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# MINNESOTA DEPARTMENT OF HEALTH



## REGULATORY GUIDE FOR NUCLEAR PHARMACIES

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## TABLE OF CONTENTS

|  |    |
|--|----|
| <b>INTRODUCTION</b> .....  | 5  |
| <b>AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY</b> .....                          | 5  |
| <b>TIMELY NOTIFICATION OF TRANSFER OF CONTROL</b> .....                                  | 5  |
| <b>TIMELY NOTIFICATION OF BANKRUPTCY PROCEEDINGS</b> .....                               | 6  |
| <b>RECORDKEEPING FOR DECOMMISSIONING AND FINANCIAL ASSURANCE</b> .....                   | 6  |
| DETERMINING NEED FOR FINANCIAL ASSURANCE FOR DECOMMISSIONING.....                        | 7  |
| <b>FILING AN APPLICATION</b> .....   | 7  |
| ITEM 1: LICENSE ACTION TYPE .....  | 8  |
| ITEM 2: NAME AND MAILING ADDRESS OF APPLICANT .....                                      | 8  |
| ITEM 3: ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED .....              | 8  |
| ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION.....                               | 9  |
| ITEM 5: RADIOACTIVE MATERIAL.....  | 9  |
| <i>Unsealed and/or Sealed Radioactive Material</i> .....                                 | 9  |
| ITEM 6: PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED .....                        | 11 |
| <i>Distribution and Redistribution of Sealed and Unsealed Materials</i> .....            | 11 |
| <i>Preparation of Radiopharmaceuticals</i> .....   | 13 |
| <i>Sealed Sources for Calibration and Checks</i> .....                                   | 13 |
| <i>Service Activities</i> .....  | 13 |
| ITEM 7: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM.....                      | 13 |
| MANAGEMENT RESPONSIBILITIES .....  | 13 |
| <i>Radiation Safety Officer</i> .....  | 14 |
| <i>Authorized Nuclear Pharmacist (ANP)</i> .....   | 15 |
| <i>Authorized Users (AU)</i> .....   | 16 |
| ITEM 8: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.....         | 17 |
| <i>Occupationally Exposed Workers and Ancillary Personnel</i> .....                      | 17 |
| <i>Personnel Involved in Hazardous Materials Package Preparation and Transport</i> ..... | 18 |
| <i>Instruction for Supervised Individuals Preparing Radiopharmaceuticals</i> .....       | 19 |
| ITEM 9: FACILITIES AND EQUIPMENT .....   | 19 |
| <i>Radiation Monitoring Equipment</i> .....  | 20 |
| <i>Dosage Measurement Systems</i> .....  | 21 |
| ITEM 10: RADIATION SAFETY PROGRAM.....   | 22 |
| <i>Audit Program</i> .....   | 22 |
| <i>Material Receipt and Accountability</i> .....   | 22 |
| <i>Occupational Dose</i> .....   | 24 |
| <i>Public Dose</i> .....   | 25 |
| <i>General Safety Procedures</i> .....   | 26 |
| <i>Emergency Procedures</i> .....  | 26 |
| <i>Surveys</i> .....   | 27 |
| <i>Leak Testing of Sealed Sources</i> .....  | 27 |
| <i>Undetected Contamination and Loss of Control of Licensed Material</i> .....           | 28 |
| <i>Transportation</i> .....  | 28 |
| <i>Minimization of Contamination</i> .....   | 29 |
| <i>Radioactive Drug Labeling for Distribution</i> .....                                  | 29 |
| <i>Radioactive Drug Shielding for Distribution</i> .....                                 | 30 |
| ITEM 11: WASTE MANAGEMENT.....   | 30 |
| <i>Disposal by Decay-in-Storage</i> .....  | 31 |
| <i>Transfer to an Authorized Recipient</i> .....   | 32 |
| <i>Release into Sanitary Sewerage</i> .....  | 32 |
| <i>Returned Wastes from Customers</i> .....  | 32 |

|  |           |
|--|-----------|
| ITEM 12: LICENSE FEE.....  | 33        |
| ITEM 13: CERTIFICATION .....   | 33        |
| <b>AMENDMENTS TO A LICENSE.....</b>  | <b>34</b> |
| <b>RENEWAL OF A LICENSE .....</b>  | <b>34</b> |
| <b>IMPLEMENTATION .....</b>  | <b>34</b> |
| <b>INSPECTIONS .....</b>   | <b>34</b> |
| <b>APPENDICES .....</b>  | <b>35</b> |
| APPENDIX A: TYPICAL DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER (RSO) .....      | 35        |
| APPENDIX B: MODEL DOSE CALIBRATOR TESTING PROGRAM.....   | 36        |
| APPENDIX C: SUGGESTED NUCLEAR PHARMACY AUDIT CHECKLIST .....                                     | 41        |
| APPENDIX D: ORDERING AND RECEIVING RADIOACTIVE MATERIAL.....                                     | 50        |
| APPENDIX E: SAFELY OPENING PACKAGES .....  | 51        |
| APPENDIX F: PERSONNEL EXPOSURE MONITORING PROGRAM .....  | 53        |
| <i>External Exposure.....</i>  | <i>53</i> |
| <i>Investigational Levels - External Exposure.....</i>   | <i>55</i> |
| <i>Declared Pregnancy And Dose To The Embryo/Fetus .....</i>                                     | <i>56</i> |
| <i>Internal Exposure .....</i>   | <i>56</i> |
| <i>Controlling Air Concentrations And Worker Doses From Noble Gases.....</i>                     | <i>57</i> |
| <i>Summary Of External And Internal Exposures.....</i>   | <i>57</i> |
| APPENDIX G: SAFE USE OF RADIOPHARMACEUTICALS .....   | 58        |
| APPENDIX H: MODEL SPILL PROCEDURES .....   | 60        |
| Minor Spills Of Liquids And Solids.....  | 60        |
| Major Spills Of Liquids And Solids.....  | 60        |
| Discussion Of Major And Minor Spills .....   | 61        |
| Spill Kits .....   | 61        |
| Spilled Gas Clearance Time .....   | 62        |
| APPENDIX I: AREA SURVEYS.....  | 63        |
| <i>Radiation Dose Rate Surveys.....</i>  | <i>63</i> |
| <i>Removable Contamination Surveys.....</i>  | <i>63</i> |
| <i>Contents of Survey Records.....</i>   | <i>65</i> |
| APPENDIX J: LEAK TESTING SEALED SOURCES .....  | 67        |
| <i>Facilities And Equipment.....</i>   | <i>67</i> |
| <i>Model Procedure For Performing Leak Testing And Analysis.....</i>                             | <i>67</i> |
| APPENDIX K: CUSTOMER RETURN RADIOACTIVE WASTE TO NUCLEAR PHARMACIES.....                         | 68        |
| APPENDIX L: DEPARTMENT OF TRANSPORTATION REQUIREMENTS.....                                       | 71        |
| <i>Limited Quantity Shipments.....</i>   | <i>71</i> |
| <i>Limited Quantity Activity Limits For Shipments Of Mixed Radionuclides.....</i>                | <i>72</i> |
| <i>US Department of Transportation Training Requirements.....</i>                                | <i>73</i> |
| Initial Training.....  | 73        |
| Recurrent Training .....   | 73        |
| Training Records.....  | 74        |
| 49 CFR References .....  | 74        |
| ATTACHMENT I: US DEPARTMENT OF TRANSPORTATION ADVISORY NOTICE – ENHANCED SECURITY MEASURES ..... | 76        |
| <b>SUMMARY OF REVISIONS .....</b>  | <b>80</b> |

## REGULATORY GUIDE FOR NUCLEAR PHARMACIES

### INTRODUCTION

This report provides guidance to an applicant applying for a commercial radiopharmacy license, as well as providing MDH with the appropriate criteria for evaluating such applications. Within this document, the phrases or terms, "commercial radiopharmacy," "radiopharmacy," "nuclear pharmacy," and "pharmacy" are used interchangeably.

Commercial radiopharmacy licenses are those licenses issued by MDH for the possession and use of radioactive materials for the manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under 4731.5000. Within this document, preparation includes the making of radiopharmaceuticals from reagent kits (i.e., Technetium-99<sup>m</sup> MAA [macro-aggregated albumin]), and from raw materials (i.e., the compounding of radioiodine capsules for diagnostic and therapeutic medical use). Commercial radiopharmacies may also be authorized to transfer for commercial distribution *in vitro* test kits, radiopharmaceuticals to licensees authorized to possess them for other than human medical use (i.e., veterinary medicine and research licensees), and radiochemicals to those licensees authorized to possess them. In addition, 4731.2000 authorizes radiopharmacies to redistribute (transfer) sealed sources for calibration and medical use initially distributed by a licensed manufacturer.

Specific guidance for applicants requesting to manufacture and initially distribute Molybdenum-99/Technetium-99<sup>m</sup> generators, *in vitro* kits, radiochemicals, and sealed sources is not within the scope of this guidance for commercial radiopharmacies. These activities require specific NRC or Agreement State authorization and must be included on a specific license.

Furthermore, specific guidance for applicants requesting authorization to manufacture, distribute, and redistribute radioactive drugs to persons exempt from licensing (i.e., Carbon-14 tagged urea) is not within the scope of this guidance. These activities require specific NRC authorization and require the issuance of a separate license for exempt distribution.

This guide identifies the information needed to complete MDH "Application for Radioactive Material License," for the use of radioactive materials in commercial radiopharmacies.

### AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Each licensee must develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and the licensee must use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA. Applicants should consider the ALARA philosophy when developing plans to work with licensed radioactive materials.

Licensees are also required to review the content of the radiation protection program and its implementation at least annually. The RSO is responsible for the day-to-day operation of the radiation protection program.

### TIMELY NOTIFICATION OF TRANSFER OF CONTROL

Licensees must provide full information and obtain MDH's *written consent* before transferring control of the license, or, as some licensees refer to the process, "transferring the license." Control may be transferred as a result of mergers, buyouts, or majority stock transfers. Although it is not MDH's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain MDH's written consent before transferring control of the license. This is to ensure the following:

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

If only the licensee's name or mailing address changes, and the name change does not constitute a transfer of control of the license, a licensee must file a written notification with MDH no later than 30 days after the date(s) of the change(s). Otherwise, prior MDH written consent must be given prior to the transfer.

### **TIMELY NOTIFICATION OF BANKRUPTCY PROCEEDINGS**

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

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

### **RECORDKEEPING FOR DECOMMISSIONING AND FINANCIAL ASSURANCE**

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

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

Licensees authorized to possess radioactive material in excess of the limits specified in 4731.3080 must also provide evidence of financial assurance for decommissioning. The requirements for financial assurance are specific to the types and quantities of radioactive material authorized on a license. Some medical use applicants and licensees may not need to take any action to comply with the financial assurance requirements because their total inventory of licensed material does not exceed the limits in 4731.3080 or because the half-life of the unsealed radioactive material used does not exceed 120 days. Applicants requesting licensed material with a half-life in excess of 120 days should determine whether

financial assurance is necessary. In addition, applicants requesting more than one radionuclide must use the sum-of-the-ratios method to determine if financial assurance is needed.

Applications for authorization to possess and use unsealed radioactive material with a half-life exceeding 120 days must be accompanied by a decommissioning funding plan or certification of financial assurance when the trigger quantities given in 4731.3080 Subpart 2 are exceeded. Acceptable methods of providing financial assurance include trust funds, escrow accounts, government funds, certificates of deposit, deposits of government securities, surety bonds, letters of credit, lines of credit, insurance policies, parent company guarantees, self guarantees, external sinking funds, statements of intent, special arrangements with government entities, and standby trust funds.

MDH will authorize sealed source possession exceeding the limits given in 4731.3080 Subpart 4 without requiring decommissioning financial assurance, for the purpose of normal sealed source exchange, for no more than 30 days.

**Determining Need for Financial Assurance for Decommissioning**

The half-lives of unsealed radioactive material used by medical licensees have traditionally been less than 120 days. Therefore, most medical use applicants need only consider licensed material in sealed sources to evaluate the need for financial assurance. Use the following table as a worksheet to determine if financial assurance is required for the sealed sources listed. If requesting sealed sources other than those listed or any other unsealed radioactive material with a half-life greater than 120 days, refer to 4731.3080 and 4731.3160 for possession limits requiring financial assurance. The sum of the fractions procedure is also depicted in the following table and must be used to determine the need for financial assurance for both sealed and unsealed radioactive material.

| <b>WORKSHEET FOR DETERMINING NEED FOR FINANCIAL ASSURANCE FOR SEALED SOURCES</b> |  |                  |                   |                     |
|--|--|------------------|-------------------|---------------------|
| <b>Step</b>  | <b>Description</b>                                 | <b>Cobalt-60</b> | <b>Cesium-137</b> | <b>Strontium-90</b> |
| <b>1</b>   | Activity possessed, in curies*                     |                  |                   |                     |
| <b>2</b>   | Activity requiring financial assurance, in curies  | 10,000           | 100,000           | 1,000               |
| <b>3</b>   | Divide data in Step 1 by data in Step 2 = FRACTION |                  |                   |                     |
| <b>4</b>   | Add the fractions determined in Step 3             |                  |                   |                     |

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

As 4731.3080 describes, if the sum of the fractions is greater than or equal to 1, the applicant will need to submit a decommissioning funding plan or financial assurance, as applicable.

**FILING AN APPLICATION**

You should apply for a license by completing the "Application for a Minnesota Radioactive Materials License." Complete Items 1 through 4 on the form itself. For Items 5 through 11, submit the information on supplementary pages. Identify and key each sheet or document with the item number on the application. All typed pages, sketches, and, if possible, drawings should be on 8 1/2 X 11 inch paper to facilitate handling and review. If larger drawings are necessary, they should be folded to 8 1/2 X 11 inches. You should complete all items in the application in sufficient detail for MDH to determine that your equipment, facilities, training and experience, and radiation safety program are adequate to protect the health and safety of the public as well as your employees.

Please note that license applications are available for review by the general public in the MDH offices. Do not submit proprietary information unless necessary. If submittal of such information is necessary, please clearly specify the proprietary information. Failure to do so may result in disclosure of this information to the public or substantial delays in processing your application.

Do not submit personal information about your individual employees unless it is necessary. For example, the training and experience of individuals should be submitted to demonstrate their ability to manage radiation safety programs or to work safely with radioactive materials. Home addresses and home telephone numbers should be submitted only if they are part of an emergency response plan. Dates of birth, social security numbers, and radiation dose information should be submitted only if specifically requested by MDH.

Submit one copy of your application to:

Radioactive Materials Unit  
Minnesota Department of Health  
625 Robert Street North  
P.O. Box 64975  
St. Paul, Minnesota 55164-0975

Retain one copy for yourself, as the license will be issued based on the statements and representations in your application, its supplements, and the requirements in the regulations. The statements and representations you make as if they were regulations will bind you.

The following comments apply to the indicated items on the Application for a Minnesota Radioactive Materials License.

**Item 1: License Action Type**

Check box A for a new license request.

Check box B for an amendment to an existing license and provide the license number. See "Amendments and Renewals to a License," section of this document.

Check box C for a renewal of an existing license and provide the license number.

**Item 2: Name and Mailing Address of Applicant**

List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent.

**Item 3: Address(es) Where Licensed Material Will Be Used or Possessed**

Applicants must provide a specific address for each location where radioactive material will be used or stored, or dispatched. Specify the street address, city, and state or other descriptive address (such as on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each permanent storage or use facility and field station. A field station is a location where licensed material may be stored or used and from which the applicant will dispatch equipment to jobsites. A Post Office Box address is insufficient because MDH needs a specific address to allow an MDH inspector to find the use and/or storage location. If devices will NOT be stored at a dispatch site or field station, indicate this. In addition, the applicant should state whether a location will be used to perform radiographic operations or only for storage of sources and devices.

If a device will be used in a permanent radiographic installation, give the specific address of each location. If applicable, describe the locations outside of the installation where radiographic operations will be conducted.

**Item 4: Person to Be Contacted About This Application**

Identify the individual who can answer questions about the application and include his or her telephone number. This is typically the proposed radiation safety officer (RSO) or knowledgeable management official. The MDH will contact this individual if there are questions about the application.

Notify MDH if the contact person or telephone number changes. This notice is for information only and does not require a license amendment or a fee.

**Items 5 through 11 should be submitted on separate sheets of paper.**

**Item 5: Radioactive Material**

***Unsealed and/or Sealed Radioactive Material***

Each authorized radioisotope is listed on an MDH license by its element name, form, and the maximum amount the licensee may possess at any one time (maximum possession limit). The applicant should list each requested radioisotope by its element name and its mass number (e.g., Technetium-99<sup>m</sup>) in item 5. 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 unsealed radioactive material, it is also necessary to specify whether requested radioisotopes will be handled in volatile or non-volatile form, since additional safety precautions are required when handling and using material in a volatile form. For example, when requesting authorization to possess and distribute Iodine-131, the applicant must specify whether the material will be manipulated at the radiopharmacy in a volatile form (e.g., compounding of Iodine-131 capsules) or received in the form in which it will be distributed (e.g., redistribution of sealed, unopened vials of Iodine-131). Applicants requesting authorization to manipulate volatile radioactive material must describe appropriate facilities, engineering controls, and radiation safety procedures for handling of such material.

The anticipated possession limit in curies (Ci) or Becquerels (Bq) 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 abilities 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 Recordkeeping for Decommissioning.

Applicants will be authorized to possess and use only those sealed sources, such as calibration and reference sources that are specifically approved or registered by the NRC or an Agreement State. A safety evaluation of sealed sources and devices is performed by the NRC or an Agreement State before authorizing a manufacturer or distributor to distribute them to specific licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) Registration Certificate. Applicants must provide the manufacturer's name and model number for each requested sealed source and device, so that MDH can verify that they have been evaluated in an SSD Registration Certificate or specifically approved on a license.

Consult with the proposed supplier, manufacturer, or distributor to ensure that requested sources and devices are compatible with and conform to the sealed source and device designations registered with



the NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective registration certificates, without obtaining MDH's prior permission in a license amendment. To ensure that applicants use sources and devices according to the registration certificates, they may want to get a copy of the certificate and review it or discuss it with the manufacturer.

The applicant must also request authorization to possess depleted uranium if it will be used for shielding of Molybdenum-99/Technetium-99<sup>m</sup> generators. Depleted uranium is frequently used as shielding for generators when the Molybdenum-99 activity is greater than 4 curies (148 gigabecquerels). Depleted uranium is exempt from the requirements for a license to the extent that the material is used as a shipping container, such as when Molybdenum-99/Technetium-99<sup>m</sup> generators are in transit from their manufacturer to the pharmacy. However, a specific license or authorization from the MDH is needed to possess and use the depleted uranium as a shield during the time that the pharmacy uses or stores the generator at its facility. The applicant must specify the total amount of depleted uranium, in kilograms, that will be needed.

If an applicant requests quantities of licensed material in excess of the limits in 4731.3150, "Radioactive Material; Emergency Plan Quantities," the applicant must:

- Submit an emergency plan for responding to a release of radioactive materials; or
- Perform an evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem (10 millisieverts) effective dose equivalent or 5 rems (50 mSv) to the thyroid<sup>1</sup>.

Licensees must submit a license amendment and receive MDH authorization before they may make changes in the types, forms, and quantities of materials possessed.

For unsealed materials:

Identify each radionuclide (element name and mass number) that will be used, the form, and the maximum requested possession limit.

For potentially volatile materials (e.g., Iodine-131):

Specify whether open containers of the materials will be manipulated at the radiopharmacy.

For sealed materials:

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 requested;

Confirm that each sealed source, device, and source/device combination is registered as an approved sealed source or device by the NRC or an Agreement State; and

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 the NRC or by an Agreement State.

For depleted uranium, specify the total amount (in kilograms).

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<sup>1</sup> For radiopharmacies, Iodine-131 is the radionuclide most likely to trigger the need for an emergency plan due to the 10 curie threshold.

## Item 6: Purpose(s) for Which Licensed Material Will Be Used

### ***Distribution and Redistribution of Sealed and Unsealed Materials***

Radiochemicals are those materials that either require further manipulation to be suitable for human use or are not intended for human use. Examples include raw materials received from a supplier not licensed under 4731.3395 (chemical grade materials). Radioactive drugs are those materials suitable for human use and include radio-biologics (e.g., monoclonal antibodies and Technetium-99<sup>m</sup>-tagged red blood cells) and radiopharmaceuticals. However, the terms, "radiopharmaceutical" and "radioactive drug" will be used interchangeably in this guidance document, and reference to one is not meant to exclude the other.

Distribution activities are normally classified as either "distribution" or "redistribution." "Distribution" applies to those radioactive drugs and radiochemicals initially prepared by the pharmacy. "Redistribution" refers to those materials received from another person, authorized pursuant to 4731.3390, 3395, or 3400, depending on the product distributed. The distribution of radioactive materials to other persons requires specific approval from the MDH, either by MDH rules or by a license authorizing the activity. A person licensed pursuant to 4731.3395 must prepare the initial distribution of radioactive drugs for medical use. The redistribution of *in vitro* kits and sealed sources containing radioactive material for medical use is authorized pursuant to 4731.3390 and 4731.3400, respectively, if the materials are not repackaged and the labels are not altered. The *in vitro* kits and sealed sources for medical use intended for redistribution must be initially distributed by a person licensed pursuant to 4731.3390 or 4731.3400, respectively. The transfer of radioactive materials for non-medical use, including radiochemicals, and sealed calibration and reference sources, is authorized pursuant to 4731.3105.

All radioactive material listed above shall be distributed only to persons authorized by an NRC or Agreement State license to receive such materials, or by a general license or equivalent Agreement State regulation) to receive *in vitro* test materials.

Initial distribution of unsealed radioactive material in the form of radiopharmaceuticals intended for human diagnostic and therapeutic use by medical licensees comprises the bulk of virtually all radiopharmacy activities. Before the transfer, distribution, or redistribution of any licensed material, the radiopharmacy must verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. The pharmacy should verify that the address to which radioactive materials are delivered is an authorized location of use listed on the customer's license. The most common form of verification is for the radiopharmacy to possess a valid copy of the customer's NRC or Agreement State license or other applicable document.

For radiopharmaceuticals, provide the following as applicable:

- Confirm that radiopharmaceuticals will be prepared under the supervision of an Authorized Nuclear Pharmacist (ANP) or will be obtained from a supplier authorized pursuant to 4731.3395, or under equivalent NRC or other Agreement State requirements.
- Describe all licensed material to be distributed or redistributed.

For generators, provide the following as applicable:

- Confirm that the generators will be obtained from a manufacturer licensed pursuant to 4731.3395, or under equivalent Agreement State requirements.
- Confirm that unused generators will be redistributed without opening or altering the manufacturer's packaging.

For redistribution of used generators<sup>2</sup>, provide the following as applicable:

- Describe the procedures and instructions for safely repackaging the generators, including the use of the manufacturer's original packaging and minimization of migration of radioactive fluids out of the generator during transport.
- Confirm that the manufacturer's packaging and labeling will not be altered.
- Confirm that the generator will not be distributed beyond the expiration date shown on the generator label.
- Confirm that the redistributed generator will be accompanied by the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator.
- Confirm that only generators used in accordance with the manufacturer's instructions will be redistributed.

For redistribution of sealed sources -- for brachytherapy or diagnosis, provide the following as applicable:

- Confirm that the sealed sources for brachytherapy or diagnosis to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy or diagnosis in accordance with a specific license issued pursuant to 4731.3400, or under equivalent Agreement State requirements; and
- Confirm that the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

For redistribution of calibration and reference sealed sources, provide the following as applicable:

- Confirm that calibration and reference sealed sources to be redistributed to medical use licensees will be obtained from a person licensed pursuant to 4731.3400 or under equivalent Agreement State requirements, to initially distribute such sources; and
- Confirm that the manufacturer's labeling and packaging will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied calibration certificate and the leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

For redistribution of prepackaged units for *in vitro* tests, confirm that the prepackaged units for *in vitro* tests to be redistributed will have been obtained from a manufacturer authorized to distribute the prepackaged units for *in vitro* tests in accordance with a specific license issued pursuant to 4731.3390, or under an equivalent license of an Agreement State.

For redistribution to general licensees:

- Confirm that the manufacturer's packaging and labeling of the prepackaged units for *in vitro* tests will not be altered in any way; and
- Confirm that each redistributed prepackaged unit for *in vitro* tests will be accompanied by the manufacturer-supplied package insert, leaflet, or brochure that provides radiation safety instructions for general licensees.

For redistribution to specific licensees:

- Confirm that the labels, package insert, leaflet, brochure, or other documents accompanying the redistributed prepackaged units for *in vitro* tests will NOT reference general licenses, exempt

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<sup>2</sup> Although redistribution of used generators may be authorized by the MDH, approval does not relieve the licensee from complying with applicable FDA or other Federal and State requirements.

quantities, or NRC's or an Agreement State's regulations that authorize a general license (e.g., 4731.3245).

- Confirm that the labeling on redistributed prepackaged units for *in vitro* tests will conform to the requirements of 4731.2300 and 2330.

### ***Preparation of Radiopharmaceuticals***

The bulk of radiopharmacy activities involve the preparation of radiopharmaceuticals for commercial distribution to medical users. The applicant should indicate the types of radiopharmaceutical preparation activities it intends to perform (e.g., compounding of Iodine-131 capsules, radio-iodination, and Technetium-99<sup>m</sup> kit preparation).

### ***Sealed Sources for Calibration and Checks***

The applicant should describe the intended use of sealed sources. This will normally be for calibration and checks performed only on the applicant's instruments and equipment. Any sources intended for use in a specific instrument calibration device should be identified, along with the manufacturer and model number of the device. The use of depleted uranium for shielding (e.g., incorporated into Molybdenum-99/Technetium-99<sup>m</sup> generators) should also be specified, if appropriate.

Supply specific information concerning the use of sealed sources for reference and calibration.

### ***Service Activities***

If the applicant intends to provide radiation protection services to customers, the services must be described. Typically, these services include instrument calibration and sealed source leak testing.

Specify the customer radiation protection services involving licensed material that will be provided. The applicant must submit specific procedures for all service activities that it intends to provide.

## **Item 7: Individual(s) Responsible for Radiation Safety Program**

Individuals responsible for the radiation protection program include the licensee senior management, the Radiation Safety Officer (RSO), Authorized Nuclear Pharmacists, and Authorized Users (AUs). MDH requires that an applicant be qualified by training and experience to use licensed materials for the purposes requested in such a manner as to protect health and minimize danger to life or property. Specific criteria for acceptable training and experience for Authorized Nuclear Pharmacists is included in 4731.4413.

The minimum training and experience criteria for RSOs and Authorized Users, though not specifically described for radiopharmacy licensees, should include a bachelor's degree in a physical science, or equivalent, and previous experience handling and supervising similar activities. Applicants should note that a resume or curriculum vitae does not usually supply all the information needed to evaluate an individual's training and experience.

### ***Management Responsibilities***

It is essential that strong management controls and oversight exist to ensure that licensed activities are conducted properly. Management responsibility and liability are sometimes underemphasized or not addressed in applications and are often poorly understood by licensee employees and managers. Senior management should delegate to the RSO, in writing, sufficient authority, organizational freedom, and management prerogative to communicate with and direct personnel regarding MDH rules. The RSO should also be given license provisions and authority to terminate unsafe activities involving radioactive material. The licensee maintains the ultimate responsibility, nevertheless, for the conduct of licensed activities.

"Management" refers to the processes for conduct and control of a radiation safety program and to the individuals who are responsible for those processes and who have *authority to provide necessary resources* to achieve regulatory compliance.

To ensure adequate management involvement, a duly authorized 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 MDH.
- Knowledge about the contents of the license and application.
- Compliance with current MDH and Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures.
- Commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the radiation protection program to ensure that public and workers are protected from radiation hazards and compliance with regulations is maintained.
- Selection and assignment of a qualified individual to serve as the 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.
- Obtaining MDH's prior written consent before transferring control of the license.
- Notifying appropriate MDH in writing, immediately following filing of petition for voluntary or involuntary bankruptcy.

#### ***Radiation Safety Officer (RSO)***

MDH requires the name, training, and experience of the proposed RSO to ensure that the applicant has identified a responsible, qualified person to oversee the radiation safety program. When selecting an RSO, the applicant should keep in mind the duties and responsibilities of the position, and select an individual who is qualified and has the time and resources to fulfill those duties and responsibilities. Typical duties and responsibilities of a radiopharmacy RSO are included in Appendix A.

The RSO needs a level of basic technical knowledge sufficient to understand the work to be performed with radioactive materials at the radiopharmacy and to be qualified by training and experience to perform the duties required for that position. Any individual who has sufficient training and experience to be named as an authorized nuclear pharmacist (ANP) is also considered qualified to serve as the facility RSO. The same is true for an Authorized User (AU) who has had adequate training and experience in the radiation safety aspects associated with the use of similar types of radioactive material.

The training and experience requirements for the RSO may be met by any of the following:

- Qualification as an Authorized Nuclear Pharmacist;
- Identification as an Authorized User on the license and experience in the use of the types and quantities of licensed material for which the individual has RSO responsibilities; or
- Didactic and work experience.

In order to demonstrate adequate training and experience, the RSO should have (1) as a minimum, a bachelor's degree or equivalent training and experience in physical, chemical, or 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 and measurement instrumentation

- Biological hazards of exposure to radiation (appropriate to types and forms of radioactive material to be used)
- MDH regulatory requirements and standards
- Hands-on use of radioactive materials commensurate with the uses proposed by the applicant

The length of training and experience will depend upon the type, form, quantity, and proposed use of the licensed material requested. The proposed RSO's training and experience should be sufficient to identify and control the anticipated radiation hazards. The requisite training may be obtained from formal courses consisting of lectures and laboratories designed for RSOs presented by academic institutions, commercial radiation safety consulting companies, or appropriate professional organizations. Each hour of training may be counted only once and should be allocated to the most representative topic.

On-the-job training may not be counted toward the hours documenting length of training unless it was obtained as part of a formal training course. A formal training course is one that incorporates the following elements:

- A detailed description of the content of the course is maintained on file at the sponsoring institution and can be made available to MDH upon request.
- Evidence that the sponsoring institution has examined the student's knowledge of the course content is maintained on file at the institution and can be made available to MDH upon request. This evidence of the student's overall competency in the course material should include a final grade or percentile.
- A permanent record that the student successfully completed the course is kept at the institution.

Provide the name of the proposed RSO and a copy of the license (NRC or Agreement State) that authorizes the uses requested and on which the individual is specifically named as the RSO, an Authorized Nuclear Pharmacist, or an Authorized User. Alternatively, submit a description of the training and experience demonstrating that the proposed RSO is qualified by training and experience applicable to commercial nuclear pharmacies.

***Authorized Nuclear Pharmacist (ANP)***

At many licensed medical facilities, an Authorized Nuclear Pharmacist is directly involved with the preparation and administration of radiopharmaceuticals.

Technologists, or other personnel, may prepare radioactive material for medical use under an Authorized Nuclear Pharmacist's supervision in accordance with 4731.4407, "Supervision," and in compliance with applicable FDA, other Federal, and State requirements. (Preparation of radioactive material for medical use may also be performed under the supervision of a physician who is an authorized user.)

Applicants are reminded of recentness of training requirements described in 4731.4415. Specifically, nuclear pharmacist applicants must have successfully completed the applicable training and experience criteria within seven years preceding the date of the application. Alternatively, nuclear pharmacist applicants must have had related continuing education and experience since initially completing the required training and experience. This time provision applies to board certification as well as to other training pathways for meeting requirements for training and experience.

Provide the following:

- Name of the proposed Authorized Nuclear Pharmacist.

**AND**

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

- Previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by an NRC master material licensee, a permit issued by an NRC or Agreement State broad scope licensee, or a permit issued by an NRC master material license broad scope permittee on which the individual was named an Authorized Nuclear Pharmacist or a copy of an authorization as an Authorized Nuclear Pharmacist from a commercial nuclear pharmacy that has been authorized to identify Authorized Nuclear Pharmacists

*For an individual qualifying in accordance with 4731.4413:*

- Copy of the certification(s) of the specialty board whose certification process has been recognized in accordance with 4731.4413 Subpart 1. Item A.

**AND**

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

**OR**

- Description of the training and experience specified in 4731.4413 Subpart 1. Item B. (1) demonstrating that the proposed Authorized Nuclear Pharmacist is qualified by training and experience.

**AND**

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

**AND**

- If applicable, description of recent related continuing education and experience as required by 4731.4415.

### ***Authorized Users (AU)***

If the applicant intends to perform functions other than the preparation and distribution of radioactive drugs, the applicant may request that an individual other than an Authorized Nuclear Pharmacist perform and/or supervise those functions. This individual, if approved, would be designated on the license as an Authorized User. These other functions may include leak testing of sealed sources or instrument calibration services for the pharmacy and its customers.

In order to demonstrate adequate training and experience, the proposed Authorized User should have (1) as a minimum, a bachelor's degree or equivalent training and experience in physical, chemical, or 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 and measurement instrumentation
- Biological hazards of exposure to radiation (appropriate to types and forms of radioactive material to be used)
- MDH regulatory requirements and standards
- Hands-on use of radioactive materials commensurate with uses proposed by the applicant

The length of training and experience listed above will depend upon the type, form, quantity, and proposed use of the licensed material requested. The proposed Authorized User's training and experience should be sufficient to identify and control the anticipated radiation hazards. The above training may be obtained from formal radiation safety courses consisting of lectures and laboratories presented by academic institutions, commercial radiation safety consulting companies, or appropriate professional organizations. Each hour of training may be counted only once and should be allocated to the most representative topic.

On-the-job training may not count toward the hours listed above unless it was obtained as part of a formal training course. A formal training course is one that incorporates the following elements:

- A detailed description of the content of the course is maintained on file at the sponsoring institution and can be made available to MDH upon request.
- Evidence that the sponsoring institution has examined the student's knowledge of the course content is maintained on file at the institution and can be made available to MDH upon request. This evidence of the student's overall competency in the course material should include a final grade or percentile.
- A permanent record that the student successfully completed the course is kept at the institution.

The Authorized User must demonstrate training and experience with the type and quantity of material that is to be used at the pharmacy. For example, someone with training and experience only with microcurie quantities of unsealed radioactive material may not be qualified to use or supervise the use of higher activity sealed radioactive sources for instrument calibration. Applicants should pay particular attention to the type of radiation involved. For example, someone experienced with gamma emitters may not have appropriate experience for high-energy beta emitters.

For each proposed Authorized User (AU), submit the user's name; identify types, quantities, and proposed uses of licensed material; and include a copy of the license (NRC or Agreement State) on which the individual was specifically named as an Authorized User for the types, quantities, and proposed uses of licensed materials.

**Item 8: Training for Individuals Working In or Frequenting Restricted Areas (Instructions to Occupationally Exposed Workers and Ancillary Personnel)**

***Occupationally Exposed Workers and Ancillary Personnel***

Individuals working with licensed material must receive radiation safety training commensurate with their assigned duties and specific to the licensee's radiation safety program. In addition, those individuals who, in the course of employment, are likely to receive in a year a dose in excess of 100 mrem (1 mSv) must receive instructions as specified in 4731.1020.

Each licensee must develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with 4731.2950. Each individual working with radioactive material must be trained in the radiation safety procedures applicable to their job before beginning work with licensed materials. Licensees should not assume that safety instruction has been adequately covered by prior employment or training. Practical, site-specific training should be provided for all individuals before beginning work with, or in the vicinity of, licensed material.



Training should also be performed whenever there is a significant change in duties, procedures, regulations, or terms of the license. Each individual should also receive periodic refresher training at a frequency sufficient to ensure that all staff remain adequately trained.

Additional training is required if an individual is likely to receive a dose in excess of 1 mSv (100 mrem) in a year. Authorized Nuclear Pharmacists and others involved in the preparation of radiopharmaceuticals are most likely to receive doses in excess of 1 mSv (100 mrem) in a year; however, potential radiation doses received by all employees must also be evaluated. The evaluation must include consideration of assigned activities during both normal and abnormal situations involving exposure to radiation and/or radioactive material that can reasonably be expected to occur during licensed activities.

If individuals making deliveries of radioactive material at the licensee's facility are likely to receive a dose in excess of 1 mSv (100 mrem) in a year from the licensee's activities, the licensee is responsible for ensuring that the person has received the training, regardless of whether that person is an employee of the licensee. If the training has been provided by someone else (such as the shipper or another licensee), the licensee does not have to provide training except for instruction in site-specific radiation hazards.

Training may be in the form of lecture, demonstrations, videotape, or self-study, and should emphasize practical subjects important to the safe use of licensed material. A method should be provided for individuals receiving instructions and training to ask questions. The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary. The person conducting the training should be a qualified individual (e.g., the RSO, an Authorized Nuclear Pharmacist, Authorized User, or radiation safety professional familiar with the licensee's program).

Licensee personnel who work in the vicinity of, but do not handle, radioactive materials (ancillary staff) are not required to have radiation safety training as long as they are not likely to receive 100 mrem (1 mSv) in a year. However, to minimize potential radiation exposure when ancillary staff are working in the vicinity of radioactive material, it is prudent for them to work under the supervision and in the physical presence of an Authorized Nuclear Pharmacist/AU or to be provided some basic radiation safety training. Such ancillary staff should be informed of the nature and location of the radioactive material and the meaning of the radiation symbol. They should also be instructed not to handle radioactive materials and to keep away from them as much as their work permits.

Some ancillary staff, although not likely to receive doses over 100 mrem (1 mSv), should receive training to ensure adequate security and control of licensed material. Licensees may provide these individuals with training commensurate with their assignments in the vicinity of the radioactive material to ensure the control and security of the material.

The applicant should state, "We have developed and will implement and maintain written procedures for a training program for each group of workers, including topics covered, qualifications of the instructors, method of training, method for assessing the success of the training, and the frequency of training and refresher training."

### ***Personnel Involved in Hazardous Materials Package Preparation and Transport***

Applicants must train personnel involved in the preparation and transport of hazardous material packages in the applicable DOT regulations<sup>3</sup>. Licensees who prepare packages of radioactive materials or transport their own packages must provide training to their employees who perform those functions. The training must include:

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<sup>3</sup> The licensee is not responsible for providing DOT-required hazardous materials training to common carriers to whom the pharmacy offers radioactive materials packages for transport.

- General awareness and familiarization training designed to provide familiarity with DOT requirements, and the ability of the employee to recognize and identify hazardous materials.
- Function-specific training concerning the DOT requirements that are specifically applicable to the functions the employee performs, (e.g., if the employee's duties require affixing DOT radioactive labels to packages, the employee must receive training in DOT's regulations governing package labeling).
- Safety training concerning emergency response information, discussed above; measures to protect the employee and other employees from the hazards associated with the hazardous materials to which they may be exposed to in the workplace; and methods of avoiding accidents, such as the proper procedures for handling packages containing hazardous materials.

The training must be provided initially, and every three years thereafter. Records of training must be maintained.

Submit the following statement: "We have developed and will implement and maintain written procedures for training personnel involved in hazardous materials package preparation and transport that meet the requirements in 49 CFR 172.700, 49 CFR 172.702, and 49 CFR 172.704, as applicable."

***Instruction for Supervised Individuals Preparing Radiopharmaceuticals***

Individuals who prepare radioactive material for medical use under the supervision of an authorized nuclear pharmacist must be instructed in the preparation of radioactive material for medical use, the principles of radiation safety, and the licensee's procedures for the use of radioactive material. They must also follow the instructions given, and have records kept reflecting their work periodically reviewed by the supervising Authorized Nuclear Pharmacist.

**Item 9: Facilities and Equipment**

Applicants must provide MDH with documentation demonstrating that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of their employees and the public. The facilities and equipment must also keep exposures to radiation and radioactive materials ALARA and minimize the risks from the uses of the types and quantities of radioactive materials. The applicant should provide clear delineations between its restricted and unrestricted areas through the use of barriers, postings, and worker instructions.

Applicants may delay completing facilities and acquiring equipment until after the application review is completed, in case changes are required because 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 cannot 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 are required to be maintained in an identifiable location. For further information, see the section entitled, "Financial Assurance and Record Keeping for Decommissioning."

Applicants must provide a description of the facilities and equipment to be made available at each location where radioactive material will be used. A diagram should be submitted showing the applicant's entire facility and identify activities conducted in all contiguous areas surrounding the facility. Diagrams should be drawn to a specified scale, or dimensions should be indicated.

Submit an annotated drawing of the room or rooms and adjacent areas. Include the following:

1. The scale. Use the same scale (preferably 1/4 inch = 1 foot) for all drawings.

2. Descriptions of the area(s) assigned for the receipt, storage, preparation, and measurement of radioactive materials and the location(s) for radioactive waste storage.
3. The type, thickness, and density of shielding materials within the facility area (including the floor and roof). Sufficient detail in the diagram to indicate the proximity of radiation sources to unrestricted areas, and other items related to radiation safety.
5. A description of the nature of the areas adjacent to the installation, and the distance to these areas.
6. Types of posting and their locations.
7. The locations of entranceways and other points of access into the installation.
8. Security controls to prevent unauthorized access.
9. The results of radiation-level calculations or actual radiation measurements adjacent to, above, and below the installation.
10. A general description of the ventilation system, including representative equipment such as 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 with the probability of becoming airborne, such as compounding radioiodine capsules and dispensing radioiodine solutions.

### ***Radiation Monitoring Equipment***

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

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

For the purposes of this document, radiation-monitoring instruments are defined as any device used to measure the radiological conditions 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
- Single or multi-channel analyzers
- Liquid Scintillation Counters (LSC)
- Gamma counters
- Proportional counters
- Solid state detectors
- 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.). Radiopharmacies typically use a broad energy

range of gamma and beta radiation emitters and need to use radiation detectors appropriate for those energies.

Applicants should discuss the types of instruments to be used for each type of survey to be performed and the availability of a sufficient quantity of these instruments at their facility.

Instrument calibrations may be performed by the pharmacy or by another person specifically authorized by NRC, an Agreement State, or a licensing state to perform that function. If the pharmacy utilizes the services of another person for instrument calibration, the pharmacy should ensure that person has been authorized by the NRC, an Agreement State, or a licensing State to perform that activity. The Calibration Regulatory Guide provides information about instrument specifications and model calibration procedures.

Licensees should provide a description of alternative minimum equipment to be used for radiation monitoring and/or alternative procedures for the calibration of radiation monitoring equipment.

### ***Dosage Measurement Systems***

Due to the potential for radiopharmacy errors to adversely affect their customers (medical facilities) and their customers' patients, each dosage of a radioactive drug must be measured before transfer to provide high confidence that the correct amount of the radioactive drug is transferred in accordance with the customer's request. The applicant must have procedures for the use of the instrumentation, including the measurement, by direct measurement or by combination of measurement and calculation, of the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs before their transfer for commercial distribution.

The procedures must ensure that the dose calibrator, or other dose measurement system, functions properly. Performing periodic checks and tests before first use, followed by checks at specified intervals, and following repairs that could affect system performance accomplish this. Equipment used to measure dosages that emit gamma, alpha, or beta radiation must be calibrated for the applicable radionuclide being measured.

Currently, no alpha-emitting nuclides are used in unsealed form in medicine; therefore, guidance is not provided in this document on the measurement of these radionuclides. For photon-emitters, activity measurement is a straightforward determination; however, for beta-emitters, a correction factor is often necessary to accurately determine the activity. There are inherent technical difficulties to overcome in the determination and application of beta-correction factors. These difficulties include dependence on geometry, lack of an industry standard for materials used in the manufacture of both vials and syringes, and lack of a National Institute of Standards and Technology (NIST) traceable standard for all radionuclides currently in use. If radiopharmacies intend to *initially* distribute, i.e., measure, prepare, and label, beta-emitting radionuclides, the applicant must provide the calculation to demonstrate its ability to accurately dispense such materials. If the applicant intends to use beta-correction factors supplied by the instrument manufacturer, or other entity, it should include a means for ensuring the accuracy of the supplied factor.

Licensees must assay patient dosages in the same type of vial and geometry as used to determine the correct dose calibrator settings. The use of different vials or syringes may result in measurement errors, for example, due to the variation of bremsstrahlung created by interaction between beta particles and the differing dosage containers. Licensees are reminded that beta emitters should be shielded using a low-atomic-numbered material to minimize the production of bremsstrahlung, followed by a high-atomic-numbered material thick enough to attenuate the bremsstrahlung intensity.

For each dose measurement system, specific periodic tests must be performed, as appropriate to the system, to ensure correct operation. Typically, all systems must be checked each day of use for constancy to ensure continued proper operation of the system. In addition, other appropriate tests may include accuracy (for the range of energies to be measured), linearity (for the range of activities to be measured), and geometry dependence (for the range of volumes and product containers).

The applicant should ensure that it possesses a sufficient number of such instruments to allow for periods when instruments are out of service for repair and calibration.

Appendix B contains a model procedure for dose calibrator testing.

The applicant must describe the types of systems (measurement or combination of measurement and calculation) it intends to use for the measurement of alpha-, beta-, and photon-emitting radioactive drugs.

Radiopharmacies that intend to initially distribute (i.e., measure, prepare, and label) beta-emitting radionuclides must provide the calculation to demonstrate its ability to accurately dispense such materials; however, a correction factor calculation is not required if radiopharmacy applicants intend to only redistribute beta-emitting radionuclides that were previously prepared and distributed by other licensees.

If applicable, the applicant must include a sample calculation for determining beta-correction factors for dose calibrators with ionization chambers and a means for ensuring the accuracy of beta-correction factors.

### **Item 10: Radiation Safety Program**

You, as the licensee, are responsible for the conduct of your radiation safety program and for all actions of your employees. The elements of a radiation safety program are contained in the appendices to this Regulatory Guide. Review each appendix carefully. (Some of these appendices have been addressed in the proceeding text and need not be re-addressed.) Commit to the specific appendix, submit your own procedures using the appendix as a guide, or indicate “not applicable.”

#### ***Audit Program***

Appendix C contains a suggested audit program that is specific to commercial radiopharmacies. Not all areas indicated in the Appendix may be applicable to every licensee, and not all items may need to be addressed during each audit. For example, licensees do not need to address areas that do not apply to their activities, and activities that have not occurred since the last audit need not be reviewed at the next audit.

Licensees must maintain records of audits and other reviews of program content and implementation for three years from the date of the record. MDH has found audit records that contain the following information to be acceptable: 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.

#### ***Material Receipt and Accountability***

Licensed materials must be tracked from receipt to disposal in order to ensure accountability, identify when licensed material could be lost, stolen, or misplaced, and ensure that possession limits listed on the license are not exceeded. Licensees exercise control over licensed material accountability by including the following items (as applicable) in their radiation protection program:

- Physical inventories of sealed sources at intervals not to exceed six months
- Ordering and receiving licensed material
- Package opening
- Maintaining material inventory within license possession limits
- Transfer of material, including distribution
- Disposal of material

Licenseses are required to develop, implement, and maintain written procedures for safely opening packages. Some packages may require special procedures that take into consideration the type, quantity, or half-life of the nuclide being delivered.

MDH regulations state the requirements for monitoring packages containing licensed material. These requirements are described in Table 1, below.

**Table 1 Package Monitoring Requirements**

| <b>PACKAGE</b>                           | <b>CONTENTS</b>                              | <b>SURVEY TYPE</b>            | <b>SURVEY TIME<sup>4</sup></b>  |
|--|--|-------------------------------|---|
| Labeled (White I, Yellow II, Yellow III) | Gas or Special Form Greater Than Type A      | Radiation Level               | As soon as practicable, but not later than 3 hours after receipt of package |
| Labeled (White I, Yellow II, Yellow III) | Not Gas Nor Special Form Greater Than Type A | Contamination Radiation Level | As soon as practicable, but not later than 3 hours after receipt of package |
| Labeled (White I, Yellow II, Yellow III) | Gas or Special Form Less Than Type A         | None                          | None  |
| Labeled (White I, Yellow II, Yellow III) | Not Gas Nor Special Form Less Than Type A    | Contamination                 | As soon as practicable, but not later than 3 hours after receipt of package |
| Not Labeled                              | Licensed Material                            | None                          | None  |
| Damaged                                  | Licensed Material                            | Contamination Radiation Level | As soon as practicable, but not later than 3 hours after receipt of package |

The licensee must immediately notify the final delivery carrier and MDH when removable radioactive surface contamination exceeds the limit of 22 disintegrations per minute per square centimeter (dpm/cm<sup>2</sup>) averaged over 300 cm<sup>2</sup>; or external radiation levels exceed 2.0 mSv/hr (200 mrem/hr) at the surface.

*Licenseses must maintain records of receipt, transfer, and disposal of licensed material.* Licensees must secure and control licensed material and should have a means of promptly detecting losses of licensed material. MDH rules require 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.

Since 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 intervals.

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

Table 2 lists the types and retention times for the records of receipt, use, transfer, and disposal (as waste) of all licensed material the applicant must maintain. Other records, such as transfer records, could be linked to radioactive material inventory records.

<sup>4</sup> Assumes packages are received during normal working hours. If packages are received outside of normal working hours, the licensee has three hours after the beginning of the next workday to perform the required surveys.

**Table 3 - Record Maintenance**

| <b>TYPE OF RECORD</b>        | <b>HOW LONG RECORD MUST BE MAINTAINED</b>   |
|------------------------------|---|
| Receipt                      | For as long as the material is possessed until 3 years after transfer or disposal |
| Transfer                     | For three years after transfer  |
| Disposal                     | Until MDH 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 the date of measurement of radioactive material.
- For each sealed source, manufacturer, model number, location and, if needed for identification, serial number
- 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, include the radionuclide, activity, date of disposal, and method of disposal (decay, sewer, etc.).

The applicant should confirm that they will:

- Implement and maintain written procedures for safely opening packages.
- Conduct physical inventories of sealed sources of licensed material at intervals not to exceed six months.
- Develop, 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 receipt, transfer, and disposal of licensed material are maintained.

Appendix D provides additional guidance for the ordering and receiving of radioactive material and Appendix E addresses the safe opening of packages.

***Occupational Dose***

The licensee should perform a prospective evaluation of the dose the individual is likely to receive before allowing the individual to receive the dose. 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 does not need to be considered in the prospective evaluation if monitoring was not required at the other facilities. This evaluation does not need to 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 ten 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% of an applicable limit, monitoring is required.

The types and quantities of radioactive material used at most commercial radiopharmacies provide a reasonable possibility for an internal intake by Authorized Nuclear Pharmacists and radiopharmacy technologists. Uses such as preparing radioiodine capsules from liquid solutions, and opening and dispensing from vials containing millicurie quantities of radioiodine and other isotopes require particular caution. Precautionary measures for personnel to follow during iodine capsule preparation should involve the use of a fume hood and glove box or shoulder length gloves. To monitor internal exposure from such operations, most pharmacies institute a routine bioassay program to periodically monitor these workers.

A program for performing thyroid uptake bioassay measurements should include adequate equipment to perform bioassay measurements, procedures for calibrating the equipment, including factors necessary to convert counts per minute into Becquerel or microcurie units and should address the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue). Thyroid bioassay procedures should also specify the interval between bioassays, action levels, and the actions to be taken at those levels. Generally, thyroid bioassays at radiopharmacies are performed weekly for those workers who routinely handle radioiodine or are in the immediate vicinity when radioiodine is being handled.

Licensees should submit the written procedures for monitoring occupational dose.

### **Public Dose**

Public dose is defined 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 from 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 occupies when the dose is received.

Many possible internal dose pathways contribute to the total effective dose equivalent (TEDE). The TEDE can, however, be broken down into three major dose pathway groups:

1. Airborne radioactive material
2. Waterborne radioactive material
3. External radiation exposure

The licensee should review these major pathways and decide which are applicable to its operations. The licensee must ensure that the total effective dose equivalent from all exposure pathways arising from licensed activities does not exceed 100 mrem (1.0 mSv) 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 10 mrem (0.1 mSv) per year from those emissions. If exceeded, the licensee must report this to MDH and take prompt actions to ensure against recurrence.

Appendix F provides more information concerning monitoring of personnel exposure. Licensees should submit an outline of the monitoring program.



### **General Safety Procedures**

The written procedures should include the following elements:

- Contamination controls
- Waste disposal practices
- Personnel and area monitoring (including limits and frequency of personnel monitoring)
- Use of protective clothing and equipment (including use of appropriate shielding and frequent glove changes to minimize exposure to the individual and to avoid spread of contamination in the laboratory)
- Safe handling of radioactive materials (including special procedures for higher risk activities, such as use of radioiodine)
- Performing Molybdenum-99 breakthrough measurements on each elution from a generator
- Posting and labeling
- Recording requirements
- Reporting requirements
- Responsibilities

Applicants should also develop radioisotope-specific procedures based on the respective hazards associated with the radioisotopes. Applicants should use these guidelines to aid in the development of their own procedures for the safe use of radioisotopes.

Appendix G discusses the safe use of radiopharmaceuticals.

### **Emergency Procedures**

Accidents and emergencies can happen during any operation with radioisotopes, including their receipt, transportation, use, 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, loss or theft of licensed material, and fires involving radioactive material can adversely affect the safety of personnel and members of the public. Applicants should therefore develop and implement procedures to minimize the potential impact of these incidents on personnel, members of the public, and the environment.

Applicants should establish written procedures to handle events ranging from a minor spill to a major accident that may require intervention by outside emergency response personnel. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of staff and the radiation safety officer. In addition, the licensee should develop procedures for routine contacts with its local fire department to inform them of its operations and identify locations of radioactive materials and elevated radiation levels in the event of their response to a fire. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, licensee staff should have a clear understanding of their limitations in an emergency with systematic instructions and clear direction of whom to contact. The licensee should establish clear delineations between minor contamination events, minor spills, and major spills and events.

Emergency spill response materials should be strategically placed in well-marked locations for use by all trained staff. All equipment should be periodically inspected for proper operation and replenished as necessary. Applicants may adopt these procedures or develop their own incorporating the safety features included in these model procedures.

The licensee should submit the written procedures for the safe use of radioactive materials that address the following:

- Facility and personnel radioactive contamination minimization, detection, and control.
- Performing molybdenum-99 breakthrough measurements on all generator elutions used to prepare radioactive drugs for human medical use.

- Use of protective clothing and equipment by personnel.
- Identifying and responding to emergencies involving radioactive material, including:
  - Lost, stolen, or missing licensed material.
  - Exposures to personnel and the public in excess of MDH regulatory limits.
  - Releases of licensed materials in effluents and the sanitary sewer in excess of NRC regulatory limits.
  - Excessive radiation levels or radioactive material concentrations in restricted or unrestricted areas.
  - Radioactive spills and contamination.
  - Fires, explosions, and other disasters with the potential for the loss of containment of licensed material.
  - Routine contacts with local fire departments.

Appendix H provides more guidance on spill procedures.

### **Surveys**

Surveys are evaluations of radiological conditions and potential hazards. These evaluations may be measurements (e.g., radiation levels measured with survey instrument or results of wipe tests for contamination), 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 that surveys accurately assess the radiological conditions. In order to meet regulatory requirements for surveying, measurements of radioactivity should be understood in terms of its properties (i.e., alpha, beta, gamma) and compared to the appropriate limits.

Surveys are required to evaluate a radiological hazard and when necessary for the licensee to comply with the appropriate 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, and equipment.
- Measurements of radioactive material concentrations in air for areas where radiopharmaceuticals are handled or processed in unsealed form and where operations could expose workers to the inhalation of radioactive material (e.g. radioiodine) or where licensed material is or could be released to unrestricted areas.
- Bioassays to determine the kinds, quantities or concentrations, and in some cases, the location of radioactive material in the human body. Radioiodine uptake in a worker's thyroid gland is commonly measured by external counting using a specialized thyroid detection probe.
- Surveys of external radiation exposure levels in both restricted and unrestricted areas.
- Surveys of radiopharmaceutical packages entering (e.g., from suppliers and returns from customers) and departing (e.g., prepared radiopharmaceuticals for shipment to customers).

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect workers from external and internal exposure.

Refer to Appendix I for more information concerning surveys.

### **Leak Testing of Sealed Sources**

When issued, a license will require performance of leak tests at intervals approved by the NRC or an Agreement State and specified in the SSD Registration Certificate. The measurement of the leak test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 0.005 microcuries (185 Bq) of radioactivity.

The following options are available for leak testing:

1. Engage the services of a consultant or commercial facility to take samples, evaluate the samples, and report the results to you.
2. Use a commercial leak test kit. You take the smear and send the smear to the kit supplier, who will report the results to you.
3. Perform the entire leak test sequence yourself, including the smears and measurement.

For Option 1, specify the name, address, and license number of the consultant or commercial organizations.

For Option 2, specify the name, address, and license number of the kit supplier. In your application, you should state that the test samples will be taken by the individuals specified in Item 8 who are responsible for your radiation safety program.

For Option 3, indicate how the test sample will be taken. Specify the instrumentation that will be used for measurement. An instrument capable of making quantitative measurements should be used. Hand-held survey meters will not normally be considered adequate for measurements. Include a sample calculation for conversion of the measurement data to microcuries. You should also specify the individual who will make the measurement and his or her qualifications. The individual should have prior experience in making quantitative measurements, and this experience should be documented in your application.

Some radiopharmacies have been authorized to perform leak testing as a service for other licensees (customers). The subsection titled "service activities" addresses requests to perform leak testing as a service for other licensees. Applicants must specifically request authorization to perform leak testing as a service to other licensees. Requests to provide leak testing as a service to other licensees will be reviewed and, if approved, MDH staff will authorize via a license condition.

Appendix J provides additional guidance on leak testing of sealed sources.

### ***Undetected Contamination and Loss of Control of Licensed Material***

Due to the large quantities of licensed material in liquid form often handled by radiopharmacy personnel, there can be a greater potential for radioactive material contamination. Radiation surveys, if properly conducted as outlined in this section, will normally detect contamination before it leaves the licensee's restricted area (e.g., radiopharmaceutical preparation and packaging areas). If detected within the restricted area during or shortly following radiopharmaceutical preparation, the licensee can normally complete standard decontamination activities to mitigate the spread of the contamination outside the restricted area.

Once the control of the radioactive material is lost, the contamination has a high probability of reaching public locations outside the radiopharmacy, including its customers. Contamination incidents can create public health, regulatory, and public relations problems for licensees.

Submit the written procedures for a survey program that specifies the performance of radiation and contamination level surveys in restricted and unrestricted areas, personnel contamination monitoring, action levels, and the frequencies and records maintenance of those surveys and monitoring.

### ***Transportation***

The types and quantities of radioactive materials shipped by commercial radiopharmacy licensees will nearly always meet the criteria for shipment in a "Type A" package, as defined by the 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 radiopharmacies who

transport their own packages, the packages must be blocked and braced, and shipping papers must be used and located properly in the driver's compartment.

Packaging used by commercial radiopharmacies typically includes military ammunition boxes, briefcases, and cardboard/fiberboard boxes. These packages will normally meet the criteria for Type A quantities, which must meet specified performance standards to demonstrate that they will maintain the integrity of containment and shielding under normal conditions of transport. Such packages will normally withstand minor accident situations and rough handling conditions. The testing criteria for Type A packages are listed in 49 CFR 173.465. Before offering a Type A package for shipment, the shipper is responsible for ensuring that the package has been tested to meet the criteria for the contents and the configuration to be shipped and maintaining a certificate of testing. Shippers are not required to personally test the packages, but must ensure that the testing was performed before use. Records of this testing must be maintained.

DOT regulations also require that individuals who perform functions related to the packaging and shipment of radioactive material receive training specific to those functions. The training must include a general awareness of DOT requirements, function-specific training for the individuals' duties, and safety training. DOT also specifies the frequency of the training and a record retention requirement for training.

The licensee should commit to transporting radioactive materials in accordance with US Department of Transportation (DOT) requirements. Appendix K provides a model program for the return of waste and Appendix L provides additional information about Department of Transportation requirements.

### ***Minimization of Contamination***

All applicants for new licenses need to consider the importance of designing and operating their facilities to minimize the amount of radioactive contamination generated at the site during its operating lifetime and to minimize the generation of radioactive waste during decontamination. In the case of commercial radiopharmacy applicants, these issues usually do not need to be addressed as a separate item, as they are included in responses to other items of the application.

The bulk of unsealed radioactive material utilized by radiopharmacies have short half-lives (under 120 days). These radionuclides do not pose a source of long-term contamination. Additionally, nearly all radioactive waste generated by radiopharmacies is stored for decay rather than transferred to a radioactive waste disposal facility.

The licensee may possess and redistribute sealed sources that contain radionuclides with long half-lives. These sealed sources have been approved by NRC or an Agreement State and, if used according to the respective SS&D Registration Certificate, usually pose little risk of contamination. Leak tests performed at the frequency specified in the SS&D Registration Certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and decontaminated, repaired, or disposed of according to MDH requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts.

### ***Radioactive Drug Labeling for Distribution***

The licensee must label each transport radiation shield to show the radiation symbol as described in 4731.2000. The label must also include the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL," the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specified date and time. The phrase transport radiation shield refers to the primary shield for the radioactive drug, which may include the syringe, vial, or syringe or vial shield. The transport radiation shield should be constructed of material appropriate for the isotope to be transferred for commercial distribution. The transport radiation shield does not refer to the outer suitcase, packaging, or other carrying device, even though that barrier may provide some radiation shielding.

The licensee must label each syringe, vial, or other container (e.g., generator or ampule) used to hold radioactive drugs to be transferred for commercial distribution to show the radiation symbol. The label must include the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL," and an identifier that ensures the syringe, vial, or other container can be correlated with the information on the transport radiation shield label. The identifier must provide a correlation between the syringe, vial, or other container and the information on the label of its transport radiation shield. Identifiers may include the prescription number, the name of the radioactive drug or its abbreviation, the name of the patient, or the clinical procedure.

The applicant must describe all labels, indicating the colors to be used, that will accompany the products and describe where each label is placed (e.g., on the transport radiation shield or the container used to hold the radioactive drug); The applicant must also agree to affix the required labels to all transport radiation shields and each container used to hold the radioactive drugs.

### ***Radioactive Drug Shielding for Distribution***

The applicant must provide appropriate transport radiation shields for the primary container of each radioactive drug that it intends to distribute. The shielding must be adequate for the types and quantities of radioactive materials that the applicant intends to distribute. Typically, transport radiation shields used by radiopharmacies have included two-piece, shielded syringe and vial containers (or "pigs"). Pharmacies have used lead and tungsten shields for gamma-emitting materials and plexiglass inserts for beta-emitters.

As general guidelines, transport radiation shields for Technetium-99<sup>m</sup> products have ensured surface radiation levels of not more than 3 mrem/hr (0.03 mSv/hr), due to the ease of shielding the low energy gamma emitted. For Iodine-131, surface dose rates on transport radiation shields have been approved up to 50 mrem/hr (0.5 mSv/hr) for diagnostic dosages and up to 150 mrem/hr (1.5 mSv/hr) for therapeutic dosages. The applicant should select appropriate shielding materials and dimensions to not only ensure that occupational doses are ALARA, but also that the transport radiation shield can be easily handled.

For each radioactive drug to be distributed (except for products intended for redistribution without manipulation and in the manufacturer's original shipping package):

- Indicate the radionuclide and the maximum activity for each type of container (e.g., vial, syringe).
- Describe the type and thickness of the transport radiation shield provided for each type of container.
- Indicate the maximum radiation level to be expected at the surface of each transport radiation shield when the radioactive drug container is filled with the maximum activity.<sup>5</sup>

### **Item 11: Waste Management**

Radioactive waste is normally generated when conducting licensed activities. Such waste may include used or unused radioactive material, unusable items contaminated with radioactive material, e.g., absorbent paper, gloves, etc. Licensees may not receive radioactive waste from other licensees for processing, storage or disposal, unless specifically authorized to do so by MDH. Commercial radiopharmacies may request to receive certain radioactive waste returned from their customers.

All radioactive waste must be stored in appropriate containers until its disposal and the integrity of the waste containers must be assured. Radioactive waste containers must be appropriately labeled. All radioactive waste must be secured against unauthorized access or removal. MDH requires commercial radiopharmacy licensees to manage radioactive waste generated at their facilities by one or more of the following methods:

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<sup>5</sup> It is not acceptable to state that the applicant will comply with DOT regulations. The dose rate limits that DOT imposes apply to the surface of the package, not the surface of the transport radiation shield.

- Decay-in-Storage (DIS);
- Transfer to an authorized recipient; and
- Release into sanitary sewerage.

Licensees may choose any one or more of these methods to dispose of their radioactive waste. However, most commercial radiopharmacies dispose of radioactive waste by decay-in-storage because the majority of licensed materials used by these facilities have short half-lives.

Applicant's programs for management and disposal of radioactive waste should include procedures for handling, safe and secure storage, characterization, minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. Regulations require that licensees maintain all appropriate records of disposal of radioactive waste.

***Disposal by Decay-in-Storage (DIS)***

MDH permits licensed materials with half-lives of less than or equal to 120 days to be disposed by DIS. The minimum holding period for decay is ten half-lives of the longest-lived radioisotope in the waste. Applicants should assure that adequate space and facilities are available for the storage of such waste. Procedures for management of waste by DIS should include methods of segregation, surveys before disposal, and maintenance of records of disposal.

Licensees 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, freeing storage space.

Used syringes/needles and vials returned from pharmacy customers (medical facilities) are considered both biohazardous and radioactive waste since these items may be contaminated with patients' blood or other body fluids. Following completion of decay-in-storage, such waste may be disposed of as biohazardous waste (medical waste) if radiation surveys (performed in a low background area and without any interposed shielding) of the waste at the end of the holding period indicate that radiation levels are indistinguishable from background.

Radioactive material labels on the used syringes/needles cannot be defaced without exposing employees to the risk of injury from the needles. Additionally, exposing employees to the risk of injury from needles would place licensees in violation of the Occupational Safety and Health Administration regulations, which requires precautions to prevent contact with blood or other potentially infectious materials, including recommendations not to manipulate used syringes/needles by hand. Thus, radiopharmacy licensee's do not have to deface or remove radiation labels from individual containers and packages (e.g., syringes, vials) inside waste barrels/containers intended for disposal as medical waste, provided the following conditions are met:

- The radioactive material labels on the outer waste barrels/containers will be defaced or removed prior to transfer to waste disposal firm.
- Waste barrels are sealed prior to delivery to the waste disposal firm.
- Waste barrels/containers will be delivered directly from the licensee's facility to a waste disposal firm for disposal.
- Medical waste is incinerated and not sent to a medical waste landfill.
- The waste disposal firm is notified that the barrels must not be opened at any point, and for any reason, before incineration.

Other pharmacy radioactive waste that has not been returned from customers and has not otherwise been exposed to blood or body fluids should not have a biohazardous component. Following decay, if it

contains no other hazardous components (e.g. needles, hazardous chemicals), such waste may be disposed as ordinary trash if radiation surveys (performed in a low background area and without any interposed shielding) of the waste at the end of the holding period indicate that radiation levels are indistinguishable from background. All radiation labels must be defaced or removed from containers and packages before final disposal as ordinary trash. If the decayed waste is compacted, all labels that are visible in the compacted mass must also be defaced or removed.

Records of DIS should include:

- the date when the waste was put in storage for decay;
- date when ten half-lives of the longest-lived radioisotope have transpired;
- date of disposal, results of final survey before disposal as ordinary trash and results of the background survey;
- identification of the instrument used to perform the survey; and
- the signature or initials of the individual performing the survey.

### ***Transfer to an Authorized Recipient***

Licensees may transfer radioactive waste to an authorized recipient for disposal. Most commercial radiopharmacies only dispose of radioactive wastes with half-lives greater than 120 days to authorized recipients (e.g., low-level radioactive waste disposal facilities). Since radiopharmacy licensees typically possess small quantities of these materials, the volume of materials disposed in this manner would also be minimal. Currently, radiopharmacies use this system for waste disposal infrequently; therefore, detailed guidance is not provided in this document on the specific requirements related to the transfer of wastes to authorized recipients for disposal.

### ***Release into Sanitary Sewerage***

Licensees will not normally be authorized to dispose of radioactive waste by release into sanitary sewerage. However, consideration will be given to requests if each of the following conditions are met:

- Material is readily soluble (or is easily dispersible biological material) in water.
- Quantity of licensed material that the licensee releases into the sewer each month averaged over the monthly volume of water released into the sewer does not exceed the concentration limits specified in 4731.2750, subpart 7, Table 3.
- If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit cannot exceed unity. Total quantity of licensed material released into the sanitary sewerage system in a year does not exceed the limits specified 4731.2750, subpart 7, Table 3.

Licensees are responsible for demonstrating that licensed materials discharged into the sewerage system are indeed readily dispersible in water and are required to maintain accurate records of all releases of licensed material into the sanitary sewerage, if that method is approved by MDH.

### ***Returned Wastes from Customers***

Commercial radiopharmacy licenses contain a license condition that permits radioactive waste, consisting of pharmacy-supplied items, to be received from their customers. The customer may return, and the radiopharmacy may accept for disposal, only items originating at the radiopharmacy that contained or contain radioactive material<sup>6</sup>. This is limited to pharmacy-supplied syringes and vials and their contents. It is *not* acceptable for customers to return items originating at their facilities that are contaminated with radioactive material supplied by the pharmacy (e.g., gloves, absorbent material, IV tubing, patient

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<sup>6</sup> Retrieval, receipt and disposal of pharmacy-supplied syringes and vials from customers is authorized via a license condition.

contaminated items). If an applicant wishes a broader authorization for radioactive waste retrieval, the applicant must apply for a separate license as a radioactive waste broker.

Radiopharmacy customers, who act as the shipper for returned materials, should be supplied with detailed written instructions on how to properly prepare and package radioactive waste for return to the radiopharmacy. These instructions should clearly indicate that only items supplied by the radiopharmacy may be returned. In addition, these instructions should be adequate to ensure that customers comply with Department of Transportation (DOT) and MDH regulations for the packaging and transport of licensed materials and for the radiation safety of drivers/couriers.

Since customers may return unused syringes and vials, which may contain significant quantities of licensed material, the radiopharmacy should do one of the following:

- Include in their instructions methods for determining that the activities of radioisotopes returned to the pharmacy are limited quantities.
- Otherwise ensure that customers prepare and offer packages for transport that meet MDH and DOT requirements if the packages contain greater than limited quantities of radioactive material.

The radiopharmacy should also have written instructions for pharmacy staff to address pick-up, receipt and disposal of the returnable radioactive waste.

If the pharmacy chooses to take the responsibility to act as the shipper for returned materials, the pharmacy must ensure that its customer follows DOT and MDH regulations for the packaging and transport of licensed materials and for the radiation safety of drivers/couriers in the return process. Submit the written procedures for customer return of pharmacy supplied syringes and vials and their contents, to specify that:

- Only pharmacy-supplied syringes and vials and their contents may be returned to the pharmacy.
- Instructions will be provided to radiopharmacy customers for the proper preparation and packaging of the radioactive waste for return to the radiopharmacy.
- Instructions will be provided to pharmacy staff for the pick-up, receipt, and disposal of the returned radioactive waste.

#### **Item 12: License Fee**

If this is an application for a new license, the full fee must be included with this application. An application received without a fee or with an inadequate fee may be returned to you or delayed in processing. Fees for processed applications are not refundable. Make check or money order payable to the Minnesota Department of Health.

For license renewals, the fee is due on the date your license expires.

#### **Item 13: Certification**

Individuals acting in a private capacity are required to sign and date the *Application for Radioactive Materials License*. Otherwise, representatives of the corporation or legal entity filing the application should sign and date the form. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. Signing the application acknowledges management's commitment and responsibilities for the radiation protection program. MDH will return all unsigned applications for proper signature. When the application references commitments, those items become part of the licensing conditions and regulatory requirements.



## **AMENDMENTS TO A LICENSE**

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application, (2) the terms and conditions of the license, and (3) the MDH rules.

It is your obligation to keep your license current. You should anticipate the need for a license amendment as far in advance as possible. If any of the information provided in your application is to be modified or changed, submit a signed application for a license amendment and include the appropriate amendment fee.

*The licensee may not place into effect any amendment until receiving written verification from MDH that the amendment has been approved.*

An application for a license amendment may be prepared either on the *Application for Radioactive Materials License* or in letter format. The application should identify your license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph. For example, if you wish to change the responsible individual, your application for a license should specify the new individual's name, training, and experience.

## **RENEWAL OF A LICENSE**

An application for the renewal of a license should be filed at least 30 days before the expiration date. This will ensure that the license does not expire before the final action on the application has been taken by MDH. The application for the renewal should not reference material that was previously submitted.

If you do not wish to renew your license and cannot dispose of all the licensed radioactive material in your possession before the expiration date, you must request a license renewal for storage only of the radioactive material. The renewal is necessary to avoid violating MDH rules that do not allow you to possess licensable material without a valid license.

## **IMPLEMENTATION**

The information in this regulatory guide is *guidance*, not requirement. The Minnesota Department of Health reviews each application to ensure that users of radioactive material are capable of complying with MDH rules. This guide provides one set of methods approved by MDH for meeting the regulations and represents the minimum acceptable standards.

## **INSPECTIONS**

MDH conducts initial inspections of new radiological programs between six and 12 months after licensed material is received and operations have begun. Subsequent routine inspections of licenses are scheduled after the initial inspection. The routine inspections are scheduled at intervals corresponding to frequency indicated in NRC Inspection Manual Chapter 2800.

**APPENDIX A**  
**TYPICAL DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER**

The RSO's duties and responsibilities include ensuring radiological safety and compliance with MDH and DOT regulations, and with the conditions of the license. Typically, these duties and responsibilities include ensuring that:

- General surveillance is provided over all activities involving radioactive material, including routine monitoring, special surveys, and responding to events.
- Incidents are responded to and investigated, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken.
- Proper authorities are notified of incidents such as damage, fire, or theft.
- Corrective actions are developed, implemented, and documented when violations of regulations or license conditions or program weaknesses are identified.
- All activities are immediately terminated following any unsafe condition or activity that is found to be a threat to public health and safety.
- He or she is the primary source of radiation protection information for personnel at all levels of responsibility.
- All radiation workers are properly trained.
- Procedures for the safe use of radioactive materials are developed and implemented.
- The licensee's procedures and controls, based upon sound radiation protection principles, are periodically reviewed to ensure that occupational doses and doses to members of the public are as low as is reasonably achievable (ALARA). Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit.
- Prospective evaluations are performed of occupational exposures, and those individuals likely to receive, in one year, a radiation dose in excess of ten percent of the allowable limits are provided personnel monitoring devices.
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained.
- The performance of fume hoods and glove boxes used for volatile radioactive material work are monitored for proper operation.
- The receipt, opening, and delivery of all packages of radioactive material arriving at the nuclear pharmacy are overseen and coordinated.
- An inventory of all radioactive materials is maintained and the types and quantities of radionuclides at the facility are limited to the forms and amounts authorized by the license.
- Sealed sources are leak tested at required intervals.
- There is effective management of the radioactive waste program, including effluent monitoring.
- Packaging and transport of radioactive material is in accordance with all applicable DOT requirements.
- An up-to-date license is maintained, and amendment, renewal requests, and notifications of new authorized nuclear pharmacists are submitted in a timely manner.
- Radiation safety program audits are performed at least annually and documented.
- He or she acts as liaison to the MDH.
- All required records are properly maintained.

## APPENDIX B MODEL DOSE CALIBRATOR TESTING PROGRAM

This model procedure can be used by applicants and licensees for checking and testing dose calibrators.

### MODEL PROCEDURE

1. Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances.
  - 1.1 Constancy, at least once each day prior to assay of patient dosages (a safe margin is considered to be below + 10%).
  - 1.2 Linearity at installation and at least quarterly thereafter (a safe margin is considered to be below + 10%).
  - 1.3 Geometry dependence at installation (a safe margin is considered to be below +10%).
  - 1.4 Accuracy, at installation and at least annually thereafter (a safe margin is considered to be below +10%).
2. After repair, adjustment, or relocation of the dose calibrator, such that proper function of the ionization chamber or electronics would likely be in doubt, repeat the above tests as appropriate.
3. Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cesium-137, Cobalt-60, Cobalt-57, or Radium-226 using a reproducible geometry each day before using the calibrator. Consider using two or more sources with different photon energies and activities.

Use the following procedure:

- 3.1 Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cesium-137 setting to assay Cesium-137).
  - 3.2 Measure background at the same setting, and subtract or confirm the proper operation of the automatic background circuit if it is used.
  - 3.3 For each source used, either plot or log (i.e., record in the dose calibrator log book) the background level for each setting checked and the net activity of each constancy source.
  - 3.4 Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
  - 3.5 Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the authorized nuclear pharmacist or the radiation safety officer of a suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator. The dose calibrator should be repaired or replaced if the error exceeds 10%.
4. The linearity of a dose calibrator should be ascertained over the range of its use between the maximum activity in a vial and 30 microcuries. *Linearity* means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This example uses a vial of

Technetium-99<sup>m</sup> that has the anticipated maximum activity to be assayed (e.g., the first elution from a new generator) and assumes your predetermined safety margin is  $\pm 5\%$ .

#### 4.1 Time Decay Method

- 4.1.1 Inspect the instrument to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).
- 4.1.2 Assay the Technetium-99<sup>m</sup> vial in the dose calibrator and subtract background to obtain net activity in millicuries.
- 4.1.3 Repeat step 4.1.2 at time intervals of 6, 24, 30, and 48 hours after the initial assay.
- 4.1.4 Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

| <u>Assay Time<sup>7</sup> (hours)</u> | <u>Correction Factor</u> |
|---------------------------------------|--------------------------|
| 0                                     | 31.6                     |
| 6                                     | 15.8                     |
| 24                                    | 2.00                     |
| 30                                    | 1.00                     |
| 48                                    | 0.126                    |

- 4.1.5 Plot both the measured net activity and the calculated activity versus time.
- 4.1.6 On the graph, the measured net activity plotted should be within  $\pm 5\%$  of the calculated activity if the instrument is linear and functioning properly. If variations greater than 5% are noted, adjust the instrument, have it repaired, or use arithmetic correction factors to correct the readings obtained in daily operations.
- 4.1.7 If instrument linearity cannot be corrected, for routine assays it will be necessary to use either a portion of the eluate that can be accurately measured or the graph constructed in step 4.1.5 to relate measured activities to calculated activities.

#### 4.2 Shield Method:

If a set of sleeves of various thicknesses is used to test for linearity, it will first be necessary to calibrate them.

- 4.2.1 Begin the linearity test by assaying the Technetium-99<sup>m</sup> syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the date, time to the nearest minute, and net activity. This first assay should be done in the morning at a regular time. After making the first assay, the sleeves can be calibrated as follows. (Steps 4.2.2 through 4.2.4 must be completed within 6 minutes.)

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<sup>7</sup> Assay times should be measured in whole hours and correction factors should be used to three significant figures as indicated. The half-life of  $T_{1/2} = 6.02$  hours has been used in calculating these correction factors.

Example: If the net activity measured at 30 hours was 15.6 mCi, the calculated activities for 6 and 48 hours would be  $15.6 \text{ mCi} \times 15.9 = 248 \text{ mCi}$  and  $15.6 \text{ mCi} \times 0.126 = 1.97 \text{ mCi}$ , respectively.

- 4.2.2 Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
- 4.2.3 Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.
- 4.2.4 Continue for all sleeves.
- 4.2.5 Complete the following decay method linearity test steps:
  - 4.2.5.1 Repeat the assay at about noon, and again at about 4:00 p.m. Continue on subsequent days until the assayed activity is less than 30 microcuries. For dose calibrators on which the range is selected with a switch, select the range normally used for the measurement.
  - 4.2.5.2 Convert the time and date information recorded to hours elapsed since the first assay.
  - 4.2.5.3 On a sheet of semi log graph paper, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Plot the data.
  - 4.2.5.4 Draw a best fit straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.  
 $(A\text{-observed} - A\text{-line}) / (A\text{-line}) = \text{deviation}$
  - 4.2.5.5 If the worst deviation is more than +0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow conversion from activity indicated by the dose calibrator to true activity.
- 4.2.6 From the graph made in step 4.2.5.3, find the decay time associated with the activity indicated with sleeve 1 in place. This is the equivalent decay time for sleeve 1. Record that time with the data recorded in step 4.2.2.
- 4.2.7 Find the decay time associated with the activity indicated with sleeve 2 in place. This is the equivalent decay time for sleeve 2. Record that time with the data recorded in step 4.2.3.
- 4.2.8 Continue for all sleeves.
- 4.2.9 The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

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

- 4.2.10 Assay the Technetium-99<sup>m</sup> syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.
- 4.2.11 Steps 4.2.12 through 4.2.14 below must be completed within 6 minutes.
- 4.2.12 Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.
- 4.2.13 Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.
- 4.2.14 Continue for all sleeves.
- 4.2.15 On a sheet of semi log graph paper, label the logarithmic vertical axis in millicuries, and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the model number and serial number of the dose calibrator.

- 4.2.16 Plot the data using the equivalent decay time associated with each sleeve.
- 4.2.17 Draw a best fit straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.  
 $(A_{\text{observed}} - A_{\text{line}})/A_{\text{line}} = \text{deviation}$ .
- 4.2.18 If the worst deviation is more than  $\pm 0.05$ , the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow conversion from activity indicated by the dose calibrator to "true activity."
5. *Geometry independence* means that the indicated activity does not change with volume or configuration. The test for geometry independence should be conducted using syringes and vials that are representative of the entire range of size, shape, and constructions normally used for injections and a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following example assumes that injections are done with 3-cc plastic syringes, that radiopharmaceutical kits are made in 30-cc glass vials, and that the predetermined safety margin is  $\pm 5\%$ .
- 5.1 In a small beaker or vial, mix 2 cc of a solution of technetium-99<sup>m</sup> with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with non-radioactive saline. Tap water may be used.
- 5.2 Draw 0.5 cc of the Technetium-99<sup>m</sup> solution into the syringe and assay it. Record the volume and millicuries.
- 5.3 Remove the syringe from the calibrator, draw an additional 0.5 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
- 5.4 Repeat the process until a volume of 2.0-cc has been assayed. The entire process must be completed within 10 minutes.
- 5.5 Select as a standard the volume closest to that normally used for injections. For all other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, graph the data and draw horizontal error lines above and below the chosen standard volume.
- 5.6 If any correction factors are greater than 1.05 or less than 0.95, or if any data points lie outside the error lines, it will be necessary to make a correction table or graph that will allow a conversion from indicated activity to true activity. If this is necessary, be sure to label the table or graph "syringe geometry dependence," note the date of the test, and indicate the model and serial number of the calibrator.
- 5.7 To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Technetium-99<sup>m</sup> solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.
- 5.8 Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.
- 5.9 Repeat the process until a volume of 19.0-cc has been assayed. The entire process must be completed within 10 minutes.
- 5.10 Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all other volumes, divide the standard millicuries by the millicuries indicated for each

volume. The quotient is a volume correction factor. Alternatively, the data may be graphed, with horizontal 5% error lines drawn above and below the chosen standard volume.

5.11 If any correction factors are greater than 1.05, or less than 0.95, or if any data points lie outside the 5% error lines, it will be necessary to make a correction table or graph that will allow conversion from indicated activity to true activity. If this is necessary, be sure to label the table or graph "vial geometry dependence," note the date of the test, and indicate the model number and serial number of the calibrator.

6. Accuracy means that, for a given calibrated reference source, the indicated millicurie value is equal to the millicurie value determined by the National Institute of Standards and Technology (NIST) or by the supplier who has compared that source to a source that was calibrated by NIST. Certified sources are available from NIST and from many radioisotope suppliers. At least two sources with different principal photon energies (such as Cobalt-57, Cobalt-60, Cesium-137) should be used. One source should have a principal photon energy between 100 keV and 500 keV. If a Radium-226 source is used, it should be at least 10 microcuries; other sources should be at least 50 microcuries.

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

6.1 Assay a calibrated reference source at the appropriate setting (i.e., use the Cobalt-57 setting to assay Cobalt-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for a total of three determinations.

6.2 Average the three determinations. The average value should be within the predetermined safety margin, which in this example is 5% of the certified activity of the reference source, mathematically corrected for decay.

6.3 Repeat the procedure for other calibrated reference sources.

6.4 If the average value does not agree within 5% with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The dose calibrator should be repaired or replaced if the error exceeds 10%.

6.5 At the same time the accuracy test is done, assay the source that will be used for the daily constancy test (it need not be a certified reference source) on all commonly used radioisotope settings. Record the settings and indicated millicurie values with the accuracy data.

6.6 Put a sticker on the dose calibrator noting when the next accuracy test must be performed.

7. The individual performing the tests will sign or initial the records of all geometry, linearity, and accuracy tests.

**APPENDIX C  
SUGGESTED NUCLEAR PHARMACY AUDIT CHECKLIST**

*Note:* All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit. For example, licensees do not need to address areas that do not apply to the licensee's activities and activities that have not occurred since the last audit need not be reviewed at the next audit.

| <b>Audit History</b>  | <b>4731</b>          | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
|---|----------------------|--------------------------|--------------------------|--------------------------|
| Were previous audits conducted annually?  | 2010                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Are records of previous audits maintained?  | 2500                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Deficiencies identified?  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Were the deficiencies corrected?  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Organization and Scope of Program</b>  | <b>4731</b>          | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| Radiation Safety Officer  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If the RSO was changed, was license amended?  | 4403                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Does new RSO meet MDH training requirements?  | 4411<br>4414<br>4415 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Is RSO fulfilling all duties?   | 4405                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Is the written agreement in place for a new RSO?  | 4405                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Authorized Nuclear Pharmacist   |                      |                          |                          |                          |
| New Authorized Nuclear Pharmacist since last audit?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Does the new Authorized Nuclear Pharmacist meet MDH training requirements?  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If a new Authorized Nuclear Pharmacist was added, was MDH notified within 30 days or was the MDH license amended?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Authorized Users  |                      |                          |                          |                          |
| New Authorized User since last audit?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Does the new Authorized User meet MDH training requirements?  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If a new Authorized User was added, or was the MDH license amended?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Are there multiple locations of use?  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Are all locations listed on the license?  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If multiple locations authorized, list locations audited.   |                      |                          |                          |                          |
| Were annual audits performed at each location? If no, explain.  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Licensed Material</b>  | <b>4731</b>          | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| Isotope, chemical form, quantity and use as authorized?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Does total amount of radioactive material possessed require financial assurance?                                    | 3080                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If so, is financial assurance adequate?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Are sealed sources possessed and used as described in the Sealed Source and Device Registration (SSDR) Certificate? | 4460                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Are copies of the SSDR Certificates possessed or accessible?  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Are manufacturer's manuals for operation of medical devices possessed?  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |



|   |                      |                          |                          |                          |
|---|----------------------|--------------------------|--------------------------|--------------------------|
| If places of use changed, was the license amended?  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If control of license was transferred, was MDH consent obtained prior to the transfer?  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Radiation Safety Program</b>   | <b>4731</b>          | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| Minor changes to program?   | 4405                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Records of changes maintained for five years?   | 4500                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Content and implementation reviewed annually by the licensee?   | 2020                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Records of reviews maintained?  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Training, Retraining, and Instruction to Workers</b>   | <b>4731</b>          | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| Have workers been provided with required instructions?  | 1020                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Is the individual's understanding of current procedures and regulations adequate?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Training program implemented?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Operating procedures?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Emergency procedures?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Periodic training required and implemented?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed and was refresher training provided, as needed?                         | 1020                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Was each supervised user instructed in the licensee's written radiation protection procedures and administration of written directives, as appropriate? | 4407                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Are initial and periodic training records maintained for each individual?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Workers cognizant of requirements for:  |                      |                          |                          |                          |
| Radiation Safety Program?   | 2010                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Annual dose limits?   | 2020<br>2090<br>2095 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10% monitoring threshold?   | 2210                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Dose limits to embryo/fetus and declared pregnant worker?   | 2080                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Grave danger posting?   | 2310                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Procedures for opening packages?  | 2350                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Supervision of individuals by authorized user and/or authorized nuclear pharmacist in accordance with 4731.4407?  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Facilities</b>   | <b>4731</b>          | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| Facilities are as described in the license application?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Storage areas:  |                      |                          |                          |                          |
| Materials secured from unauthorized removal or access?  | 2290                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Licensee controls and maintains constant surveillance of licensed material not in storage?  | 2290                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Dose Calibrator:  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Constancy checked?  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Linearity tested quarterly?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Accuracy tested annually?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Geometry dependence test?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Readings mathematically corrected if linearity error is greater than 10%?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Records maintained and include required information?  | 4502                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Determination of dosages of unsealed radioactive material:  |                      |                          |                          |                          |
| Each dosage determined and recorded prior to medical use?   | 4422                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Measurement of unit dosages made by direct measurement or by decay correction?  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

|   |             |                          |                          |                          |
|---|-------------|--------------------------|--------------------------|--------------------------|
| For other than unit dosages, dose determined by direct measurement of radioactivity or by combination of radioactivity or volumetric measurement and calculation? |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Licensee uses generators?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Are generators located in separate room and/or properly shielded to keep doses ALARA?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| First eluate after receipt is tested for Molybdenum-99 breakthrough?  | 4509        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| No radiopharmaceuticals administered with Mo-99 concentrations over 0.15 µCi per mCi of Tc-99 <sup>m</sup> ?  |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Records maintained?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Dose Measurement Systems</b>   |             |                          |                          |                          |
| Calibrated for each isotope used?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Constancy tests completed at least once each day prior to assay of patient dosages (+10%)?  |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Linearity at installation and quarterly (+10%)?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Accuracy at installation and at intervals not to exceed 12 months (+10%)?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Geometry at installation (+10%)?  |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| After repair, adjustment or relocation of the dose calibrator were Geometry, Accuracy, Linearity, and Constancy tests completed?                                  |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Radiation Protection And Control Of Radioactive Material</b>   | <b>4731</b> | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| <b>Use of radiopharmaceuticals</b>  |             |                          |                          |                          |
| Protective clothing worn?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Personnel routinely monitor their hands?  |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| No eating/drinking in use/storage areas?  |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| No food, drink, or personal effects kept in use/storage areas?  |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Proper dosimetry worn?  |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Radioactive waste disposed of in proper receptacles?  |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Syringe shields and vial shields used?  |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Radiation Survey Instruments</b>   | <b>4731</b> | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| Sufficient portable and fixed survey instruments possessed?   | 4421        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Calibrations completed before first use?  |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Instrument calibrated annually (intervals not to exceed 12 months)?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Calibrations within 20 percent on each scale or decade of interest?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Calibration records maintained?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Area Surveys</b>   | <b>4731</b> | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| Radiation surveys performed in accordance with the licensee's procedures and the regulatory requirements?   | 2200        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Are area surveys being performed at applicable locations?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Are area surveys being performed at required frequencies?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Are contamination surveys being performed at applicable locations?  |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Are contamination surveys being performed at required frequencies?  |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Trigger levels established?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Corrective action taken and documented if trigger level exceeded?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Techniques can detect 0.1 mR/hr, 2000dpm?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Leak Tests</b>   | <b>4731</b> | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| Was each Sealed Source leak tested every six months or at prescribed intervals?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

|   |                                      |                          |                          |                          |
|---|--------------------------------------|--------------------------|--------------------------|--------------------------|
| Were leak tests performed according to the license?   |                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Records maintained?   |                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| MDH notified of any leaking sources?  |                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Sealed Source Inventory</b>  | <b>4731</b>                          | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| Records of receipt for sources maintained?  |                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Sealed sources physically inventoried at intervals not to exceed six months?  |                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Records of inventories retained?  |                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Public Dose</b>  | <b>4731</b>                          | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| Is licensed material used in a manner to keep doses below 1mSv (100 mrem) in a year?  | 2090                                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Has a survey or evaluation been performed?  | 2200                                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation? |                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour?   | 2090                                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Is licensed material used or stored in a manner that would prevent unauthorized access or removal?  | 2290                                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Records maintained?   |                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Radioactive Waste</b>  | <b>4731</b>                          | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| Disposal:   |                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Decay-in-storage  | 4429                                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Procedures followed?  |                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Labels removed or defaced?  | 2330<br>4429                         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Special procedures performed as required?   |                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Authorized disposals?   | 2400                                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Records maintained?   | 2510<br>2560                         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Effluents:  |                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Release to sanitary sewer?  | 2420                                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Material is readily soluble or readily dispersible?   | 2420                                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Monthly average release concentrations do not exceed 2750 Subpart 4?  |                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| No more than 5 Ci of H-3, 1 Ci of C-14 and 1 Ci of all other radionuclides combined released in a year?   | 2420                                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Procedures to ensure representative sampling and analysis implemented?  | 2200                                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Release to septic tanks? (Note: Release to septic tanks is not authorized.)   |                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Waste incinerated?  |                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| License authorizes?   | 2430                                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Directly monitor exhaust?   |                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Airborne releases evaluated and controlled?   | 2095<br>2200                         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Air effluents and ashes controlled?   | 2010<br>2020<br>2090<br>2200<br>2400 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Air effluent less than 10 mrem constraint limit?  | 2010                                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If no, reported appropriate information to MDH.   |                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Corrective actions implemented and on schedule?   |                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

|   |                      |                          |                          |                          |
|---|----------------------|--------------------------|--------------------------|--------------------------|
| Description of effluent program:  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Monitoring system hardware adequate?  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Equipment calibrated, as appropriate?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Air samples/sampling technique (i.e., charcoal, HEPA, etc.) analyzed with appropriate instrumentation?                    |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Waste storage   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Protection from elements and fire?  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Control of waste maintained?  | 2290                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Containers properly labeled and area properly posted?   | 2310<br>2320         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Package integrity adequately maintained?  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Waste disposal:   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Sources transferred to authorized individuals?  | 2400<br>2450<br>3105 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Name of organization:   |                      |                          |                          |                          |
| Records of surveys and material accountability are maintained?  | 2510<br>2560         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Receipt And Transfer of Radioactive Material</b>   | <b>4731</b>          | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| Describe how packages are received and by whom.   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Written package opening procedures established and followed?  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| All incoming packages with a DOT label monitored for radioactive contamination, unless exempted (gases and special form)? | 2350                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Incoming packages surveyed?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Monitoring in (C) and (D) performed within time specified?  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Transfer(s) performed per MDH requirements?   | 3105                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| All sources surveyed before shipment and transfer?  | 2200                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Records of surveys and receipt/transfer maintained?   | 2510<br>3115         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Package receipt/distribution activities evaluated for compliance with 4731.2090?  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Transportation (10 CFR 71.5(a) and 49 CFR 171-189)</b>   | <b>4731</b>          | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| Shipments are:  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| delivered to common carriers;   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| transported in own private vehicle;   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| both;   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| no shipments since last audit.  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Return radiopharmacy doses or sealed sources?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Licensee assumes shipping responsibility?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| NO, describe arrangements made between licensee and radiopharmacy for shipping responsibilities:                          |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Packages:   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Authorized packages used?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Performance test records on file?   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| DOT-7A packages   |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Special form sources  |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Two labels (White-I, Yellow-II, Yellow-III) with TI, Nuclide, Activity, and Hazard Class?                                 |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Properly marked (Shipping Name, UN Number, Package Type, RQ, "This End Up" (liquids), Name and Address of consignee)?     |                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

|   |                              |                          |                          |                          |
|---|------------------------------|--------------------------|--------------------------|--------------------------|
| Closed and sealed during transport?   |                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Shipping Papers:  |                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Prepared and used?  |                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Proper Shipping Name, Hazard Class, UN Number, Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, Category of Label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, "Limited Quantity" (if applicable), "Cargo Aircraft Only" (if applicable)? |                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Readily accessible during transport?  |                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Personnel Radiation Protection</b>   | <b>4731</b>                  | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| Exposure evaluation performed?  | 2200                         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| ALARA program implemented?  | 2010                         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| External Dosimetry:   |                              |                          |                          |                          |
| Monitors workers per 4731.2210?   |                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| External exposures account for contributions from airborne activity?  | 2040                         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Supplier Frequency  |                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Supplier is NVLAP-approved?   | 2200                         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Dosimeters exchanged at required frequency?   |                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Internal Dosimetry  |                              |                          |                          |                          |
| Monitors workers per 4731.2210?   |                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Briefly describe program for monitoring and controlling internal exposures?   | 2240                         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Monitoring/controlling program implemented (includes bioassays)?  |                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Respiratory protection equipment?   |                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Review of Records and Reports   |                              |                          |                          |                          |
| Reviewed by Frequency   |                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|   |                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Auditor reviewed personnel monitoring records for period to _____   |                              |                          |                          |                          |
| Prior dose determined for individuals likely to receive doses?  | 2520                         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Maximum exposures TEDE Other  |                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Maximum CDEs Organs   |                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Maximum CEDE  |                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Internal and external summed?   | 2030                         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Were occupational limits met?   | 2020                         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| MDH Forms 5 or equivalent provided to all monitored employees?  | 2520<br>2540                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If a worker declared her pregnancy during the audit period, then was the dose in compliance and were the records maintained?  | 2030<br>2540                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Who performed any planned special exposures at this facility (number of people involved and doses received)?  | 2060<br>2520<br>2530<br>2630 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Records of exposures, surveys, monitoring, and evaluations maintained?  | 2500<br>2510<br>2540         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Confirmatory Measurements</b>  | <b>4731</b>                  | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| Detail location and results of confirmatory measurements.   |                              | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Notification and Reports</b>   | <b>4731</b>                  | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |

|  |             |                          |                          |                          |
|--|-------------|--------------------------|--------------------------|--------------------------|
| In compliance with 4731.1030, 4731.3110 (reports to individuals, public and occupational, monitored to show compliance)?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| In compliance with 4731.2600, 4731.3110 (theft or loss)?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| In compliance with 4731.2610, 4731.3110 (incidents)?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| In compliance with 4731.2620, 4731.3110 (overexposures and high radiation levels)?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Aware of MDH phone number?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| In compliance with 4731.2620 (Constraint on air emissions)?  |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Posting and Labeling</b>  | <b>4731</b> | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| MDH Form, "Notice to Workers" is posted?   | 1010        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Other posting and labeling per 4731.2310, 4731.2330 and not exempted by 4731.2320, 4731.2340?  |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Recordkeeping for Decommissioning</b>   | <b>4731</b> | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination? | 3080        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Records include all information outlined in?   | 3080        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Amendments Since Last Audit</b>   | <b>4731</b> | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| Any Amendments since last audit?   | 4403        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Notifications Since Last Audit</b>  | <b>4731</b> | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| Any Notifications since last audit?  | 4403        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Appropriate documentation provided to MDH for authorized nuclear pharmacist no later than 30 days after the individual starts work?  | 4403        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| MDH notified within 30 days after any of the following stops work or changes name:   |             |                          |                          |                          |
| Authorized Nuclear Pharmacist;   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Radiation Safety Officer (RSO)   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| MDH notified within 30 days after:   |             |                          |                          |                          |
| licensee's mailing address changes;  |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| licensee's name changes without a transfer of control of the license; or   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Bulletins and Information Notices</b>   | <b>4731</b> | <b>N/A</b>               | <b>Yes</b>               | <b>No</b>                |
| Bulletins, Information Notices, etc., received?  |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Appropriate action in response to Bulletins, Information Notices, Generic Letters, etc.?   |             | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

**Special License Conditions or Issues**

Special license conditions or issues to be reviewed:

Evaluation:

**Audits and Findings**

Summary of findings:

Corrective and preventive actions:

Audit conducted by:

Date:



## **APPENDIX D ORDERING AND RECEIVING RADIOACTIVE MATERIAL**

You may want to use the following guidance to control the ordering and receipt of radioactive material. If you follow all the guidance, you may state on your application, "We will establish and implement the model guidance for ordering and receiving radioactive material that is published in Appendix D to the MDH Regulatory Guide for Nuclear Pharmacies."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, state on your application, "We have developed a procedure for ordering and receiving radioactive material that is appended as Appendix D," and submit your procedure.

### **MODEL GUIDANCE**

1. The Radiation Safety Officer (RSO) or a designee should ensure that the requested materials and quantities are authorized on the license. The material and quantity must also be approved for the requesting Authorized User. Checks should be made to ensure that possession limits are not exceeded.
2. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:
  - a. For routinely used materials:
    - (1) Written records identifying  
Authorized User or department  
isotope  
chemical form  
activity  
supplier
    - (2) Verification that material received was ordered by an Authorized User.
  - b. For occasionally used materials (e.g., therapeutic dosages):
    - (1) The Authorized User who will perform the procedure will make a written request to confirm that the material received is what was ordered.
    - (2) The person who receives the material will check the physician's request to confirm that the material received is what was ordered.
3. For deliveries during normal working hours, the RSO shall instruct carriers to deliver radioactive packages directly to specified areas.

**APPENDIX E**  
**SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL**

In addition to 4731.2350

You may use the following model procedure for opening packages. If you follow the model procedure, you may indicate on your application, "We will establish and implement the model procedure for opening packages published in Appendix E to the MDH Regulatory Guide for Nuclear Pharmacies."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. Indicate on your application, "We have developed a procedure for safely opening packages containing radioactive material that is appended as Appendix E," and submit your procedure.

**MODEL PROCEDURE**

1. All labeled packages containing radioactive material must be monitored for radiation levels and radioactive surface contamination upon receipt.
2. The following procedures for opening each package will be followed:
  - a. Put on gloves to prevent hand contamination.
  - b. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the Radiation Safety Officer (RSO).
  - c. Measure the exposure rate from the package at 1 meter and at the package surface. If it is more than 10 millirems per hour at 3 feet (1 meter), stop and notify the RSO. (The transport index noted on packages with Yellow II or Yellow III labels is the approximate dose rate, in millirem per hour, at 1 meter from the package surface).
  - d. Measure the dose rate on the surface of the package. The surface dose rate for such packages should not exceed 200 millirem per hour at any point on the package. The dose rate from packages with White I labels should be less than 0.5 millirem per hour on the external surface of the package.
  - e. Wipe the external surface of the package, approximately 300 square centimeters in the most appropriate location to detect contamination. The amount of radioactivity measured on any single wiping material when averaged over the surface wiped, must not exceed the following limits:

|  |                         |
|--|-------------------------|
| Beta-gamma-emitting radionuclides; all radionuclides with half-lives less than ten days..... | 22 dpm/cm <sup>2</sup>  |
| All other alpha-emitting radionuclides.....  | 2.2 dpm/cm <sup>2</sup> |

- f. Open the package with the following precautionary steps:
      - (1) Remove packing slip.
      - (2) Open outer package following the supplier's instructions, if provided.
      - (3) Open inner package and verify that the contents match the packing slip.
      - (4) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
      - (5) If anything is other than expected, stop and notify the RSO.
    - g. If there is any reason to suspect contamination, wipe the external surface of the final source container and remove the wipe sample to a low-background area. Assay the wipe

sample to determine if there is any removable radioactivity. (The licensee should specify in the procedure manual which instrument [for example, a thin-end-window GM survey meter, a NaI(Tl) crystal and ratemeter, a liquid scintillation counter, or a proportional flow counter] should be used for these assays. The detection efficiency must be determined to convert wipe samples counts per minute to disintegrations per minute. Note that a dose calibrator is not sufficiently sensitive for this measurement. Take precautions against the potential spread of contamination.

- h. Check the user request to ensure that the material received is the material that was ordered.
  - i. Monitor the packing material and the empty packages for contamination with a radiation survey meter before discarding.
    - (1) If contaminated, treat this material as radioactive waste.
    - (2) If not contaminated, remove or obliterate the radiation labels before discarding it.
  - j. Make a record of the receipt.
3. For packages received under the general license, the following procedure for opening each package will be followed.
- a. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop the procedure and notify the RSO.
  - b. Check to ensure that the material received is the material that was ordered.

## **APPENDIX F PERSONNEL EXPOSURE MONITORING PROGRAM**

You may use the following model program to monitor personnel external exposure. If you follow the guidance in the program, you may state on your application. "We will establish and implement the model personnel exposure monitoring program published in Appendix F of the MDH Regulatory Guide for Nuclear Pharmacies."

If you prefer, you may develop your own program for review. You should consider for inclusion all the features in the model program and carefully review the requirements of MDH rules. State on your application, "We have developed an external exposure monitoring program for your review that is appended as Appendix F" and submit your monitoring program.

"Dosimetry" is a broad term commonly applied to the use of monitoring devices, bioassay, and other methods to measure or otherwise quantify radiation doses to individuals. The licensee must control occupational doses and provide individuals with monitoring devices in accordance with the requirements of 4731.2210. 4731.2020 provides the occupational dose limits for adults. Adults likely to receive in one year a dose in excess of 10 percent of those dose limits must be provided with dosimetry. If monitoring is required, each licensee shall maintain records of doses received and individuals must be informed on at least an annual basis of their doses.

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

### **The As Low As Reasonably Achievable "ALARA" Program**

4731.2020 states that "each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities..." and, "the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." Additionally, licensees are required to periodically review the content of the radiation protection program and its implementation.

### **External Exposure**

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

There are three dose limits included in 4731.2020 that apply to external exposure: deep dose to the whole body (5 rem or 0.05 Sv), shallow dose to the skin or extremities (50 rem or 0.5 Sv), and dose to the lens of the eye (15 rem or 0.15 Sv). The (DDE) to the whole body is considered to be at a tissue depth of 1 cm (1000 mg/cm<sup>2</sup>), shallow-dose equivalent to the skin or extremities at 0.007 cm (7 mg/cm<sup>2</sup>), and eye dose equivalent at 0.3 cm (300 mg/cm<sup>2</sup>). In evaluating the eye dose equivalent, it is acceptable to take credit for the shielding provided by protective lenses.

4731.2210 requires the use of individual monitoring devices for the following:

- Adults likely to receive, in one year, from sources external to the body, a dose in excess of 10 percent of the occupational dose limits in 4731.2020. Monitoring devices are accordingly required for adults with an annual dose in excess of
  - 0.5 rem (0.005 Sv) DDE

- 1.5 rem (0.015 Sv) eye dose equivalent
  - 5 rem (0.05 Sv) shallow-dose equivalent to the skin
  - 5 rem (0.05 Sv) shallow-dose equivalent to any extremity.
- Minors who are likely to receive an annual dose in excess of
  - rem (1.0 mSv) DDE
  - 0.15 rem (1.5 mSv) eye dose equivalent
  - 0.5 rem (5 mSv) shallow-dose equivalent to the skin
  - 0.5 rem (5 mSv) shallow-dose equivalent to any extremity.
- Declared pregnant women likely to receive an annual dose in excess of 0.1 rem (1.0 mSv) DDE during the entire pregnancy.
- Individuals entering a high or a very high radiation area.

To demonstrate that monitoring of occupational exposure is not necessary for a group of radiation workers, it must be demonstrated that doses will not exceed 10% of the applicable limits. In these cases, MDH does not require licensees to monitor radiation doses for this class of worker. The following methods may be used to demonstrate that doses are expected to be within 10% of regulatory limits:

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

External dose is determined by using individual monitoring devices, such as film badges, optically stimulated luminescence dosimeters (OSLs), or TLDs. These devices must be evaluated by a processor that is National Voluntary Laboratory Accreditation Program (NVLAP) approved, as required by 4731.2200.

The device for monitoring the whole body dose, eye dose, skin dose, or extremity dose must be placed near the location expected to receive the highest dose during the year. When the whole body is exposed fairly uniformly, the individual monitoring device is typically worn on the front of the upper torso. If the radiation dose is highly non-uniform, causing a specific part of the whole body (head, trunk, arms above the elbow, or legs above the knees) to receive a substantially higher dose than the rest of the whole body, the individual monitoring device shall be placed near that part of the whole body expected to receive the highest dose. For example, if the dose rate to the head is expected to be higher than the dose rate to the trunk of the body, a monitoring device shall be located on or close to the head.

If, after the exposure is received, the licensee somehow learns that the maximum dose to a part of the whole body, eye, skin, or extremity was substantially higher than the dose measured by the individual monitoring device, an evaluation shall be conducted to estimate the actual maximum dose.

4731.2540 requires that the recording for individual monitoring be done on MDH Form 5 or equivalent. MDH Form 5 is used to record doses received for the calendar year. The monitoring year may be adjusted as necessary to permit a smooth transition from one monitoring year to another, as long as the year begins and ends in the month of January, the change is made at the beginning of the year, and no day is omitted or duplicated in consecutive years.

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

In order to demonstrate compliance with occupational dose limits, the licensee needs to perform and document an evaluation of the dose the individual received and to add it to the employee's dose record, if an individual's dosimeter is lost. Sometimes the most reliable method for estimating an individual's dose is to use his/her recent dose history. In other cases, particularly if the individual does non-routine types of work, it may be better to use doses of co-workers as the basis for the dose estimate. It also may be possible to estimate doses by modeling and calculation (i.e., reconstruction) of scenarios leading to dose.

**Investigational Levels – External Dose Monitoring**

The investigational levels in this program are not new dose limits. As noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," investigational levels serve as check points above which the results are considered sufficiently important to justify investigation.

In cases where a worker's or a group of workers' doses need to exceed an Investigational Level, a new, higher Investigational Level may be established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new Investigational Levels should be documented.

When the cumulative annual exposure to a radiation worker exceeds Investigational Level I in Table 1 (i.e., 10 percent of the annual limit for occupational exposure), the Radiation Safety Officer or the RSO's designee should investigate the exposure and review the actions that might be taken to reduce the probability of recurrence. When the cumulative annual exposure exceeds Investigational Level II in Table 1 (i.e., 30 percent of the annual limit for occupational exposure), the RSO or the RSO's designee will investigate the exposure and review actions to be taken to reduce the probability of recurrence, and management should review the report of the actions to be taken to reduce the probability of occurrence.

**Table -1 – Investigational Levels**

|  | Investigational Levels<br>(mrem per year) |                  |
|--|---|------------------|
|  | Level I                                   | Level II         |
| whole body; head and trunk; arms above the elbows; legs above the knee; active blood-forming organs; or gonads | 500 (5 mSv)                               | 1500 (15 mSv)    |
| Skin of whole body, extremities  | 5,000 (50 mSv)                            | 15,000 (150 mSv) |
| Lens of eye  | 1,500 (15 mSv)                            | 4,500 (45 mSv)   |

The results of personnel monitoring should be review and recorded. The actions listed below should be taken when the investigation levels in Table 1 are reached:

- Personnel dose less than Investigational Level I.

Except when deemed appropriate by the RSO or the RSO's designee, no further action must be taken if an individual's dose is less than Table 1 values for Investigational Level I.

- Personnel dose equal to or greater than Investigational Level I but less than Investigational Level II.

When the dose of an individual whose dose equals or exceeds Investigational Level I, the RSO or the RSO's designee should conduct a timely investigation and review the actions that might be taken to reduce the probability of recurrence, following the period when the dose was recorded. If the dose does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the RSO or the RSO's designee. Factors that led to the radiation exposure and the radiation doses and work habits of other individuals engaged in similar tasks should be considered to determine if improvements additional safety measures are needed to reduce exposures. The results of investigations and evaluations should be documented.

- Personnel dose equal to or greater than Investigational Level II.

The RSO should investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II. Actions should be taken by the RSO to reduce the probability of occurrence, and a report of the actions should be reviewed by the licensee's management at its first meeting following completion of the investigation.

- Re-establishment of Investigational Level II to a level above that listed in Table 1.

### **Declared Pregnancy And Dose To Embryo/Fetus**

4731.2080 states that the licensee shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman. If the pregnancy is declared in writing and includes the worker's estimated date of conception, the dose equivalent to an embryo/fetus shall be taken as the sum of:

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

### **Internal Exposure**

With respect to internal exposure, licensees are required to monitor occupational intake of radioactive material and assess the resulting dose if it appears likely that personnel will receive greater than 10 percent of the annual limit on intake (ALI) from intakes in one year.

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

The derived air concentration (DAC) for each class of radionuclide is the concentration of airborne radioactivity in  $\mu\text{Ci/ml}$  that, if an occupational worker were to be continuously exposed to for 2,000 hours (1 year), would result in either a CEDE of 5 rem (0.05 Sv) to the whole body or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue, with no consideration for the contribution of external dose. The ALI and DAC for each radionuclide in a specific chemical form are listed in 4731.2750.

The total effective dose equivalent concept makes it possible to combine both the internal and external doses in assessing the overall risk to the health of an individual. The ALI and DAC numbers reflect the doses to all principal organs that are irradiated. The ALI and DAC were derived by multiplying a unit intake by the appropriate organ weighting factors (WT), for the organs specifically targeted by the radionuclide compound, and then summing the organ-weighted doses to obtain a whole body risk-weighted "effective dose." When an ALI is defined by the stochastic dose limit, this value alone is given.

When the ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses.

The types and quantities of radioactive material manipulated at most medical facilities do not provide a reasonable possibility for an internal intake by workers. However, uses such as preparing radioiodine capsules from liquid solutions, and opening and dispensing radioiodine from vials containing millicurie quantities require particular caution. To monitor internal exposures from such operations, a routine bioassay program to periodically monitor workers should be established.

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

- adequate equipment to perform bioassay measurements,
- procedures for calibrating the equipment, including factors necessary to convert counts per minute into Becquerel or microcurie units,
- the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue),
- the interval between bioassays,
- action levels, and
- the actions to be taken at those levels.

#### **Controlling Air Concentrations And Worker Doses From Noble Gases**

Noble gases such as xenon in the air present could contribute to a worker's exposure. To ensure that the doses to workers from gases are minimized, licensees should:

- administer gases in an area that has negative ventilation;
- check the area's negative ventilation flow rate every six months or when changes are made to the area's ventilation systems; and
- collect the spent gases in a shielded trap and monitor the trap regularly. (Licensees do not have to monitor the trap effluent of single-use devices.)

Charcoal traps can significantly reduce air contamination. They can also become saturated or be spoiled by improper use, humidity, chemicals, or inadequate maintenance.

- If the trap effluent is continuously monitored by a radiation detector designed to monitor effluent gas, check the detector according to the manufacturer's instructions. Keep a record of the checks.
- If the trap effluent is not continuously monitored, check the trap upon receipt and once each month. Keep a record of the date, background radiation level, and trap radiation level. If there is a significant increase in the measured activity, the trap must be replaced.

#### **Summation Of External And Internal Doses**

Pursuant to 4731.2030, the external and internal doses must be summed if the licensee is required to monitor both under 4731.2210.



## **APPENDIX G SAFE USE OF RADIOPHARMACEUTICALS**

You may use the following model rules as they appear here, stating on your application, "We will establish and implement the model safety rules published in Appendix G to the MDH Regulatory Guide for Nuclear Pharmacies."

If you prefer, you may develop your own rules for safe use of radiopharmaceuticals for review. If you do so, you should consider for inclusion all the items in the MDH rules. State on your application, "We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as Appendix G," and submit your model rules for the safe use of radiopharmaceuticals.

### **MODEL RULES**

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.
2. Wear disposable gloves at all times while handling radioactive materials.
3. Either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area with an appropriate survey instrument.
4. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
5. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.
6. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.
7. Wear a finger exposure monitor during the elution of generators; during the preparation and assay of radiopharmaceuticals.
8. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
9. Never pipette by mouth.
10. Wipe-test by-product material, preparation and administration areas daily for contamination and each week where radioactive materials are stored. If necessary, decontaminate or secure the area for decay.
12. With a radiation survey meter, survey daily for contamination the generator storage and kit preparation areas. If necessary, decontaminate or secure the area for decay as appropriate.
13. Confine radioactive solutions in shielded containers that are clearly labeled. Multi-dose diagnostic vials and therapy vials should be labeled with the isotope, the name of the compound, and the date and time of receipt or preparation. A logbook should be used to record the preceding information and total prepared activity, specific activity as mCi/cc at a specified time, total volume prepared, total volume remaining, and any other appropriate information. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.

14. Assay each dosage in the dose calibrator.
15. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
16. Because sources with even small amounts of radioactivity exhibit a high dose rate on contact, you should consider the use of a cart or other device to move waste and other radioactive material.

## **APPENDIX H MODEL SPILL PROCEDURES**

You may use the following model procedures as they appear here, stating on your application, "We will establish and implement the model spill procedure published in Appendix H to the MDH Regulatory Guide for Nuclear Pharmacies."

If you prefer, you may develop your own spill procedures for review. If you do so, you should consider for inclusion all the items in the model procedures. State on your application, "We have developed spill procedures for your review that are appended as Appendix H" and submit your spill procedures.

### **MODEL PROCEDURES**

#### **MINOR SPILLS OF LIQUIDS AND SOLIDS**

1. Notify persons in the area that a spill has occurred.
2. Prevent the spread of contamination by covering the spill with absorbent paper.
3. Wearing gloves and protective clothing such as lab coats and disposable booties, clean up the spill 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. Also put contaminated gloves and any other contaminated disposable material in the bag.
4. Survey the area with a low-range radiation detector meter. Check the area around the spill. Also, check your hands, clothing, and shoes for contamination.
5. The RSO will review the radioactive spill contamination survey records for trends.

#### **MAJOR SPILLS OF LIQUIDS AND SOLIDS**

1. Clear the area. Notify all persons not involved in the spill to vacate the room.
2. Prevent the spread of contamination by covering the spill with absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated.
3. Shield the source if possible. This should be done only if it can be done without further contamination or a significant increase in radiation exposure.
4. Close the room and lock or otherwise secure the area to prevent entry.
5. Notify the RSO immediately.
6. Decontaminate personnel by removing contaminated clothing. Flush the contaminated skin with lukewarm water. Wash the affected area with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration.

## DISCUSSION OF MAJOR SPILLS AND MINOR SPILLS

The decision to implement a major spill procedure instead of a minor spill procedure depends on many incident-specific variables. These variables include the number of individuals affected, other hazards present, likelihood of spread of contamination, and types of surfaces contaminated as well as the radio-toxicity of the spilled material. For some spills of short-lived radionuclides, the best spill procedure may be restricted access pending complete decay.

Estimate the amount of radioactivity spilled. Initiate a major spill procedure based on the following dividing line. Spills above these millicurie amounts are considered major. Spills of the amounts shown below are considered minor.

Estimate the amount of radioactivity spilled. Initiate a major spill procedure based on the following dividing line. Spills above these millicurie amounts are considered major, below are considered minor.

| Relative Hazards of Common Radionuclides |             |                    |             |
|--|-------------|--------------------|-------------|
| RADIONUCLIDE                             | MILLICURIES | RADIONUCLIDE       | MILLICURIES |
| P-32                                     | 1           | Tc-99 <sup>m</sup> | 100         |
| Cr-51                                    | 100         | In-111             | 10          |
| Co-57                                    | 10          | I-123              | 10          |
| Co-58                                    | 10          | I-125              | 1           |
| Fe-59                                    | 1           | I-131              | 1           |
| Co-60                                    | 1           | Sm-153             | 10          |
| Ga-67                                    | 10          | Yb-169             | 10          |
| Se-75                                    | 1           | Hg-197             | 10          |
| Sr-85                                    | 10          | Au-198             | 10          |
| Sr-89                                    | 1           | Tl-201             | 100         |

### Spill Kit

Assemble a spill kit that may contain the following items:

- Disposable gloves and housekeeping gloves;
- Disposable lab coats;
- Disposable head coverings;
- Disposable shoe covers;
- Roll of absorbent paper with plastic backing;
- Masking tape;
- Plastic trash bags with twist ties;
- "Radioactive Material" labeling tape;
- Marking pen;
- Pre-strung "Radioactive Material" labeling tags;
- Contamination wipes;
- Instructions for "Emergency Procedures";
- Clipboard with copy of Radioactive Spill Report Form;
- Pencil; and
- Appropriate survey instruments, including batteries.

### Spilled Gas Clearance Time

Because normal room ventilation is usually not sufficient to ensure clearance of spilled gas, calculations should be made to determine for how long a room must be evacuated in case of an airborne spill. The clearance time should be posted in the room or at a location readily accessible to workers.

Collect the following data:

- A The highest activity of gas in a single container, in microcuries.
- Q The total room air exhaust determined by measuring, in milliliters per minute, the airflow to each exhaust vent in the room. The exhaust should be vented and not re-circulated within the facility. This may be the normal air exhaust or a specially installed exhaust gas system.
- C The allowable air concentrations for occupational exposure in restricted areas (derived air concentrations-hour [DAC-hour]). The DAC values to determine when a nuclear medicine technologist (NMT) or authorized user may return to a spill in a restricted area are:

Xenon-133 is  $1 \times 10^{-4} \mu\text{Ci/ml}$   
Xenon-137 is  $4 \times 10^{-5} \mu\text{Ci/ml}$

- V the volume of the room in milliliters. ( $1 \text{ ft}^3 = 28317 \text{ ml}$  –or-  $28317 \text{ ml/ft}^3$ )

2. Make the following calculations for each room:

- The airflow supply should be less than the airflow exhaust to ensure the room is at negative pressure.
- The evacuation time (t)

$$t = -V/Q \times \ln(C \times V/A)$$

### Sample Calculation

|   |  |
|---|--|
| Evacuation Time   | $t = -V/Q \times \ln(C \times V/A)$  |
| Volume of room<br>(in ml)                               | $V = 12 \text{ ft} \times 30 \text{ ft} \times 8 \text{ ft} = 2,880 \text{ ft}^3 \times 28,317 \text{ ml/ft}^3 = 81,552,960$   |
| Room exhaust<br>(in ml/minute)                          | $Q = 900 \text{ cfm} \times 28,317 \text{ ml} = 25,485,300$  |
| Effluent concentration limit<br>(in $\mu\text{Ci/ml}$ ) | $C = 5 \times 10^{-7}$ (Xe-133)  |
| Activity<br>(in $\mu\text{Ci}$ )                        | $A = 10 \text{ mCi} = 10,000$  |
| Clearance time  | $t = -81,552,960/25,485,300 \times \ln(5 \times 10^{-7} \times 81,552,960/10,000)$<br>$t = -3.2 \times \ln(0.0040776)$<br>$t = -3.2 \times -5.50$<br><br><b>t = 17.6 minutes</b> |

## APPENDIX I AREA SURVEYS

You may use the following procedure to perform area surveys. If you follow this procedure, you may state on your application, "We will establish and implement the model procedure for area surveys that is published in Appendix I to the MDH Regulatory Guide for Nuclear Pharmacies."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model procedure. State on your application, "We have developed survey procedures for your review that are appended as Appendix I" and submit your survey procedures.

### MODEL PROCEDURE

#### ***Radiation Dose Rate Surveys***

1. Surveys -- Restricted Areas:
  - a. In areas such as *in vitro* labs where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey *monthly* with a radiation detection survey meter.
  - b. In sealed source storage areas, survey *quarterly* with a radiation survey meter.
  - c. Protective clothing should be surveyed by the wearer after use if significant contamination is possible. Contaminated clothing should be removed before leaving a restricted work area. Hands should be washed and surveyed. Personal clothing should also be surveyed before leaving the restricted areas. Any contamination above expected levels should be reported to the RSO.
2. Surveys -- Unrestricted Areas:

Quarterly surveys should be accomplished in areas:

  - adjacent to restricted areas
  - through which radioactive materials are transferred
  - where radioactive material is temporarily stored before shipment

More frequent surveys will be necessary if radiation levels are suspect.

| AREA SURVEYED TRIGGER LEVEL |                   |                |
|-----------------------------|-------------------|----------------|
| Type of Survey              | Ambient Dose Rate | Trigger Levels |
| Ambient Dose Rate           | Unrestricted      | 0.1 mR/hr      |
| Ambient Dose Rate           | Restricted        | 5.0 mR/hr      |

#### ***Removable Contamination Surveys***

Perform contamination surveys using instruments suitable for removable and fixed contamination to identify areas of contamination that might result in doses to workers or to the public. Removable contamination can be detected and measured by conducting a wipe test of the surface, counted in an

appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

Contamination surveys are performed in areas where unsealed forms of materials are used:

- To evaluate radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, and equipment;
- After any spill or contamination event;
- When procedures or processes have changed;
- To evaluate contamination of users and the immediate work area, at the end of the day, when licensed material is used;
- In unrestricted areas at frequencies consistent with the types and quantities of materials in use, but not less frequently than monthly;
- In areas adjacent to restricted areas and in all areas through which licensed materials are transferred and temporarily stored before shipment.

Use methods for conducting surveys for removable contamination that are sufficiently sensitive to detect contamination for those radionuclides in use and for which the most restrictive limits apply for restricted areas and for unrestricted areas (e.g., 200 dpm/100 cm<sup>2</sup> for isotopes of Iodine-131 in unrestricted areas).

A radioactive source with a known amount of activity should be used to convert sample measurements, which are usually in counts per minute (cpm), to dpm.

The area should be decontaminated, shielded, or posted and restricted from use if it cannot be decontaminated.

If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Example trigger levels for restricted areas are presented in the following table. Contamination found in unrestricted areas and on personal clothing will be immediately decontaminated to background levels.

| SURFACE CONTAMINATION LEVELS IN RESTRICTED AREAS (DPM/100 CM <sup>2</sup> ) |  |  |
|---|--|--|
| Area, clothing  | P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, Y-90, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Lu-177, Au-198 | Cr-51, Co-57, Ga-67, Tc-99 <sup>m</sup> , Hg-197, Tl-201 |
| Restricted areas, protective clothing used only in restricted areas         | 2000   | 20000  |

| SURFACE CONTAMINATION LEVELS IN UNRESTRICTED AREAS (DPM/100 CM <sup>2</sup> )   |                          |                          |                            |
|---|--------------------------|--------------------------|----------------------------|
| Nuclide <sup>1</sup>  | Average <sup>2,3,6</sup> | Maximum <sup>2,4,6</sup> | Removable <sup>2,5,6</sup> |
| I-125, I-126, I-131,<br>I-133, Sr-90  | 1000                     | 3000                     | 200                        |
| Beta-gamma emitters<br>(nuclides with decay<br>modes other than alpha<br>emission or<br>spontaneous fission)<br>except Sr-90 and others<br>noted above.   | 5000                     | 15000                    | 1000                       |
| <p><sup>1</sup> Where surface contamination by multiple nuclides exists, the limits established for each nuclide should apply independently.</p> <p><sup>2</sup> As used in this table, dpm means the rate of emission by radioactive material, as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.</p> <p><sup>3</sup> Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.</p> <p><sup>4</sup> The maximum contamination level applies to an area of not more than 100 cm<sup>2</sup>.</p> <p><sup>5</sup> The amount of removable radioactive material per 100 cm<sup>2</sup> 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.</p> <p><sup>6</sup> The average and maximum radiation levels associated with surface contamination resulting from beta/gamma emitters should not exceed 0.2 mR/hour at one centimeter and 1.0 mR/hour at 1 centimeter, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.</p> |                          |                          |                            |

### Contents of Survey Records

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

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



| <b>RECOMMENDED ACTION LEVELS IN DPM/100 CM<sup>2</sup> FOR SURFACE CONTAMINATION</b>  |  |  |
|---|--|--|
|   | P-32, Co-58, Fe-59, Co-60,<br>Se-75, Sr-85, In-111, I-123,<br>I-125, I-131, Yb-169, Au-198 | Cr-51, Co-57, Ga-67,<br>Tc-99m, Hg-197, Tl-201 |
| 1. Unrestricted areas,<br>personal clothing   | 200  | 2,000  |
| 2. Restricted areas,<br>protective clothing used<br>only in restricted areas,<br>skin | 2,000  | 20,000   |

3. Maintain records for three years.

## APPENDIX J LEAK TESTING SEALED SOURCES

### Model Leak Test Program

This model provides acceptable procedures for sealed source leak testing and analysis. Applicants may either adopt these model procedures or develop alternative procedures.

### Facilities And Equipment

- To ensure achieving the required sensitivity of measurements, leak tests should be analyzed in a low-background area.
- Consider using a NaI(Tl) well counter system with a single or multi-channel analyzer to analyze samples obtained from gamma-emitting sources (e.g., Cs-137).
- Consider using a liquid scintillation or gas-flow proportional counting system to analyze samples obtained from beta-emitting sources (e.g., Sr-90).
- Instrumentation used to analyze leak test samples must be capable of detecting 185 Bq (0.005  $\mu$ Ci) of radioactivity.

### Model Procedure For Performing Leak Testing And Analysis

- For each source to be tested, list identifying information such as sealed source serial number, radionuclide, and activity.
- Use a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate identifying information for each source.
- Wear gloves.
- Obtain samples at the most accessible area where contamination would accumulate if the sealed source were leaking.
- Measure the background count rate and record.
- Check the instrument's counting efficiency, using either a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within  $\pm 5$  percent of the stated value and traceable to a primary radiation standard, such as those maintained by NIST.
- Calculate efficiency of the instrument. For example,

$$\text{Efficiency} = \frac{[(\text{counts per minute from standard}) - (\text{counts per minute from background})]}{(\text{activity of standard in microcurie})}$$

- Analyze each wipe sample to determine net count rate.
- For each sample, calculate the activity in microcurie and record.
- The activity on the wipe sample is given by:
- Leak test records will be retained in accordance with 35.2067 for 3 years. Licensees should include the following in records:
  - The model number and serial number (if assigned) of each source tested;
  - The identity of each source radionuclide and its estimated activity;
  - The measured activity of each test sample expressed in microcurie;
  - A description of the method used to measure each test sample;
  - The date of the test; and
  - The name of the individual who performed the test.
- If the wipe test reveals 185 Bq (0.005  $\mu$ Ci) or greater:
  - Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with MDH requirements.
  - File a report within five days of the leak test in accordance with 4731.4527.

## **APPENDIX K CUSTOMER RETURN OF RADIOACTIVE WASTES TO NUCLEAR PHARMACIES**

Return only items that contained or contain radioactive materials supplied by the radiopharmacy (e.g., pharmacy-supplied syringes and vials and their contents). Most return shipments to radiopharmacies will qualify as excepted packages of limited quantity, in accordance with DOT requirements. For those packages containing radioactive material in excess of the limited quantity, customers should ensure that all applicable DOT requirements are met for the packages. This includes, but is not limited to, certification packaging (Type A), package marking and labeling, and shipping papers. For specific guidance on preparing these types of packages, please follow your in-house procedures for shipping radioactive material packages or contact the pharmacy for guidance.

Preparation of radioactive materials for return as excepted package of limited quantity:

- Ensure that the activities of material being returned are limited quantities as defined by DOT (see table below). Special attention should be given for the return of unused doses that may still contain significant activities of radionuclides. The amount of radioactivity in unused doses may necessitate that a syringe or vial be held for decay to reduce the activity to that permitted for shipment of limited quantities.
- Place the syringe or vial in the original, labeled, lead shield in which it was delivered.
- Place shielded waste into the shipping package (e.g., padded briefcase or ammo box) in which it was delivered. Note: Packages used to ship radioactive material to customers meet the DOT package requirements for transport of limited quantities.

Preparation of package:

- Using a calibrated survey meter, measure the radiation levels at all points on the surface of the package to ensure that levels are less than or equal to 0.5 mrem/hr;
- Use contamination wipes on the surface of the package to ensure that the removable contamination does not exceed 22 dpm/cm<sup>2</sup> over a 300 cm<sup>2</sup> area.
- Label the package as "Excepted Package - Limited Quantity of Material."
- Seal the package so it will be evident upon receipt if the package accidentally opened during shipment.

Shipping papers are not required when shipping limited quantities. However, the statement specified in 49 CFR 173.422 ("This package conforms to the conditions and limitations specified in 49 CFR 173.421 for radioactive material, excepted package-limited quantity of material, UN2910.") must be included in, on, or otherwise provided with the shipment.

Limited Quantities (49 CFR 173.421) For Typical Radionuclides as Liquid Used by Radiopharmacies (49 CFR 173.425 - Table 7)

**Table 1 - Limited Quantity Values for Liquid Radioactive Material Packages**

| Liquid Radionuclides | A2 Value (Ci)   | Limited Quantity Shipment (mCi)<br>A2 X 10 <sup>-4</sup> |
|----------------------|-----------------|--|
| Co-57                | 216             | 21.6   |
| Co-58                | 27              | 2.7  |
| Cr-51                | 811             | 81.1   |
| Ga-67                | 162             | 16.2   |
| I-123                | 162             | 16.2   |
| I-125                | 54.1            | 5.41   |
| I-131                | 13.5            | 1.35   |
| In-111               | 54.1            | 5.41   |
| Mo-99                | 20 <sup>8</sup> | 2  |
| P-32                 | 8.11            | 0.81   |
| Se-75                | 81.1            | 8.1  |
| Sr-89                | 13.5            | 1.35   |
| Tc-99 <sup>m</sup>   | 216             | 21.6   |
| Tl-201               | 270             | 27   |

**Table 2 - Limited Quantity Values for Gaseous Radioactive Material Packages**

| Radionuclide<br>Uncompressed Gas | A2 Value (Ci) | Limited Quantity Shipment (mCi)<br>A2 X 10 <sup>-3</sup> |
|----------------------------------|---------------|--|
| Xe-133 (uncompressed)            | 1541          | 1541   |

**Table 3 - Limited Quantity Values for Special Form Radioactive Material Packages**

| Solid Radionuclide<br>Special Form | A1 Value (Ci) | Limited Quantity Shipment (mCi)<br>A1 X 10 <sup>-3</sup> |
|------------------------------------|---------------|--|
| Ir-192                             | 27            | 27   |
| Cs-137                             | 54.1          | 54.1   |

The values above are derived from 49 CFR 173.423, Table 7, and the Table of A1 and A2 values for radionuclides in 49 CFR 173.435. If shipping more than one radionuclide in the same package, the limits in 173.433(d) apply as follows: The sum of the ratios of the activity of each radionuclide divided by its respective A2 value must be less than or equal to one. For special form material, the sum of the ratios of the activities of each radionuclide divided by its respective A1 value must be less than, or equal to, one.

***Procedure for Driver or Courier for Pick-up of Radioactive Waste from Customers***

- Ensure that the shipping package is properly labeled “Excepted Package - Limited Quantity of Material.”
- Ensure that the shipping package has been sealed.
- Do not accept any package that is not properly labeled and sealed.

***Procedure for Receipt and Opening of Packages from Customers Containing Radioactive Waste***

- Place all returned packages in an identifiable location within the radiopharmacy.
- Put on disposable gloves.
- Monitor the package for removable contamination. If wipe tests indicate contamination levels greater than 22 dpm/cm<sup>2</sup> over a 300 cm<sup>2</sup> area, take the following actions:
  - Notify the customer and the MDH.

<sup>8</sup> For domestic use

- Survey the driver/courier who retrieved the waste and the vehicle used to transport the waste to the radiopharmacy.
- Decontaminate the package or remove it from service for decay.

Open the package and identify each nuclide in the shielded containers.

Dispose of radioactive waste into the appropriate container for the half-life of the nuclide being disposed, in accordance with the radiopharmacy's procedures for disposal of waste by decay-in-storage.

Survey the dose shields for contamination with a low-level survey meter. Any dose shields that indicate activity exceeding background should be decontaminated or removed from service.

**APPENDIX L  
DEPARTMENT OF TRANSPORTATION REQUIREMENTS**

The United States Department of Transportation (DOT) has recently updated portions of the regulations pertaining to the transportation of radioactive materials. Several such changes were to the allowable activity limits for the packages used to transport materials being returned to nuclear pharmacies. If you will be returning your radioactive waste to a nuclear pharmacy, your facility will become a shipper of a radioactive material.

MDH is providing you with the following system to ensure you properly prepare packages for return.

**Limited Quantity Shipments**

Return shipments should be shipped as Limited Quantity Shipments. In accordance with 49 CFR 173.421, packages that meet the following requirements can be classified as a Limited Quantity Shipment and are exempt from the specification packaging and labeling requirements:

- The amount of radioactivity in the package does not exceed a specified amount.
- The radiation level at any point on the external surface of the package does not exceed 0.5 mR/hr.
- The non-fixed (removable) radioactive surface contamination on the external surface of the package does not exceed 6600 dpm per 300 cm<sup>2</sup> area, as specified in CFR 173-443(a).
- The label and marking cards are attached to the delivery case with the Limited Quantity side facing outwards.

To meet the above requirements, licensees must ensure that the waste being returned does not exceed the specified limits for Limited Quantity Shipments. This can be determined by reviewing the table with activity limits for nuclides. The total quantity of activity being returned cannot exceed the specified Limited Quantity Shipment activity whether returning used dose material or unused doses.

Example of estimating return activity for Tc-99<sup>m</sup> products.

**Unused Products.** If an unused syringe of a 25 mCi dose is held for 24 hours (4 half lives), the remaining activity is:

$$(25 \text{ mCi}) \times (0.5) \times (0.5) \times (0.5) \times (0.5) = 1.56 \text{ mCi}$$

A maximum of seven of these syringes could be returned and remain below the 11 mCi limit for Tc-99<sup>m</sup>.

**Used Products.** Assume 5 percent remains in the syringe after an injection. If the syringe is held for 24 hours (4 half lives), the remaining activity from a 25 mCi dose is:

$$(25 \text{ mCi}) \times (0.05) \times (0.5) \times (0.5) \times (0.5) \times (0.5) = 0.078 \text{ mCi}$$

If ten unit dose syringes were returned, and all ten had been 25 mCi doses, the package would contain only 781  $\mu$ Ci, which is well below the 11 mCi limit in the attached table.

**Limited Quantity Activity Limits for Shipments Of Mixed Radionuclides**

When shipping more than one radionuclide in the same package, the limit on the radioactivity that may be shipped is the lowest activity assigned for the radionuclide shipped. (See attached table) For example, if Tc-99<sup>m</sup> and I-131 were being shipped in the same package, only 1.9 mCi of total activity could be shipped.

| <b>Limited Quantity Returns</b> |  |
|---------------------------------|--|
| <b>Radionuclide</b>             | <b>LIMITED SHIPMENT QUANTITY (mCi)</b> |
| Ba-133                          | 8.1                                    |
| C-14                            | 8.1                                    |
| Co-57                           | 27                                     |
| Cr-51                           | 81                                     |
| Cs-137                          | 1.6                                    |
| F-18                            | 1.6                                    |
| Ga-67                           | 8.1                                    |
| Ho-166                          | 1.1                                    |
| I-123                           | 8.1                                    |
| I-125                           | 8.1                                    |
| I-131                           | 1.9                                    |
| In-111                          | 8.1                                    |
| Lu-177                          | 1.9                                    |
| Mo-99                           | 2                                      |
| N-13                            | 1.6                                    |
| Na-22                           | 1.4                                    |
| Ni-63                           | 81                                     |
| P-32                            | 1.4                                    |
| Pd-103                          | 110                                    |
| Sm-153                          | 1.6                                    |
| Sr-89                           | 1.6                                    |
| Sr-90                           | 0.81                                   |
| Tc-99 <sup>m</sup>              | 11                                     |
| Tl-201                          | 11                                     |
| Xe-133                          | 270 (gas), 27 (liquid)                 |
| Y-90                            | 0.81                                   |

Note: Multiply values listed above by 10 for solid or sealed sources.

- Place materials into delivery boxes in the same configuration as received.
- Ensure that the radiation level at any point on the surface of the package does not exceed 0.5 mR/hr. Measure all sides of the package. If the radiation levels exceed 0.5 mR/hr at any point on the surface of the package, please call the nuclear pharmacy for further instructions.
- Ensure that the non-fixed (removable) radioactive surface contamination on the external surface of the package does not exceed 6600 dpm when wiped over a 300 cm<sup>2</sup> area. If this limit is exceeded, please call the nuclear pharmacy for further instructions.
- If the package activity, radiation levels and wipe tests are within the limits outlined above, ensure the shipping container is marked as the Limited Quantity Shipment information.

***Packages that have not been prepared for shipment back to the nuclear pharmacy in the manner described above should not be accepted for transport.***

### **US Department of Transportation Training Requirements**

The *Federal Hazardous Materials Transportation Law* requires the training of all hazardous material (HAZMAT) employees. "Hazardous material" means a substance or material capable of posing an unreasonable risk to health, safety, or property when transported in commerce. The training requirements are to increase a HAZMAT employee's safety awareness. As such, training is considered an essential element in reducing hazardous material incidents. As it pertains to a medical facility, a HAZMAT employee is any person who directly affects hazardous material transportation safety including a person who:

- loads, unloads, or handles hazardous material;
- marks packages for use in the transportation of hazardous material;
- prepares hazardous material for transportation;
- is responsible for safety of transporting hazardous material; or
- operates a vehicle used to transport hazardous material.

Each employer must train, test, certify, and retain records of current training for each HAZMAT employee to ensure knowledge of hazardous materials and the Hazardous Material Regulations as well as to ensure that the employee can perform assigned HAZMAT functions properly. (See 49 CFR 172.700 through 172.704.) HAZMAT training must include:

- general awareness/familiarization
- function-specific;
- safety;
- security awareness;
- In-depth security training, if a security plan is required; and
- driver training (for each HAZMAT employee who will operate a motor vehicle).

### **Initial training**

A new employee, or an employee who changes job functions, may perform HAZMAT job functions before completing training, provided:

- the employee does so under the direct supervision of a properly trained and knowledgeable HAZMAT employee; and
- the HAZMAT training is completed within 90 days of employment of change in job function.

### **Recurrent Training**

Training is required at least once every three years. The three-year period begins on the actual date of training. Relevant training received from a previous employer or source may be used to satisfy the



requirements provided a current record of training is obtained from the previous employer or other sources.

### **Training records**

Training records must include the following information:

- HAZMAT employee's name;
- completion date of most recent training;
- training materials (copy, description, or location);
- name and address of HAZMAT training; and
- certification that the HAZMAT employee has been trained and tested.

### **49 CFR References**

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

- Table of Hazardous Materials and Special Provisions 49 CFR 172.101: Purpose and use of hazardous materials table;
- Shipping Papers 49 CFR 172.200-204: Applicability, general entries, description of hazardous material on shipping papers, additional description requirements, shipper's certification;
- Package Marking 49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324: Applicability, general marking requirements for non-bulk packagings, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging;
- Package Labeling 49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440: General labeling requirements, prohibited labeling, Class 7 (radioactive) material, placement of labels, label specifications, radioactive white-I label, radioactive yellow-II label, radioactive yellow-III label;
- Placarding of Vehicles 49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556: Applicability of placarding requirements, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, general specifications for placards, RADIOACTIVE placard;
- Emergency Response Information 49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604: Applicability and general requirements, emergency response information, emergency response telephone number;
- Training 49 CFR 172.702, 49 CFR 172.704: Applicability and responsibility for training and testing, training requirements;
- Shippers – General Requirements for Shipments and Packaging 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.411, 49 CFR 173.412, 49 CFR 173.413, 49 CFR 173.415, 49 CFR 173.416, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.471, 49 CFR 173.475, 49 CFR 173.476: Definitions, general design requirements, industrial packages, additional design requirements for Type A packages, requirements for Type B packages, authorized Type A packages, authorized Type B packages, requirements for determining A1 and A2 values for radionuclides and for the listing of radionuclides on shipping papers and labels, table of A1 and A2 values for radionuclides, radiation level limitations, requirements for U.S.
- NRC-approved packages, quality control requirements prior to each shipment of Class 7 (radioactive) materials, approval of special form Class 7 (radioactive) materials; 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>>.

## ATTACHMENT I

### US DEPARTMENT OF TRANSPORTATION ADVISORY NOTICE

#### ENHANCED SECURITY MEASURES

Shippers and carriers can do a lot to enhance the security of hazardous materials shipments during transportation. The Department of Transportation and other federal agencies can provide timely and accurate information to assist you with your personnel, facility, and en route security issues.

In the wrong hands, hazardous materials pose a significant security threat, particularly those that may be used as weapons of mass destruction. If you offer, transport, or store hazardous materials in transit, you should review your security measures and make any necessary adjustments to improve the secure transport and storage of hazardous materials and shipments.

This brochure identifies several voluntary security measures you may wish to consider. It also addresses personnel, facility, and en route security issues and includes contact points for obtaining additional, more detailed information.

We encourage you to consider implementation of the following measures as appropriate to your industry and operations. You should consider actions commensurate with the level of threat posed by the specific hazardous materials you handle.

In addition, you should be aware that there are security requirements that may apply to your operations.

#### **Security Plan**

The most important action a shipper or carrier should consider is the development and implementation of a security plan. You can use a risk management model to assess security risks and develop appropriate measures to reduce or eliminate risk. Most risk management models utilize the following steps.

- Identify areas of concern and partners that may be affected or with whom coordination may be appropriate;
- Assemble detailed information on system operations;
- Identify control points where intervention can reduce or eliminate risk;
- Select and prioritize options to meet identified security goals;
- Take action to implement the strategy;
- Verify implementation of the strategy; and
- Evaluate the effectiveness of the strategy to determine whether additional actions are necessary.

#### **Begin with a list**

You may first want to list materials you handle, and identify those materials with the potential for use as weapons of mass destruction or targets of opportunity. Then, consider a review of your current activities and operations from a transportation security perspective. Ask yourself, "What are we doing now? What could be wrong? What can we do differently?" The next step is to consider how to reduce the risks you have identified. For hazardous materials transportation, a security plan likely will focus on personnel, facility and en route security issues. To assist you in performing appropriate risk assessments, we have posted a Risk Management Self-Evaluation Framework on our website <http://hazmat.dot.gov>

## **Personnel Security**

Your employees can be one of your most critical assets as you endeavor to improve the security of your shipping or transportation operations. You should consider taking one or more of the following actions:

- Ensure your employees are familiar with your security plan and properly trained in its implementation. Training should include company security objectives, specific security procedures employee responsibilities, and organizational security structure.
- Encourage your employees to report suspicious incidents or events.
- Implement routine security inspections.
- Convene regular employee/management meetings on security measures and awareness.
- Communicate with your staff using an internal communication system to provide information on facts, trends, updates, and the like. Because others may access Internet communications, consider alternative methods for communicating sensitive information.

## **Employees as a security risk**

You should be aware of the possibility that someone you hire may pose a potential security risk. You should consider establishing a process to verify the information provided by applicants on application forms or resumes, including checking with former and current employers and personal references provided by job applicants.

## **Facility Security**

Access to your facility should be another security concern and you should consider taking one or more of the following steps to prevent unauthorized access to your facility.

### *Actions you should take*

- Establish partnership with local law enforcement officials, emergency responders and other public safety agencies with jurisdiction over your facility. Through such relationships, you can learn about threats, trends, and unsuccessful security programs.
- Request a review of your facility and security program by local law enforcement officials.
- Restrict availability of information related to your facility and the materials you handle. Encourage authorities in possession of information about your facility to limit disclosure of that information on a need-to-know basis.
- Add security guards and increase off-hours patrols by security or law enforcement personnel.
- Improve fencing around your facility. Check the adequacy of locks and other protective equipment. Consider equipping access gates with timed closure devices. Conduct frequent inspections.
- Install additional lights, alarm systems, or surveillance cameras.
- Restrict access to a single entry or gate.
- Place limits on visitor access; require visitors to register and show photo identification and have someone accompany visitors at all times.
- Require employees to display identification cards or badges.
- Conduct security spot checks of personnel and vehicles.
- Upgrade security procedures for handling pick-ups and deliveries at your facilities. Verify all paperwork and require pick-ups and deliveries be handled only by appointment with known vendors. Require vendors to call before a delivery and to provide the driver's name vehicle number. Accept packages and deliveries only at the facility front gate.
- Secure hazardous materials in locked buildings or fenced areas. Have a sign-out system for keys.
- Secure valves, man ways, and other fixtures on transportation equipment when not in use. Lock all vehicle and delivery trailer doors when not in use. Secure all rail, truck, and barge containers when stored at your location.
- Use tamper-resistant or tamper-evident seals and locks on cargo compartment openings.

- Periodically inventory the quantity of hazardous materials you have on site in order to recognize if a theft has occurred.
- Keep records of security incidents. Review records to identify trends and potential vulnerabilities.
- Report any suspicious incidents or individuals to your local Federal Bureau of Investigation (FBI) office and to local law enforcement officials.

### **En Route**

Shippers and carriers can work together to assure the security of hazardous materials shipments en route from origin to destination.

Shippers should assess the transportation modes or combinations of modes-available for transporting specific materials and select the most appropriate method of transportation to ensure efficient and secure movement of product from origin to destination.

#### *Know your carriers*

Yes, know your carrier and have a system for qualifying the carriers used to transport hazardous materials.

- Use carrier safety ratings, assessments, safety surveys, or audits and ask the carrier to provide information on security measures it has implemented.
- Verify the carrier has an appropriate employee hiring and review process, including background checks, and an on-going security training program.
- Verify the identity of the carrier and/or driver prior to loading a hazardous material.
- Ask the driver for photo identification and commercial drivers license for comparison with information provided by the carrier.
- Ask the driver to tell you the name of the consignee and the destination for the material and confirm with your records before releasing shipments.
- Identify preferred and alternative routing, including acceptable deviations.
- Strive to minimize product exposures to communities or populated areas, including downtown areas; avoid tunnels and bridges where possible; and expedite transportation of the shipment to its final destination.
- Minimize stops en route; if you must stop, select locations with adequate lighting on well-traveled roads and check your vehicle after each stop to make sure nothing has been tampered with.
- Consider using two drivers or driver relays to minimize stops during the trip. Avoid layovers, particularly for high hazard materials.
- Shippers and rail carriers should cooperate to assure the security of rail cars stored temporarily on leased tracks.
- If materials must be stored during transportation, make sure they are stored in secure facilities.
- Train drivers in how to avoid highjacking or stolen cargo-keep vehicles locked when parked and avoid casual conversations with strangers about cargoes and routes.
- Consider whether a guard or escort for a specific shipment of hazardous material is appropriate.
- Consider using advanced technology to track or protect shipments en route to their destinations. For example, you may wish to install tractor and trailer anti-theft devices or use satellite tracking or surveillance systems. As an alternative, consider frequent checks with drivers by cell phone to ensure everything is in order.
- Install tamper-proof seals on all valves and package or container openings.
- Establish a communication system with transport vehicles and operators, including a crisis communication system with primary and back-up means of communication among the shipper, carrier, and law enforcement and emergency response officials.
- Implement a system for a customer to alert the shipper if a hazardous materials shipment is not received when expected.
- When products are delivered, check the carrier's identity with shipping documents provided by the shipper.

- Get to know your customers and their hazardous materials programs. If you suspect you shipped or delivered a hazardous material to someone who may intend to use it for a criminal purpose, notify your local FBI office or local law enforcement officials.
- Report any suspicious incidents or individuals to your local FBI office and to local law enforcement officials.

**Additional Information**

Up-to-date information is a key element of any security plan. You should consider methods to:

- Gather as much data as you can about your own operations and those of other businesses with similar product lines and transportation patterns;
- Develop a communications network to share best practices and lessons learned;
- Share information on security incidents to determine if there is a pattern of activities that, when considered in isolation are not significant, but when taken as a whole generate concern; and
- Revise your security plans as necessary to take account of changed circumstances and new information.

**SUMMARY OF REVISIONS**

| <u>REVISION</u> | <u>SECTION</u>                             | <u>DESCRIPTION</u>                       |
|-----------------|--|--|
| 5-6-2005        | Item 10                                    | Removed 'kit model number' from Option 2 |
| 9/16/05         | Title page<br>and filing an<br>application | Address and section name change.         |
| 12/13/05        | Appendix E                                 | Added e which was missing from number 2. |
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