point, the calculated exposure rate or count rate, the indicated exposure rate or count rate, the deduced correction factor (the calculated exposure rate or count rate divided by the indicated exposure rate or count rate) and the scale selected 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 whether the shielding was in place or removed during the calibration procedure;
- The exposure rate or count rate from a check source, if used; and
- 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:

- For exposure rate meters, the source isotope used to calibrate the instrument (with correction factors) for each scale;
- The efficiency of the instrument, for each isotope the instrument will be used to measure (if efficiency is not calculated before each use);
- For each scale or decade not calibrated, an indication the scale or decade was checked only for function but not calibrated;
- The date of calibration and the next calibration due date; and
- The apparent exposure rate or count rate from the check source, if used.

Air Sampler Calibration

In order to assess accurately the air concentration of radioactive materials in a given location, the volume of air sampled and the quantity of contaminant in the sample should be determined. Accurate determination of the volume of air sampled requires standard, reproducible and periodic calibration of the air metering devices that are used with air sampling instruments.

The publication titled “Air Sampling Instruments” found in the 9th Edition, American Conference of Governmental Industrial Hygienists, 2001, provides guidance on total air sample volume calibration methods acceptable to ODH staff, as supplemented below.

Frequency of Calibration

- A licensee committed to a routine or emergency air sampling program should perform an acceptable calibration of all airflow or volume metering devices at least annually.
- Special calibrations should be performed at any time there is reason to believe that the operating characteristics of a metering device have been changed, by repair or alteration or whenever system performance is observed to have changed significantly.
- Routine instrument maintenance should be performed as recommended by the manufacturer.
- Primary or secondary standard instruments used to calibrate air sampling instruments should be inspected frequently for consistency of performance.

Error Limit For Measurement of Air Sample Volume

Most methods for calibrating airflow or air volume metering devices require direct comparison to a primary or secondary standard instrument, to determine a calibration curve or a correction factor. An example of a primary standard is a spirometer that measures total air volume directly with high precision by liquid displacement. An example of a secondary standard is a wet-test meter that has been calibrated against a primary standard. Primary standards are usually accurate to within ± 1 percent and secondary standards to within ± 2 percent.

The following are significant errors associated with determining the total air volume sampled:

E_c : The error in determining the calibration factor. (An acceptable estimate is the percentage error associated with the standard instrument used in the calibration).³

E_s : Intrinsic error in reading the meter scale. (An acceptable estimate is the percentage equivalent of one-half of the smallest scale division, compared to the scale reading).

E_t : The percentage error in measurement of sampling time that should be kept within 1 percent.

E_v : The most probable value of the cumulative percentage error in the determination of the total air volume sampled.

E_v : can be calculated from the following equation, provided there are no additional significant sources of errors:

$$E_v = [E_s^2 + E_c^2 + E_t^2]^{1/2}$$

The most probable value of the cumulative error E_v , in the determination of total volume, should be less

than 20%.

A sample calculation of the most probable value of the cumulative error in total volume measured is as follows: If accuracies of the scale reading, the calibration factor and sample time are ± 4 , 2 and 1 percent, respectively, and there are no other significant sources of error, the cumulative error would be:

$$E_v = [4^2 + 2^2 + 1^2]^{1/2} = 4.58 \text{ percent or about 5 percent}$$

If there are significant differences in pressure and temperature between the calibration site and the sampling site, appropriate corrections should be made using the ideal gas laws provided below:

$$V_s = V_1 * (P_1/760) * (273/T_1)$$

where: V_s = volume at standard conditions (760 mm & 0C)

V_1 = volume measured at conditions P_1 and T_1

T_1 = temperature of V_1 in K

P_1 = pressure of V_1 in mm Hg

³

The calibration factor should be based on two kinds of determinations. First, correction factors should be determined at several flow rates distributed over the full-scale range. Each flow rate correction factor should be determined while adjusting flow rates upscale and again while adjusting flow rates downscale, and the two sets of data should be compared. Second, subsequent calibrations should compare the new correction factors to those determined during the previous calibration. If observed differences are significant compared to the overall volume error limit of 20 percent, an additional error term should be included in the calculation above.

Documentation of Calibration of Air Metering Devices

The licensee should maintain records of all routine and special calibrations of airflow or volume metering devices, including the primary or secondary standard used, method employed and estimates of accuracy of the calibrated metering devices. All instruments should be clearly labeled as to the date and results of the most recent calibration and should include the appropriate correction factors to be used.

References:

NUREG-1556 Vol. 18, "Program-Specific Guidance About Service Provider Licenses," dated November 2000.

Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992.

NUREG-1400, "Air Sampling in the Workplace," dated September 1993.

Additional References:

The Health Physics & Radiological Health Handbook, Third Edition, Edited by Bernard Shleien, dated 1998.

ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration." Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018 or ordered electronically at the following address: <http://www.ansi.org>.

"Air Sampling Instruments," American Conference of Governmental Industrial Hygienists, 9th Edition, dated 2001.

APPENDIX H
Guidance for Demonstrating That
Individual Members of the Public Will
Not Receive Doses Exceeding the
Allowable Limits

This appendix describes methods for determining radiation doses to members of the public.

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 millisievert (mSv) [100 mrem] in one calendar year resulting from the licensee's possession and/or use of licensed materials;
- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour; and
- Air emissions of radioactive material to the environment will not result in a TEDE in excess of 10 mrem (0.1 mSv) per year.

Members of the public include persons who live, work, study or may be near locations where byproduct material is used or stored and employees whose assigned duties do not include the use of byproduct material but may work in the vicinity where such materials are used or stored.

Doses to Members of the Public

INCLUDES doses from:

- Radiation and/or radioactive material released by a licensee;
- Sources of radiation under the control of a licensee; or
- Air effluents from sources of licensed radioactive materials.

DOES NOT INCLUDE doses from:

- Sanitary sewerage discharges from licensees;
- Natural background radiation;

- Medical administration of radioactive material; or
- Participation in medical research.

Typical unrestricted areas may include offices, shops, areas outside building's property and storage areas (where access is neither limited nor controlled by the licensee).

The licensee may show compliance with the annual dose limit for individual members of the public by:

- Demonstrating by measurement or calculation that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv (100 mrem);
- Demonstrating that the annual average concentration of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area does not exceed the values specified in OAC Chapter 3701:1-38; and if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (2 mrem) in an hour and 0.5 mSv (0.05 rem) in a year; and
- Demonstrating that air emissions of radioactive materials do not result in doses greater than the constraint limit of 0.1mSv (10 mrem) TEDE.

In order to perform a dose assessment, licensees should identify all potential sources of external and internal radiation exposure to members of the public and all locations of use, transport and storage of radioactive material at their facilities. Licensees must then take radiation measurements or perform calculations to demonstrate compliance with public dose limits.

Measurements

The licensee may use measurements to demonstrate that the average annual releases are within regulatory limits, as well as to demonstrate that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 1 mSv (100 mrem). These measurements may include:

- Dose rate surveys for radiation exposures from external radiation sources; and
- Measurements of radionuclides in air and water effluent.

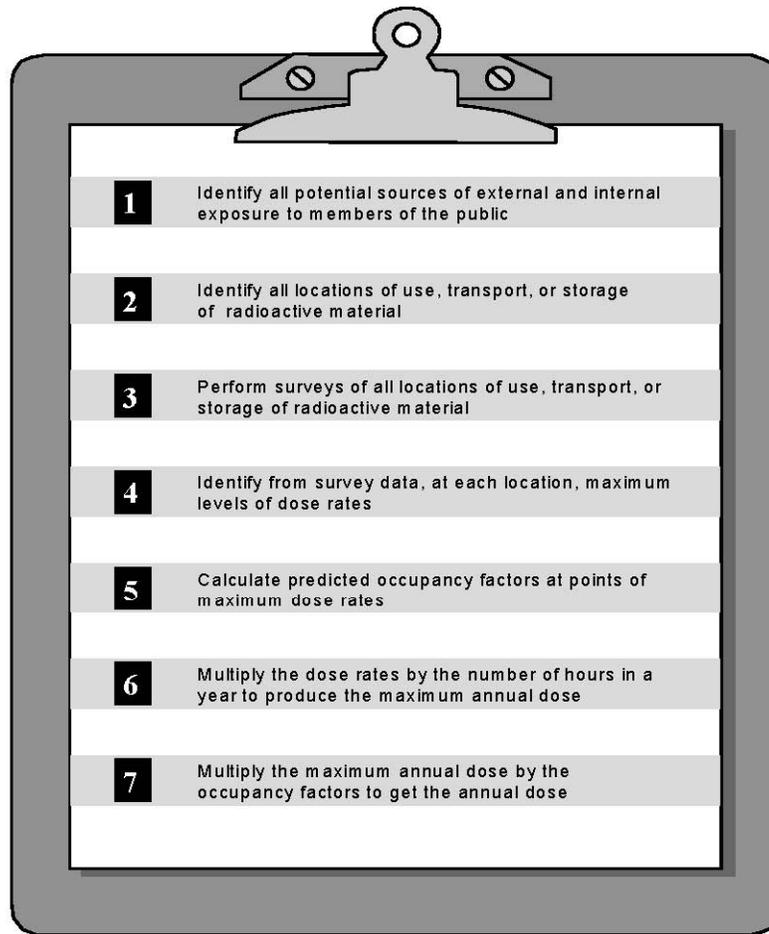
The method used to measure dose will depend upon the nature of the radiation source. If the source of radiation is constant, it may be adequate to measure the dose rate and integrate it over time. If the source of radiation differs or changes over time, it may be necessary to perform continuous measurements.

Radioactivity releases may be determined by effluent monitoring or by effluent sampling and analysis. Airborne effluents may be discharged when accelerator targets rupture during accelerator operation. Due to the uncertainty of this type of discharge, it is important to perform effluent monitoring continuously or at least during the operation of the accelerator. Liquid effluents may be discharged continuously or may be stored and subsequently discharged on a batch basis. For each type of source and for each route of potential exposure, consider the location of measurement points, whether continuous or periodic monitoring is required, the frequency of sampling and measurement and any additional information. For discharges of airborne radionuclides, for example, it may be necessary to obtain information on the efficiency of filters and the air flow rate of the discharge system, as well as meteorological data and the distance to the nearest individual member of the public.

Calculation Method

Using a calculation method, the licensee should determine the highest dose an individual is likely to receive at the boundary of the unrestricted area. The licensee must take into account the individual's exposure from external sources and the concentration of radionuclides in gaseous and liquid releases. In practice, the licensee may wish to make conservative assumptions to simplify the dose calculation.

The public dose limit applies to the individual who is likely to receive the highest dose from licensed operations. Therefore, the dose calculations must consider the location with the potential for the highest internal and external exposures. A conservative calculation should assume the individual was continuously present 24 hours a day, 365 days a year, or an occupancy factor of 1 (see Table I.1). If the result of the calculation using an occupancy factor of 1 demonstrates the public dose limit is not exceeded, then there is no need for further evaluation. Figure I.1 provides the steps on how to calculate the annual dose to an individual member of the public.



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Figure I.1 Calculating Public Dose. *Steps to calculate the annual dose to an individual member of the public.*

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If the calculation demonstrates the public dose limit is exceeded with an occupancy factor of 1, then more realistic assumptions of the individual's occupancy at the points of highest internal and external exposures may be made. The licensee may use the occupancy factors in Table I.1 or may calculate a specific occupancy factor by determining the likely fraction of time that the individual is present.

Table I.1 Standard Occupancy Factors.

Occupancy Factor	Description
1	Work areas such as offices, laboratories, shops, and occupied space in nearby buildings or outdoor areas.
1/4	Corridors, lounges, elevators using operators, unattended parking lots.
1/16	Waiting rooms, rest rooms, stairways, unattended elevators, janitor's closets, outside areas used only for pedestrians or vehicular traffic.

Records

The licensee must maintain records to demonstrate compliance with the dose limit for individual members of the public until ODH terminates the license. In general, survey and monitoring records of ambient radiation and effluent radioactivity should be adequate.

Records demonstrating the dose to an individual member of the public should identify the instruments used in the survey; the name of the surveyor; the date of the survey; the location of the survey(s), including a description or drawing of the area surveyed; survey results; and if applicable, the occupancy factors used and justification for their use. In addition, records demonstrating the dose to an individual member of the public that involve effluent sampling analysis should include information on concentrations of specific radionuclides, minimum detectable activity of the system and the estimated uncertainty of measurements.

APPENDIX I

General Topics for Safe Possession and Use of Radioactive Materials and Model Emergency Procedures

This appendix describes general topics for safe possession and use of radioactive materials, and procedures for handling and reporting emergencies.

General Topics for Safe Possession and Use of Radioactive Materials

Each area where radioactive material is produced, handled or stored should have general rules, so that workers know what is required. Typical instructions should include:

- Wear a laboratory coat or other protective clothing at all times in areas where licensed materials are handled;
- Wear disposable gloves at all times when handling licensed materials;
- After each procedure or before leaving the area, monitor hands, shoes and clothing for contamination in a low-background area;
- Do not eat, drink, smoke or apply cosmetics in any area where licensed material is stored or used;
- Do not store food, drink or personal effects in areas where licensed material is stored or used (see Figure J.1);
- Wear personnel monitoring devices, if required, at all times while in areas where licensed materials are handled or stored;
- Dispose of radioactive waste only in designated, labeled and properly shielded receptacles;
- Never pipette by mouth;
- Store radioactive solutions in clearly labeled containers; and
- Secure all licensed material when it is not under the constant surveillance and immediate control of the user(s).

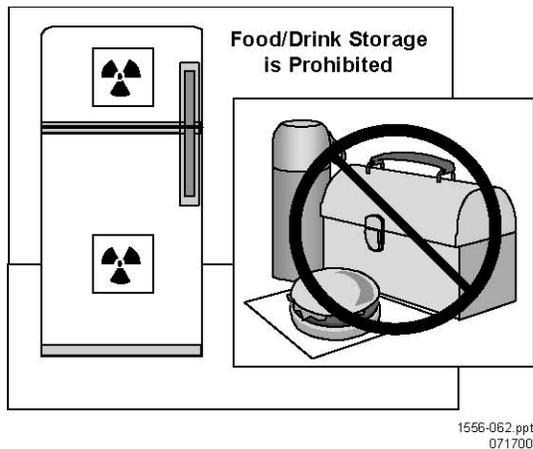


Figure J.1 Storage of Food and Drink. *Food or drink shall not be stored in refrigerators with radioisotopes.*

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Radionuclide-Specific Procedures

Licenseses should develop written procedures for use of different radionuclides so users know the types of shielding, protective clothing, survey instruments, surveys and decontamination activities that are required. Examples of such procedures are included below.

Example 1:

If requesting more than 37 MBq (1 mCi) of iodine-123 or iodine-131, special safety instructions should be provided to users, including provisions for the following:

- A mandatory radiation survey and wipe test for radioactive contamination after each use;
- Bioassay procedures for individuals working with millicurie quantities of radioiodine;
- The use of vented hoods for iodination and for the storage of millicurie quantities of radioiodine;
- A dry run prior to the performance of unfamiliar procedures, in order to preclude unexpected complications. In addition, it is recommended that the RSO be present during new procedures; and
- Procedures for measuring the concentration of radioiodine effluents from the hoods.

Example 2:

If requesting more than 37 MBq (1 mCi) of fluorine-18, special safety instructions should be provided to users, including provisions for the following:

- The use of high-density materials (e.g., lead, tungsten), layered properly, in order to keep radiation exposure to a minimum;
- A mandatory radiation survey and wipe test for radioactive contamination after each use;
- The use of extremity monitors for procedures that involve one millicurie or more; and
- A dry run prior to the performance of unfamiliar procedures in order to preclude unexpected complications. In addition, it is recommended that the RSO be present during new procedures.

Model Procedures for Handling Emergencies

The following are acceptable procedures for responding to emergencies:

Appropriate first aid and other immediate medical needs of injured individuals should not be neglected, delayed or ignored due to suspected contamination.

General Safety Procedures to Handle Spills

Name and telephone number of RSO or an alternate person(s) should be posted conspicuously in areas of use, so that they are readily available to workers in case of emergencies. The licensee should have emergency equipment readily available for handling spills. Spill kits should include the following:

- Disposable gloves;
- 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;
- Box of wipes;
- Instructions for “Emergency Procedures”;
- Clipboard with a copy of the Radioactive Spill Report Form for the facility;
- Pen or pencil; and

- Appropriate calibrated survey instruments including batteries (for survey meters).

Minor Spills of Liquids and Solids

Instructions to Workers:

- Notify persons in the area that a spill has occurred;
- Prevent the spread of contamination by covering the spill with absorbent paper (paper should be dampened if solids are spilled);
- Clean up the spill, wearing disposable gloves and using absorbent paper;
- Carefully fold the absorbent paper with the clean side out and place in a plastic bag for transfer to a radioactive waste container. Put contaminated gloves and any other contaminated disposable material in the bag;
- Survey the area with an appropriate low-range radiation detector survey meter or other appropriate technique. Check the area around the spill for contamination. Also check hands, clothing and shoes for contamination;
- Report the incident to the RSO promptly;
- Allow no one to return to work in the area unless approved by the RSO;
- Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples); and
- Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

Reminders to RSO:

- Follow up on the decontamination activities and document the results;
- As appropriate, determine cause and corrective actions needed; consider bioassays if licensed material may have been ingested, inhaled and/or absorbed through the skin; and
- If necessary, notify BRP.

Major Spills of Liquids and Solids

- Instructions to Workers:

Clear the area. If appropriate, survey all persons not involved in the spill and vacate the room;

Prevent the spread of contamination by covering the spill with absorbent paper (paper should be dampened if solids are spilled), but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated:

- Shield the source only if it can be done without further contamination or significant increase in radiation exposure;
- Close the room and lock or otherwise secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred;
- Notify the RSO immediately;
- Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with a mild soap;
- Allow no one to return to work in the area unless approved by the RSO;
- Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples); and
- Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision of bioassay samples, requested documentation).

Reminders to RSO:

- Confirm decontamination of personnel. If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration;
- Supervise decontamination activities and document the results. Documentation should include location of surveys and decontamination results;
- Determine cause and needed corrective actions; consider the need for bioassays if licensed material may have been ingested, inhaled and/or absorbed through the skin; and
- If necessary, notify BRP.

Note: For production facilities, the criteria for minor or major spills are generally determined based on exposure rate (e.g., minor spills < 50 mR/hr, major spills \approx 50 mR/hr).

Incidents Involving Radioactive Dusts, Mists, Fumes, Organic Vapors and Gases

Instructions to Workers:

- Notify all personnel to vacate the room immediately;
- Shut down the ventilation system, if appropriate, to prevent the spread of contamination throughout the system and other parts of the facility;
- Vacate the room.
- Seal the area, if possible;
- Notify the RSO immediately;
- Ensure that all access doors to the area are closed and posted with radiation warning signs, or post guards (trained) at all access doors to prevent accidental opening of the doors or entry to the area;
- Survey all persons who could have possibly been contaminated. Decontaminate as directed by the RSO;
- Promptly report suspected inhalation and ingestion of licensed material to the RSO;
- Decontaminate the area only when advised and/or supervised by the RSO;
- Allow no one to return to work in the area unless approved by the RSO;
- Cooperate with RSO/RSO staff (e.g., investigation of root cause, provision of requested bioassay samples); and
- Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, provision and collection of bioassay samples, requested documentation).

Reminders to RSO:

- Supervise decontamination activities;
- Perform air sample surveys in the area before permitting resumption of work with licensed materials;

- Provide written directions to potentially contaminated individuals about providing and collecting urine, breath, blood or fecal samples, etc;
- Consider the need for a medical exam and/or whole body count before permitting involved individuals to return to work with licensed material;
- Determine cause and corrective actions needed; consider the need for bioassays if licensed material may have been ingested, inhaled, and/or absorbed through the skin. Document incident; and
- If necessary, notify Ohio Bureau of Radiation Protection.

Minor Fires

Instructions to Workers:

- If possible, immediately attempt to put out the fire by approved methods (e.g., fire extinguisher) if other fire hazards or radiation hazards are not present;
- Notify all persons present to vacate the area and have one individual immediately call the RSO and fire department or 911 (as instructed by RSO);
- Once the fire is out, isolate the area to prevent the spread of possible contamination;
- Ensure that injured personnel receive medical attention;
- Survey all persons involved in combating the fire for possible contamination;
- Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water, then washing with a mild soap;
- In consultation with the RSO, determine a plan of decontamination and the types of protective devices and survey equipment that will be necessary to decontaminate the area;
- Allow no one to return to work in the area unless approved by the RSO; and
- Follow the instructions of the RSO (e.g., decontamination techniques, surveys, provision and collection of bioassay samples, requested documentation).

Reminders to RSO:

- Notify emergency medical personnel of any injured individuals who may be contaminated. Provide radiation safety assistance (e.g., monitoring) as needed or requested;

- Supervise decontamination activities at the facility;
- If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration;
- Consult with fire safety officials to ensure there is no likelihood of fire restarting and it is safe to re-enter the building;
- Determine cause and needed corrective actions; consider the need for bioassays if licensed material may have been ingested or inhaled. Document incident; and
- If necessary, notify BRP.

Fires, Explosions, or Major Emergencies

Instructions to Workers:

- Notify all persons in the area to leave immediately;
- Notify the fire department or 911;
- Notify the RSO and other facility safety personnel;
- Ensure injured personnel receive medical attention;
- Upon arrival of firefighters, inform them where radioactive materials are stored or where radioisotopes were being used; inform them of the present location of the licensed material and the best possible entrance route to the radiation area, as well as any precautions to avoid exposure or risk of creating radioactive contamination by use of high pressure water;
- Allow no one to return to work in the area unless approved by the RSO; and
- Follow the instructions of the RSO (e.g., decontamination techniques, surveys, provision and collection of bioassay samples, requested documentation).

Reminders to RSO:

- Notify emergency medical personnel of any injured individuals who may be contaminated. Provide radiation safety assistance (e.g., monitoring) as needed or requested;

- Coordinate activities with local fire department or other emergency personnel;
- Consult with the firefighting personnel or other emergency personnel and set up a controlled area where personnel can be surveyed for contamination of their protective clothing and equipment after the fire is extinguished;
- Once the fire is extinguished, provide assistance to firefighters or other emergency personnel who may need to re-enter restricted areas to determine the extent of the damage to the licensed material use and storage areas. To the extent practical, assist firefighters and emergency personnel in maintaining their exposures ALARA if the fire resulted in a significant release of radioactive material or loss of shielding capability, such that excessive radiation levels (greater than 100 mrem per hour) are created;
- Perform thorough contamination surveys of firefighters and emergency personnel and their equipment before they leave the controlled area, and decontaminate if necessary;
- Supervise decontamination activities;
- Consider bioassays if licensed material may have been ingested or inhaled. Document incident; and
- If necessary, notify BRP.

Copies of emergency procedures should be provided to all users. A current copy of the emergency procedures should be posted in each area where radioactive material is used.

APPENDIX J
Typical Notification and Reporting
Requirements

This appendix lists some typical notification and reporting requirements found in Title 10 of the Code of Federal Regulations. It is not meant to be all inclusive.

Table K.1 Typical Ohio Notifications and/or Reports.

Event	Telephone Notification	Written Report	Regulatory Requirement
Theft or loss of material (for certain quantities)	immediate	30 days	OAC rule 3701:1-38-21
Whole body dose greater than 0.25 Sv (25 rems)	immediate	30 days	OAC rule 3701:1-38-21
Extremity dose greater than 2.5 Sv (250 rems)	immediate	30 days	OAC rule 3701:1-38-21
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	OAC rule 3701:1-38-21
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	OAC rule 3701:1-38-21
Whole body dose greater than 0.05 Sv (5 rems)	none	30 days	OAC rule 3701:1-38-21
Dose to individual member of public greater than 1 mSv (100 mrems)	none	30 days	OAC rule 3701:1-38-21
Defect in equipment that could create a substantial safety hazard	2 days	30 days	OAC rule 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	OAC rule 3701:1-40-20
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	OAC rule 3701:1-40-20
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material (for certain conditions)	24 hours	30 days	OAC rule 3701:1-40-20

Note: Telephone notifications shall be made to BRP at 614-644-2727.

APPENDIX K

Radiation Safety Survey Topics

This appendix provides applicants and licensees with additional information on surveys, including training requirements, survey frequency, contamination limits and bioassays.

Training

Before allowing an individual to perform surveys, the RSO should ensure that he or she has sufficient training and experience to perform surveys independently.

Academic training may be in the form of lecture, videotape or self-study and will cover the following subject areas:

- Principles and practices of radiation protection;
- Radioactivity measurements, monitoring techniques and using instruments;
- Mathematics and calculations;
- Using and measuring radioactivity; and
- Biological effects of radiation.

Appropriate on-the-job-training consists of the following:

- Observing authorized personnel using survey equipment, collecting samples and analyzing samples; and
- Using survey equipment, collecting samples and analyzing samples under the supervision and in the physical presence of an individual authorized to perform surveys.

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, survey samples should be analyzed in a low-background area.
- A gamma counter system with a single or multichannel analyzer can be used to count samples containing gamma emitters (e.g., cesium-137, cobalt-60).
- A liquid scintillation or gas-flow proportional counting system can be used to count samples containing alpha emitters, beta emitters and gamma emitters (if efficiency is great enough to achieve the required sensitivity for measurements).

Ambient Radiation Level Surveys

- Dose-rate surveys, at a minimum, should be performed 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. It is also recommended that area monitors be used in areas where high-energy gamma/photon-emitting radioactive materials or radiation are produced and handled.
- OAC rule 3701:1-38-13 requires that the total effective dose equivalent to an individual member of the public from the licensed operation does not 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 (2 mrem) in any one hour.

Contamination Surveys

Licenses' contamination surveys should be sufficient to identify areas of contamination that might result in doses to workers or to the public. Combined removable and fixed contamination should be surveyed using appropriate radiation detection equipment. Removable contamination can be detected and measured through a wipe test of the surface, which is 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.

Contamination surveys should be performed:

- To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, work benches 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, or 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 quarterly; and
- In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.

Contamination Survey Frequency

Personnel should survey for contamination in locations where individuals are working with an unsealed form of radioactive material in an amount greater than or equal to 10 percent of the smallest ALI (either the inhalation or ingestion ALI) listed for that radionuclide in OAC Chapter 3701:1-38.

These surveys should be done at a frequency appropriate to the types and quantities of radioactive materials in use, but at a minimum, quarterly. If amounts are used that are greater than or equal to the smallest ALI listed for that radionuclide in OAC Chapter 3701:1-38, detailed, documented surveys should be performed at least monthly.

Table L.1 contains the suggested contamination survey frequency from Regulatory Guide 8.23. (See Tables L.2, L.3, and L.4 for alternate survey frequencies).

Table L.1 Suggested Frequency of Contamination Surveys from Regulatory Guide 8.23.

Areas Where RAM Has Been Used	Frequency
Areas where > 7.4 MBq (200 μ Ci) is used at any one time	Weekly
Areas where < 7.4 MBq (200 μ Ci) is used at any one time	Monthly

Alternate Survey Frequency Classification of Laboratories or Areas of Use Table L.2

Survey Frequency Category.

Group	Low	Medium	High
1	< 370 kBq (10 μ Ci)	370 kBq (10 μ Ci) to 37 MBq (1 mCi)	> 37 MBq (1 mCi)
2	< 37 MBq (1 mCi)	37 MBq (1 mCi) to 3.7 GBq (100 mCi)	> 3.7 GBq (100 mCi)
3	< 3.7 GBq (100 mCi)	3.7 GBq (100 mCi) to 370 GBq (10 Ci)	>370 GBq (10 Ci)
4	< 370 GBq (10 Ci)	370 GBq (10 Ci) to 37 TBq (1000 Ci)	> 37 TBq (1000 Ci)

Proportional fractions should be used for more than one isotope.

Table L.3 Survey Frequency Category Modifiers.

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 nonoccupational persons	x 0.1
Dry and dusty operations (e.g., grinding)	x 0.01

The object is to determine how often to survey the laboratory or area of use. To do this, multiply the activity range under the LOW, MEDIUM and HIGH survey frequency in Table L.2 by the appropriate Modifying Factor to construct a new set of FCI ranges for LOW, MEDIUM and HIGH survey frequency.

Survey Frequency:

- Low – Not less than once a month;
- Medium – Not less than once per week; and
- High – Not less than once per normal working day.

Table L.4 Isotope Groups.

Group 1	Pb-210 Po-210 Ra-223 Ra-226 Ra-228 Ac-227 Th-227 Th-228 Th-230 Pa-231 U-230 U-232 U-233 U-234 Np-237 Pu-238 Pu-239 Pu-240 Pu-241 Pu-242 Am-241 Am-243 Cm-242 Cm-243 Cm-244 Cm-245 Cm-246 Cf-249 Cf-250 Cf-252
Group 2	Na-22 Cl-36 Ca-45 Sc-46 Mn-54 Co-56 Co-60 Sr-89 Sr-90 Y-91 Zr-95 Ru-106 Ag-110m Cd-115m In-114m Sb-124 Sb-125 Te-127m Te-129m I-124 I-125 I-126 I-131 I-133 Cs-134 Cs-137 Ba-140 Ce-144 Eu-152 (13 y) Eu-154 Tb-160 Tm-170 Hf-181 Ta-182 Ir-192 Tl-204 Bi-207 Bi-210 At-211 Pb-212 Ra-224 Ac-228 Pa-230 Th-234 U-236 Bk-249
Group 3	Be-7 C-14 F-18 Na-24 Cl-38 Si-31 P-32 S-35 Ar-41 K-42 K-43 Ca-47 Sc-47 Sc-48 V-48 Cr-51 Mn-52 Mn-56 Fe-52 Fe-55 Fe-59 Co-57 Co-58 Ni-63 Ni-65 Cu-64 Zn-65 Zn-69m Ga-72 As-73 As-74 As-76 As-77 Se-75 Br-82 Kr-85m Kr-87 Rb-86 Sr-85 Sr-91 Y-90 Y-92 Y-93 Zr-97 Nb-93m Nb-95 Mo-99 Tc-96 Tc-97m Tc-97 Tc-99 Ru-97 Ru-103 Ru-105 Rh-105 Pd-103 Pd-109 Ag-105 Ag-111 Cd-109 Cd-115 In-115m Sn-113 Sn-125 Sb-122 Te-125m Te-127 Te-129 Te-31m Te-132 I-130 I-132 I-134 I-135 Xe-135 Cs-131 Cs-136 Ba-31 La-140 Ce-141 Ce-143 Pr-142 Pr-143 Nd-147 Nd-149 Pm-147 Pm-149 Sm-151 Sm-153 Eu-152 Eu-155 Gd-153 Gd-159 Dy-165 Dy-166 Ho-166 Er-169 Er-171 (9.2 hr) Tm-171 Yb-175 Lu-177 W-181 W-185 W-187 Re-183 Re-186 Re-188 Os-185 Os-191 Os-193 Ir-190 Ir-194 Pt-191 Pt-193 Pt-197 Au-196 Au-198 Au-199 Hg-197 Hg-197m Hg-203 Tl-200 Tl-201 Tl-202 Pb-203 Bi-206 Bi-212 Rn-220 Rn-222 Th-231 Pa-233 Np-239
Group 4	H-3 O-15 Ar-37 Co-58m Ni-59 Zn-69 Ge-71 Kr-85 Sr-85m Rb-87 Y-91m Zr-93 Nb-97 Tc-96m Tc-99m Rh-103m In-113m I-129 Xe-131m Xe-133 Cs-134m Cs-135 Sm-147 Re-187 Os-191m Pt-193m Pt-197m Th-232 Th-Nat U-235 U-238 U-Nat

Contamination in Unrestricted Areas

Contamination found in unrestricted areas should be immediately decontaminated to background levels. When it is not possible to get to background levels, the licensee should ensure the amounts do not exceed the contamination levels listed in Table L.5.

Table L.5 Acceptable Surface Contamination Levels.

Nuclide¹	Average^{2,3}	Maximum^{2,4}	Removable^{2,5}
I-123, I-125, I-129	1.7 Bq/100 cm ² (100 dpm/100 cm ²)	5.0 Bq/100 cm ² (300 dpm/100 cm ²)	0.3 Bq/100 cm ² (20 dpm/100 cm ²)
I-126, I-131, I-133, Sr-90	16.7 Bq/100cm ² (1,000 dpm/ 100 cm ²)	50.0 Bq/100 cm ² (3,000 dpm/ 100 cm ²)	3.3 Bq/100 cm ² (200 dpm/100 cm ²)
Alpha emitters	8.33 Bq/100 cm ² (500 dpm/100 cm ²)	25 Bq/100 cm ² (1500 dpm/100 cm ²)	1.67 Bq/100 cm ² (100 dpm/100 cm ²)
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	83.3 Bq/100 cm ² (5,000 dpm/100 cm ²)	250 Bq/100 cm ² (15,000 dpm/ 100 cm ²)	16.7 Bq/100 cm ² (1,000 dpm/100 cm ²)

¹ Where surface contamination by both alpha- and beta-gamma-emitting nuclides exists, the limits established for alpha- and beta-gamma-emitting nuclides should apply independently.

² As used in this table, dpm (disintegration per minute) 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 100 square centimeters. 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.

When equipment or facilities that are potentially contaminated are to be released for unrestricted use, the above table provides the maximum acceptable residual levels. To the extent practicable, it is appropriate to decontaminate to below these levels. Surface contamination surveys should be conducted for both removable and fixed contamination before these facilities or equipment are released from restricted to unrestricted use, to ensure they meet these limits. A standardized method for smear testing of a relatively uniform area should be used to aid in comparing contamination at different times and places. A smear taken from an area of about 100 cm² is acceptable to indicate levels of removable contamination.

Survey Record Requirements

Each survey record should include the following:

- A diagram of the area surveyed (See Figure L.1);
- A list of items and equipment surveyed;
- Specific locations on the survey diagram where the wipe test was taken;
- Ambient radiation levels with appropriate units;
- Contamination levels with appropriate units;
- Make, model and serial number of the instruments used;
- Background levels; and
- Name of the person making the evaluation and recording the results and date.

Area Diagram Radioactive

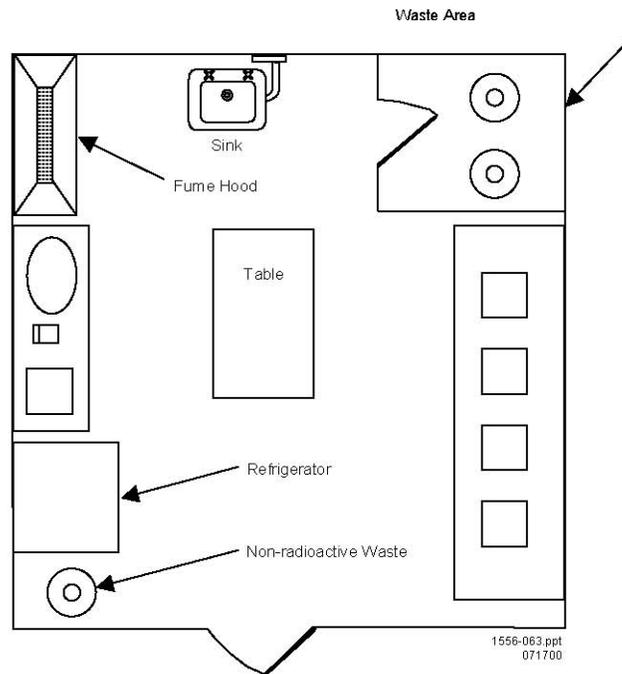


Figure L.1 Area Diagram. *This is an example of a laboratory survey map.*

Licenseses should record contamination levels observed and procedures followed for incidents involving contamination of individuals. The record should 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.

Air Monitoring in the Workplace

Air monitoring can be used to do the following:

- Determine whether the confinement of radioactive materials is effective;
- Measure airborne radioactive material concentrations in the workplace;
- Estimate worker intakes of radioactive material;
- Determine posting requirements;

- Determine what protective equipment and measures are appropriate; and
- Warn of significantly elevated levels of airborne radioactive materials.

If bioassay measurements are used to determine worker doses of record, air sampling may be used to determine time of intake and to determine which workers should have bioassay measurements. The use of engineering controls and a good air sampling program can eliminate the need for bioassays.

Refer to Regulatory Guide 8.25, Revision 1, “Air Sampling in the Workplace,” dated June 1992, and NUREG-1400, “Air Sampling in the Workplace,” dated September 1993, or the current revision, for further guidance on air sampling.

Airborne Effluent Release Monitoring

When practicable, airborne radioactive effluents should be released from monitored release points (e.g., monitored stacks, discharges, vents) to provide accurate measurements to estimate public exposure. Licensees should verify the performance of effluent monitoring systems by regular calibration (at least annually) to ensure their reliability.

Regulatory Guide 4.20, “Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors,” dated December 1996, provides guidance on methods acceptable (calculation or COMPLY code) to BRP for compliance with the constraint on air emissions to the environment.

Regulatory Guide 8.37, “ALARA Levels for Effluents from Materials Facilities,” dated July 1993, provides guidance on designing an acceptable program for establishing and maintaining ALARA levels for gaseous and liquid effluents at materials facilities.

For release points for which monitoring is not practicable, the licensee should estimate the magnitude of the unmonitored effluents. These unmonitored releases will occur any time unsealed material is handled outside a fume hood or other device that will control the releases. The licensee should include these estimates when demonstrating compliance with dose limits and ALARA goals. Unmonitored releases may be estimated based on the quantity of material used in these areas or the number of procedures performed or other appropriate methods. The unmonitored effluents should not exceed 30 percent of the total estimated effluent releases or 10 percent of the permissible air effluent concentrations found in OAC Chapter 3701:1-38, whichever is greater.

Effluent monitoring systems should be designed in accordance with ANSI N13.1 (1969), “Document to Sampling Airborne Radioactive Materials in Nuclear Facilities,” and ANSI N42.18, “Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents.”

Liquid Effluent Release Monitoring

The licensee should evaluate the concentrations of radioactive material in water that is released to the environment and to the sanitary sewer. The licensee must show these releases meet the limits in OAC rules 3701:1-38-13 and 3701:1-38-19, respectively.

The topic of sanitary sewer releases is more fully discussed in Appendix N.

Bioassay Monitoring Frequency of Required Bioassay Measurements

Determining the appropriate frequency of routine bioassay measurements depends upon the exposure potential and the physical and chemical characteristics of the radioactive material, and the route of entry to the body. Consider the following elements:

- Potential exposure of the individual;
- Retention and excretion characteristics of the radionuclide;
- Sensitivity of the measurement technique; and
- Acceptable uncertainty in the estimate of intake and committed dose equivalent.

Bioassay measurements used for demonstrating compliance with the occupational dose limits should be conducted often enough to identify and quantify potential exposures and resultant intakes that, during any year, are likely to collectively exceed 0.1 times the ALI. The 10 percent ALI criterion is consistent with OAC rule 3701:1-38-14, which require licensees to monitor intakes and assess occupational doses for exposed individuals who are likely to exceed 10 percent of the applicable limit (i.e., intakes likely to exceed 0.1 ALI for adults).

Separate categories of bioassay measurements, routine measurements and special measurements further determine the frequency and scope of measurements.

Routine Measurements

Routine measurements include baseline measurements, periodic measurements and termination measurements. These measurements should be conducted to confirm appropriate controls exist and to assess dose. The method of bioassay selected (for example, whole body counting and urinalysis) and the samples collected will vary according to the radionuclides and the compound to which it is attached. Sample collection procedures should be developed to ensure appropriate types, sizes and numbers of samples are collected that will provide appropriate physiological information for the dose assessment.

An individual's baseline measurement of radioactive material within the body should be conducted before beginning work that involves exposure to radiation or radioactive materials for which monitoring is required.

In addition to the baseline measurements, periodic bioassay measurements should be performed. The frequency of periodic measurements should be based on the likelihood of significant exposure of the individual. In determining the worker's likely exposure, consider such information as the worker's access, work practices, measured levels of airborne radioactive material and exposure time.

Periodic measurements should be made when the cumulative exposure to airborne radioactivity is > 0.02 ALI (40 DAC hours). Noble gases and airborne particulates with a radioactive half-life of less than two hours should be excluded from the evaluation, because external exposure generally controls these radionuclides.

At a minimum, periodic measurements should be conducted annually. Periodic measurements provide additional information on any long-term accumulation and retention of radioactive material in the body, especially for exposures to concentrations of airborne radioactive material below monitoring thresholds.

When an individual is no longer subject to the bioassay program because of a change in employment status, a termination bioassay measurement should be made, when practicable, to ensure any unknown intakes are quantified.

Collection of Emergency Bioassay Samples

In the event of an emergency where an individual becomes contaminated and radioactive material has been taken into the body through skin absorption or other means, or is suspected of having ingested or inhaled radioactive material, an estimate of the amount of material taken into the body should be performed. Frequently, this estimate is made by performing a bioassay of the individual. Bioassays may be performed through direct methods such as whole body counting or thyroid counting, where the radioactive material in the body can be directly measured using appropriate instruments. Bioassays may also be performed through indirect means such as sampling urine or other excreta from the body and calculating the intake from the amount of material detected in the samples, the time between suspected intake and sample collection, and knowledge of the rate of excretion of the compound and/or radionuclide from the body. While there are many ways to perform the calculations, including using computer models, the method of calculation is only as good as the quality of the samples and analyses performed. Because a dose estimate may be required, bioassay procedures for a suspected intake may differ from those in a routine bioassay screening program, and the licensee's Radiation Safety Program should include procedures and equipment for appropriate sample collection in an emergency.

The following items should be considered in developing your procedures:

- Type of bioassay that must be performed (direct or indirect);
- Number of samples or data points to be collected;
- Frequency of sampling (hourly, daily, weekly, once, etc.);
- Size of the sample to be collected (e.g., 24-hour urine collection);
- Ease/difficulty of sample collection; and
- Need for written instructions to be provided to the sample collector, who may be the contaminated individual.

Special Monitoring

Because of uncertainty in the time of intakes and the absence of other data related to the exposure (e.g., physical and chemical forms, exposure duration), correlating positive results to actual intakes for routine measurements can sometimes be difficult. Abnormal and inadvertent intakes from situations such as a failed respiratory protective device, inadequate engineering controls, inadvertent ingestion, contamination of a wound or skin absorption, should be evaluated on a case-by-case basis. When determining whether potential intakes should be evaluated, consider the following circumstances:

- The presence of unusually high levels of facial and/or nasal contamination;
- Entry into airborne radioactivity areas without appropriate exposure controls;
- Operational events with a reasonable likelihood that a worker was exposed to unknown quantities of airborne radioactive material (e.g., loss of system or container integrity);
- Known or suspected incidents of a worker ingesting radioactive material;
- Incidents that result in contamination of wounds or other skin absorption; and
- Evidence of damage to or failure of a respiratory protective device.

References:

Regulatory Guide 4.20, "Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," dated December 1996.

Regulatory Guide 8.9, Revision 1, "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program," dated July 1993.

Regulatory Guide 8.25, Revision 1, "Air Sampling in the Workplace," dated June 1992.

Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," dated July 1993.

NUREG-1400, "Air Sampling in the Workplace," dated September 1993 or current revision.

NUREG/CR- 4884, "Interpretation of Bioassay Measurements," dated July 1987 or current revision.

ANSI N13.1 (1969), "Document to Sampling Airborne Radioactive Materials in Nuclear Facilities," dated 1991.

ANSI N42.18, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents," 1991.

APPENDIX L

Model Leak Test Program

Model Leak Test Program

Training

Before allowing an individual to perform leak testing, the licensee should ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak tests independently.

Classroom training may be in the form of lecture, videotape, or self-study and should cover the following subject areas:

- Principles and practices of radiation protection;
- Radioactivity measurements, monitoring techniques and using instruments;
- Mathematics and calculations used for measuring radioactivity;
- Biological effects of radiation. Appropriate on-the-job-training consists of:
- Observing authorized personnel collecting and analyzing leak test samples; and
- Collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak tests.

Facilities and Equipment

Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as manufacturer, model number, serial number, radionuclide and activity.
- If available, use a survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area (but not directly from the surface of a source) where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 185 becquerels (0.005 microcurie) of the radionuclide and ensure its calibration is current.

- Using the selected instrument, count and record background count rate.
- Calculate efficiency of the detector. A sample calculation is shown in the next box.
- Count the sample.

For Example:

$$\frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{activity of std in Bq}} = \text{efficiency in cpm/Bq}$$

cpm = counts per minute
 std = standard
 bkg = background
 Bq = Becquerel

- Count each wipe sample; determine net count rate.
- For each sample, calculate and record estimated activity in becquerels (or microcuries).

$$\frac{[(\text{cpm from wipe sampls}) - (\text{cpm from bkg})]}{\text{effeciency in cpm/Bq}} = \text{Bq on wipe sample}$$

- Sign and date the list of sources, data and calculations. Retain records for three years (OAC 3701:1-38-20(C)).
- If the wipe test activity is 185 Bq (0.005 mCi) or greater, notify the RSO, so the source can be withdrawn from use and disposed of properly.
- Notify BRP.

Frequency for Conducting Leak Tests of Sealed Sources

Leak tests must be conducted at the frequency specified in the respective SSDR certificate.

Reference: See NUREG-1556 Vol. 18, “Program-Specific Guidance About Service Provider Licenses,” dated November 2000.

APPENDIX M

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

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 nonbulk packaging, prohibited marking, marking requirements, radioactive material, hazardous substances in nonbulk 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 NRC-approved packages, quality control requirements prior to each shipment of Class 7 (radioactive) materials, approval of special form Class 7 (radioactive) materials; and
- Carriage by Public Highway 49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842: Driver training, shipping papers, general requirements (packages secured in a vehicle), Class 7 (radioactive) material.

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

APPENDIX N

Waste Disposal

General Discussion

- All radioactivity labels must be defaced or removed from containers and packages prior to disposal into nonradioactive waste streams. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
- Remind workers that nonradioactive waste such as leftover reagents, boxes and packaging material should not be mixed with radioactive waste.
- Occasionally monitor all procedures to ensure radioactive waste is not created unnecessarily. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
- In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity, flammability), and costs.
- The waste management program should include waste handling procedures for the users within their laboratories or assigned areas, and for waste handlers who may collect waste from areas of use to bring to the storage area for eventual disposal.
- Housekeeping staff should be provided adequate training to avoid the possibility of unauthorized disposal or exposure of these individuals to radioactive materials or radiation.

Model Procedure for Decay-In-Storage (DIS)

Licensees can minimize the need for storage space if the waste is segregated according to physical half-life.

- Only waste with a physical half-life of less than or equal to 120 days may be disposed of by DIS.
- Waste with a half-life of greater than 65 days but less than or equal to 120 days should be segregated at the source of generation from waste which has a half-life of less than or equal to 65 days.
- Waste should be stored in suitable well-marked containers, the containers should provide adequate shielding, and the waste's physical form should be compatible with the waste container.

- Liquid and solid wastes should be stored separately.
- Filled containers should be sealed. Sealed containers should be identified with labels affixed or attached to them.
- The identification label should include the date when the container was sealed, the longest-lived radioisotope in the container, total activity and the initials of the individual who sealed the container. The container may then be transferred to the DIS area. When large quantities are held for DIS, sufficient quantities may be present even after 10 half-lives so that persons performing surveys should be aware of the potential for measurable radiation.

Prior to disposal as ordinary trash, each container should be monitored as follows:

- Check the radiation detection survey meter for proper operation with a radiation source;
- Survey the contents of each container in a low- background area;
- Remove any shielding from around the container;
- Monitor all surfaces of the container;
- Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity (i.e., surface readings are indistinguishable from background readings); and
- If the surveys indicate residual radioactivity, return the container to the DIS area and contact the RSO for further instructions.

If the surveys indicate no residual radioactivity, record the date the container was sealed, the disposal date, type of waste (used or unused material, gloves, etc.), survey instrument used and the initials of the individual performing surveys and disposing of the waste.

Note: All radiation labels should be defaced or removed from containers and packages prior to disposal as ordinary trash.

Model Procedure for Disposal of Liquids Into Sanitary Sewerage

- Confirm the sewer system is a public system, not a private sanitary sewer, septic system or leach field.

- Confirm the liquid waste being discharged is readily soluble (or is easily dispersible biological material) in water.
- Calculate the amount of each radioisotope that can be discharged by using the information from prior, similar discharges and the information in Chapter 3701:1-38 of the Ohio Administrative Code.
- Make sure the amount of each radioisotope does not exceed the monthly and annual discharge limits specified in rule 3701:1-38-19 of the Ohio Administrative Code and table III of appendix C to rule 3701:1-38-12 of the Ohio Administrative Code (records for individual users/laboratories).
- If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in table III of appendix C to rule 3701:1-38-12 of the Ohio Administrative Code should not exceed unity.
- Make sure the total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 GBq (5 Ci) of H-3 (tritium), 37 GBq (1 Ci) of C-14, and 37 Gbq (1 Ci) of all other radioisotopes combined.
- Record the date, radioisotope(s), estimated activity of each radioisotope, location where the material is discharged and the initials of the individual discharging the waste.
- Liquid waste should be discharged only via designated sinks or toilets.
- Discharge liquid waste slowly to minimize splashing, with water running to dilute it and to ensure the material moves out of the sink into the sewer system.
- Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remains in the sink or on work surfaces. Decontaminate as appropriate.
- Prior to leaving the area, decontaminate all areas or surfaces if found to be contaminated.
- For all releases to the sanitary sewer from the licensed facility, maintain records of each radioisotope and the quantity and concentration that is released into the sewer system in order to demonstrate compliance with the regulatory limits for total quantity released and concentrations released by the licensed facility.

Model Procedure for Incineration

These guidelines apply to noncommercial waste disposal (e.g., incineration of a licensee's own waste). Specific approval is not necessary in order to incinerate certain categories of radioactive waste. For example, rule 3701:1-38-19 of the Ohio Administrative Code provides that tritium and carbon-14 in low level concentrations, in liquid scintillation media and animal tissue, may be disposed of without regard to radioactivity. After reviewing the disposal program and confirming the existence of waste that requires specific approval for incineration, provide the following information in the license application:

- Describe the training and experience of the person who will be responsible for the on-site and day-to-day supervision of incinerator operations.
- Describe the waste that is proposed to be incinerated to include the chemical and/or physical form of the waste containing licensed material and a description of how the waste is segregated, packaged and labeled for transfer from the generation site to the incinerator; the name of the radioisotope, concentration of radioactivity averaged over the weight of the material to be incinerated (microcurie per gram of waste medium) for each isotope to be incinerated; and the total radioactivity of each isotope per burn and the total number of burns per year.
- Describe procedures for ensuring these frequencies and activities will not be exceeded.
- Describe the procedures for the packaging, handling, securing and monitoring of waste to prevent contamination and/or unnecessary exposure to personnel or property during the waste life cycle.
- Describe the method for measuring or estimating the concentration of radioactive material remaining in the ash residue. Describe the procedures for collection, handling and disposal of the ash residue.
- Describe the recordkeeping procedures for the waste incineration program. Records should be adequate to document all receipts, incineration, environmental releases of effluents and any disposals of ash generated in the incineration process. These records should be maintained in the same units as applicable regulations.
- Describe the characteristics of the incinerator and site location including: height of the stack; rated air flow (cubic feet per hour or similar units); proximity of the stack or other discharge to occupied areas (e.g., residences, school, hospital); and distance to the nearest air intake ducts of adjacent buildings. Describe any scrubbers, filters or air cleaning equipment that are present.
- State how the concentration of radionuclides released, both as airborne effluent and as any liquid effluent from scrubbers, condensers or associated systems, will be measured or otherwise determined.

- Describe any stack monitoring that is planned.
- Provide a copy of the written safety analysis that demonstrates the applicant will be able to incinerate the types and quantities of radioactivity specified in the application without exceeding the environmental release limits specified in OAC Chapter 3701:1-38.
- Provide a written commitment that the applicant has coordinated with appropriate state and local authorities and that such permits and other authorizations as may be necessary have been obtained.
- Provide a copy of the radiation safety procedures for monitoring personnel involved in incineration operations, and for monitoring all effluent generated by the incineration process. The procedures should ensure that regulatory limits for environmental releases of radioactivity will not be exceeded. The applicant should describe disposal procedures for any ash generated exceeding regulatory limits.

Model Procedure for Compaction

The following information should be provided by licensees who propose to compact waste [rule 3701:1-38-20 of the Ohio Administrative Code]:

- Describe the compactor to demonstrate it is adequately designed and manufactured to safely compact the type and quantity of waste generated during licensed operations (e.g., manufacturer's specifications, annotated sketches, photographs);
- Describe the type, quantities and concentrations of waste to be compacted;
- Provide an analysis of the potential for airborne release of radioactive material during compaction activities;
- State the location of the compactor(s) within the waste processing area(s), as well as a description of the ventilation and filtering systems used in conjunction with the compactors. Include a description of the procedures for monitoring filter blockage and exchange;
- Discuss the methods used to monitor worker breathing zones and/or exhaust systems;
- Discuss the types and frequencies of surveys that will be performed for contamination control in the compactor area; and
- Discuss the instruction provided to compactor operators, including instructions for protective clothing, checks for proper functioning of equipment, method of handling uncompacted waste and examination of containers for defects.