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# MINNESOTA DEPARTMENT OF HEALTH



## REGULATORY GUIDE FOR FIXED GAUGES

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## TABLE OF CONTENTS

<b>INTRODUCTION.....</b>	<b>4</b>
<b>AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY .....</b>	<b>4</b>
<b>FILING AN APPLICATION .....</b>	<b>4</b>
<b>CONTENTS OF APPLICATION.....</b>	<b>5</b>
ITEM 1: LICENSE ACTION TYPE .....	5
ITEM 2: NAME AND MAILING ADDRESS OF APPLICANT .....	5
<i>Timely Notification of Transfer of Control</i> .....	5
ITEM 3: ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED .....	6
ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION .....	6
ITEM 5: RADIOACTIVE MATERIAL.....	6
<i>Financial Assurance and Recordkeeping for Decommissioning</i> .....	7
ITEM 6: PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED .....	7
ITEM 7: INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM.....	8
<i>Radiation Safety Officer (RSO)</i> .....	8
<i>Authorized Users</i> .....	8
ITEM 8: TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.....	9
ITEM 9: FACILITIES AND EQUIPMENT .....	9
ITEM 10: RADIATION SAFETY PROGRAM.....	10
<i>Leak Testing of Sealed Sources</i> .....	10
<i>Lock-out Procedures</i> .....	11
<i>Maintenance</i> .....	11
<i>Radiation Detection Equipment</i> .....	11
<i>Personnel Monitoring Equipment</i> .....	12
<i>Inventories</i> .....	12
<i>Annual Audits</i> .....	12
<i>Operating and Emergency Procedures</i> .....	13
<i>Transportation of Devices</i> .....	14
ITEM 11: WASTE MANAGEMENT.....	14
ITEM 12: LICENSE FEE.....	14
ITEM 13: CERTIFICATION .....	14
<b>AMENDMENTS TO A LICENSE.....</b>	<b>14</b>
<b>RENEWAL OF A LICENSE .....</b>	<b>15</b>
<b>IMPLEMENTATION .....</b>	<b>15</b>
<b>INSPECTIONS .....</b>	<b>15</b>
<b>APPENDICES .....</b>	<b>16</b>
APPENDIX A: TYPICAL DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER .....	16
APPENDIX B: CRITERIA FOR ACCEPTABLE TRAINING FOR RADIATION SAFETY OFFICERS AND AUTHORIZED USERS.....	17
APPENDIX C: INFORMATION NEEDED TO SUPPORT APPLICANT'S REQUEST TO PERFORM NON-ROUTINE OPERATIONS.....	19
APPENDIX D: MODEL PROCEDURE FOR LEAK TESTING SEALED SOURCES .....	21
APPENDIX E: SUGGESTED FIXED GAUGE AUDIT CHECKLIST .....	23
APPENDIX F: US DEPARTMENT OF TRANSPORTATION TRAINING REQUIREMENTS .....	29
<i>US Department of Transportation Training Requirements</i> .....	29
Initial Training.....	29
Recurrent Training .....	29
Training Records .....	29

49 CFR References .....	30
<b>SUMMARY OF REVISIONS .....</b>	<b>31</b>

## **REGULATORY GUIDE FOR FIXED GAUGES**

### **INTRODUCTION**

This guide is designed to describe the type and extent of information needed by the Minnesota Department of Health (MDH) to evaluate an application for a license to use and possess sealed sources in gauging devices. An example of a gauging device is a density gauge that contains a gamma emitting sealed source, Cesium-137.

The information in this guide is not a substitute for radiation safety training or for developing and implementing an effective radiation safety program. You should carefully study this guide and all the regulations identified in this guide and then complete the application. MDH may request additional information when necessary to provide reasonable assurance that you have established an adequate radiation protection program.

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

Every reasonable effort should be made to maintain radiation exposures and releases of radioactive material in effluents to unrestricted areas as low as is reasonably achievable (ALARA). As an applicant, you should consider the ALARA philosophy in the development of work plans involving radioactive materials.

The success of an ALARA program depends on the cooperation of each person who works at your facility. Management should make a formal policy commitment to the ALARA philosophy and implement that commitment with adequate resources.

The Radiation Safety Officer (RSO) and management are required to audit the radiological program to ensure the continued safe use of radioactive material. The RSO is also responsible for the day-to-day operations of the radiation safety program.

A model ALARA management program is contained in Appendix A to this guide. Applicants are required to consider the ALARA philosophy in the development of plans for radioactive materials.

### **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 is 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 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  
PO 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.

***Timely Notification of Transfer of Control***

Licensees must provide full information and obtain MDH's prior written consent before transferring control of the license, directly or indirectly, or, as some licensees call it, "transferring the license." Transfers of control may be the results of mergers, contractual agreements, 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 prior MDH written consent. 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 radiography devices.
- Public health and safety are not compromised by the use of such materials.

**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, 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 installation, give the specific address of each location.

If operations will be conducted at temporary jobsites (i.e., locations where work is conducted for limited periods of time), specify "temporary jobsites anywhere in the Minnesota where MDH maintains jurisdiction."

**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**

Applicants must provide the manufacturer's or distributor's name and model number for each requested sealed source and device. Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by NRC or an Agreement State. NRC or an Agreement State performs a safety evaluation of gauges before authorizing a manufacturer or distributor to distribute the gauges to specific licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) Registration Certificate. Before the SSD registration process was formalized, older gauges may not have been evaluated in a separate document; but were specifically approved on a license. Licensees can continue to use the gauges that are specifically listed on their licenses.

Consult with the proposed manufacturer or distributor to ensure that requested sources and devices are compatible and conform to the sealed source and device designations registered with NRC or an Agreement State. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective registration certificates, without obtaining MDH's prior permission in a license amendment. Such changes may necessitate a custom registration review, increasing the time needed to process a licensing action.

SSD Registration Certificates contain sections on "Conditions of Normal Use" and "Limitation and Other Considerations of Use." These sections may include limitations derived from conditions imposed by the manufacturer or distributor, by particular conditions of use that would reduce radiation safety of the device, or by circumstances unique to the sealed source or device. For example, working life of the device or appropriate temperature and other environmental conditions may be specified. Except as

specifically approved by MDH, licensees are required to use gauges according to their respective SSD Registration Certificates. Accordingly, applicants may want to obtain a copy of the certificate and review it with the manufacturer or distributor or with NRC or the issuing Agreement State to ensure that it correctly reflects the radiation safety properties of the source or device.

Identify each radionuclide that will be used in each source in the gauging device(s).

Identify the manufacturer or distributor and model number of each type of 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 NRC or an Agreement State and will be possessed and used in accordance with the conditions specified in the registration certificate.

Confirm that the activity per source and maximum activity per device will not exceed the maximum activity listed on the approved certificate of registration issued by NRC or by an Agreement State<sup>1</sup>.

### ***Financial Assurance and Recordkeeping for Decommissioning***

The requirements for financial assurance are specific to the types and quantities of radioactive material authorized on a license. Most gauge applicants and licensees do not need to take any action to comply with the financial assurance requirements because their total inventory of licensed material does not exceed the possession thresholds. A licensee would need to possess many gauges before the financial assurance requirements would apply.

The standard gauge license does not specify the maximum number of gauges that a licensee may possess (allowing flexibility in obtaining additional gauges specifically authorized by the license as needed without amending its license). It contains a condition requiring the licensee to limit its possession of gauges to quantities not requiring financial assurance. Applicants and licensees desiring to possess gauges exceeding the threshold amounts must submit evidence of financial assurance.

Even if no financial assurance is required, licensees are required to maintain, in an identified location, decommissioning records related to structures and equipment where gauges are used or stored and to leaking sources. Licensees must transfer records important to decommissioning either to the new licensee prior to conducting licensed activities or to MDH before the license is terminated. For gauge licensees whose sources have never leaked, acceptable records important to decommissioning are sketches or written descriptions of the specific locations where each gauge was used or stored.

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

Gauges should be used only for the purposes for which they were designed, according to the manufacturer's or distributor's recommendations and instructions, as specified in an approved SSD Registration Certificate, and as authorized on an NRC or Agreement State license. Uses other than those listed in the SSD Registration Certificate require review and approval by the NRC or an Agreement State. Requests to use gauges for purposes not listed in the SSD Registration Certificate will be reviewed on a case-by-case basis. Applicants need to submit sufficient information to demonstrate that the proposed use will not compromise the integrity of the source or source shielding, or other radiation safety-critical components of the device. MDH will evaluate the radiation safety program for each type and use of gauge requested.

If the gauge(s) will be used for the purposes listed on the SSD Registration Certificate<sup>2</sup>, do the following:

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<sup>1</sup> For information on SSD registration certificates, contact the Registration Assistant by calling NRC's toll free number (800) 368-5642 and then asking for extension 415-7217.

- You should state, "The gauge(s) will be used for the purposes described on the SSD Registration Certificate(s)"
- Provide a specific description of use for each type of gauge requested, e.g., "for fill measurements or for use in measuring thickness of material, etc."

If the gauge will be used for purposes other than those listed on the SSD Registration Certificate, specify these other purposes and submit safety analyses (and procedures, if needed) to support safe use.

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

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

The person responsible for the radiation protection program is called the Radiation Safety Officer (RSO). The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. MDH requires the name of the RSO on the license to ensure that licensee management has always identified a responsible, qualified person and that the named individual knows of his or her designation as RSO<sup>3</sup>.

Radiation Safety Officers (RSOs) must have adequate training and experience. Successful completion of training of one of the following is evidence of adequate training and experience:

- Gauge manufacturer's or distributor's course for users or for Radiation Safety Officer's
- An equivalent course that meets Appendix B criteria

The licensee should provide the name of the proposed RSO and information demonstrating that the proposed RSO is qualified by training and experience.

As an alternative, the licensee should state that:

- Before obtaining licensed materials, the proposed RSO will have successfully completed the training described in Appendix B of this guide; or
- The new RSO will receive training described in Appendix B of this guide within a specified time after being appointed.

### ***Authorized Users***

An authorized user is a person whose training and experience meet MDH criteria, who is named explicitly or implicitly on the license, and who uses or directly supervises the use of licensed material. Authorized users must ensure the proper use, security, and routine maintenance of gauges containing licensed material. Therefore, prior to the use of gauges, they must attend the training and instruction provided by a manufacturer or they must receive equivalent training and instruction.

An Authorized user is considered to be supervising the use of licensed material when he or she directs personnel in operations involving the material. Although the authorized user may delegate specific tasks to supervised users (e.g., maintaining records), he or she is still responsible for safe use of licensed material.

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<sup>2</sup> Allowed uses of gauges normally include process control methods such as measuring the thickness of paper, the density of coal, the level of material in vessels and tanks, etc. Unusual uses will be evaluated on a case-by-case basis and the authorized use condition will reflect approved uses.

<sup>3</sup> It is important to notify MDH, as soon as possible, of changes in the designation of the RSO.

Authorized users must have adequate training and experience. Successful completion of a gauge manufacturer's or distributor's course for users will satisfy the training requirements.

### **Item 8: Training for Individuals Working In or Frequenting Restricted Areas**

Individuals who in the course of employment are likely to receive occupational doses of radiation in excess of 100 mrem (1 mSv) in a year must receive training. The extent of this training must be commensurate with potential radiological health protection problems present in the work place.

Licensees need to perform a prospective evaluation to determine radiation doses likely to be received by different individuals or groups. Authorized users would be most likely to receive doses in excess of 100 mrem (1 mSv) in a year.

Licensee personnel who work in the vicinity of a gauge but do not use gauges (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 a gauge, it is prudent for them to work under the supervision and in the physical presence of an authorized user or to be provided some basic radiation safety training. Such ancillary staff should be informed of the nature and location of the gauge and the meaning of the radiation symbol, and should be instructed not to touch the gauge and to keep away from it as much as their work permits.

Some ancillary staff, although not likely to receive doses over 100 mrem, should receive training to ensure adequate security and control of licensed material. Licensees may provide these individuals with training commensurate with their assignments near the gauge to ensure the control and security of licensed material.

Submit the training program for individuals who in the course of employment are likely to receive occupational doses of radiation in excess of 100 mrem (1 Sv) in a year (occupationally exposed workers) and ancillary personnel.

### **Item 9: Facilities and Equipment**

Fixed gauges incorporate many engineering features to protect the user from unnecessary radiation exposure in a wide variety of environments. Fixed gauges may be located in harsh environments involving variables such as pressure, vibration, mounting height/method, temperature, humidity, air quality, corrosive atmospheres, corrosive chemicals including process materials and cleaning agents, possible impact or puncture conditions, and fire, explosion, and flooding potentials. Applicants need to consult the sections on the SSD Registration Certificate entitled, "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" to determine the appropriate gauge for a location. In those instances when a proposed location is not consistent with the SSD Registration Certificate, the applicant may ask the source or device manufacturer or distributor to request an amendment to modify the SSD Registration Certificate to include the new conditions. If the manufacturer or distributor does not request an amendment, the applicant must provide MDH with specific information demonstrating that the proposed new conditions will not impact the safety or integrity of the source or device.

An application will be approved if, among other things, the applicant has equipment and facilities that are adequate to protect health and to minimize danger to life or property. Therefore, you should provide the following information concerning your equipment and facilities:

- A sketch or description of the proposed location of each gauge within your facility.
- The environmental conditions to which gauges will be exposed (e.g., elevated temperature, corrosive atmosphere, and vibration).

- If the ambient temperature will exceed the maximum operating temperature specified by the manufacturer, thus creating a need to maintain a lower temperature by means of cooling jackets or similar measures, a description of the cooling system should be provided. In addition, provide a discussion of how the cooling system will be maintained and the consequences of a failure of the cooling system.
- If a cooling system is used to maintain the temperature below the maximum operating temperature specified by the manufacturer, submit a description of the method and procedures for detecting a cooling system failure and your procedures for coping with a cooling system failure.
- Confirm that the fixed gauge is secured to prevent unauthorized removal or access.

#### **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. If the device distributor or another person specifically licensed to install, survey, maintain, relocate or remove the device will perform those services, you do not need personnel monitoring equipment or radiation detection equipment. Your application should specifically state the name, address, and NRC or Agreement State license number of the person or firm who will provide the services.

The elements of a radiation safety program are contained in the appendices. 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.”

#### ***Leak testing of sealed sources***

As a licensee, you must perform leak tests to ensure that sources are not leaking. MDH requires tests to determine if there is any leakage from the sealed sources in the devices. Normally, leak tests should be performed at 6-month intervals. Some sealed source/device combinations have been authorized for a leak test interval of three years. Information about sealed source/device combinations that have three-year leak test intervals may be obtained from suppliers and manufacturers.

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 smears and send them to the kit supplier, who will report the results to you.
3. Perform the entire leak test sequence yourself, including taking the smears and their measurements.

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

For Option 2, specify the name, address, and license number of the leak test kit supplier. You should state that the test samples will be taken by the individual specified in Item 4 who is responsible for the program. Commit to the procedures in Appendix D or submit your own procedures.

For Option 3, describe the procedure for taking the sample and 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. Commit to Appendix D or submit your own procedures.

### ***Lock-out procedures***

It is possible that a major portion of an employee's body could receive exposure from the radiation beam from certain devices. For example, the radiation beam of a level gauge could traverse the bin or tank in such a way that an employee entering the bin or tank could receive a radiation exposure.

You must have "lockout" procedures so that personnel will not be subjected to unnecessary exposure. The procedures should specify the means for preventing employees from entering the radiation beam during maintenance, repairs, or other work in, on, or around the bin, tank, or hopper on which the device is mounted. You do not need to submit the procedures.

You should state in your application that you will prepare such procedures, that you will provide them to your personnel, and that the procedures will be posted so that personnel can see them. You should specify that the individual who will be responsible for ensuring that the lockout procedures are followed is the "responsible individual" named in Item 4.

### ***Maintenance***

Submit the information on the maintenance of gauges, including (but not limited to) frequency, checks for proper shutter operation, checks that labels are legible and visible, and checks that gauges are protected against corrosive materials or materials at high temperature.

If you have requested authorization to perform non-routine maintenance on your gauges, you should state in your application that you will follow the written procedures provided by the device manufacturer for each service operation requested. In addition, review Appendix C and provide all applicable information.

### ***Radiation Detection Equipment***

If you plan to perform gauge servicing such as installation, initial radiation survey, maintenance, device relocation, removal, etc., you must have a survey meter that is calibrated annually and after servicing. Electronic calibrations alone are not acceptable. Battery changes are not considered "servicing." Provide the type and range of the meter and the name and address of the company who will calibrate the meter.

State that before using the survey meter, you will check the response of the instrument with a check source and that you will not use the meter until it is repaired and operable if the meter does not respond properly.

### ***Personnel Monitoring Equipment***

Applicants must do either of the following:

- Maintain, for inspection by MDH, documents demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits as specified in 4731.2000.

OR

- Personnel monitoring equipment must be used by individuals who receive or are likely to receive occupational exposure in one year from sources external to the body, in excess of 10% of the dose specified in paragraph 4731.2000. Individuals under 18 years or declared pregnant women are required to use personnel monitoring equipment if they receive or are likely to receive a dose in excess of 10% of the specified dose.

If you propose to service the gauges yourself (e.g., install the gauges and perform the initial radiation survey, relocate gauges, ship devices), you should provide personnel monitoring devices for your personnel who will perform the operations. Film badges, thermoluminescent dosimeters (TLDs), or optically stimulated dosimeters (OSD) are acceptable. You should:

- Make a commitment in your application that personnel monitoring devices will be worn by personnel when they are servicing the gauges.
- Specify the type of personnel monitoring devices that will be used and the frequency of their exchange. The changes should be made at intervals not to exceed 1 month for film badges and three months for TLDs and OSDs.
- Provide the name and address of the company that will provide your personnel monitoring devices.

### ***Inventories***

State that you will conduct inventories at intervals not to exceed six (6) months to account for all sealed sources and gauges received and possessed under your license. You should maintain records of the inventories for at least five (5) years from the date of the inventory. The records should include the radionuclide and amount of material in each source, the manufacturer's name, model number and serial number of each gauge, the location of each, and the date of the inventory.

### ***Annual audits***

Licensees must review the content and implementation of their radiation protection programs at intervals not to exceed 12 months to ensure compliance with MDH rules and the terms and conditions of the license. Records of audits and other reviews of program content are maintained for three years.

As part of the audit programs, you should consider performing unannounced audits of your authorized users. The purpose is to determine that proper radiation safety and operating procedures are followed.

It is essential once problems are identified that they are corrected promptly and comprehensively. MDH will review a licensee's audit program and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. MDH will normally exercise discretion and not cite violations previously identified and corrected by the licensee. The licensees are encouraged to regulate their own compliance.

An audit program for a fixed gauge should include a review of:

- ✓ leak test records and procedures
- ✓ inventory records
- ✓ training

- ✓ the operating and emergency procedures
- ✓ survey instrument calibration records and procedures (if applicable)

See Appendix E for questions to consider in an annual audit. You, as the licensee, are responsible for the content and implementation of your radiation safety program and for all actions of your employees.

***Operating and emergency procedures***

State on your application that you will provide the operating and emergency procedures to each person responsible for the gauge. Submit the detailed operating and emergency procedures for review. The following topics should be covered:

- Instructions for operating the gauge.
- Instructions for performing routine cleaning and maintenance (e.g., calibration and lubrication) according to the manufacturer's or distributors recommendations and instructions.
- Instructions for testing each gauge for the proper operation of the on-off mechanism (shutter) and indicator, if any, at intervals not to exceed six months or as specified in the SSD certificate.
- Instructions for lock-out procedures, if applicable, that are adequate to assure that no individual or portion of an individual's body can enter the radiation beam.
- Instructions to prevent unauthorized access, removal, or use of fixed gauges.
- Steps to take to keep radiation exposures ALARA.
- Steps to maintain accountability (i.e., inventory).
- Instructions to ensure that non-routine operations such as installation, initial radiation survey, repair and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement and disposal of sealed sources, alignment, or removal of a gauge from service are performed by the manufacturer, distributor or person specifically authorized by the NRC or an Agreement State.
- Steps to ensure that radiation warning signs are visible and legible.
- Develop, implement, and maintain emergency procedures for gauge malfunction or damage containing the following elements for each type of fixed gauge:
  - Stop use of the gauge.
  - Restrict access to the area.
  - Contact responsible individuals. (Telephone numbers for the RSO, authorized users, the gauge manufacturer or distributor, fire department or other emergency response organization, and the MDH should be posted or easily accessible.)
  - Do not attempt repair or authorize others to attempt repair of the gauge except as specifically authorized in a license issued by the NRC or an Agreement State.
  - Take additional steps, dependent on the specific situations.
- Provide copies of operating and emergency procedures to all gauge users.
- Post copies of operating and emergency procedures at each location of use or if posting procedures is not practicable, post a notice that briefly describes the procedures and states where they may be examined.

Operating and emergency procedures should be developed, maintained, and implemented to ensure that gauges are used only as they were designed to be used, control and accountability are maintained, and radiation doses received by occupational workers and members of the public are ALARA.

Improper operation could lead to the damage or malfunction of a gauge and elevated exposure rates in the gauge's immediate vicinity. Emergency procedures should be developed to address a spectrum of incidents (e.g., fire, explosion, mechanical damage, flood, or earthquake).

### ***Transportation of devices***

The transport of licensed material must be carried out in accordance with the applicable requirements of the Department of Transportation (DOT).

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

The only option for disposal of the licensed material contained in fixed gauges is to transfer the material to an authorized recipient. You should state that disposal will be by transfer of the radioactive material to a licensee specifically authorized to possess it. Authorized recipients are the original suppliers of the device, a commercial firm licensed by an Agreement State or the NRC to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material. No one else is authorized to dispose of your licensed material.

### **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 both MDH rules and the conditions of the license. Typically, the RSO's duties and responsibilities include ensuring the following:

- Activities involving licensed material that the RSO considers unsafe are stopped.
- Radiation exposures are ALARA.
- Development, maintenance, distribution, and implementation of up-to-date operating and emergency procedures.
- Individuals that use fixed gauges are properly trained.
- Possession, installation, relocation, use, storage, routine maintenance and non-routine operations of fixed gauges are consistent with the limitations in the license, the SSD Registration Certificate(s), manufacturer's or distributors recommendations and instructions.
- Safety consequences of non-routine operations are analyzed before conducting any such activities that have not been previously analyzed.
- Non-routine operations are performed by the manufacturer, distributor or person specifically authorized by the NRC or an Agreement State.
- Prospective evaluations are performed demonstrating that individuals likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits are provided personnel monitoring devices.
- Personnel monitoring devices, if required, are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained.
- Documentation is maintained to demonstrate, by measurement or calculation, that the TEDE to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit as specified in 10 CFR 20.1301.
- Fixed gauges are properly secured.
- Notification of proper authorities of incidents such as damage to or malfunction of fixed gauges, fire, loss, or theft.
- Investigation of unusual occurrences involving the fixed gauge (e.g., malfunctions or damage), identification of cause(s), implement of appropriate and timely corrective action(s).
- Radiation safety program audits are performed at intervals not to exceed 12 months and development, implement, and documentation of timely corrective actions.
- When the licensee identifies violations of regulations or license conditions or program weaknesses, corrective actions are developed, implemented, and documented.
- Licensed material is transported according to all applicable DOT requirements.
- Licensed material is disposed of properly.
- Appropriate records are maintained.
- An up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner.
- Posting of documents or posting a notice indicating where these documents can be examined.

**APPENDIX B**  
**CRITERIA FOR ACCEPTABLE TRAINING FOR RADIATION SAFETY OFFICERS AND AUTHORIZED**  
**USERS**

Classroom training may be in the form of lecture, videotape, or self-study emphasizing practical subjects important to safe use of the gauge. Training should include the following topics:

**Radiation Safety:**

- Radiation vs. contamination
- Internal vs. external exposure
- Biological effects of radiation
- Types and relative hazards of radioactive material possessed
- ALARA concept
- Use of time, distance, and shielding to minimize exposure
- Location of sealed source within the gauge

**Regulatory Requirements:**

- Applicable regulations
- License conditions, amendments, renewals
- Locations of use and storage of radioactive materials
- Material control and accountability
- Annual audit of radiation safety program
- Transfer and disposal
- Recordkeeping
- Prior events involving fixed gauges
- Handling incidents
- Recognizing and ensuring that radiation warning signs are visible and legible
- Licensing and inspection by regulatory agency
- Need for complete and accurate information
- Employee protection
- Deliberate misconduct
- Practical Explanation of the Theory and Operation for Each Gauge Possessed by the Licensee:
- Operating and emergency procedures
- Routine vs. non-Routine maintenance
- Lock-out procedures

*On-the-job training must be done under the supervision of an authorized user or RSO.*

**Supervised Hands-on Experience Performing:**

- Operating procedures
- Test runs of emergency procedures
- Routine maintenance
- Lock-out procedures

### **Training Assessment**

Management will ensure that proposed authorized users are qualified to work independently with each type of gauge with which they may work. Management will ensure that proposed RSO's are qualified to work independently with and are knowledgeable of the radiation safety aspects of all types of gauges to be possessed by the applicant. This may be demonstrated by written or oral examination or by observation.

### **Course Instructor Qualifications**

Instructor should have:

- Bachelor's degree in a physical or life science or engineering
- Successful completion of a fixed gauge manufacturer's or distributor's course for users (or equivalent)
- Successful completion of an 8 hour radiation safety course; and
- 8 hours hands-on experience with fixed gauges

**OR**

- Successful completion of a fixed gauge manufacturer's or distributor's course for users (or equivalent)
- Successful completion of 40-hour radiation safety course and 30 hours of hands-on experience with fixed gauges.

**OR**

- The applicant may submit a description of alternative training and experience for the course instructor.

Additional training is required for those applicants intending to perform non-routine operations such as installation, initial radiation survey, repair, and maintenance of components related to the radiological safety of the gauge, gauge relocation, replacement, and disposal of sealed sources, alignment, or removal of a gauge from service. See Appendix C - "Non-Routine Operations."

## **APPENDIX C INFORMATION NEEDED TO SUPPORT APPLICANT'S REQUEST TO PERFORM NON-ROUTINE OPERATIONS**

Applicants should review the section in this document on "Maintenance," that discusses, in general, licensee responsibilities before any maintenance or repair is performed. Non-routine operations include installation of the gauge, initial radiation survey, repair or maintenance involving or potentially affecting components (including electronics) related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding). Non-routine operations also include gauge relocation, replacement, and disposal of sealed sources, alignment, removal of a gauge from service, and any other activities during which personnel could receive radiation doses exceeding MDH limits.

Any non-manufacturer/non-distributor supplied replacement components or parts, or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer or distributor need to be evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration. Licensees also need to ensure that, after maintenance or repair is completed, the gauge is tested and functions as designed, before the unit is returned to routine use.

If non-routine operations are not performed properly with attention to good radiation safety principles, the gauge may not operate as designed and personnel performing these tasks could receive radiation doses exceeding MDH limits. Radionuclides and activities in fixed gauges vary widely. For illustrative purposes, in less than one minute an unshielded Cesium-137 source with an activity of 100 millicuries can deliver 5 rems (0.05 Sv) to a worker's hands or fingers (i.e., extremities), assuming the extremities are 1 centimeter from the source. However, gauges can contain sources of even higher activities with correspondingly higher dose rates. The threshold for extremity monitoring is 5 rems (0.05 Sv) per year.

Applicants wishing to perform non-routine operations must use personnel with special training and follow appropriate procedures consistent with the manufacturer's or distributors instructions and recommendations that address radiation safety concerns (e.g., use of radiation survey meter, shielded container for the source, and personnel dosimetry (if required)).

- Describe the types of work, maintenance, cleaning, repair that involve installation, relocation, or alignment of the gauge
- Components, including electronics, related to the radiological safety of the gauge (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding)
- Replacement and disposal of sealed sources
- Removal of a gauge from service
- A potential for any portion of the body to come into contact with the primary radiation beam; or
- Any other activity during which personnel could receive radiation doses exceeding MDH limits.

The principal reason for obtaining this information is to assist in the evaluation of the qualifications of individuals who will conduct the work and the radiation safety procedures they will follow.

A licensee may initially mount a gauge, without specific NRC or Agreement State authorization, if the gauge's SSD Certificate explicitly permits mounting of gauges by users and under the following conditions:

- The gauge must be mounted according to written instructions provided by the manufacturer or distributor;
- The gauge must be mounted in a location compatible with the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" in the certificate of registration issued by NRC or an Agreement State;
- The on-off mechanism (shutter) must be locked in the off position, if applicable, or the source must be otherwise fully shielded;

- The gauge must be received in good condition (package was not damaged); and
- The gauge must not require any modification to fit in the proposed location.
- Mounting does not include electrical connection, activation, or operation of the gauge.
- The source must remain fully shielded and the gauge may not be used until it is installed and made operational by a person specifically licensed by the NRC or an Agreement State to perform such operations.

Identify who will perform non-routine operations and their training and experience. Acceptable training would include manufacturer's or distributors courses for non-routine operations or equivalent.

Submit procedures for non-routine operations. These procedures should ensure the following:

- doses to personnel and members of the public are within regulatory limits and ALARA (e.g., use of shielded containers or shielding);
- the source is secured against unauthorized removal or access or under constant surveillance;
- appropriate labels and signs are used;
- manufacturer's or distributors instructions and recommendations are followed;
- any non-manufacturer/non-distributor supplied replacement components or parts, or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer or distributor are evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration; and
- before being returned to routine use, the gauge is tested to verify that it functions as designed and source integrity is not compromised.

Confirm that individuals performing non-routine operations on gauges will wear both whole body and extremity monitoring devices or perform a prospective evaluation demonstrating that unmonitored individuals performing non-routine operations are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits.

Describe steps to be taken to ensure that radiation levels in areas where non-routine operations will take place do not exceed MDH limits. For example, applicants can do the following:

- commit to performing surveys with a survey instrument (as described above);
- specify where and when surveys will be conducted during non-routine operations; and
- commit to maintaining, for 3 years from the date of the survey, records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements).

## **APPENDIX D LEAK TESTING SEALED SOURCES**

You may use the following model procedure to leak test sealed sources. If you follow the model procedure you may indicate on your application, "We will establish and implement the model procedure for leak testing sealed sources published in Appendix D to the MDH Regulatory Guide for Fixed Gauges."

You may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of Minnesota Rules. State on your application, "We have developed a leak test procedure for your review that is appended as Appendix D" and submit your leak test procedure.

### **MODEL PROCEDURE FOR TAKING TEST SAMPLES**

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.
2. If you will be testing sources stronger than a few millicuries, set out a survey meter, preferably with a speaker, so you can monitor your exposure rate.
3. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable. Number each wipe so you will know for which source it is to be used. Samples should be taken as follows:
  - a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints. However, do not wipe the port of beta applicators.
  - b. For larger sealed sources and devices (survey meter calibrator), take the wipe near the radiation port and on the activating mechanism.
  - c. If you are testing radium sources, they should also be checked for radon leakage. This can be done by submerging the source in a vial of fine-grained charcoal or cotton for a day. Then remove the source and analyze the absorbent sample as described below. A survey should be done to be sure that sources are adequately shielded during the leak test period.

### **MODEL PROCEDURE FOR ANALYZING TEST SAMPLES**

The samples will be analyzed as follows:

1. Select an instrument that is sufficiently sensitive to detect 0.005 microcuries. For beta sources, a proportional flow counter, liquid scintillation counter, or thin-end-window GM survey meter may be appropriate. For gamma sources, a GM instrument or a scintillation detector with either a ratemeter or scaler may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive.
2. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a check source that has the same isotope as the sealed source. The source activity should be certified by the supplier. If one is not available, it will be necessary to use a certified check source with a different isotope that has a similar spectrum. If calculations demonstrate that the instrument is not sufficiently sensitive to detect 0.005 microcuries, a different instrument must be used.

3. Assay the wipe sample. It must be in the same geometry relative to the detector as was the certified check source.
4. Record the wipe sample in counts per minute. Then calculate and record the estimated activity in microcuries on the wipe sample.
5. Continue the same analysis procedure for all wipe samples.
6. If the wipe sample activity is 0.005 microcuries or greater, notify the RSO. The source must be withdrawn from use to be repaired or disposed of in accordance with MDH rules.
7. Record model number and serial number (if assigned) of each source tested, radionuclide and estimated activity, measured activity of each test sample in microcuries, description of method used to test each sample, date of test, and signature of RSO. Maintain these records for five (5) years.

**APPENDIX E  
SUGGESTED FIXED GAUGE AUDIT CHECKLIST**

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 their 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?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does new RSO meet MDH training requirements?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is RSO fulfilling all duties?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the written agreement in place for a new RSO?		<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, quantity, and use as authorized?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are all gauge models and types listed on license?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are gauges and sealed sources described in the Sealed Source and Device Registration (SSDR) Certificate?		<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 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>
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"/>
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 2090 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"/>
Workers observed using a gauge?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Workers observed performing routine maintenance of a gauge?		<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>
Facilities are as described in the license application?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Materials secured from unauthorized removal or access?	2290	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Proper dosimetry worn?		<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>
Survey instruments possessed?		<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 required frequencies?		<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"/>
<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>Gauge Inventory</b>	<b>4731</b>	<b>N/A</b>	<b>Yes</b>	<b>No</b>
Records of receipt for gauges maintained?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Gauges 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>Radioactive Waste</b>	<b>4731</b>	<b>N/A</b>	<b>Yes</b>	<b>No</b>
Sources transferred to authorized individuals?	2400 2450 3105	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Name of organization:				
Records of surveys and material accountability are maintained?	2510 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?	2350	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Records of receipt/transfer maintained?	2510 3115	<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:				
Delivered to common carriers?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No shipments since last audit?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Packages:				
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"/>
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, 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:				
Prepared and used?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Proper Shipping Name, Hazard Class, UN Number, Quantity, Package Type, Nuclide, Radioactive Material, Physical and Chemical Form, Activity, Category of Label, TI, RQ, Shipper's Name, Certification and Signature, Emergency Response Phone Number?		<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"/>
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"/>
Review of Records and Reports				
Reviewed by Frequency		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Auditor reviewed personnel monitoring records for period to _____		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Prior dose determined for individuals likely to receive doses?	2520	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Were occupational limits met?	2020	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MDH Form 5 or equivalent provided to all monitored employees?	2520 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 2540	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Records of exposures, monitoring, and evaluations maintained?	2500 2510 2540	<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 4731.2600, 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"/>
<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?				
<b>Notifications Since Last Audit</b>	<b>4731</b>	<b>N/A</b>	<b>Yes</b>	<b>No</b>
Any Notifications since last audit?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MDH notified within 30 days after Radiation Safety Officer (RSO) stops work or changes name?		<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		<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 F US DEPARTMENT OF TRANSPORTATION TRAINING REQUIREMENTS**

The following information summarizes The Department of Transportation training requirements and provides a reference to other DOT regulations.

### **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>>.

