



Protecting, maintaining and improving the health of all Minnesotans

December 14, 2004

Paul H. Lohaus, Director
Office of State and Tribal Programs
US Nuclear Regulatory Commission
One While Flint North
11555 Rockville Pike, 3rd Floor
Rockville, Maryland 20852

Dear Mr. Lohaus:

In response to your Final Application Comments dated October 19, 2004, and related communications from your office, the Minnesota Department of Health (MDH) has revised its Final Agreement State Application. As indicated in the enclosed response, MDH has incorporated the rule changes requested by your staff as well as changes requested by the Administrative Law Judge that approved the final rules. A copy of the modified rules, which indicates those changes, is being provided to assist in the review.

After your review of the enclosed response, MDH requests that you provide an updated timeline for the Agreement State process. As previously indicated, MDH is planning on assuming that responsibility in September of 2005. The timeline should assist in identifying whether or not that goal remains achievable.

If you have any questions concerning the Minnesota's Final Agreement State Application, please contact George F. Johns, Jr. at (651) 642-0492 or me at (651) 215-0945.

Sincerely,

Linda B. Bruemmer, Manager
Asbestos, Indoor Air, Lead & Radiation
Environmental Health Division
P.O. Box 64975
St. Paul, Minnesota 55164-0975

Attachments: Response Document
Enclosures 1 through 15
Chapter 4731

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STP

SISP Review Complete

STP-006 Template
RIDS-SP07

MINNESOTA DEPARTMENT OF HEALTH



RESPONSE TO STATE OF MINNESOTA FINAL APPLICATION COMMENTS

The logo for the Radiocative Materials Group (RAM) is circular. It features a stylized ram's head in the center. The text "Radiocative Materials Group" is written along the top inner edge of the circle, and "Minnesota Department of Health" is written along the bottom inner edge. The acronym "RAM" is positioned at the bottom center of the circle.	<p style="text-align: center;">Radiation Control Unit Asbestos, Lead, Indoor Air & Radiation Section Division of Environmental Health Minnesota Department of Health</p>
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Sincerely,

A handwritten signature in cursive script, appearing to read "Linda B. Bruemmer".

Linda B. Bruemmer, Manager
Asbestos, Indoor Air, Lead & Radiation
Environmental Health Division
P.O. Box 64975
St. Paul, Minnesota 55164-0975

Attachments: Response Document
Enclosures 1 through 15
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STP

December 16, 2004

**THE STATE OF MINNESOTA
RESPONSE TO US NUCLEAR REGULATORY COMMISSION'S
FINAL APPLICATION COMMENTS DATED OCTOBER 19, 2004**

Section 4.1 Legal Elements

Section 4.1.1 Statutory Authority

Review Team Comments: The Minnesota rule 4731.3015, Exemption; Use of Radioactive Material Under Certain Federal Contracts, paragraph B.(2) states that the NRC will determine whether the conditions have been met for an exemption for a prime contractor or subcontractor of the Department of Energy or the NRC. In accordance with STP Procedure SA-700 Handbook, Section 4.1.1.2, Evaluation Criteria, paragraph (e)(iv.), the Minnesota rule should state that the NRC and Minnesota will jointly make the determinations.

Response: Minnesota rule 4731.3015, Exemption; Use of Radioactive Material Under Certain Federal Contracts, paragraph B.(2) has been revised to read: "the NRC and the commissioner determine that...."

4.1.2 Program Organization Review Team Comments:

1. Section 4.1.2, "Program Organization," page 2. This section provides information on the Radiation Control Unit (RCU); however, the organizational charts do not include the RCU. The organization charts include the "Asbestos, Indoor Air, Lead and Radiation Section" and the "Radioactive Materials Group." In discussions with Minnesota staff, we understand that the RCU is divided into two Groups, the Radioactive Materials Group and the X-ray Group. The information in this section should be revised to reflect this organization. In addition, this section should be revised to ensure that the information provided on page 2 is consistent with the organizational charts (e.g., the organizational location of the RCU, the X-ray Group and the Asbestos, Indoor Air, Lead and Radiation Section).

Response: The Radiation Control Unit consists of two groups: The X-ray Group and the Radioactive Materials Group. MDH has revised discussion concerning the Radiation Control Unit to correct and clarify the information. See enclosure 1.

2. Section 4.1.2, page 2, under the RCU. This section should be revised to clearly identify the organization that will carry out the day-to-day operations of the Agreement Program, (e.g., the Radioactive Materials Group). This information has been provided informally to

NRC; however, the Minnesota application should be revised to include this information.

Response: The Radioactive Materials Group is responsible for the day-to-day operations of the Agreement Program. This statement has been added to the verbiage in enclosure 1.

3. Section 4.1.2, page 2, under the RCU, in discussions with Minnesota staff, we understand that the State regulates PET and radium as the only forms naturally occurring or accelerator-produced radioactive material (NARM) regulated by the State. The radium is in the form of 45 radium gauge licensees and one PET licensee. The radium and PET licensees are inspected every four-years. In addition, we understand that the State requires NARM registration. Section 4.1.2, page 2, should be revised to reflect this information. This information has been provided informally to NRC; however, the Minnesota application should be revised to include this information.

Response: The Minnesota Department of Health regulates Radium-226, which is a naturally occurring isotope, and accelerator produced radioactive materials (NARM) within Minnesota. There are approximately 45 facilities that use Radium-226 in fixed and portable gauges. Staff in the Radioactive Materials Group continues to conduct routine inspections of these facilities. In addition, the Radioactive Materials Group is tasked with inspecting the nuclear pharmacy¹ with cyclotrons, which produce short-lived isotopes for medical applications, as well as the ten facilities that only use accelerator-produced materials². This information has been added to enclosure 1.

4.1.3 Content of the Proposed Agreement Review Team Comments:

1. On page 1, paragraph one, line three of the Proposed Agreement, the wording "any State" should be deleted and the wording "the State of Minnesota" should be inserted.

Response: The Proposed Agreement has been revised. See enclosure 2.

2. On page 1, paragraph one, line six, the wording "with respect to byproduct materials as defined in Sections 11 e.(1) and (2) of the Act" is included in the proposed Minnesota Agreement. In the July 6, 2004 request from Governor Pawlenty to Chairman Diaz 11 e.(2) byproduct material was not included. Since Minnesota is not requesting authority for 11 e.(2) materials, which include uranium milling activities, the State should delete the wording "and (2)" from paragraph one of the Proposed Agreement. Please see STP Procedure SA-700 Handbook, Sections 4.1.3.1, Information Needed and 4.1.3.2, Evaluation Criteria, and Management Directive 5.8, *Proposed 274b Agreements with*

¹ A second cyclotron is expected to be operational in November of 2004.

² The NRC does not license these facilities.

States.

Response: The Proposed Agreement has been revised. See enclosure 2.

4.2 Regulatory Requirements Program Elements

Comments on these program elements were provided to Minnesota by letter dated September 17, 2004 from Josephine Piccone to George Johns.

Response: All of the items have been incorporated in the revised rule. These items are addressed in enclosure 3. In addition, the Administrative Law Judge of the Minnesota Office of Administrative Hearings recommended changes to several rule parts. Those changes have been incorporated and are summarized on pages 4 through 6 of enclosure 3.

4.3 Licensing Program Elements

Review Team Comments:

1. The Section 4.3.1 of the Minnesota application, includes an excerpt from the *Regulatory Guide for Diagnostic and Therapeutic Medical Procedures*. The excerpt includes a section entitled "Annotated Drawings." At bullet three, line four, a reference is made to 10 CFR 20.1003. Rather than referencing NRC regulations, the guide should reference Minnesota regulations (i.e., Section 4731 of the MDH regulations) or provide a rationale why this guide references NRC's regulation.

Response: The *Regulatory Guide for Diagnostic and Therapeutic Medical Procedures* has been revised to eliminate the reference to 10 CFR 20.1003. See page 13 of enclosure 4.

2. The Section 4.3.1 of the Minnesota application includes the *Regulatory Guide for Decommissioning*. The regulatory guide did not provide adequate guidance for termination of licenses. In addition, on page 2 of the regulatory guide a reference is made to NUREG/CR-5849, "Manual for Conducting Radiological Surveys and Supports of Licensing Termination," which has been superseded by NUREG-1757, *Consolidated NMSS Decommissioning Guidance*. To ensure up-to-date and adequate decommissioning guidance, Minnesota may want to adopt by reference or commit to using NUREG-1757 or provide other appropriate regulatory guidance. Please see STP Procedure SA-700 Handbook, Section 4.3.1.2, Evaluation Criteria, which requires that procedures for evaluating decommissioning should address decontamination, disposal and any restrictions on future use of the property.

Response: The decommissioning regulatory guide has been revised to reference NUREG 1757, address license termination and to include a discussion of radiological program that do not require decommissioning plans. See enclosure 5.

3. The Minnesota rules have some provisions on actions to be taken in the event a licensee files for bankruptcy; however, supporting licensing procedures or guides are silent on this licensing related activity. Minnesota should submit a procedure for handling change of control and bankruptcy actions. The State may adopt by reference or commit to using model procedures in NUREG-1556 Vol. 15 or provide other appropriate regulatory guidance.

Response: Refer to enclosure 6, which is the document created to address change of control and bankruptcy actions.

4. The *Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments, Appendix A, Model Program for Maintaining Occupational Radiation Exposure ALARA*, page 15, Table A-1 Investigational levels, provides dose investigational levels to serve as check points above which the Radiation Safety Officer would perform a review of occupational exposures. As noted in NUREG-1 556, Vol. 9, Appendix M, pages M-3 and M-4, the ICRP recommended value for Investigational Level I is 10 percent of the annual limit for occupational exposure and 30 percent for Investigational Level II. The values presented in the Minnesota regulatory guide are much higher than those recommended. For example, the NRC guidance document provides an Investigational Level I of 500 mrem per year for the whole body, while, the Minnesota guide provides a value of 2400 mrem per year. The State should modify the information provided in Table A-1.

Response: *Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments, Appendix A, Model Program for Maintaining Occupational Radiation Exposure ALARA*, page 15, Table A-1 Investigational levels has been revised. See enclosure 7.

5. The *Regulatory Guide for Industrial Radiography, Appendix C, Model Annual Audit Checklist*, page 25, section on Transportation (10 CFR 49), does not include the requirement for checking whether the licensee has a valid Certificate of Compliance, issued by NRC, for the Type B package that may be used for transportation of devices. For further information see NUREG-1 556, Vol. 2, *Program Specific Guidance About Industrial Radiography*, Appendix I, Transportation (10 CFR 71.5(a) and 49 CFR (170-185).

Response: *Regulatory Guide for Industrial Radiography, Appendix C, Model Annual Audit Checklist*, page 25, section on Transportation (10 CFR 49), has been revised to include the requirement for checking whether the licensee has a

valid Certificate of Compliance. See page 25 of enclosure 8 (Transportation, item c).

4.4 Inspection Program Elements Review Team Comments:

1. In Section 4.4.1 *Inspection Procedures*, of the Minnesota application, the State provided the Minnesota Instrument Inventory. The inventory does not address the State's neutron monitoring capabilities. Neutron sources are currently licensed in the State. Please see STP Procedure SA-700 Handbook, Sections 4.4.1.2 Evaluation Criteria.

Response: The Minnesota Department of Health has calibrated its neutron detection instrument and added it to the calibration schedule. See enclosure 9.

2. In the *Inspection Procedures Manual*, the section "Determining Inspection Priorities," provides a listing of inspection priorities to which licensees can be assigned. The Manual discusses Priority 7 inspections; however, they are not included in the listing of inspection priorities. Thus, it is not clear whether Priority 6 or Priority 7 inspections are the longest inspection intervals. This information should be clarified.

Response: Reference to Priority 7 inspections has been deleted. The longest priority inspection is a telephonic inspection. The references throughout the manual have been eliminated. See enclosure 10.

3. The *Inspection Procedures Manual*, page 7, in the section, "Scheduling Inspections," provides a discussion on follow-up inspections. The discussion is not clear as to the length of time between escalated enforcement actions and follow-up inspections. For example, the section "Follow-up Inspections" indicates that these inspections will occur within six months; whereas, the section "Intervals between Inspections," indicates that an inspection will occur within one year. The State should clarify this information.

Response: MDH has deleted the conflicting language. See page 6 of enclosure 10.

4. The *Inspection Procedures Manual*, page 36, Section IV, "Processing Inspection Reports," subsection, "Peer Review Process," refers to licensing actions as opposed to inspection activities. This section should be rewritten to correctly address the inspection process.

Response: This portion of the *Inspection Procedures Manual* has been revised. See page 35 of enclosure 10.

5. The *Licensing and Inspection Qualification Journal* indicates that the Radiation Control

Unit Supervisor or another qualified inspector will make periodic evaluations of inspectors. NRC Manual Chapter 2800 requires that an inspection supervisor evaluate the performance of each inspector, during actual inspections, at least once per year. The Journal should be revised to indicate that these evaluations will be made by the Minnesota inspection supervisor.

Response: Despite the fact that SA 102 states that senior inspection staff can audit an inspector in small states, the mandate to conduct semi-annual audits by qualified inspectors or the supervisor has been deleted. The *Licensing and Inspection Qualification Journal* now requires annual audits by the Radiation Control Unit Supervisor. See page 16 of enclosure 11.

4.6 Technical Staffing and Training Program Elements

Review Team Comments:

1. Section 4.6.1 of the Minnesota application provides information on the Minnesota staff and their training. Subsequent to this submittal, we were informed that the Radiation Specialist 1 (Johnson) left the program. Section 4.6 of the Minnesota application should be revised to reflect that Ms. Johnson is no longer with the Minnesota Program and that there is a vacant position (e.g., revise the organizational chart for the Radioactive Materials Group and the Professional Staff Assignments). Please provide further information on the status of this newly vacant position. For example, has a vacancy announcement been prepared for this position?

Response: Reference to Ms. Johnson has been deleted. As indicated in the following comment, this position provides additional staffing only to supplement the program requirements; however, the vacant position has been filled. Brandon Juran began employment on December 1, 2004. The Organization Chart has been updated. See enclosure 12 for that chart and a copy of Mr. Juran's resume.

2. In Section 4.6.1 of the Minnesota application, the "Professional Staff Assignments" and the organization chart, indicated that five professional staff are assigned to the proposed Agreement Program along with one supervisor. However, the "Staff Needs Analysis" provides staffing support from only three individuals, who will be providing a 2.4 staff effort (0.8x3) to the Agreement Program. Please provide information on the overall FTE allocated to the Minnesota Agreement Program. This information should include a breakdown of the individual FTE effort provided by the Radiation Specialist 3 (McClanahan), and the Environmental Health Supervisor (Johns). In addition, please clarify the FTE for administrative support provided to the proposed Agreement program. Although this information has been provided informally to the NRC, the Minnesota application should be revised to include this information.

Response: The applicable FTEs for the Radiation Specialist 3 and the Radiation Control Unit Supervisor have been incorporated. In addition, an FTE for the clerical support position (Ms. Tina Leland) has been added. In addition, the newest staff member has been added. See enclosure 13.

3. Section 4.6.2 of the Minnesota application provided the *MDH Licensing and Inspection Qualification Journal*. The journal does not provide any time frames for completion of staff training. The STP Procedure SA-700 Handbook, Sections 4.6.2.2 Evaluation Criteria indicates that the qualification journal should specify the time frame for completing requirements. Although this information has been provided informally to the NRC, the Minnesota application should be revised to include this information.

Response: The statement that the core training courses are normally completed within two years has been added to reflect the requirement in MC 1246. See page 7 of enclosure 11.

4. Section 4.6.3 of the application provided Current Technical Staff Qualification. This section should be updated to reflect the "on-the-job" training of Minnesota staff who accompanied State of Iowa and NRC inspectors. Although this information has been provided informally to the NRC, the Minnesota application should be revised to include this information.

Response: The information that was informally provided to the Office of State and Tribal Programs has been included. See enclosure 14.

5. Section 4.6.3 of the application should be updated to reflect the State's request to the NRC Region III Office for practical licensing training of their material licensing reviewers. Any updates on the status of this training should be included in the State's revisions.

Response: In the first week of November 2004, Timothy Donakowski received training in material licensing at Region III. Craig Verke is scheduled to receive that training in the Spring of 2005.

4.7 Event and Allegation Response Program Elements Review Team Comments:

1. Section 4.7.1 of the application did not reference nor did it include a copy of the Minnesota procedure "*Response Manual for Allegations*." Section 4.7.1 should be revised to include a copy of the procedure and references to the procedure.

Response: MDH has prepared a response manual for allegations. See enclosure 15.

Enclosure 1

BACKGROUND OF THE MINNESOTA DEPARTMENT OF HEALTH

The Minnesota Department of Health's (MDH) mission is to protect, maintain and improve the health of all Minnesotans. The Department operates programs in the areas of disease prevention and control, health promotion, family and community health, environmental health, health care policy, and regulation of health care providers and facilities. Among its many duties, the department does the following:

- Investigates disease outbreaks, and works to prevent both chronic and infectious diseases.
- Protects the quality of the food in restaurants, the safety of public water supplies, and the air inside public places.
- Identifies and evaluates potential health hazards in the environment—from simple sanitation problems to the health risks associated with toxic waste sites.
- Provides sophisticated laboratory services, including techniques and procedures for screening biological and chemical samples that are available nowhere else in the state.
- Works to help people lower their health risks by giving them information and support for making healthier lifestyle choices.
- Safeguards the quality of our state's health care, and regulates many of the people and institutions responsible for providing that care.
- Develops and implements strategies to contain health care costs, while broadening access to affordable, high-quality health care coverage for all Minnesotans.

Improving health is not just MDH's job—it requires coordinated efforts on the part of all levels of government, the private sector, community groups, and citizens themselves. The public health system—MDH working together with local public health agencies across the state—plays a key role in building and supporting the partnerships needed to improve health for individuals and communities.

History:

Minnesota became the fourth state to establish a state board of health in 1872, preceded by Massachusetts, California, and Virginia. The labs were originally located in Red Wing, but were moved to the University of Minnesota campus in 1893. The following year the offices of the board were moved to the Pioneer Building in St. Paul.

In 1902, the legislature appropriated funds for a laboratory animal house. Additional space was provided in 1907 in what is now the University's psychology building.

Albert J. Chesley, M.D. served the longest term as Secretary and Executive Officer of the State Board of Health from May 13, 1921 until his death at the age of 78 on October 15, 1955. During his tenure the board had offices in the University's Westbrook and Eddy Halls from 1922-1938. The Board's Maternal and Child Health Unit was housed on the University's St. Paul campus, and from 1932-1969 the board also had offices in the State Capitol and the State Office Building.

A building on the University of Minnesota-Minneapolis campus was dedicated to the Board on July 13, 1969. This building now houses the laboratory, disease prevention and control and vital records, with other functions housed in other locations.

In 1977, the State Board of Health's name was changed to the Minnesota Department of Health (MDH), and the powers and duties were transferred to the commissioner of health. This position became a gubernatorial appointment and part of the governor's cabinet.

Environmental Health Division:

This division is responsible for protecting the public from potential health hazards associated with drinking water, food and beverage establishments, hotels and resorts, plumbing, swimming pools, lead, asbestos, radiation, and other forms of environmental exposure to potentially hazardous physical or chemical agents. The division oversees licensing programs and regulatory activity relating to these areas. It performs examinations and inspections for MDH and other government agencies to identify potential problems associated with chemical or physical agents, bacterial contamination, or exposure to radiation.

Radiation Control Unit:

In preparation for becoming an Agreement State, the Radiation Control Unit was restructured to include two subdivisions: The X-ray Group and the Radioactive Materials Group. The functions have been re-aligned as follows:

X-ray Group

The X-ray Group registers and inspects all x-ray machines and other sources of ionizing radiation at medical, dental, veterinary, industrial and educational facilities on a four-year cycle. It annually inspects mammography facilities for compliance with the Federal Mammographic Quality Standards Act.

Radioactive Materials Group

The Radioactive Materials Group conducts environmental sampling statewide and near the state's two nuclear power plants. It regulates Radium-226, which is a naturally occurring isotope, and accelerator produced radioactive materials (NARM) within Minnesota. There are approximately 45 facilities that use Radium-226 in fixed and portable gauges. Staff in the Radioactive Materials Group continues to conduct routine inspections of these facilities. In addition, the Radioactive Materials Group is tasked with inspecting the nuclear pharmacy¹ with cyclotrons, which produce short-lived isotopes for medical applications, as well as the ten facilities that only use accelerator-produced materials². This group will be responsible for the day-to-day operations of the Agreement Program.

Radiation Control Unit staff (staffs in the X-ray and Radioactive Materials Groups) respond to accidents and emergencies involving radiation. In addition, both staffs provide technical assistance to the general public, answering consumer concerns about radiation.

¹ A second cyclotron is expected to be operational in November of 2004.

² These facilities are not licensed by the NRC.

Enclosure 2

**AN AGREEMENT
BETWEEN
THE UNITED STATES NUCLEAR REGULATORY COMMISSION
AND
THE STATE OF MINNESOTA
FOR THE
DISCONTINUANCE OF CERTAIN COMMISSION REGULATORY AUTHORITY
AND
RESPONSIBILITY WITHIN THE STATE PURSUANT TO
SECTION 274 OF THE ATOMIC ENERGY ACT OF 1954, AS AMENDED**

WHEREAS, The United States Nuclear Regulatory Commission (hereinafter referred to as the Commission) is authorized under Section 274 of the Atomic Energy Act of 1954, as amended (hereinafter referred to as the Act), to enter into agreements with the Governor of Minnesota State providing for discontinuance of the regulatory authority of the Commission within the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to byproduct materials as defined in Sections 11e.(1) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass; and,

WHEREAS, The Governor of the State of Minnesota is authorized under §144.1202 Subdivision 1, Minnesota Statutes, to enter into this Agreement with the Commission; and,

WHEREAS, The Governor of the State of Minnesota certified on [date], that the State of Minnesota (hereinafter referred to as the State) has a program for the control of radiation hazards adequate to protect public health and safety with respect to the materials within the State covered by this Agreement, and that the State desires to assume regulatory responsibility for such materials; and,

WHEREAS, The Commission found on [date] that the program of the State for the regulation of the materials covered by this Agreement is compatible with the Commission's program for the regulation of such materials and is adequate to protect public health and safety; and,

WHEREAS, The State and the Commission recognize the desirability and importance of cooperation between the Commission and the State in the formulation of standards for protection against hazards of radiation and in assuring that State and Commission programs for protection against hazards of radiation will be coordinated and compatible; and,

WHEREAS, The Commission and the State recognize the desirability of the reciprocal recognition of licenses, and of the granting of limited exemptions from licensing of those materials subject to this Agreement; and,

WHEREAS, This Agreement is entered into pursuant to the provisions of the Atomic Energy Act of 1954, as amended;

NOW, THEREFORE, It is hereby agreed between the Commission and the Governor of the State acting in behalf of the State as follows:

ARTICLE I

Subject to the exceptions provided in Articles II, IV, and V, the Commission shall discontinue, as of the effective date of this Agreement, the regulatory authority of the Commission in the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to the following materials:

- A. Byproduct materials as defined in Section 11e.(1) of the Act;
- B. Source materials;
- C. Special nuclear materials in quantities not sufficient to form a critical mass.

ARTICLE II

This Agreement does not provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to:

- A. The regulation of the construction and operation of any production or utilization facility or any uranium enrichment facility;
- B. The regulation of the export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility;
- C. The regulation of the disposal into the ocean or sea of byproduct, source, or special nuclear materials waste as defined in the regulations or orders of the Commission;
- D. The regulation of the disposal of such other byproduct, source, or special nuclear material as the Commission from time to time determines by regulation or order should, because of the hazards or potential hazards thereof, not be so disposed without a license from the Commission;
- E. The evaluation of radiation safety information on sealed sources or devices containing byproduct, source, or special nuclear materials and the registration of the sealed sources or devices for distribution, as provided for in regulations or orders of the Commission.
- F. The regulation of the land disposal of by-product, source, or special nuclear material waste received from other persons;
- G. The extraction or concentration of source material from source material ore and the management and disposal of the resulting byproduct material.

ARTICLE III

With the exception of those activities identified in Article II.A through D, this Agreement may be amended, upon application by the State and approval by the Commission, to include one or more of the additional activities specified in Article II, paragraphs E, F, and G, whereby the State may then exert regulatory authority and responsibility with respect to those activities.

ARTICLE IV

Notwithstanding this Agreement, the Commission may from time to time by rule, regulation, or order, require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license or an exemption from licensing issued by the Commission.

ARTICLE V

This Agreement shall not affect the authority of the Commission under Subsection 161b or 161i of the Act to issue rules, regulations, or orders to protect the common defense and security, to protect restricted data, or to guard against the loss or diversion of special nuclear material.

ARTICLE VI

The Commission will cooperate with the State and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that Commission and State programs for protection against hazards of radiation will be coordinated and compatible. The State agrees to cooperate with the Commission and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that the State's program will continue to be compatible with the program of the Commission for the regulation of materials covered by this Agreement.

The State and the Commission agree to keep each other informed of proposed changes in their respective rules and regulations, and to provide each other the opportunity for early and substantive contribution to the proposed changes.

The State and the Commission agree to keep each other informed of events, accidents, and licensee performance that may have generic implication or otherwise be of regulatory interest.

ARTICLE VII

The Commission and the State agree that it is desirable to provide reciprocal recognition of licenses for the materials listed in Article I licensed by the other party or by any other Agreement State. Accordingly, the Commission and the State agree to develop appropriate rules, regulations, and procedures by which such reciprocity will be accorded.

ARTICLE VIII

The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the State, or upon request of the Governor of the State, may terminate or suspend all or part of this agreement and reassert the licensing and regulatory authority vested in it under the Act if the Commission finds that (1) such termination or suspension is required to protect public health and safety, or (2) the State has not complied with one or more of the requirements of Section 274 of the Act. The Commission may also, pursuant to Section 274j of the Act, temporarily suspend all or part of this agreement if, in the judgment of the Commission, an emergency situation exists requiring immediate action to protect public health and safety and the State has failed to take necessary steps. The Commission shall periodically review actions taken by the State under this Agreement to ensure compliance with Section 274 of the Act which requires a State program to be adequate to protect public health and safety with respect to the materials covered by this Agreement and to be compatible with the Commission's program.

ARTICLE IX

This Agreement shall become effective on [date], and shall remain in effect unless and until such time as it is terminated pursuant to Article VIII.

Done at [City, State] this [date] day of [month], [year].

FOR THE UNITED STATES NUCLEAR
REGULATORY COMMISSION

_____, Chairman

FOR THE STATE OF MINNESOTA

_____, Governor

Enclosure 3

NRC EDITORIAL SUGGESTIONS

1. 4731.0100, Subpart 259. In the definition for "Very High Radiation Area", the word "generates" should be replaced by "penetrates".

Response: Corrected. See page 56 of Chapter 4731.

2. 4731.3040, Subpart 2. This should read as follows: "A person who possesses radioactive material received or acquired before September 25, 1971 under the general license then provided under Code of Federal Regulations, title 10, section 31.4, is exempt from parts...."

Response: Corrected. See page 442 of Chapter 4731.

3. 4731.3225, Subpart 1., Item B. Subitem 2. The State should insert ", the NRC " after the second instance of the phrase "commissioner" for consistency with the rest of the paragraph.

Response: Corrected. See page 526 of Chapter 4731.

4. 4731.3240, Subpart 1., Item B. The State should insert "the commissioner, the NRC or" before the last occurrence of the phrase "an agreement state" for consistency with the rest of the paragraph.

Response: Corrected. See page 530 of Chapter 4731.

5. 4731.3320. The concentration of Sc-46 should be 1.4×10^{-3} mCi/ml.

Response: Corrected. See page 539 of Chapter 4731.

6. 4731.4411, Item B. Subitem 2. Remove the words "or agreement state" from the phrase "NRC or agreement state master material licensee." Agreement States do not issue Master Material Licenses.

Response: Corrected. See page 653 of Chapter 4731.

7. 4731.4433, Item C. Subitem 2. The State incorrectly references their equivalent requirements to 10 CFR Part 35.100. The State lists 4731.4443 when it should be 4731.4432.

Response: Corrected. See page 669 of Chapter 4731.

8. 4731.4475, Subpart 2., Item D. Insert the word "tube" after the word "transfer" in the phrase "transfer-applicator interfaces" to provide clarity and accurately reflect the intent of the rule.

Response: Corrected. See page 712 of Chapter 4731.

9. 4731.7070, Subpart 3, Item B.(3). States that the report must "include any contamination". The State should revise this sentence to state that the report should "describe any contamination".

Response: Corrected. See page 784 of Chapter 4731.

10. 4731.0100 (90). Should read as follows: "Government agency" means an executive department, commission, independent establishment, or corporation wholly or partly owned by the United States or the State of Minnesota and which is an instrumentality of the United States or the State of Minnesota or a board bureau, division, service, office, officer, authority, administration or other establishment in the executive branch of federal or state government.

Response: Corrected. See page 19 of Chapter 4731.

11. 4731.0790 (5). Should read as follows: "Specific licenses for uranium and thorium milling are exempt from subpart 4, items...."

Response: Corrected. See page 208 of Chapter 4731.

12. 4731.0405. Uses the term "certification holder" instead of the legal term "certificate holder". The State should revise their regulations to use the correct legal term "certificate holder".

Response: Corrected. See pages 77, 78, and 79 of Chapter 4731.

13. 4731.0405. Deliberate Misconduct. The proposed regulations use the term "certification holder" instead of the legal term, "certificate holder." The State should revise their regulations to use the correct legal term "certificate holder" rather than "certification holder".

Response: Corrected. See pages 77, 78, and 79 of Chapter 4731.

**NRC COMMENTS ON PROPOSED MINNESOTA REGULATIONS
AGAINST COMPATIBILITY & HEALTH AND SAFETY CATEGORIES**

1. 4731.0100, Subpart 215. Sievert - The State has incorrectly shown the conversion from Sievert to REM To meet compatibility the State needs to change its regulations to read: "1 Sievert = 100 rem."

Response: Corrected. See page 46 of Chapter 4731. Note: The rule revision incorrectly incorporated the term "rems." This will be corrected in future rulemaking.

2. 4731.2950 The following definition is missing "High integrity container." The State needs to adopt this NRC definition to achieve compatibility.

Response: Corrected. See Subpart 96a on page 20 of Chapter 4731.

3. 4731.3220 **General License to Install Devices Generally Licensed in 31.5** - The State's rule as currently written provides the State authority to grant specific licensees of the State, NRC, or other Agreement States general licenses to install and service such devices in areas of NRC jurisdiction. The intention of 10 CFR 31.6 is to provide reciprocal recognition of licenses.

The State needs to revise the language in 4731.3220 to read: Any person who holds a specific license issued by the NRC or by an Agreement State authorizing the holder to manufacture, install, or service a device described in 10 CFR 31.5 within areas of NRC or Agreement State jurisdiction is hereby granted a general license to install or service such devices in areas subject to the commissioner's authority.

Response: Corrected. See page 525 of Chapter 4731.

4. 4731.0100 **Dose Commitment** - This definition is missing. The State needs to adopt the NRC definition to achieve compatibility.

Response: Corrected. See Subpart 64a on page 15 of Chapter 4731.

5. 4371.4120 **Conducting Industrial Radiographic Operations** - In Subp. 3, "Offshore Water Operations," the State requires that procedures for lay-barge, off shore platform, and underwater radiography can only be approved by the Commissioner (MN) prior to these operations being conducted in the State. 10 CFR 34.41 (c) allows the operations listed above to be conducted under reciprocity in NRC and in Agreement State jurisdictions if the procedures have been approved by the NRC or any Agreement State.

To meet the compatibility category for this requirement, the State should revise the language of 4731.4120 Subpart 3 to read: "A licensee may conduct lay barge, offshore platform, or underwater radiography if procedures have been approved by the Commissioner, the Nuclear Regulatory Commission or by an Agreement State."

Response: Corrected. See page 613 of Chapter 4731.

**CHANGES REQUESTED BY THE ADMINISTRATIVE LAW JUDGE
MINNESOTA OFFICE OF ADMINISTRATIVE HEARINGS**

1. 4731.0100, Subp. 6. – Subpart 92 defines "guide tube" or "projection sheath" together in the first sentence of the definition, but defines only the term "guide tube" in the second sentence. If the Department's intent is to define both terms to mean the same thing, the Department may want to consider amending the second sentence of the definition to read as follows: "Guide tube or projection sheath includes the connections necessary for attachment to the exposure device and to the exposure head."

Response: *The sentence was amended. See page 19 and 20 of Chapter 4731. The NRC reference is 10 CFR 34.3.*

2. 4731.0200, Subp. 1. – This part begins with a purpose and describes the reasons the Department is adopting rules pertaining to radiation safety. The purpose of a rule is to define the rights and responsibilities of regulated parties and the regulatory need and reasonableness established for this statement of purpose. Other parts of the rule also contain purpose sections, but the need and reasonableness of those parts was established because they were taken directly from existing federal regulations. The Department demonstrated that it adopted federal regulations in those cases in which it was required to do so. The Department has not shown that this was one of those cases.

Response: *The Department deleted this subpart. There is no corresponding NRC language.*

3. 4731.0200, Subp. 6 – This section states that no interpretation of this chapter by any employee, other than a written interpretation by the Attorney General, is binding upon the commissioner. This subpart raised several questions, such as under what circumstances the commissioner might specifically authorize binding herself to the interpretation of an agency employee, and whether the characterization of the binding nature of written interpretations of the attorney general was accurate. This language is not required for adoption by an agreement state.

Response: *The subpart was deleted. This is a "D" compatibility item.*

4. 4731.0355, Subp. 3, Item E. States that the Commissioner may waive the requirement for filing additional notifications [for reciprocity].... Corresponding language does not exist in 10 CFR 150.20.

Response: *This subpart was deleted. There is no corresponding NRC language.*

5. 4731.0620, Subp. 2.C. – Subpart 2 requires a 24-hour notification to the commissioner "after discovery of any of the following events involving licensed material." Items A-D are the events, any of which would require notification. The conjunction which connects the events ought to be "or" in keeping with the intent that any of the following events trigger the notification requirement. Instead, the rule reads, A...B...C...and D. The "and" should be changed to an "or"

in order to accurately convey the requirement of notification in any of the situations described. Changing this language is needed and reasonable and will not result in rules that are substantially different than those originally proposed.

Response: *The "and" was replaced with "or". See page 165 of Chapter 4731. The NRC reference is 10 CFR 70.50.*

6. 4731.0750, Subp. 2. – Subpart 2 as proposed reads as follows: "the general license issued under subpart 1 applies only to industrial products or devices that have been manufactured according to a specific license issued under part 4731.0770 or according to a specific license issued *to by* the NRC or an agreement state that authorizes manufacture of the products or devices to persons generally licensed by the NRC or an agreement state." There is either an extra word or a missing word in the portion of the sentence that is italicized.

Response: *The Department deleted the word "to". See page 180 of Chapter 4731.*

7. 4731.0780, Subps. 2-3. – Subparts 2 and 3 concern the possession and use of certain quantities of source material in a readily dispersible form. Subpart 2 regulates the possession and use of more than 100 millicuries of source material" while subpart 3 regulates "possession and use of quantities of source material greater than 10 millicuries (370 MBq) but less than 100 millicuries..." In changing the text of the federal rules in these proposed rules, the state has changed the meaning of the rules, so that while the proposed rules regulate less than 100 millicuries, and more than 100 millicuries, there is no provision regulating exactly 100 millicuries.

The equivalent of proposed subpart 3 in the federal regulations reads: "each applicant for a specific license authorizing possession and use of quantities of source material greater than 10 millicuries (370 MBq) but less than or equal to 100 millicuries in the readily dispersible form..." The Department should consider modifying the proposed rules to regulate an amount of readily dispersible material equal to 100 millicuries in subpart 3.

Response: *The Department inserted the words "or equal to" in the appropriate portion of Subpart 3. See page 193 of Chapter 4731. The NRC reference is 10 CFR 40.36.*

8. 4731.1090. – This part reads: "No person, on the grounds of sex, race, or other discriminations, may be excluded from participation in..." "Other discriminations" is not a term of art that automatically brings to mind all of the types of protected classes against whom one could discriminate. The Department should consider listing all types of discrimination that it intends to prohibit, as in proposed part 4731.4360.

In addition, the use of the word "may" indicates that the prohibition against discrimination is not mandatory. The equivalent portion of the federal regulations states "No person shall...be excluded..."

Response: *The Department has amended the language to read: "No person, on the grounds of race, color, creed, religion, national origin, sex, disability, sexual*

orientation, or age, shall be excluded from participation in..." See page page 230 of Chapter 4731. The NRC reference is 10 CFR 19.32, which is a "D" compatibility.

9. 4731.2600, Subp. 2. There is a question as to who is supposed to receive a written report. It would help to include some language making it clear who gets a written report.

Response: *As a Compatibility "C" item, MDH should have some latitude in the language. Therefore, the subpart should be revised to state "...make a written report to the commissioner that includes..." See page 284 of Chapter 4731. The NRC reference is 10 CFR 20.2201.*

Enclosure 4

MINNESOTA DEPARTMENT OF HEALTH



REGULATORY GUIDE FOR DIAGNOSTIC AND THERAPEUTIC MEDICAL PROCEDURES

	<p>Radiation Control Unit Asbestos, Lead, Indoor Air & Radiation Section Division of Environmental Health Minnesota Department of Health</p>
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January 2005

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REGULATORY GUIDE FOR MEDICAL USE OF RADIOACTIVE MATERIAL IN DIAGNOSTIC AND THERAPEUTIC PROCEDURES

INTRODUCTION

The Minnesota Department of Health (MDH) regulates the intentional internal or external administration of radioactive material and the radiation produced by the material itself, to human beings. This type of use is called medical use, and a specific license is required. The regulations governing medical use are contained in Radioactive Materials Rules, Chapter 4731.4400.

MDH usually issues a single radioactive material license to cover the radioisotope program. However, separate licenses must be obtained for the following:

- Gamma stereotactic radiosurgery devices (gamma knives)
- High, medium, and low dose rate afterloaders
- Irradiators
- Nuclear powered pacemakers
- Teletherapy devices

Separate licenses are not normally issued to different departments of a hospital or to individuals employed by a hospital. You should carefully study this guide and all the regulations identified in 4731.4400 through 4731.4527 before completing the application form. The MDH may request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation protection program

This guide is designed to describe the type and extent of information needed by the MDH to evaluate an application for a medical use license and to describe the radioactive material regulations for medical use. Separate guidance has been developed to meet the specific needs of a teletherapy applicant.

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.

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
Snelling Office Park
1645 Energy Park Drive, Suite 300
St. Paul, MN 55108-2970

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 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.

If radiography equipment will be stored and/or used at a field station, give the specific address of each field station.

If radiography 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 Materials and Item 6: Purpose

Radioactive material for medical use is divided into types of use. Using the table format of Table 1 as a guide, you may indicate only the types of use you want and the maximum amount. You may state, "As needed" in the "Amount" column as shown. For implant material, express the total amount in millicuries (mCi). If you plan to have an eye applicator, list it as a separate item and note its total activity in mCi.

For 4731.4432, 4433, and 4434 use, the applicant should define the purpose of use by stating the applicable section and the description of the applicable modality (e.g., any uptake dilution and excretion procedure for which a written directive is not required). The use of unsealed radioactive material in therapy (4731.4440) involves administering a radioactive material, either orally or by injection, to treat or palliate a particular disease. The most common form of use of unsealed radioactive material for therapy is the treatment of hyperthyroidism with Iodine-131 (I-131), sodium iodide. Other therapeutic procedures include, for example, ablation of thyroid cancer metastasis, treatment of malignant effusions, treatment of polycythemia vera and leukemia, palliation of bone pain in cancer patients, and radiation synovectomy for rheumatoid arthritis patients. References to particular diagnostic or treatment modalities in this section are intended to be examples and are not intended to imply that licensees are limited to these uses.

Table 1

RADIOACTIVE MATERIAL	AMOUNT	PURPOSE
5.a Material in 4731.4432	As needed	6.a Medical use
5.b Material in 4731.4433	As needed	6.b Medical use
5.c Material in 4731.4434	As needed	6.c Medical Use
5.d Material in 4731.4440	mCi	6.d Medical use
5.e Implant and Material in 4731.4450	mCi	6.e Medical use

(Note: Broad Scope medical use applicants may request "Any radioactive material with atomic numbers 3 through 84 for medical use.")

If you need other items, make a separate line entry for each isotope. Each line entry must identify the radionuclide, the physical form, maximum amount available for use expressed in millicuries, and the purpose for which the material will be used.

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

For use of brachytherapy sources (4731.4450), the applicant should define the purpose of use by stating the applicable section of 10 CFR Part 35 (i.e., 10 CFR 35.400). If a source is to be used in a device, applicants may need to define the purpose of use by describing the manufacturer's name and model number of the device. The licensee should relate the sealed sources listed in Item 5 to the devices described in this item. In manual brachytherapy several types of treatments are available. These may include, for example:

- Interstitial Treatment of Cancer
- Eye Plaque Implants. (This is considered interstitial, not topical, treatment.)

- Intracavitary Treatment of Cancer¹
- Topical (Surface) Applications

For use of sealed sources for diagnosis (4731.4460), the applicant should define the purpose of use by describing the manufacturer's name(s) and model number(s) of devices containing sealed sources (where applicable). The licensee should correlate the sealed sources listed in Item 5 with the devices described in this item. Typically, a licensee should use the sealed sources according to manufacturer's radiation safety and handling instructions and must use the sources as approved in the SSDR.

For use of a sealed source in a remote afterloader, teletherapy unit, or a gamma stereotactic radiosurgery unit (4731.4463), the applicant should define the purpose of use (e.g., teletherapy, remote afterloading, GSR) and describing the manufacturer's name(s) and model number(s) of the device containing a sealed source(s) (e.g., for use in a Manufacturer's Name and Unit Type, Model xxxx radiation therapy unit for the treatment of humans). The applicant should correlate the sealed source(s) listed in Item 5 with the device described in this item. If applicable, the applicant should state that depleted uranium is used as shielding for the device and specify that an additional source is requested to be stored in its shipping container incident to source replacement.

Applicants must apply for authorization to use radioactive material, or radiation therefrom, in medical applications under other medical uses of radioactive material or radiation from radioactive material when 4731.4463 does not cover the type of use. When applying for use under the provisions of 4731.4403, applicants should describe the purpose of use and submit the information required under Section 4731.4403, review regulatory requirements in other parts of the medical uses rules, and use them as a guide on how to determine what should be included in an application. It is anticipated that many of the uses of radioactive material under the provisions of 4731.4403 may involve research or product development; thus, applicants should ensure review and compliance with 4731.4401, "Provisions for the protection of human research subjects." Use of radioactive material in a source or device after approval by the U.S. Food and Drug Administration, e.g., under an IDE (investigational device exemption) or an IND (investigational new drug exemption), does not relieve individuals of the responsibility to obtain a license to use the radioactive material in medicine.

Remote afterloading and teletherapy devices should not be included in this application. Special requirements for these devices are included in separate guides available upon request from the MDH.

Calibration, Transmission, and Reference Sources: For calibration, transmission, and reference sources covered in 4731.4423, the specific sources do not need to be listed on the license as long as the licensee is authorized pursuant to 4731.4400 for medical use of radioactive material.

Item 7: Individual Users Responsible for the Radiation Safety Program

Responsible individuals are the authorized users and the Radiation Safety Officer (RSO). 4731.4411 requires that an applicant be qualified by training and experience to use the requested radioactive materials for the purposes requested in such a manner as to minimize danger to public health and safety or property. Note that curriculum vitae do not usually supply all the information needed to evaluate an individual's training and experience. Submit a description or chart of the overall organization pertaining to the radioactive materials program that specifies the name and title of each individual who has responsibility for management or supervision of the program.

¹ For purposes of sealed source and device (SSDR) evaluation on radiation safety issues, intraluminal use is considered analogous to intracavitary use.

Authorized Users For Medical Uses

Authorized users involved in medical use have the following special responsibilities:

1. Examination of patients and medical records to determine if a radiation procedure is appropriate.
2. Prescription of the radiation dosage or dose and how it is to be administered.
3. Actual use or direction of technologists or other paramedical personnel in the use of radioactive material.
4. Interpretation of diagnostic procedures and the evaluation of therapy procedures.

Applicants must meet recency of training requirements as described in 4731.4415. Authorized user applicants must have successfully completed the applicable training and experience criteria within seven years preceding the date of the application. Alternatively, applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Technologists, therapists, or other personnel may use radioactive material for medical use under an authorized user's supervision in accordance with 4731.4407, "Supervised Individuals."

There is no MDH requirement that an authorized user must render an interpretation of a diagnostic image or results of a therapeutic procedure. MDH recognizes that the authorized user may or may not be the physician who interprets such studies. Additionally, MDH rules do not restrict who can read and interpret diagnostic scans or the results of therapeutic procedures involving the administration of radioactive material to individuals.

All training for users of high dose rate afterloader units must comply with the specifications in 4731.4479.

Authorized Users For Non-Medical Use

List the full name of each individual proposed as an authorized user for non-medical use. Submit a complete description of the person's training and experience in non-medical use areas.

For *in-vitro* and animal research (or other uses that do not involve the intentional exposure of humans), the list of proposed authorized users should include those individuals who will actually be responsible for the use of the requested radioactive material. Indicate which user will be involved with which use by reference to Items 5 and 6 of the application. Those authorized users may direct the use of the radioactive material by technologists or other individuals for the requested use.

Radiation Safety Officer (RSO)

Radiation Safety Officers must have adequate training and experience. The training and experience requirements for the RSO are described in 4731.4411 and allow for the following four training pathways:

- Certification by one of the professional boards recognized by MDH, the NRC or another Agreement State.
- Didactic training, work experience, and preceptor statement as described in 4731.4411(B).
- Identification on the license as an Authorized User (AU), Authorized Medical Physicist (AMP), or Authorized Nuclear Pharmacist (ANP) with experience in the radiation safety aspects of similar types of radioactive material use for which the individual has RSO responsibilities.

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

The RSO is responsible for day-to-day oversight of the radiation protection program. In accordance with 4731.4405, the licensee must provide the RSO sufficient authority, organizational freedom, time, and resources to perform his or her duties. Additionally, the RSO must have a sufficient commitment from management to fulfill the duties and responsibilities to ensure that radioactive materials are used in a safe manner. MDH requires the name of the RSO on the license, and an agreement in writing from the RSO to

ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation and assumes the responsibilities of an RSO.

Usually, the RSO is a full-time employee of the licensed facility. MDH has authorized individuals that are not employed by the licensee, such as a consultant, to fill the role of RSO or to provide support to the facility RSO. In order to fulfill the duties and responsibilities, the RSO should be on site periodically to conduct meaningful, person-to-person interactions with licensee staff, commensurate with the scope of licensed activities, to satisfy the requirements of 4731.4405.

RSO Responsibilities

Some of the typical duties and responsibilities of Radiation Safety Officers include ensuring the following:

- Unsafe activities involving licensed materials are stopped
- Radiation exposures are ALARA
- Material accountability and disposal
- Interaction with MDH
- Timely and accurate reporting and maintenance of appropriate records
- Annual program audits
- Proper use and routine maintenance
- Personnel training
- Investigation of incidents involving radioactive material (e.g., medical events)

Appendix B contains a detailed list of typical duties and responsibilities of the RSO. Applicants are reminded of recentness of training requirements. Specifically, RSO applicants must have successfully completed the applicable training and experience criteria within seven years preceding the date of the application. Alternatively, RSO applicants must have had related continuing education and experience since completing the required training and experience. This time provision applies to board certification as well as to other recognized training pathways.

Provide the following:

- Name of the proposed RSO.
- Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO.

One of the following is also needed:

- Copy of the certifications for the boards recognized by NRC and as applicable to the types of use for which he or she has RSO responsibilities.
- Description of the training and experience specified in 10 CFR 35.900(b).
- Description of the training and experience demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which he or she has RSO responsibilities.

In addition, provide both of the following:

- Written certification, signed by a preceptor RSO, that the above training and experience has been satisfactorily completed and that a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee has been achieved.
- If applicable, description of recent related continuing education and experience as required by 4731.4415.

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 ANP's supervision in accordance with 4731.4407, "Supervision." (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 recognized training pathways.

Provide the name of the proposed ANP and one of the following:

- Previous license number or a copy of the license (if issued by the NRC an Agreement State) on which the individual was specifically named ANP.
- Copy of the certification(s) for the radiopharmacy board(s) identified in 4731.4413 or 4731.4491.
- Description of the training and experience demonstrating that the proposed Authorized Nuclear Pharmacist is qualified by training and experience.

Also provide the following:

- Written certification, 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 (4731.4413), or
 - independently operate a nuclear pharmacy (4731.4491).
- If applicable, submit a description of recent related continuing education and experience as required by 4731.4415.

Authorized Medical Physicist (AMP)

At many licensed medical facilities conducting radiation therapy treatments, an Authorized Medical Physicist is directly involved with the calculation and administration of the radiation dose. The American Association of Physicists in Medicine (AAPM) suggests that a medical physicist limit his or her involvement in radiation therapy to areas for which he or she has established competency.

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

Provide the name of the proposed AMP and one of the following:

- Previous license number or a copy of the license (if issued by the NRC an Agreement State) on which the individual was specifically named as an Authorized Medical Physicist for the units requested.
- Copy of the certification(s) for the board(s) recognized by NRC in 4731.4412 or 4731.4490.
- Description of the training and experience demonstrating that the proposed Authorized Medical Physicist is qualified by training and experience identified in 4731.4490 for the units requested.
- Description of the training and experience demonstrating that the proposed Authorized Medical Physicist is qualified by training and experience identified in 4731.4412 for the units requested.

Also provide one of the following:

- Written certification, signed by a preceptor AMP, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an Authorized Medical Physicist has been achieved.
- If applicable, description of recent related continuing education and experience as required by 4731.4415.

Item 8: Training For Individuals Working In or Frequenting Restricted Areas

Describe your training program for individuals who work with or near radioactive material. Include the training for individuals who handle non-medical radioactive materials.

Item 9: Facilities And Equipment

Applications will be approved if, among other things, the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. Facility and equipment requirements depend on the scope of the applicant's operations (e.g., planned use of the material, the types of radioactive emissions, the quantity and form of radioactive materials possessed, etc.). Applicants should focus particularly on operations using large quantities of radioactive materials; preparation steps involving liquids, gases, and volatile radioactive materials; and the use of alpha-emitters, high-energy photon-emitters, and high-energy beta emitters.

Applicants must describe the proposed facilities and equipment. The facility diagram should include the room or rooms and adjacent areas where radioactive material is prepared, used, administered, and stored that is sufficient to demonstrate that the facilities and equipment are adequate to protect health and minimize danger to life or property.

For use of unsealed radioactive material for uptake, dilution, or excretion, or for imaging and localization (4731.4432 or 4731.4433), applicants should provide room numbers for areas in which radioactive materials are used or prepared for use (i.e., "hot labs"). When information regarding an area or room is provided, adjacent areas and rooms, including those above and below, should be described.

For radiopharmaceutical therapy and manual brachytherapy (4731.4440 and 4731.4450), applicants should provide the above information and in addition they should provide the locations where sources are stored. Describe the rooms where patients will be housed if they cannot be released in accordance with 4731.4427. The discussion should include a description of shielding, if applicable.

For a remote afterloader, teletherapy unit, or gamma knife (4731.4463), the applicant should provide all of the information discussed above and the shielding calculations for the facility as described in the diagram.

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

The applicant should demonstrate that the dose limits for individual members of the public (4731.2090) will not be exceeded. If the calculations demonstrate that these limits cannot be met, indicate any further steps that will be taken to limit exposure to individual members of the public. The applicant may consider the following options:

- Adding shielding to the barrier in question, with corresponding modification of the facility description if necessary.
- Requesting prior MDH authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem) and demonstrating that the requirements will be met. The applicant must demonstrate the need for and the expected duration of operations that will

result in an individual dose in excess of the limits. A program to assess and control dose within the 5 mSv (0.5 rem) annual limit and procedures to be followed to maintain the dose ALARA must be developed.

If applicants are proposing to use portable shielding to protect health and minimize danger to life or property, they should describe the alternative equipment and administrative procedures they propose to use for evaluation and approval by MDH. If applicants elect to use portable shielding they should commit to having administrative procedures to control configuration management to maintain dose within regulatory limits.

If radiopharmaceutical therapy and brachytherapy patient rooms are added after the initial license is issued, additional room diagrams should be submitted if the room design (including shielding) and the occupancy of adjacent areas are significantly different from the original diagrams provided. A written description should be submitted for simple changes.

For teletherapy units, it may be necessary to restrict use of the unit's primary beam if the treatment room's walls, ceiling, or floor will not adequately shield adjacent areas from direct or scattered radiation. The licensee should specify the electrical, mechanical, or other physical means (rather than administrative controls) used to limit movement or rotation of the unit (e.g., electrical or mechanical stops).

Annotated Drawings

Provide the following on the facility diagrams:

- Drawings should be to scale, and indicate the scale used.
- Location, room numbers, and principal use of each room or area where radioactive material is prepared, used or stored.
- Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms; indicate whether the room is a restricted or unrestricted area as defined in 4731.0100 Subparts 205 and 256.
- Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including the dimensions of any portable shield, if one is used; source storage safe, etc.).

In addition to the above, for teletherapy and GSR facilities, applicants should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.

Radiation Monitoring Instruments

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

The radiation protection program that licensees are required to develop, document, and implement in accordance with 4731.2010 must include provisions for survey instrument calibration (4731.2200). Licensees shall possess instruments used to measure radiation levels, radioactive contamination, and radioactivity, as applicable. Instruments used for quantitative radiation measurements must be calibrated for the radiation measured. The instruments should be available for use at all times when radioactive material is in use. The licensee should possess survey instruments sufficiently sensitive to measure the type and energy of radiation used, including survey instruments used to locate low energy or low activity seeds (e.g., I-125, Pd-103) if they become dislodged in the operating room or patient's room.

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

Qualified personnel must perform survey meter calibrations. One method a licensee may use to determine if the service is qualified to perform these activities is to determine that it has an MDH (or equivalent NRC or Agreement State) license. Alternatively, an applicant may choose to develop, implement, and maintain procedures to ensure instruments are calibrated, or propose an alternate method for calibration.

Provide one or both of the following:

- A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations."
- A statement that: "We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 4731.2200 and that meet the requirements of 4731.4421." Instruments must be calibrated annually and after servicing or repair. Electronic calibrations alone are not acceptable. Battery changes are not considered "servicing."

Also provide both of the following:

- A description of the instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multi-channel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys. As an example:

MANUFACTURER	MODEL NUMBER	RANGE
Geotronics Industries	OMG-12	0.01 - 50 mR/hr
Flick Manufacturing Co.	BBSM-42	1 - 1000 mR/hr
Short Scientific, Inc.	LGD-310	1 - 100000 cpm

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

Dose Calibrator and Other Equipment Used To Measure Dosages of Unsealed Radioactive Material

As described in 4731.4422, dosage measurement is required for licensees who prepare patient dosages.

- If the licensee uses only unit dosages made by a manufacturer or a nuclear pharmacy and does not split, combine, or otherwise modify unit dosages, the licensee is not required to possess an instrument to measure the dosage. Furthermore, licensees may rely on the provider's dose label for the measurement of the dosage and decay-correct the dosage to the time of administration.
- If the licensee performs direct measurements of dosages in accordance with 4731.4422 (e.g., prepares its own dosages, breaks up unit dosages for patient administration, or decides to measure unit dosages) the licensee is required to possess and calibrate all instruments used for measuring patient dosages.

Equipment used to measure dosages must be calibrated in accordance with nationally recognized standards (e.g., ANSI) or the manufacturer's instructions. The measurement equipment may be a well ion

chamber, a liquid scintillation counter, etc., as long as the instrument can be calibrated appropriately and is both accurate and reliable.

For other than unit dosages, the activity must be determined by direct measurement, by a combination of radioactivity measurement and mathematical calculation, or by a combination of volumetric measurement and mathematical calculation. However, there are inherent technical difficulties to overcome. For beta-emitting radionuclides, these difficulties include dependence on geometry, lack of an industry standard for materials used in the manufacture of vials and syringes, and lack of a NIST-traceable standard for some radionuclides used. For instance, when determining the dosage of P-32, assays with a dose calibrator may result in inaccuracies caused by inherent variations in geometry; therefore, a volumetric measurement and mathematical calculation may be more accurate.

Licensees must assay patient dosages in the same type of vial and geometry as used to determine the correct dose calibrator settings. Using different vials or syringes may result in measurement errors due, for example, to the variation of bremsstrahlung created by interaction between beta particles and the differing dosage containers. Licensees are reminded that beta emitters should be shielded using a low-atomic-numbered material to minimize the production of bremsstrahlung. When a high activity source is involved, consideration should be given to adding an outer shield made from material with a high atomic number to attenuate bremsstrahlung.

Item 10: Radiation Safety Program

The elements of a radiation safety program are contained in Appendices A through R. 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."

Appendix A	Model Program for Maintaining Occupational Radiation Exposure ALARA
Appendix B	Duties and Responsibilities of the Radiation Safety Officer
Appendix C	Calibrating Dose Calibrators
Appendix D	Personnel Exposure Monitoring Program
Appendix E	Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority
Appendix F	Leak Testing Sealed Sources
Appendix G	Safe Use of Radiopharmaceuticals
Appendix H	Spill Procedures
Appendix I	Ordering and Receiving Radioactive Material
Appendix J	Safely Opening Packages Containing Radioactive Material
Appendix K	Records of Radioactive Material Use
Appendix L	Area Surveys
Appendix M	Monitoring, Calculating, and Controlling Air Concentrations
Appendix N	Radiation Safety During Radiopharmaceutical Therapy
Appendix O	Radiation Safety During Implant Therapy
Appendix P	Waste Disposal
Appendix Q	Medical Use of Strontium-90 Eye Applicators
Appendix R	Model Annual Audit Checklist

Sealed Source Inventories

State that you will conduct inventories, at intervals not to exceed three months, to account for all sealed sources received and possessed under your license. You should maintain records of the inventories for at least three years from the date of the inventory. The record should include:

- Model number of each source
- Serial number if one has been assigned

- Identity of each source radionuclide
- Estimated activity
- Location of each source
- Date of inventory
- Initials or name of individual performing the inventory
- Signature of the Radiation Safety Officer

Annual Audit of the Radiation Safety Program

4731.2010 requires that licensees review at least annually the radiation protection program content and implementation. Currently the MDH emphasis in inspections is to perform observations of work in progress. As part of their audit programs, applicants should consider performing unannounced audits of their authorized users. The purpose is to determine that proper radiation safety and operating procedures are followed.

It is essential that problems are promptly and comprehensibly corrected. All identified deficiencies as well as the corrective actions taken should be documented. Subsequent audits should review the corrective actions to verify their effectiveness. The MDH will review a licensee's audit program and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence.

The MDH recognizes that some licensees may use a consulting service to perform audits. However, it is the licensee's responsibility to maintain compliance with MDH rules.

A model audit program is included in this Regulatory Guide.

Item 11: Waste Management

Submit your procedures for waste disposal, including a procedure for all material listed in Item 5. See Appendix R for more information on these procedures.

Item 12: License Fees

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
MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE ALARA

You may use the text as it appears here, stating on your application, "We will establish and implement the model ALARA program published in Appendix A to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures." Submit the signed commitment in Section 6 of this appendix.

If you prefer, you may develop your own ALARA program for MDH review. If you do so, you should consider for inclusion all the features in the model. State on your application, "We have developed an ALARA program for your review that is appended as Appendix A," and submit your program along with the signed commitment in Section 6 of this appendix.

ALARA PROGRAM

1. Management Commitment

- a. We, the management of this facility, are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC), and a Radiation Safety Officer (RSO).
- b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.
- c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been recommended but not implemented, and we will be prepared to describe the reasons for not implementing the changes.
- d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Review of Proposed Users and Uses

- a. The RSC will thoroughly review the qualifications of each applicant. To ensure that the applicant will be able to maintain ALARA, the review should include the types and quantities of materials used and methods of use.
- b. When considering the use of radioactive material, the RSC will review efforts of the applicant to maintain exposure ALARA.
- c. The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.
- d. The RSC will delegate authority for enforcement of an ALARA program to the RSO.

- e. The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.
- f. The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
- g. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table A-1 are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.

Table A-1 – Investigational Levels

	Investigational Levels (mrems per month)	
	Level I	Level II
Total Dose Equivalent: whole body; head and trunk; active blood-forming organs; or gonads	200	400
Skin of whole body, extremities	2000	4000
Lens of eye	600	1200

- h. The RSC will evaluate its institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. Radiation Safety Officer Commitment

a. Annual and Quarterly Review

- The RSC, along with the RSO, will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
- The RSC, along with the RSO, will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 5 of this appendix.

b. Education Responsibilities for ALARA Program

- The RSO will schedule briefing and educational sessions to ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy. They should also be informed that management and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

- Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.
- The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

- The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those programs.
 - Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.
- d. **Reviewing Instances of Deviation from Good ALARA Practices:**
- The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.
- e. The RSO is also responsible for assisting the RSC in the performance of its duties and serving as its secretary.

4. Authorized Users Commitment

- a. **New methods of Use Involving Potential Radiation Doses**
- The authorized user will consult the RSO and/or RSC during the planning stage before using radioactive materials for new uses.
 - The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.
- b. **Authorized User's Responsibility to Supervised Individuals**
- The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
 - The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in health physics practices and in maintaining exposures ALARA.

5. Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Doses¹

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table A-1. These levels apply to the exposure of individual workers.

The RSO will review and record on MDH Form, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter. The following actions will be taken at the investigational levels as stated in Table A-1:

- a. Personnel dose less than Investigational Level I

¹ MDH emphasizes that the investigational levels in this program are not new dose limits but serve as check points above which the results are considered sufficiently important to justify investigations.

- Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table A-1 values for the investigational Level I.
- b. Personnel doses equal to or greater than Investigational Level I but less than Investigational Level II
- The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter 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 Committee. However, the Committee will review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality. This review will be recorded in the Committee minutes.
- c. Personnel dose equal to or greater than Investigational Level II
- The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and any actions taken will be presented to the management following completion of the investigation. The report should include a copy of the individual's "Occupational Exposure Record for Monitoring Period" and "Cumulative Occupational Exposure History," or its equivalent.
- d. Re-establishment of investigational levels to levels above those listed in Table I
- In cases where a worker's or a group of workers' doses need to exceed an investigation level, a new, higher investigational level may be established with good ALARA practices. Justification for new investigational level will be documented.

The RSC will review the justification for and must approve all investigational level revisions.

6. Signature of Certifying Official¹ Sign and submit as part of Appendix A.

I hereby certify that this institution has implemented the ALARA Program as set forth above.

Signature

Name (Print or type)

Title

¹ The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

**APPENDIX B
DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER (RSO)**

You may use the following model guidelines to make commitments for your RSO. If you follow the model procedure, you may state on your application, "We will establish and implement the model procedure for RSO that was published in Appendix B to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

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

MODEL PROCEDURE

The RSO is responsible for implementing the radiation safety program and ensuring that radiation safety activities are performed in accordance with approved procedures and regulatory requirements. The RSO's duties and responsibilities include:

1. Ensure that licensed material possessed by the licensee is limited to the kinds, quantities and forms listed on the license.
2. Ensure that individuals using the material are properly trained; designated by the RSO; have received refresher training at least annually; and are informed of all changes in regulatory requirements and deficiencies identified during annual audits or MDH inspections.
3. Ensure that personnel monitoring devices are used as required and that reports of personnel exposure are reviewed in a timely manner.
4. Ensure that material is properly secured against unauthorized removal at all times when material is not in use.
5. Ensure that proper authorities are notified in case of accident, damage, fire, or theft.
6. Ensure that audits are performed at least annually to ensure that:
 - a. The licensee is abiding by MDH and DOT regulations and the terms and conditions of the license (e.g., periodic leak tests, inventories, transportation, and use by trained users);
 - b. The licensee's radiation protection program content and implementation achieve occupational doses and doses to members of the public that are ALARA; and
 - c. The licensee maintains required records with all required information (e.g., records of personnel exposure; receipt, transfer, and disposal of licensed material; user training) sufficient to comply with MDH requirements.
7. Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented, provided to management for review, and maintained for at least three years. Ensure prompt action is taken to correct deficiencies.
8. Ensure that audit results and corrective actions are communicated to all personnel who use licensed material (regardless of their location or the license under which they normally work).

9. Ensure that all incidents, accidents, and personnel exposure to radiation exceeding ALARA levels or limits in 4731 are investigated and reported to MDH within the required time limits.
10. Ensure that fume hood flow rates are tested at appropriate intervals and that employees use hoods in accordance with the safe use of radiopharmaceuticals.
11. Ensure that licensed material is transported in accordance with all applicable DOT requirements.
12. Ensure that licensed material is disposed of properly.
13. Ensure that the facility has up-to-date copies of MDH's regulations, completing a review of new or amended MDH regulations, and revising licensee procedures, as needed, to comply with MDH regulations.
14. Ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to MDH in the licensing process.

APPENDIX C CALIBRATING DOSE CALIBRATORS

You or your contractor may use the following model procedure for checking and testing the dose calibrator. If you or the contractor follow the model procedure, you may state on your application, "We will establish and implement the model procedure for calibrating our dose calibrator that was published in Appendix C to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

If you develop your own dose calibrator calibration procedure for review, you should carefully review all the features in the model procedure. State on your application, "We have developed a dose calibrator calibration procedure for your review that is appended as Appendix C," and submit your dose calibrator calibration procedure.

MODEL PROCEDURE

Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances. The recommended tolerances of ± 5 are more restrictive than those in the regulations to ensure that corrective action will be taken before the dose calibrator is outside permissible tolerances and must be removed from service.

1. Constancy

Constancy means reproducibility in measuring a source over a long period. Consider the use of two or more sources with different photon energies and activities. Use the following procedure:

- a. Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cs-137 setting to assay Cs-137).
 - b. Measure background at the same setting, and subtract or confirm the proper operation of the automatic background subtract circuit, if it is used.
 - c. Either plot on graph paper or log in a book the background level for each setting checked and the net activity of each constancy source.
 - d. Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.
 - e. Establish an action level at which the individual performing the test will automatically notify the supervision of the suspected malfunction of the calibrator. These action levels should be written in the logbook or posted on the calibrator. The regulation requires repair or replacement if the error exceeds ± 10 percent.
2. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that the instrument is zeroed according to the manufacturer's instructions.
- #### 3. Linearity
- Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This test is done using a vial or syringe of Tc-99^m whose activity is at least as large as the maximum activity normally assayed.

DECAY METHOD

- a. Assay the Tc-99^m 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, for example, 8 a.m.
- b. Repeat the assay at about noon, and again at about 4 p.m. Continue on subsequent days until the assayed activity is less than the minimum activity used. For dose calibrators with a range selection switch, select the range you would normally use for the measurement.
- c. Convert the recorded time and date to hours elapsed.
- d. 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. Then plot the data.
- e. 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. $(A_{\text{observed}} - A_{\text{line}})/A_{\text{line}} = \text{deviation}$.

SHIELD METHOD

If you decide to use a set of sleeves to test for linearity, it will first be necessary to calibrate them. The manufacturer provides specific procedures. Note that the decay method must be used upon initial installation. Calibration of the "sleeves" must be performed each time the dose calibrator is returned from repair.

Follow the manufacturer's instructions when performing the linearity test.

4. Geometry independence

Geometry means that the indicated activity does not change with volume or configuration. This test should be done using a syringe that is normally used for injections. Licensees who use generators and radiopharmaceutical kits should also do the test using a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following test assumes injections are done with 3-cc plastic syringes and that the radiopharmaceutical kits are made in 30-cc glass vials. If you do not use these, change the procedure so that your syringes and vials are tested throughout the range of volumes commonly used.

- a. In a small beaker or vial, mix 2.0 cc of a solution of Tc-99^m with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with non-radioactive saline. You may also use tap water.
- b. Draw 0.5 cc of the Tc-99^m solution into the syringes and assay. Record the volume and millicuries.
- c. 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.
- d. Repeat the process until you have assayed a 2.0 - cc volume.
- e. Select as a standard the volume closest to that normally used for injections. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume correction factor. Alternatively, you may graph the data and draw horizontal five (5) percent error lines above and below the chosen standard volume.
- f. If any correction factors are greater than 1.05 or less than 0.95, it will be necessary to make a correction table or graph that will allow you to convert from indicated activity to true activity. This will also be necessary if any data points lie outside the five (5) percent error lines. Be sure

to label the table or graph "syringe geometry dependence," and note the date of the test and the model number and serial number of the calibrator.

- g. To test the geometry dependence of a 30-cc glass vial, draw 1.0 cc of the Tc-99^m solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.
- h. Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of the non-radioactive saline or tap water, and assay again. Record the column and millicuries indicated.
- i. Repeat the process until you have assayed a 19.0-cc volume. The entire process must be completed within 10 minutes.
- j. Select as a standard the volume closest to that normally used for mixing radiopharmaceuticals kits. For all the other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, you may graph the data and draw horizontal five (5) percent error lines above and below the chosen standard volume.
- k. If any correction factors are greater than 1.05 or less than 0.95, it will be necessary to make a correction table or graph that will allow you to convert from indicated activity to true activity. This will also be necessary if any data points lie outside the five (5) percent error lines. Be sure to label the table or graph, note the date of the test, and indicate the model number and serial number of the calibrator.

5. Accuracy

Accuracy means that the indicated millicurie value for a reference source is equal to the millicurie values determined by the National Bureau of Standards (NBS) or by the supplier. The supplier must compare that source to a source that was calibrated by the NBS. Certified sources are available from the NBS and from many radioisotope suppliers. Consider using at least one reference source whose activity is within the range of activities normally assayed.

- a. Assay a calibrated reference source at the appropriate setting (i.e., use the Co-57 setting to assay Co-57), and then remove the source and measure background. Subtract background from the indicated activity to obtain the net activity. Record this measurement. Repeat for three determinations.
- b. Average the three determinations. The average value should be within five (5) percent of the certified activity of the reference source, mathematically corrected for decay.
- c. Repeat the procedure for other calibrated reference sources.
- d. If the average value does not agree, within five (5) percent, with the certified value of the reference source, the dose calibrator may need to be repaired or adjusted. The regulation requires repair or replacement if the error exceeds 10 percent.
- e. 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.

6. The RSO will review and sign the records of all geometry, linearity, and accuracy tests.

APPENDIX D 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 D.1 and/or D.2 to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

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

D.1. MODEL PROGRAM FOR EXTERNAL EXPOSURE

1. The RSO will promptly review all exposure records to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records; for example, pocket ionization chambers, when the monitor of record is a film badge, thermoluminescent dosimeter (TLD), or optically stimulated dosimeter (OSD).
2. All individuals who are occupationally exposed to ionizing radiation on a regular basis will be issued a film badge, TLD, OSD, or other approved whole body monitor.
3. All individuals who, on a regular basis, handle radioactive material that emits ionizing radiation will be issued a film or TLD finger monitor.
4. All individuals who are exposed to radiation on an occasional basis will not normally be issued exposure monitors. Examples of such personnel are service personnel who deliver packages, secretarial personnel who work in the nuclear medicine clinic but do not work with patients, and nurses who occasionally care for patients who have received diagnostic dosages.
5. Submit the name, address, and license number of the company who will process the personnel monitoring as part of this procedure.
6. Instructions will be given to all employees about how and where dosimetry devices are to be stored when not in use. The storage place should be cool and dry.

D.2. MODEL PROGRAM FOR INTERNAL EXPOSURE

Medical personnel who administer substantial doses of radioiodine to patients may inhale or otherwise ingest some of the radioiodine, leading to possible significant thyroid burdens. Historically, bioassays for medical personnel have been required only in cases of administration to hospitalized patients because these are the patients receiving substantial doses of radiopharmaceuticals. This in turn meant that the medical personnel who prepared or administered the dosages to these patients handled substantial amounts of radioactive material, and therefore were at greatest risk for intakes. Patients who did not need to be confined after administration of radiopharmaceuticals were generally those patients who received relatively small dosages of these materials. The preparation or administration of these smaller dosages posed a relatively lower risk to the medical personnel involved.

The change in the criteria for release of patients who have been administered radiopharmaceuticals may involve the administration of relatively large dosages of radioactive materials without requiring patient

confinement. Bioassays are only applicable to the administration of radiopharmaceuticals at levels that require hospitalization. It may be possible for medical personnel to prepare or administer substantial doses of radiopharmaceuticals without meeting the requirement to perform a bioassay.

Although licensees may no longer be tied to a bioassay program because of the new patient release criteria, they remain subject to the requirements of 4731.2210, "Conditions requiring individual monitoring of external and internal occupational dose." This requires the licensee to monitor all occupationally exposed personnel who may receive, in one (1) year, an intake in excess of the applicable ALI in 4731.2750.

Licensees are required to review the potential exposures of their employees and to monitor them if there is likelihood that the intake may exceed ten percent of the limit in the year. Monitoring as it applies to intake means the implementation of a bioassay program designed to monitor and quantify intakes throughout the year. The bioassay program may include one or a combination of whole body or thyroid counting, urine or fecal analysis, or any other form of bioassay depending on the isotope or combination of isotopes handled during the monitoring period. For medical licensees using primarily radioiodine, thyroid monitoring may continue to be the preferable form of bioassay. Baseline surveys should be completed for all individuals likely to require future monitoring.

**APPENDIX E
RADIATION SAFETY COMMITTEE CHARTER AND
RADIATION SAFETY OFFICER DELEGATION OF AUTHORITY**

You may use the following text as it appears here, stating on your application, "We will issue the model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that is published in Appendix E to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures ". Include the signed Delegation of Authority shown on the following page.

If you prefer, you may develop your own statement of authority, duties, administrative procedures, and delegation of authority. If you do so, you should consider for inclusion all the features in the model text. State on your application, "We will issue the Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that are appended as Appendix E," and submit your charter and Delegation of Authority shown on the following page.

MANAGEMENT

1. Management may appoint alternate members to participate in meetings in the case of absence of principal members and should consider appointing, as adjunct members, representatives from security, physical plant, housekeeping, and other departments. Adjunct members should abstain from balloting on radiation safety questions.
2. To the extent that they do not interfere with the mission of the Committee, management may assign other responsibilities such as x-ray radiation safety, quality assurance oversight, and research project review and approval.

MODEL CHARTER CHARGE

The Committee shall:

1. Ensure that licensed material will be used safely. This includes review, as necessary, of training programs, equipment, facility, supplies, and procedures.
2. Ensure that licensed material is used in compliance with MDH regulations and the institutional license.
3. Ensure that the use of licensed material is consistent with the ALARA philosophy and program.
4. Establish a table of investigational levels for individual occupational radiation exposures.
5. Identify program problems and solutions.

RESPONSIBILITIES

The committee shall:

1. Be familiar with all pertinent MDH regulations, the license application, the license, and the amendments. Ensure that the radioactive material license is amended, if required, before making any changes in facilities, equipment, policies, procedures, and personnel.
2. Review the RSO's summary report of the radiation safety program at least annually. The review should be sufficient to determine that all activities are being conducted safely, in accordance with MDH regulations and the conditions of the license, and consistent with the ALARA program and

- philosophy. The review should include an examination of records, reports from the RSO, results of MDH inspections, written safety procedures, and the adequacy of the management control system.
3. Recommend remedial action to correct any deficiencies identified in the radiation safety program.
 4. Support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.
 5. Perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 1 of Appendix A are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.
 6. Delegate authority to the Radiation Safety Officer (RSO) by submitting the following as part of Appendix E:

MODEL DELEGATION OF AUTHORITY	
MEMO TO:	All Employees
FROM:	Chief Executive Officer
SUBJECT:	Delegation of Authority
<p>_____ has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radiation. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; ensuring compliance with regulations; and maintaining ALARA. The Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities.</p>	
<p><u>SIGNATURE OF CERTIFYING OFFICIAL¹</u></p>	
<p>_____</p> <p style="text-align: center;">Signature</p>	
<p>_____</p> <p style="text-align: center;">Name (Print or type)</p>	
<p>_____</p> <p style="text-align: center;">Title</p>	

¹The person who is authorized to make commitments for the administration of the institution (e.g., CEO, president, etc.).

APPENDIX F LEAK TESTING SEALED SOURCES

As a licensee, you must perform leak testing of sealed sources. The MDH requires tests to determine whether or not there is any leakage from the radioactive source. The leak test should be performed at six-month intervals unless otherwise authorized by your license. You may use the following model procedure to leak test sealed sources. If you follow the model procedure you may state on your application, "We will establish and implement the model procedure for leak testing sealed sources that was published in Appendix (F.1 and/or F.2) to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

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

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. Take the sample using a commercial leak test kit and send the sample to the kit supplier who will report the results to you.
3. Perform the test and analysis yourself.

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

For Option 2, specify the kit model number and the name, address, and license number of the kit supplier and company who will analyze the samples. Commit to Appendix F.1 or submit your own procedures.

For Option 3, describe the procedure for taking the test sample. Identify 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 these measurements. Include the minimum sensitivity for the instrument used for analysis and 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.

F.1 MODEL PROCEDURE FOR TAKING TEST SAMPLES (Option 2)

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 greater 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, bone mineral analyzer source), take the wipe near the radiation port and on the activating mechanism.
- c. For the teletherapy machines, take the wipe with the source in the off position. Wipe the area near the shutter mechanism, taking care not to touch the field light, mirror or crosshairs. Wipe the primary and secondary collimators and trimmers.
- d. If you are testing radium sources, you should also check for radon leakage. Submerging the source in a vial of fine-grained charcoal or cotton for a day can do this. 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.

F.2. MODEL PROCEDURE FOR ANALYZING TEST SAMPLES

(Option 3)

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 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 is the same isotope and whose activity the supplier certifies. 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 records for three years.

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 Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

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 model. 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 long-sleeved 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. Before leaving the restricted area, monitor your hands for contamination in a low-background area with an appropriate survey instrument.
4. Use syringe shields for routine preparation of multi-dose vials and administration of radiopharmaceuticals to patients, except in those circumstances in which their use is contraindicated (e.g., recessed veins or infants). In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve so syringe shields can still be used).
5. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.
6. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.
7. 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.
8. Wear a finger exposure monitor while handling radioactive material including during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals; and while in contact with patients that have been administered radiopharmaceuticals.
9. Dispose of radioactive waste only in designated, labeled, and properly shielded receptacles.
10. Never pipette by mouth.
11. Wipe-test radioactive 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 the generator storage, kit preparation, and injection areas daily for contamination. 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.
14. A log should be used to record additional information such as:
 - The total prepared activity
 - Specific activity (in mCi/cc) at a specified time
 - Total volume prepared
 - The measured activity of each patient dosage
 - Any other appropriate information
15. Syringes and unit dosages should be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patient's name.
16. Assay each patient dosage in the dose calibrator before administration. Only use a dosage that differs by more than ten percent of the prescribed dosage with approval of an authorized user (except for prescribed dosages of less than 10 microcuries). When measuring the dosage, the radioactivity that adheres to the syringe wall or remains in the needle does not need to be considered.
17. Check the patient's name, the prescribed radionuclide, and the dosage before administering.
18. Always keep flood sources, syringes, waste, and other radioactive material in shielded containers.
19. Because sources with even small amounts of radioactivity exhibit a high dose rate on contact, you should use a cart or wheelchair to move flood sources, waste, and other radioactive material.

APPENDIX H 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 Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

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. Clean up the spill using disposable gloves and 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

radiotoxicity 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.

Table H-1 – Relative Hazards of Common Radionuclides

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.	
RADIONUCLIDE	MILLCURIES
Co-60, Sr-89, I-125, I-131	1
F-18, P-32, Co-58, Fe-59, Se-75, Sr-85, Y-90, In-111, I-123, Sm-153, Yb-169, Au-198	10
Cr-51, Co-57, Ga-67, Hg-197, Tc-99 ^m , Tl-201	100

APPENDIX I
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 was published in Appendix I to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should include 4731.2350. State on your application, "We have developed a procedure for ordering and receiving radioactive material that is appended as Appendix I," and submit your procedure.

MODEL GUIDANCE

1. The Radiation Safety Officer (RSO) or a designee must 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 the authorized user or department, isotope, chemical form, activity, and 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.
4. For deliveries during off-duty hours, the RSO shall instruct security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum below.

SAMPLE MEMORANDUM

MEMO TO: Chief of Security

FROM: Radiation Safety Officer

SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty shall accept delivery of packages containing radioactive material that arrives during other than normal working hours. Packages should be placed on a cart or wheelchair and taken immediately to the Nuclear Medicine Department, Room _____. Unlock the door, place the package on top of the counter, and re-lock the door.

If the package appears damaged or leaking, you should immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that the driver and the delivery vehicle are not contaminated.

If you have any questions concerning this memorandum, please call our hospital Radiation Safety Officer,

_____, at _____.
Name Home Telephone

Radiation Safety Officer: _____

Chief of Nuclear Medicine: _____

Chief of Nuclear Medicine Technologist: _____

Nuclear Medicine Technologist on call
(Call page operator at extension _____)

Nuclear Medicine Physician on call
(Call page operator at extension _____)

APPENDIX J
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 that was published in Appendix J to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should consider for inclusion 4731.2350. Indicate on your application, "We have developed a procedure for safely opening packages containing radioactive material that is appended as Appendix J," and submit your procedure.

MODEL PROCEDURE

1. All shipping packages received and known to contain radioactive material must be monitored for radiation levels and radioactive surface contamination in accordance with 4731.2350.
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 one (1) meter and at the package surface. If it is more than 10 millirem per hour at three (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 one (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 ²
All other alpha-emitting radionuclides	2.2 dpm/cm ²
 - 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) 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 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 K RECORDS OF RADIOACTIVE MATERIAL USE

GENERAL

Many suppliers include pressure-sensitive stickers or forms that have much of the information required by the regulations. You may use these in your records and need not duplicate the information on them. Be sure to write down whatever additional information is required but is not cued or printed on them. Information does *not* have to replicate entries. For example, if you prepare a multi-dose vial for use one day, you do not have to record the date each time you draw a dose from it. If you take thirty Ir-192 seeds that are 0.5 millicuries each, you do not have to list each seed individually.

RECORDS OF UNIT DOSAGE USE

You may use the following model procedure to keep a record of unit dosage use. If you will follow the model procedure, you may indicate on your application, "We will establish and implement the model procedure for a unit dosage record system that was published in Appendix K to MDH Medical Use Of Radioactive Material For Diagnostic and Therapeutic Procedures."

If you prefer, you may develop your own unit dosage record system for review. If you do so, you should consider for inclusion all the features in the model procedures in the model procedure. Indicate on your application, "We have developed a procedure for a unit dosage record system for your review that is appended as Appendix K" and submit your unit dosage record procedure.

MODEL PROCEDURE

For each unit dosage received from a supplier, make a record of the:

1. Radionuclide
2. Generic name or its abbreviation or trade name
3. Date of receipt
4. Supplier
5. Lot number or control number, if assigned, and expiration date
6. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time
7. If administered,
 - a. Prescribed dosage (unless already recorded in clinical procedure manual)
 - b. Measured activity in millicuries or microcuries and date and time of assay and administration
 - c. Patient name and identification number if one has been assigned
8. If discarded, the date and method of disposal
9. Initials of the individual who performed the assay

Maintain these records for three (3) years.

RECORDS OF MULTI-DOSE VIAL USE

You may use the following model procedure to keep a record of multi-dose vial use. If you will follow the model procedure, you may state on your application, "We will establish and implement the model procedure for a multi-dose vial record system that was published in Appendix K to MDH Medical Use Of Radioactive Material For Diagnostic and Therapeutic Procedures."

If you prefer, you may develop your own multi-dose vial record system for review. If you do so, you should consider for inclusion all the features in the model system. State on your application, "We have developed

a procedure for a multi-dose vial record system for your review that is submitted as Appendix K" and submit your multi-dose vial record procedure.

MODEL PROCEDURE

For each multi-dose vial that you receive from a supplier or that you prepare, make a record of the:

1. Radionuclide
2. Generic name or its abbreviation or trade name
3. Date of receipt or preparation
4. Date and time of initial assay and amount in both millicuries and cubic centimeters (cc) or milliliters (ml)
5. Supplier or kit manufacturer
6. If administered,
 - a. Prescribed dosage (unless already recorded in clinical procedure manual)
 - b. Date and time dosage was drawn and measured
 - c. Calculated volume that is needed for the prescribed dosage
 - d. Measured activity in millicuries or microcuries
 - e. Patient name and identification number if one has been assigned
7. If discarded, the method of disposal and date
8. Initials of the individual who performed the assay

Maintain these records for three (3) years.

MEASURING AND RECORDING MOLYBDENUM CONCENTRATION

Each licensee who uses a technetium generator to prepare radiopharmaceuticals must complete a test for molybdenum concentration. This measurement is usually made with a dose calibrator. Licensees may not distribute or administer radiopharmaceuticals that contain more than 0.15 microcuries of Mo-99 per millicurie of Tc-99^m at the time of administration. If an elution or extraction has a higher concentration, there may be a manufacturing defect.

The model procedure for measuring molybdenum concentration is based on the use of a molybdenum breakthrough pig. Your dose calibrator manufacturer will usually supply, as an option, a molybdenum breakthrough pig made of lead. The pig is usually thick enough to shield all the technetium photons but only a fraction of the molybdenum photons. The manufacturer will specify the Mo-99 correction factor to convert the measured Mo-99 to total Mo-99.

The following model procedure may be used to measure the molybdenum concentration in Mo-99/Tc-99^m generator elution. If you will follow the model procedure, you may state on your application, "We will establish and implement the model procedure for measuring and recording molybdenum concentration that is published in Appendix K to MDH Medical Use Of Radioactive Material For Diagnostic and Therapeutic Procedures."

If you prefer, you may develop your own molybdenum concentration procedure for review. If you do so, you should consider the inclusion of all the features in the model procedure. State on your application, "We have developed a procedure for measuring and recording molybdenum concentration for your review that is appended as Appendix K," and submit your procedure for measuring and recording molybdenum concentration.

MODEL PROCEDURE

Each time a generator is eluted, record the following information:

1. Date the generator was received.
2. Product of the measured Mo-99 activity and the correction factor. This is noted by the manufacturer.

Maintain these records for three (3) years.

An action level of 0.07 allows for the decay of the Tc-99^m throughout the day of use. It is assumed that the material will be used within six (6) hours, at which time the concentration of Mo-99 to Tc-99^m would have doubled.

INVENTORY OF IMPLANT SOURCES

You may use the following model procedure to keep an inventory and use record for implant sources. If you will follow the model procedure, you may state on your application, "We will establish and implement the model procedure for keeping an inventory of implant sources that was published in Appendix K to MDH Medical Use Of Radioactive Material For Diagnostic and Therapeutic Procedures."

If you prefer, you may develop your own procedure for keeping an inventory and use record for implant sources. If you do so, you should consider for inclusion all the features in the model system. State in your application, "We have developed a procedure for keeping an inventory of implant sources for your review that is appended as Appendix K." Submit your procedure for keeping an inventory and use record for implant sources.

MODEL PROCEDURES

1. Use a locking installed cabinet or safe to store all implant sources.
2. Make a list of names of those individuals you allow to handle the implant sources and have them initial beside their names.
3. For long-lived sources, draw a map of the storage drawer and indicate the activity of the source at each storage point. For short-lived sources that you store in the manufacturer's shipping container, indicate the area in the safe where you put the container. Also, be sure to add the sources to the inventory log.
4. Post the map and the list of individuals whom you permit to handle the sources in the storage area or on the inventory log.
5. Each time you return sources to storage, immediately count them to ensure that every source removed has been returned. Make appropriate records.
6. If you ever perceive a discrepancy between the record and the number of sources in use and in storage, notify the RSO immediately.

APPENDIX L 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 was published in Appendix L to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

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 L," and submit your survey procedures.

MODEL PROCEDURE

AMBIENT DOSE RATE SURVEYS

1. Surveys -- Restricted Areas:
 - a. In areas where only small quantities of gamma-emitting radioactive material are processed (less than 200 microcuries at a time), survey *monthly* with a radiation survey meter.
 - b. In sealed source and brachytherapy storage areas, survey *quarterly* with a radiation survey meter.
 - c. The wearer should survey protective clothing 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.

REMOVABLE CONTAMINATION SURVEYS

1. Survey Areas:

In any area where the potential for spreading contamination is likely to occur (e.g., cafeterias, snack bars, furniture and equipment), survey at least *quarterly*. Random wipe testing of floors alone is acceptable for most unrestricted areas. If such surveys reveal that radioactive contamination is being transferred out of restricted areas, immediate corrective action should be taken to eliminate such transfers. Surveys that are more frequent should be conducted until a trend of negative results is again established.
2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm² of removable contamination (200-dpm/100 cm² for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute to disintegrations per minute).
3. Immediately notify the RSO if you find levels that exceed the established action levels. Recommended removable surface contamination action levels are published in NRC Regulatory

Guide 8.23, "Radiation Safety Surveys at Medical Institutions" or see Table N-1 below for guidance in establishing your action levels.

RECORDS

1. Records must contain the following:
 - The date of the survey.
 - A sketch of each area surveyed.
 - Action levels established for each area.
 - The measured dose rate at several points in each area expressed in millirem (microSievert) per hour or the removable contamination in each area expressed in disintegrations per minute (becquerels) per 100 square centimeters.
 - The serial number and the model number of the instrument used to make the survey or analyze the samples.
 - The initials of the individual who performed the survey.

2. In those cases in which radiation or contamination action levels were exceeded, a follow-up survey should be completed and recorded. The RSO should promptly review and sign survey records that document the results of any actions implemented to correct the excessive radiation or contamination levels.

3. Maintain these records for three (3) years.

Recommended Action Levels

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

**APPENDIX M
MONITORING, CALCULATING, AND CONTROLLING
AIR CONCENTRATIONS**

WORKER DOSE FROM NOBLE GASES

Noble gases such as xenon in the air present an external source of radiation exposure that must be calculated. Many commercially available dosimeters and survey instruments are not capable of accurately measuring worker doses from immersion in noble gases.

You may respond by stating, "We will collect spent noble gas in a shielded trap and monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions."

If you are not monitoring trap effluent, you must estimate worker dose by calculation. If you exhaust spent gas to the atmosphere, you must also estimate worker dose by calculation. It is not necessary to submit the calculations, but you should keep them for MDH review during inspections. If you will follow the model procedure for calculating worker dose from noble gases, you may respond by stating, "We will follow the model procedure for calculating worker dose from noble gases that was published in Appendix M of the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

If none of the above applies, you may develop your own procedure for review. State on your application, "We have developed a procedure for monitoring worker dose due to submersion in noble gases that is appended as Appendix M," and append your procedure for monitoring worker dose from noble gases.

WORKER DOSE FROM AEROSOLS

You may respond by stating, "We will collect spent aerosol in a shielded trap and, for reusable traps, monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions." You do not have to monitor the trap effluent of single-use devices.

If you are not monitoring reusable trap effluent or if you are exhausting spent aerosol to the atmosphere, you must estimate worker dose by calculation. (You do not have to submit the calculations, but you should keep them for MDH review during inspections.) If you follow the model procedure below for calculating worker dose from aerosols, you may respond by saying "We will follow the model procedure for calculating worker dose from aerosol concentrations that is appended as Appendix M.2." Submit your procedure for monitoring worker dose from aerosols.

M.1 MODEL PROCEDURE FOR CALCULATING WORKER DOSE FROM CONCENTRATIONS OF GASES AND AEROSOLS IN WORK AREAS

1. Determine the highest dose to an individual from all external radiation for the previous 12-month period by reviewing personnel monitoring records (film, TLD, OSD, etc.). If necessary, modify the dose to account for an anticipated increase or decrease in patient workload.
2. Modify the derived air concentration (DAC) for Xenon-133 (or other gas to be used) to allow for the estimated annual external exposure. A simplified method is to subtract the estimated external dose from the occupational dose limit of five (5) rem (50 mSv) and divide this number by five (5) rem.

- a. This yields the fraction of the dose limit of five (5) rem that would still be permitted from internal sources. Multiplying this fraction by the DAC value yields a modified DAC. These DAC values are provided in 4731.2750.
 - b. If the highest annual external dose is 2 rem, and the listed DAC value for Xenon-133 is $1E-4$ mCi/ml, then the modified DAC value should be based on 3 rem that could still be incurred from internal exposure.
3. The following calculations must be made:
- a. The sum of all measured exhaust rates and the sum of all measured supply rates. If the former is larger than the latter, this ensures that the imaging room is at negative pressure.
 - b. The estimated activity released to the restricted areas.
 - (1) The total activity released to the restricted area divided by the total air exhausted must be less than the applicable DAC for a restricted area. The total activity released to the restricted area is activity used each week multiplied by estimated fractional loss per study. The total air exhausted is the sum of all exhaust rates multiplied by the length of the workweek.
 - (2) If this is not the case, plan for fewer studies and do the calculations again. An increase in the ventilation rate will not significantly reduce the downwind effluent concentration because it is primarily a function of the natural dispersion in the atmosphere.

M.2 MODEL PROCEDURE FOR CALCULATING AIRBORNE EFFLUENT CONCENTRATION

1. Divide the total activity released to an unrestricted area (activity used each week that is released in an exhaust system) by the total volume of air exhausted over the week ("on" time multiplied by measured airflow rate). The quotient must be less than the applicable DAC value for an unrestricted area.
2. If this is not the case, plan for fewer studies and do the calculation again. Alternatively, you may consider collection and decay-in-storage for waste, or restriction of access to the release point and calculation of concentration at the boundary of the restricted area.

M.3 MODEL PROCEDURE FOR MONITORING OR CHECKING TRAP EFFLUENT

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

1. 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.
2. If you do not continuously monitor the trap effluent, check it on receipt and once each month. During one patient study, collect the effluent from the trap in a plastic bag and then monitor the activity in the bag by holding the bag against a camera. With the camera adjusted to detect the noble gas, compare its counts per minute (cpm) to background cpm with no other radioactivity in the area. Keep a record of the date, background cpm, and bag cpm. *If there is a significant increase in the activity measured on the bag, the trap must be replaced.*

3. The charcoal Xenon trap should be replaced at time intervals recommended by the manufacturer.

PUBLIC DOSE FROM AIRBORNE EFFLUENT

Effluent release presents a potential source of dose to the public. Usually a calculation of concentration at the release point is done and compared to the appropriate value 4731.2750.

If you are not directly venting aerosols and gases to the atmosphere, you may respond by saying "We will not directly vent spent aerosols and gases to the atmosphere and, therefore, no effluent estimation is necessary."

If you are going to vent aerosols or gases to the atmosphere, you must estimate effluent concentrations by calculation. (You do not have to submit the calculations with your application, but you should keep them for MDH review during inspections.) If you will follow the model procedure below for calculating release concentrations, you may respond by stating "We will follow the model procedure for calculating airborne effluent concentration that was published in Appendix M.3 to MDH Medical Use Of Radioactive Material For Diagnostic and Therapeutic Procedures."

If neither of the above applies, you may develop your own procedure for review. Say on your application, "We have developed a procedure for monitoring airborne effluent concentration that is appended as Appendix M.3" and append your procedure for monitoring airborne effluent concentration.

SPILLED GAS CLEARANCE TIME

Because normal room ventilation is usually not sufficient to ensure clearance of spilled gas, the calculations described in Appendix M.4 should be done to determine for how long a room should be cleared in case of a gas spill. This clearance time should be posted in the room.

M.4 MODEL PROCEDURE FOR CALCULATING SPILLED GAS CLEARANCE TIME

1. Collect the following data:
 - a. A -- the highest activity of gas in a single container, in microcuries.
 - b. Measured airflow supply from each vent in the room (if different during heating and cooling seasons, use the lesser values), in milliliters per minute.
 - c. 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 exhaust system
 - d. C -- the modified derived air concentrations (DAC) in restricted areas. These should be figured according to M.1, Numbers 1 and 2.
 - e. V -- the volume of the room in milliliters.
2. Make the following calculations for each room:

- a. The airflow supply should be less than the airflow exhaust to ensure the room is at negative pressure.
 - b. The evacuation time $t = -V/Q \times \ln (C \times V/A)$.
3. The radiation levels in unrestricted areas from operations or releases of radionuclides in effluents are restricted
 - 2.0 mrem in any one (1) hour from external sources, and
 - 100 mrem in a year (Total Effective Dose Equivalent) for individual members of the public.

Depending on how the facility areas are controlled and monitored, hallway areas outside patient diagnostic areas will usually need to be limited to the radiation levels for unrestricted areas.

APPENDIX N RADIATION SAFETY DURING RADIOPHARMACEUTICAL THERAPY

You may use the following procedure for reducing worker and public dose during radiopharmaceutical therapy. If you will follow the model procedure, you may state on your application, "We will establish and implement the model procedure for radiation safety during radiopharmaceutical therapy that was published in Appendix N to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

If you prefer, 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 a procedure for radiation safety during therapeutic use of radiopharmaceuticals for your review that is appended as Appendix N" and include your procedure.

MODEL PROCEDURE

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care and still allows staff to control access. Access can be controlled by routine surveillance and by posting instructions for hospital staff and visitors at the entrance to the patient's room
2. Prepare the room for the procedure as follows:
 - a. Use the leak-proof absorbent paper to cover large surfaces (the bed, chairs, and the floor around the toilet) that are likely to be contaminated. Small items (telephone, doorknobs, bed remote control, television control, and nurse call cord) may be covered with absorbent paper or plastic bags.
 - b. Prepare separate boxes for linen, disposable waste, and non-disposable contaminated items. Place a single large, re-closing plastic bag in each box, or supply several small plastic bags.
 - c. Prepare a station with disposable gloves and shoe covers (booties) outside the restricted area.
 - d. Prepare a station inside the restricted area, near the exit, for disposal of gloves and booties upon exiting the restricted area. All waste must be considered contaminated until surveyed and verified that it is not radioactive.
 - e. Determine whether urine will be discarded by release to the sanitary sewer or collected. If urine will be collected, prepare collection containers.
 - (1) Containers should be unbreakable and re-closing.
 - (2) If there is no need for assay or volumetric determination and urine will be decayed in storage, add to each container an absorbent such as vermiculite.
 - (3) To avoid room contamination in the case of a spill, place containers in a box or deep tray that has been lined with a plastic bag and absorbent paper or vermiculite.
 - (4) Supply a few half-value layers of shielding for each container. (For I-131, one half-value layer is approximately three (3) mm of lead.)
 - (5) Supply a wide-mouth anti-splash funnel.

- f. Stock additional disposable gloves, absorbent paper, and radioactive waste labels in the room for use as necessary by nursing, nuclear medicine, and radiation safety personnel.
3. Order disposable table service for the duration of the patient's stay. Inform the Housekeeping Office that personnel should stay out of the room until otherwise notified.
4. Supply the nurses with film badges, TLDs, OSDs, or pocket ionization chambers.
5. Brief the nurses on radiation safety precautions. Include instruction on entering and exiting the restricted area. The instruction should include wearing disposable gloves and booties upon entering the restricted area and the proper removal and disposal of those items upon exiting. A sample form is included in this regulatory guide. Allow time for questions and answers during the briefing. Leave a written copy of the radiation safety precautions in the patient's chart or at the nurses' station.
6. Limit laboratory testing as much as possible. If laboratory testing, such as blood testing and urinalysis, is not avoidable, provide radiation safety instruction to the laboratory personnel.
7. Brief the patient on radiation safety procedures for the dosage administration, visitor control, urine collection, radioactive waste, and other items as applicable.
8. Only those persons needed for medical, safety, or training purposes should be present during the administration.
9. Mark a visitor safe line on the floor with tape as far from the patient as possible.
10. Following administration of the dosage, measure the exposure rate in mR/hr at bedside, at one (1) meter from bedside, at the visitor safe line, and in the surrounding hallways and rooms. Record this and any other necessary information on the nursing instruction form or the nurses' dosimeter sign-out form. Post the room with a "Radioactive Materials" sign.
11. As the therapy proceeds, pick up waste for transfer to a decay-in-storage or decontamination area.
12. Do not release any patient until they have met the criteria of 4731.4427.
13. Before using the room for general occupancy, it must be decontaminated and released to the Admitting Office.
 - a. Remove all absorbent paper and place it in the appropriate container.
 - b. Transfer all containers to a decay-in-storage or decontamination area.
 - c. Use a radiation detection survey meter to check for room contamination. Clean contaminated areas until removable contamination is less than 200-dpm/100 cm².
 - d. Call the Housekeeping Office to remove the cleaning restriction and call the Admitting Office to return the room to the vacant list.

**Model Radiation Safety Checklist for
Iodine Therapy**

Patient Name: _____ Room: _____ Date: _____

PREPARATION:

- Private room with private sanitary facilities.
- Large room surfaces and walk areas covered with absorbent paper.
- Devices that the patient will come in contact with are protected (e.g., telephone, doorknobs, toilet handles etc.)
- Station containing disposable gloves and booties placed outside room.
- Housekeeping notified not to clean the room until further notice.
- Plastic trash bags located inside the room for waste.
- Brief nursing staff on radiation safety precautions.
- Issue personnel dosimetry devices to nursing staff and instruction regarding proper wear.
- Insure that nursing staff caring for the patient is neither pregnant nor breast feeding.
- Order disposable table service.
- Prepare urine containers if urine is collected.
- If laboratory analysis is needed, instruct laboratory personnel in radiation safety precautions.

ADMINISTRATION:

- Clear the room of all unnecessary personnel.
- Brief patient on the clinical procedure and radiation safety precautions.
- Administer dose.
- Measure dose rates at bedside, one (1) meter from bedside, visitor safe line, and unrestricted areas around the patient's room.
- Calculate visiting and care time.
- Post room with "Caution- Radioactive Materials" sign.

FOLLOW-UP:

- Periodically survey dose rates at bedside, one (1) meter from patient, and door.
- Measure the thyroid burden of all personnel involved in the preparation and administration of the dose.
- Release patient when he/she meets the criteria in 4731.4427.
- Survey and decontaminate the patient room. Remove postings.
- Release room for general use.

List Individuals involved in the preparation and administration of the patient dose:

NAME	DEPARTMENT

**Model Nursing Instructions for Patients Receiving
Radiopharmaceutical Therapy and Hospitalized**

Patient Name: _____

Patient ID Number: _____

Authorized User: _____

Contact Number: _____

Patient Room: _____

Dose: _____ mCi of _____ Time: _____ Date: _____

Authorized User Signature: _____ Date: _____

Radiation Exposure Rates

Unrestricted Areas Surveyed and Dose Rates (mR/hr):

Initial Exposure Rate at one (1) meter from Patient (mR/hr):

Patient Position: _____

DATE	TIME	BEDSIDE	1 METER FROM PATIENT	DOOR

Instructions

Visitor Restrictions:

- No visitors.
- No visitors under 18 years of age, breast feeding, or pregnant.
- No visitors in the patient room more than _____ minutes per day.
- Visitor must stay behind line on floor at all times.

Nursing Restrictions:

- Patient is restricted to the room.
- No nurses who are pregnant or breast-feeding may render care.
- No nurse shall be in the patient's room for more than _____ minutes per day.

Patient Care:

- Wear disposable gloves and booties when entering the patient's room.
- Properly dispose of gloves and booties when exiting the patient's room.
- Properly dispose of linen, bedclothes, plates, utensils, dressings, etc.
- Discard urine and feces in toilet. Flush three times.
- Housekeeping personnel are not permitted to enter the room unless authorized by the RSO.
- Practice proper wearing of personnel dosimetry when caring for the patient.
- Do not share personal dosimetry. Return dosimetry to designated area before end of shift.
- Emergency Procedures.

Acknowledgment of Training:

NAME	SIGNATURE

In the case of emergency, or if any questions arise call:

Radiation Safety Officer: _____

Work: _____

Home: _____

Pager: _____

**APPENDIX O
RADIATION SAFETY DURING IMPLANT THERAPY**

You may use the following procedure to reduce worker and public dose during implant therapy. If you will follow the model procedure, indicate on your application, "We will establish and implement the model procedure for radiation safety implant therapy that was published in Appendix O to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

If you prefer, you may develop your own procedure for review. Indicate on your application, "We have developed a procedure for radiation safety and implant therapy for your review that is appended as Appendix O," and submit your procedure.

ITEMS TO BE CONSIDERED

A model checklist is provided in this Appendix.

1. The patient's room will be as far away from the nursing station and heavy traffic hallways as is consistent with good medical care. It will be a private room unless the dose at one meter from the implant meets the requirements in 4731.2090.
2. Supply the nurses with film badges, TLD's, OSDs, or pocket ionization chambers.
3. Brief the nurses on radiation safety precautions. Allow time for questions and answers during the briefing.
4. Brief the patient on radiation safety procedures for confinement to bed, visitor control, and other items as applicable, consistent with good medical care.
5. Only those persons needed for medical, safety, or training purposes should be present during the implant procedure.
6. Mark a visitor safe line on the floor with tape as far from the patient as possible.
7. Following the implant, measure the exposure in mR/hr at bedside, at one (1) meter from bedside, at the visitor safe line, and in the surrounding hallways and rooms. Record all necessary information on the nursing instruction form or the nurses' dosimeter sign-out form. Post the room with a "Radioactive Materials" sign.
8. Do not release any patient who has received a temporary implant from the hospital until a radiation survey of the patient and a count of implant sources, trains, or ribbons confirms that all sources have been removed from the patient. Perform this check immediately after the removal of the sources. Keep a record confirming the source count and radiation survey on the implant source running inventory form. For low-activity seeds (less than one (1) millicurie), use an individual seed to check the survey meter to be sure it will easily detect a seed that has not been removed or has been lost.
9. Do not release any patient who has received a permanent implant from the hospital until the exposure rate from the patient is less than five (5) mR/hr at one (1) meter. Measure this exposure rate at a distance of one (1) meter from the umbilicus while the patient is standing.

**Model Radiation Safety Checklist for
Temporary Implant Therapy**

Patient Name: _____ Room: _____ Date: _____

PREPARATION:

- Private room with private sanitary facilities preferably in a low traffic area.
- Housekeeping notified not to clean the room until further notice.
- Plastic trash bags located inside the room for waste.
- Brief nursing staff on radiation safety precautions.
- Issue personnel dosimetry devices to nursing staff and instruct on proper wear.
- Ensure that nursing staff caring for the patient is neither pregnant or breast feeding.

ADMINISTRATION:

- Clear the room of all unnecessary personnel.
- Brief patient on the clinical procedure and radiation safety precautions.
- Insert implant(s).
- Measure dose rates at bedside, one (1) meter from bedside, visitor safe line, and unrestricted Areas around the patient's room.
- Calculate visiting and care time.
- Post room with "Caution- Radioactive Materials" sign.

FOLLOW-UP:

- Perform a survey of the patient to ensure that all sources were removed.
- Survey linen, bedclothes and dressings to ensure no sources were dislodged.
- Count the number of sources removed to ensure that all sources were removed.
- Remove postings and release room for general use.

Temporary Implant Therapy Removal Log

NUMBER OF SOURCES REMOVED	SOURCE STRENGTH	DATE REMOVED

**Model Nursing Instructions for Patients Receiving
Temporary Implant Therapy and Hospitalized**

Patient Name: _____ Patient ID#: _____

Authorized User: _____ Contact No.: _____ Patient Room: _____

Dose: _____ mCi of _____ Time: _____ Date: _____

The sources will be removed: Time: _____ Date: _____

Authorized User Signature: _____ Date: _____

NUMBER OF SOURCES INSERTED	SOURCE STRENGTH	DATE INSERTED

Radiation Exposure Rates

UNRESTRICTED AREAS SURVEYED AND DOSE RATES (MR/HR):	
Patient Position:	

Survey Results

DATE	TIME	BEDSIDE	1 METER FROM PATIENT	DOOR

Instructions:

Visitor Restrictions:

- No visitors.
- No visitors under 18 years of age or pregnant.
- No visitors in the patient room more than _____ minutes per day.
- Visitors must stay behind line on floor at all times.

Nursing Restrictions:

- Patient is restricted to the room.
- Patient is restricted to bed.
- Patient must not move.
- No nurses who are pregnant or breast-feeding may render care.
- No nurse shall be in the patient's room for more than _____ minutes per day.

Patient Care:

- If the source becomes dislodged, call the attending physician and RSO.
- Omit bed bath.
- No perineal care. Pad may be changed as necessary.
- Save linen, bedclothes, and dressings for survey .
- Housekeeping personnel are not permitted to enter the room unless authorized by the RSO.
- Proper wearing of personnel dosimetry when caring for the patient.
- Do not share personnel dosimetry. Return dosimetry to designated area before end of shift.
- Emergency Procedures.

Acknowledgment of Training:

NAME	SIGNATURE

In the case of emergency, or if any questions arise, call:

Radiation Safety Officer: _____

Work: _____

Home: _____

Pager: _____

APPENDIX P WASTE DISPOSAL

The following general guidance and procedure may be used for disposal of radioactive waste. If you follow all the general guidance and procedures, you may state on your application, "We will establish and implement the general guidance and model procedures for waste disposal that is published in Appendix P to the MDH Regulatory Guide for Medical Use of Radioactive Material in Diagnostic and Therapeutic Procedures."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the general guidance. State on your application, "We have developed a procedure for waste disposal for your review that is appended as Appendix P," and attach your procedure.

OVERVIEW

There are four commonly used methods of waste disposal:

- Release to the environment through the sanitary sewer or by evaporative release
- Decay-in-storage (DIS)
- Transfer to a burial site or back to the manufacturer
- Release to in-house waste

With the exception of the patient excreta and generally licensed *in-vitro* kit exemptions, nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material.

GENERAL GUIDANCE

1. All radioactivity labels must be defaced or removed from containers and packages before disposal. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
2. Remind employees that non-radioactive waste, such as leftover reagents, boxes, and packing material, should not be mixed with radioactive waste.
3. Occasionally monitor all procedures to ensure that no unnecessary radioactive waste is created. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, and pathogenicity), and expense.

MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

Release to the sanitary sewer or evaporative release to the atmosphere may be used to dispose of liquids. This does not relieve licensees from complying with other regulations regarding toxic or hazardous properties of these materials.

1. Regulations for disposal in the sanitary sewer appear in 4731.2420. There are specific limits based on the total sanitary sewerage release of your facility. (Excreta from patients undergoing medical diagnosis or therapy are exempt from all the above limitations.) Make a record of the date,

radionuclide, estimated activity that was released (in millicuries or microcuries), and of the sink or toilet at which the material was released.

2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in 4731.2750. These limits normally apply at the boundary of the restricted area. Make a record of the date, radionuclide, estimated activity and concentration that was released (in millicuries or microcuries), and the vent site at which the material was released.
3. Liquid scintillation-counting media containing 0.05 microcuries per gram of H-3 or C-14 may be disposed of without regard to its radioactivity. Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed of.

MODEL PROCEDURE FOR DISPOSAL BY DECAY-IN-STORAGE (DIS)

Short-lived material (physical half-life less than 120 days) may be disposed of by DIS. If you use this procedure, keep material separated according to half-life.

1. Consider using separate containers for different types of waste (e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container). Smaller departments may find it easier to use just one container for all DIS waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for material.
2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the DIS area.
3. Decay the material for at least 10 half-lives.
4. Before disposal as in-house waste, monitor each container as follows:
 - a. Check your radiation detection survey meter for proper operation.
 - b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area.
 - c. Remove any shielding from around the container.
 - d. Monitor all surfaces of each individual container. Record the date on which the container was sealed, the disposal date, and the type of material (e.g., paraphernalia, unused dosages).
 - e. Discard as in-house waste only those containers that cannot be distinguished from background. Check to be sure that no radiation labels are visible.
 - f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.
5. If possible, Mo-99/Tc-99^m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, and then work forward chronologically. Hold each individual column in contact with the radiation detection survey meter in a low-background (less than 0.05 mR/hr) area. Record the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

MODEL PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for DIS and some animal carcasses, solids must be transferred to a burial site. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet that the transfer agent gave you.

MODEL PROCEDURE FOR RETURNING GENERATORS TO THE MANUFACTURER

Used Mo-99/Tc-99^m generators may be returned to the manufacturer. This permission does not relieve licensees from the requirement to comply with Department of Transportation (DOT) regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container. See DOT regulations, 49 CFR 173.415(a).
2. Assemble the package in accordance with the manufacturer's instructions.
3. Perform the dose rate and removable contamination surveys.
4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

MODEL PROCEDURE FOR RELEASE TO IN-HOUSE WASTE

Waste from *in-vitro* kits that are generally licensed is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

APPENDIX Q
MEDICAL USE OF STRONTIUM-90 EYE APPLICATORS

New Sr-90 eye applicators typically contain a 54-millicurie (2 Gigabecquerel) source, exhibiting a surface dose rate of about 0.50 Gy (50 rad/sec). The half-life of the parent Sr-90 is 28.5 years. The maximum beta energy equal to 0.54 MeV, and the Yttrium-90 daughter half-life is 64.2 hours (beta-max, 2.27 MeV); therefore, both isotopes are in equilibrium on the eye applicator. Since Sr-90 and Y-90 are in equilibrium, emissions from both isotopes must be accounted for in dosimetry calculations.

The source output or activity that is used for ophthalmic treatments must be determined using a dosimetry system that has been calibrated using a system or source traceable to the National Institute of Science and Technology (NIST) and published protocols accepted by nationally recognized bodies, or calibrated by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The licensee is allowed to use measurements provided by the source manufacturer, or by a calibration laboratory accredited by the AAPM, that are made in accordance with the requirements of 10 CFR 35.432(a). Most licensees possessing Sr-90 eye applicators do not have their applicators calibrated to current standards. It should be noted that NIST-traceable calibrations of Sr-90 eye applicators preceding August of 1990 do not meet the revised criteria. In August of 1990, NIST implemented a new Sr-90 eye applicator calibration procedure that established the currently accepted national standards. Any NIST-traceable calibrations performed after this date should ensure compliance.

Licensees must develop written procedures for any brachytherapy dose, including assurance that the prescribed dose is the administered dose. A necessary part of this is to ensure that the dose rate emitted from an applicator is correct. If the manufacturer's certificate of calibration or original activity/dose rate nameplate is missing, the licensee should arrange with a qualified expert to determine the dose rate from the Sr-90 source. Only an authorized medical physicist can calculate the activity of each Sr-90 source that is used to determine the treatment times for ophthalmic treatments. Medical licensees who use Sr-90 eye applicators should check calibration records and take steps to assure that they will be in compliance.

**APPENDIX R
MODEL ANNUAL AUDIT CHECKLIST**

ORGANIZATIONAL STRUCTURE

- a. Radiation Safety Committee (RSC)
 - (1) Meetings held quarterly. N/A Yes No
 - (2) Quorums established. N/A Yes No
 - (3) Committee reviews program annually. N/A Yes No
 - (4) Record of Committee meetings. N/A Yes No
- b. Radiation Safety Officer (RSO) same as listed on the license N/A Yes No
- c. Visiting Authorized User(s)
 - (1) Has written permission. N/A Yes No
 - (2) Visitor authorized user's license on file. N/A Yes No
 - (3) Performs only those procedures authorized on visitor's license. N/A Yes No
 - (4) Uses materials under licensee's license or 60 days per year or less. N/A Yes No
 - (5) Records maintained three years after the visiting authorized user's last visit. N/A Yes No
- d. Mobile Nuclear Medicine Service meets technical requirements. N/A Yes No

AUDIT HISTORY

- a. Last audit conducted on: _____ N/A Yes No
- b. Deficiencies identified? N/A Yes No
- c. Were they corrected? N/A Yes No

SCOPE OF PROGRAM

- a. Are there multiple authorized locations of use?
If multiple locations authorized, list locations audited. N/A Yes No
- b. Have there been radiation safety program changes?
If yes, list changes. N/A Yes No

TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS

- a. Instructions to workers provided. N/A Yes No
- b. Training program conducted according to license commitments. N/A Yes No

FACILITIES, MATERIALS, AND EQUIPMENT

- a. Facilities are as described in the license application. N/A Yes No
- b. Storage and use of radioactive material
 - (1) Adequate method to prevent unauthorized individuals from entering restricted area. N/A Yes No
 - (2) Radioactive material secured to prevent unauthorized removal or access. N/A Yes No
- c. Dose Calibrator
 - (1) Constancy checked. N/A Yes No
 - (2) Linearity tested. N/A Yes No
 - (3) Accuracy tested. N/A Yes No
 - (4) Geometry dependence test. N/A Yes No

- (5) Readings mathematically corrected if linearity error is greater than 10%. N/A Yes No
- (6) Records maintained. N/A Yes No
- (7) RSO signs linearity, accuracy, and geometry dependence tests. N/A Yes No
- d. Survey instruments.
 - (1) Appropriate operable survey instruments. N/A Yes No
 - (2) Calibration, as required. N/A Yes No
 - (3) Records maintained. N/A Yes No
- e. Syringes containing RAM properly labeled and shielded, unless contraindicated. N/A Yes No
- f. Syringes properly labeled. N/A Yes No
- g. Vials containing RAM properly shielded. N/A Yes No
- h. Vials properly labeled. N/A Yes No

RADIOLOGICAL PROTECTION PROCEDURES

- a. Individual has understanding of procedures. N/A Yes No
 - (1) In general, rules for safe use. N/A Yes No
 - (2) In emergency procedures N/A Yes No

MATERIALS

- a. Molybdenum-99 breakthrough tests performed. N/A Yes No
- b. Records Molybdenum-99 breakthrough tests maintained. N/A Yes No
- c. Leak tests of sealed sources performed at appropriate intervals. N/A Yes No
 - (1) Leak test records in units of microcuries. N/A Yes No
 - (2) Leak test records signed by RSO. N/A Yes No
 - (3) Records of leak tests kept for three years. N/A Yes No
- d. Inventories N/A Yes No
 - (1) Quarterly inventory of sealed sources. N/A Yes No
 - (2) Inventory records signed by RSO. N/A Yes No
 - (3) Records of leak tests and inventories kept for three years. N/A Yes No

RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

- a. Procedure for opening packages adequate. N/A Yes No
- b. Incoming packages monitored for radioactive contamination. N/A Yes No
- c. Incoming packages monitored for external radiation levels. N/A Yes No
- d. Transfers performed, as required. N/A Yes No
- e. Records of receipt surveys. N/A Yes No
- f. Records of receipt, transfer, & disposal of radioactive material. N/A Yes No

AREA SURVEYS

- a. Ambient dose rate surveys performed. N/A Yes No
- b. Contamination surveys conducted. N/A Yes No
- c. Trigger levels established. N/A Yes No
- d. Dose rate survey records in mR/hr. N/A Yes No
- e. Contamination survey records maintained in dpm/100 cm². N/A Yes No

RADIOPHARMACEUTICAL THERAPY

- a. Oral and written safety instructions provided to personnel caring for patients. N/A Yes No
- b. Record of training maintained. N/A Yes No
- c. Patient room surveys. N/A Yes No

- d. Record of room survey. N/A Yes No
- e. Performed according to license commitments. N/A Yes No
- f. Release of patients containing radiopharmaceuticals meets 4731.4427 criteria. N/A Yes No
- g. Thyroid burden measurements on all individuals involved in dose administration. N/A Yes No
- h. Record of thyroid measurements. N/A Yes No

BRACHYTHERAPY

- a. Oral and written safety instructions provided to personnel caring for patients. N/A Yes No
- b. Record of training maintained. N/A Yes No
- c. Patient area surveyed. N/A Yes No
- d. Release of patients containing permanent implants according to license commitments. N/A Yes No
- e. Surveys performed before releasing patients being treated with temporary implants. N/A Yes No
- f. Record of patient survey. N/A Yes No
- g. Brachytherapy sources inventoried each time sources are returned to storage after use. N/A Yes No
- h. Record of brachytherapy source utilization. N/A Yes No
- i. Brachytherapy sources inventoried each quarter. N/A Yes No
- j. Record of inventory. N/A Yes No
- k. Brachytherapy source storage area surveyed. N/A Yes No
- l. Record of survey of storage area. N/A Yes No

PERSONNEL RADIATION MONITORING – EXTERNAL

- a. Supplier NVLAP approved. N/A Yes No
- b. Dose(s) exceeded regulatory limits. N/A Yes No
- c. ALARA program implemented.
 - (1) Annual review by radiation safety committee completed. N/A Yes No
 - (2) Written description of ALARA program available. N/A Yes No

PERSONNEL RADIATION MONITORING – INTERNAL

- a. Bioassay program implemented and performed at proper intervals N/A Yes No
- b. Radioactive gases
 - (1) Clearance time and safety procedures are posted. N/A Yes No
 - (2) Reusable collection system checked monthly. N/A Yes No
 - (3) Ventilation rates checked for negative pressure at six-month intervals. N/A Yes No

WASTE DISPOSAL

- a. Radioactive material disposed of as authorized. N/A Yes No
- b. Record of disposal by decay in storage maintained. N/A Yes No
- c. Survey of waste before disposal. N/A Yes No
- d. Records of waste surveys. N/A Yes No

NOTIFICATION AND REPORTS

- a. Notifications and reports provided to individuals. N/A Yes No
- b. Reporting theft or loss compliant with rules. N/A Yes No
- c. Compliant regarding notification of incidents. N/A Yes No

- d. Compliant regarding reporting of excessive levels and concentrations. N/A Yes No
- e. Termination reports furnished, if requested by workers. N/A Yes No

MISADMINISTRATIONS

- a. Misadministrations occurred N/A Yes No
- b. Compliant with reporting requirements for misadministration. N/A Yes No
- c. Appropriate action taken to prevent recurrence. N/A Yes No
- d. Records maintained. N/A Yes No

POSTING AND LABELING

- a. Radiation Areas posted. N/A Yes No
- b. High Radiation Areas posted. N/A Yes No
- c. Use or storage areas posted "Caution- Radioactive Material." N/A Yes No
- d. Containers or devices labeled. N/A Yes No
- e. Notice to Workers posted. N/A Yes No
- f. Notice to Employees posted. N/A Yes No

TRANSPORTATION 49 CFR 171-178

- a. Authorized packages used. N/A Yes No
- b. DOT-7A performance test records on file. [173.415(a)] N/A Yes No
- c. For special form sources, performance test records on file. [173.476(a)] N/A Yes No
- d. Packages properly labeled. [172.403(b)] N/A Yes No
- e. Packages properly marked. [172.301(a)] N/A Yes No
- f. Proper shipping papers prepared. [172.200] N/A Yes No
- g. Shipping paper contains emergency response telephone number. [172.201(d)] N/A Yes No

ATTACHMENT I

US DEPARTMENT OF TRANSPORTATION REQUIREMENTS FOR THE SAFE TRANSPORTATION OF HAZARDOUS MATERIALS

The Federal hazardous materials transportation law (49 U.S.C. 5101 et seq.) is the basic statute pertaining to the transportation of hazardous materials (HAZMAT) in the United States. This law requires the training of all HAZMAT employees. The purposes are to increase a HAZMAT employee's safety awareness and to be an essential element in reducing HAZMAT incidents. The Hazardous Materials Regulations (HMR) include training requirements in several sections of Title 49 Code of Federal Regulations (CFR) as follows:

General	§ 173.1
Specific	§ 172.704
Modal	
Air	§ 175.20
Vessel	§ 176.13
Highway	§§ 177.800, 177.816

Each HAZMAT employer must:

- train and test,
- certify; and
- develop and retain records of current training (inclusive of preceding three years) for each HAZMAT employee (during the period of employment and 90 days thereafter).

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 conducted by OSHA, EPA and other Federal or international agencies, may be used to satisfy the training requirements in 172.704(a) to the extent that such training addresses the training components specified in paragraph (a) of this section.

Training records must include:

- 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.

DEFINITIONS

Hazardous Material means a substance or material capable of posing an unreasonable risk to health, safety, or property when transported in commerce.

HAZMAT Employer means a person who uses one or more employees in connection with:

- transporting HAZMAT in commerce;
- causing HAZMAT to be transported or shipped in commerce; or
- representing, marking, certifying, selling, offering, reconditioning, testing, repairing, or modifying packagings as qualified for use in the transportation of HAZMAT.

The term "HAZMAT employer" also includes any department, agency or instrumentality of the United States, a State, a political subdivision of a State, or an Indian tribe engaged in offering or transporting HAZMAT in commerce. This term includes an owner-operator of a motor vehicle, which transports hazardous materials in commerce.

HAZMAT Employee means a person who is employed by a HAZMAT employer and who directly affects HAZMAT transportation safety including;

- an owner-operator of a motor vehicle which transports HAZMAT;
- a person (including a self-employed person) who:
 - loads, unloads, or handles HAZMAT;
 - tests, reconditions, repairs, modifies, marks, or otherwise represents packagings as qualified for use in the transportation HAZMAT;
 - prepares HAZMAT for transportation;
 - is responsible for safety of transporting HAZMAT; or
 - operates a vehicle used to transport HAZMAT.

Training means a systematic program (consistent approach, testing, and documentation) that ensures that a HAZMAT employee has knowledge of hazardous materials and the HMR, and can perform assigned HAZMAT functions properly. See §172.700 through §172.704.

ATTACHMENT II

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 of 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.

Enclosure 5

MINNESOTA DEPARTMENT OF HEALTH



REGULATORY GUIDE FOR DECOMMISSIONING

The logo is circular with a ram's head in the center. The text "Radioactive Materials Group" is written along the top arc, "Minnesota Department of Health" along the bottom arc, and "RAM" in the center below the ram's head.	<p>Radiation Control Unit Asbestos, Lead, Indoor Air & Radiation Section Division of Environmental Health Minnesota Department of Health</p>
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January 2005

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REGULATORY GUIDE FOR DECOMMISSIONING

Purpose

The purpose of this document is to:

- illustrate the decommissioning process to licensees, and the general public,
- provide guidance to MDH licensees for terminating the most common MDH radioactive materials licenses and to make available methods, acceptable to MDH staff, for implementing specific parts of the decommissioning rules;
- delineate techniques and criteria used by MDH staff in evaluating decommissioning actions;
- provide guidance to MDH staff overseeing decommissioning programs to evaluate a licensee's decommissioning actions; and
- maintain a risk-informed, performance-based, and flexible decommissioning approach
- provide guidance for staff tasked with inspection of decommissioning activities.

This document provides guidance regarding decommissioning leading to termination of a license for facilities that do not require a decommissioning plan. Guidance for radiological programs that are not included in this document can be found in NUREG 1757. "*Consolidated NMSS Decommissioning Guidance.*"

Introduction

Licensees decommissioning their facilities are required to demonstrate to MDH that their proposed methods will ensure that the decommissioning can be conducted safely and that the facility, at the completion of decommissioning activities, will comply with MDH requirements for license termination. MDH staff overseeing the decommissioning program materials sites should use the policies and procedures to evaluate a licensee's decommissioning actions.

This guidance is not a substitute for regulations, and compliance with it is not required. Methods and solutions different than those in this guidance will be acceptable, if they provide a basis for concluding that the decommissioning actions are in compliance with the MDH rules.

The majority of terminated licensees are those that used and possessed sealed sources or relatively limited amounts of unsealed radioactive material. Due to the amounts, forms, and types of radioactive material used by these licensees, most licensees do not need to submit decommissioning plans or perform complex remedial activities to decommission their facilities in accordance with MDH criteria. However, certain licensees need to submit information regarding either (1) the status of their facilities when they request license termination or (2) the activities that they intend to use to remediate their facilities. The types of information required could range from very simple descriptions of the radiological status of the facilities and the disposition of radioactive material possessed by the licensees to, in the case of licensees who proposed license termination under restricted conditions, very detailed descriptions of institutional controls, dose estimates to potential future critical groups, and arrangements to ensure that adequate financial assurance mechanisms are in place at license termination in the form of a detailed decommissioning plan.

The best approach to decommissioning is to develop detailed descriptions of the types of information needed to evaluate proposed decommissioning activities and to tailor the information needed from the licensees based on the complexity and safety significance of the decommissioning project. This approach is implemented through several interactions between MDH staff and licensees.

Timing of the Decommissioning Process

The decommissioning process begins when the licensee determines that decommissioning of all or a portion of a site is necessary or desirable. MDH staff identifies facilities undergoing decommissioning by the activities performed during the operation of the facilities or the types of licensed material possessed by the licensee. Facilities undergoing decommissioning are evaluated based on the amount of residual radioactivity, the location of that material, and the complexity of the activities needed to decommission the

site. The licensees range from a sealed source facility that has not experienced any leakage to a large facility with contamination that would result in the license being terminated with restrictions on future site use and require an environmental impact statement to support the action.

Once the decision has been made to decommission, the next step is to determine what information the licensee needs to provide to demonstrate site conditions successfully. When MDH staff is informed that a licensee has decided to permanently cease licensed operations, or has not conducted licensed activities for a period greater than 24 months, and must decommission all or part of its facility, MDH staff should contact the licensee and determine if the licensee will need to submit a decommissioning plan to support its request for license termination.

Licensed facilities, areas, and buildings convert from "active" status to "decommissioning" status when one of the following occurs:

- The license expires or is revoked by the MDH.
- The licensee decides to permanently cease operations with licensed material at the entire site or in any separate building or outdoor area that contains residual radioactivity, such that the area is unsuitable for release in accordance with MDH requirements.
- Twenty-four (24) months have elapsed since principal activities have been conducted under the license, or
- No principal activities have been conducted in a separate building or outdoor area for a period of 24 months, and residual radioactivity is present that would preclude its release in accordance with MDH requirements.

Within 60 days of the occurrence of any of the above, the licensee is required to inform MDH of the occurrence in writing. In addition, the licensee is required to (a) begin decommissioning the facility, (b) submit within 12 months a decommissioning plan in accordance with the plan when it is approved by MDH. Unless otherwise approved by MDH, licensees are required to complete decommissioning their facilities within 24 months of initiating decommissioning operations.

The Decommissioning Process

The decommissioning process consists of a series of integrated activities, beginning with the licensee notifying MDH and changing the licensee's program from "active" to "decommissioning" status, and concluding with the termination of the license and release of the site. Depending on several factors, including the type of license, the use of radioactive material at the facility, or past management of radioactive material at the facility, the decommissioning may be either relatively simple and straightforward or complex.

While the steps may vary for different sites, the basic process is the same. The steps in the process are as follows:

- Stop operations, either in a specific area or building or for the entire facility.
- Notify MDH of the decision within 60 days.
- Determine locations and concentrations of remaining radiological contamination.
- If necessary, develop a decommissioning plan that includes all of the following:
 - the current radiological contamination at the site;
 - the criteria for the final condition of the site;
 - the activities to remediate existing contamination that are not currently authorized by the license;
 - procedures to protect workers;
 - decommissioning cost estimates;
 - the final survey method to demonstrate compliance with MDH criteria; and
 - provides the schedule for remediation activities and license termination.
- Clean up contamination, as needed.
- Conduct Final Status Survey to show compliance with dose limits for license termination.
- Request that MDH terminate the license.

Note that it is important for licensees to notify MDH promptly when operations cease. It is also important that the staff meet with the licensee to discuss the decommissioning requirements early in the process.

Safety Evaluation

The staff should review the technical content of the information provided by the licensee to ensure that the licensee used defensible assumptions and models to calculate the potential dose to the average member of the critical group. The staff should also verify that the licensee provided enough information to allow an independent evaluation of the potential dose resulting from the residual radioactivity after license termination and provided reasonable assurance that the decommissioning option will comply with regulations.

Radiological Criteria for Decommissioning

Dose-based requirements for licensees seeking license termination are found in 4731.2100 to 4731.2200. These regulations establish two final states for licensee termination: unrestricted use and restricted use. In addition MDH requires licensees to maintain ALARA doses. This means the licensee must make every reasonable effort to reduce the dose as far below the specified limits as is practical, taking into account the state of technology and economics.

The use of a dose limit allows both the licensee and the regulator to take site-specific information into account in determining acceptable concentrations of residual radioactivity at the site using dose models and exposure scenarios that are as realistic as necessary.

Unrestricted Use

Residual radioactivity, distinguishable from background, results in a calculated dose from all pathways to the average member of the critical group that is not in excess of 0.25 mSv/y (25 mrem/y).

Restricted Use Conditions

The basic requirement for license termination under restricted use conditions is that the licensee provide institutional controls that limit the calculated dose to 0.25 mSv/year (25 mrem/year). Further, the licensee must reduce residual radioactivity so that if these controls fail, the calculated dose would not exceed 1 mSv/year (100 mrem/year). In rare instances, the calculated dose may exceed 1 mSv/y (100 mrem/year), but it may not exceed 5 mSv/year (500 mrem/year). Additional institutional controls would be established to meet regulatory requirements.

To qualify for license termination under restricted conditions, the licensee must meet all of the criteria:

- Demonstrate that further reductions in residual radioactivity would either cause net environmental harm or are technically or economically not feasible.
- Demonstrate provisions for legally enforceable controls to limit dose to 0.25 mSv/year (25 mrem/year).
- Provide financial assurance to allow a third party to control and maintain the site.
- Demonstrate that advice from affected parties on the adequacy of the proposed institutional controls and financial assurance has been obtained and used in developing the decommissioning plan

Alternative Criteria

In the unlikely event that a licensee is not able to reduce residual radioactivity to a level that limits the calculated dose such that it is not in excess of 0.25 mSv/year (25 mrem/year) with restrictions in place, the licensee may request permission from the MDH to use alternate criteria. In doing so, the licensee must demonstrate all of the following:

- The calculated dose from all man-made sources is unlikely to exceed 100 mrem (1 mSv) per year by identifying these sources and the expected dose from each.
- Institutional controls will minimize the dose from the site.
- The licensee has obtained public advice on the proposed institutional controls and financial assurance.

Licenses That Require No Decommissioning Plan

Group I Licenses

Facilities that typically involve licensed material used in a way that would preclude its release into the environment, would not cause the activation of adjacent materials, or would not have contaminated work areas are:

- Licensees who possessed and used only sealed sources, and whose most recent leak test results are current and demonstrate that the source(s) did not leak while in the licensee's possession; or
- Licensees who possessed and used relatively short-lived radioactive material (i.e., $T_{1/2}$ less than or equal to 120 days) in an unsealed form and, within timeliness constraints, the maximum activity authorized under the license has decayed to less than the quantity specified in 4731.2800, and the licensee's survey, performed in accordance with 4731.3085, does not identify any residual levels of radiological contamination greater than decommissioning screening criteria.

Termination of these licenses would not require the licensee to submit a decommissioning plan. The following licensee actions are required:

- Notify MDH.
- Dispose of the licensed material in accordance with MDH requirements, usually by returning the material to the manufacturer.
- For other than sealed sources, perform a radiation survey and submit the results, or demonstrate that the facility, or portion of the facility, meets MDH criteria for unrestricted use.
- For all sealed sources, including those no longer in licensee's possession, provide to MDH results from the most recent leak tests demonstrating there has been no leakage.
- Transfer the decommissioning records, as appropriate, or affirm that they are not required to retain or transfer these records.
- Submit a "Certificate of Disposition of Materials," or equivalent information to MDH. Written confirmation from the recipient that the material has been transferred should be included

Simplified Survey Procedures

The licensee should establish a method to identify individual measurement/sampling points on each surface in the indoor area that was involved in licensed material use. At a minimum, the licensee's termination survey should consist of the following:

- One hundred percent scanning of all surfaces in the area of the facility where licensed material was used or stored, using an appropriate radiation detection instrument (including scan sensitivity);
- Evaluations for total and removable radioactive material at each area exhibiting elevated radiation levels, or at a frequency of one wipe comprising 100 cm² per 300 ft²; and
- Evaluations of radiation levels at one meter above surfaces.

Particular attention should be afforded any drains, air vents, or other fixtures or equipment that may have become contaminated during licensed material use. This is especially significant in situations where renovations have occurred and potentially contaminated areas may be inaccessible under current conditions.

MDH staff should:

- Determine that the facility meets the appropriate criteria.
- Initiate initial processing of the decommissioning action.

- Review, after verifying the disposition of the licensed material, the information submitted by the licensee to demonstrate that its facility is suitable for unrestricted use.
- Review leak test results, verify that the type and number of identified sources are in agreement and the most recent leak test results are current and indicate that the sources did not leak.
- Review licensee's survey, paying particular attention to anomalies such as the use of inappropriate radiation survey and analytical instrumentation, incomplete evaluation of radioactive material use/storage areas, and spurious survey results.
- Contact the licensee if the licensee's if the leak test results are inconclusive with respect to the condition of the sealed sources.

An environmental assessment for termination of the license is not necessary.

Group 2 Licenses

Some facilities may have residual radiological contamination present in building surfaces and soils. However, licensees may be able to demonstrate that their facilities meet the provisions of 4731.2100 ("Radiological Criteria for Unrestricted Use"). Additionally, licensees typically possess historical records of material receipt, use, and disposal, such that quantifying past radiological material possession and use may be developed with a high degree of confidence. Furthermore, these licensees have radiological survey records that characterize the residual radiological contamination levels present within the facilities and at their sites. That is, they are able to demonstrate residual radiological contamination levels without more sophisticated survey procedures (greater than those used for operational surveys) or dose modeling. These licensees do not need to use site-specific parameters or establish site-specific DCGLs in order to demonstrate acceptability for release of their sites.

Activities that may fall this category are:

- The licensee possessed and used only sealed sources, but the most recent leak tests indicate that the sources leaked.
- The licensee used unsealed radioactive material, and the licensee's survey demonstrated that levels of radiological contamination on building surfaces or surface soils are less than decommissioning screening criteria.

These licensees did not have releases into the environment in excess of MDH limits and did not activate adjacent materials. Because levels of persistent contamination of work areas, building surfaces, and limited surface soil contamination may exist, decommissioning efforts differ from those listed above.

Typical licensees in this category are:

- licensees who can demonstrate compliance with 4731.2100 ("Radiological Criteria for Unrestricted Use"); and
- licensees who possess and use only sealed sources that cannot demonstrate current leak-tight integrity.

These licensees decommissioning are not be required to develop a decommissioning plan for the following reasons:

- Decommissioning workers would not be entering areas normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation.
- Procedures would involve techniques applied routinely during cleanup or maintenance operations.
- Procedures would not result in significantly greater airborne concentrations of radioactive materials than are present during operation.
- Procedures would not result in significantly greater releases of radioactive material to the environment than those associated with operation.

Licensees using small quantities of C-14 or H-3 may be decommissioned under may fall into this category depending on the total activity of C-14 or H-3 possessed under the license and the authorized use of the radioactive material.

Although submission of a decommissioning plan is not required for decommissioning, these licensees are required to determine the radiological status of their facility and demonstrate that their facility meets MDH requirements for unrestricted use. This is accomplished by remediating the site as necessary, performing a radiation survey, and conducting dose evaluations.

The following licensee actions are required:

- Notify MDH.
- Dispose of the licensed material in accordance with MDH requirements, usually by returning sealed sources to the manufacturer or disposing of licensed material as outlined in MDH regulations.
- For all sealed sources, including sources no longer in the licensee's possession, provide to MDH results from the most recent leak tests.
- Transfer the decommissioning records discussed, as appropriate, or affirm that they are not required to retain or transfer these records.
- Determine the radiological status of the facility and perform further remediation, if necessary, to meet MDH screening criteria for unrestricted use.
- Demonstrate that the facility, or portion of the facility, meets MDH criteria for unrestricted use.
- Submit a "Certificate of Disposition of Materials," or equivalent information to MDH. Written confirmation from the recipient to confirm that the material has been transferred should be included.

In performing the decommissioning of its facility, the licensee should first identify any areas in the facility that were involved in licensed material use by reviewing facility records and conducting a survey of the licensed material use area. This survey should be similar to the routine contamination surveys conducted under the licensee's radiological safety plan. The licensee should then remediate all surfaces in the areas at the facility that were involved in licensed material use or storage and dispose of all radioactive material and waste as discussed in 4731.2400. If a survey is required to demonstrate that its facility is suitable for unrestricted use, the licensee should design the survey so it is of sufficient scope and quality.

MDH should:

- Determine whether the decommissioning meets the criteria summarized above.
- Initiate initial processing of the decommissioning action
- Upon receipt of the radiation survey from the licensee, perform a "completeness" review to determine whether the radiation survey contains sufficient type and quality of information to begin the in-depth technical review.
- Review the radiation survey to ensure that it adequately demonstrates that the facility is suitable for unrestricted use.
- Ensure that the licensee has transferred the decommissioning records, as appropriate, or has affirmed that they are not required to retain or transfer these records.
- As the final step in terminating the license, notify the licensee by license amendment after MDH has verified the suitability of its facility for unrestricted use.

NUREG – 1757 should be used to determine the appropriate decommissioning procedures for licensees with more complex radiological programs.

Decommissioning Plan Review

If a decommissioning plan is required, licensees are strongly encouraged to meet with MDH prior to the submittal of their plan and at any stage in this process. A decommissioning plan is required if one is specified in the existing license or if new activities or procedures—those not currently authorized in the license—are needed to conduct remediation. The decommissioning plan is processed as follows:

- MDH meets with licensee to determine which items in the Decommissioning Plan Evaluation Checklist in are applicable.

- Licensee submits decommissioning plan for all or part of the facility.
- MDH conducts an acceptance review to decide if the plan is complete:
- MDH determines if there is sufficient information to evaluate the proposed decommissioning alternative:
 - current condition of site;
 - release criteria and important values (e.g., residual concentrations);
 - land use scenario and critical group(s); and
 - final survey plan.
- If the decommissioning plan is not complete, the licensee is informed in writing.
- After acceptance for technical review, MDH conducts a detailed evaluation of the plan from environmental and safety perspectives.
- If the information in the plan is not sufficient for MDH to complete the environment and safety reviews, additional information is requested.
- When the licensee revises the plan; the revised plan is reviewed, as above.
- MDH issues license amendment approving the decommissioning plan.
- Upon approval, the licensee implements the plan.
- MDH should conduct in-process inspections to verify compliance.
- At the completion of remediation, the licensee conducts a final status survey to demonstrate compliance with license termination criteria.
- MDH verifies the survey by one or more of the following:
 - QA/QC reviews;
 - side-by-side or split sampling; and
 - independent, confirmatory surveys.
- If the survey does not demonstrate compliance, additional remediation and/or surveys are required.
- When the survey demonstrates compliance with release criteria, MDH terminates, or modifies the license for partial site release.

More detailed guidance for Decommissioning Plans can be found in NUREG 1757. "*Consolidated NMSS Decommissioning Guidance.*"

INSPECTIONS

The inspector should use *all* the inspection requirements from the licensee's operations that carry over to decommissioning. The inspector should develop an inspection program to observe the adequacy of routine activities that can significantly effect the health and safety of workers and the public and the environment around the licensee's operations.

Some of the most important inspection elements should include:

- security and control of contaminated material
- radiation protection for workers
- radiological waste generation, storage, transportation, and disposal
- effluent releases and environmental monitoring
- management organization and controls
- essential systems and services to support decommissioning

Aside from the inspection activities described above, the inspector should also use other parts of the MDH Inspection Field Notes that are routinely used on typical inspections and which are included in the Inspection Procedures Manual.

Inspection of Key Decommissioning Activities

The inspector should develop an inspection program to observe key decommissioning activities being performed by the licensee. Key activities occur in all phases of the decommissioning process and include

the following for facilities requiring significant decommissioning activities, such as building dismantling, soil removal, and groundwater cleanup:

1. **Inspections Before Dismantling** -- This is the pre-decommissioning activity and decommissioning planning stage after the shutdown of operations and before dismantling and remediation. Essential activities and conditions may include the following:
 - Removal of licensed materials from the facility (if required by license condition)
 - Compliance with decommissioning timeliness requirements
 - Compliance with record keeping requirements for decommissioning
 - Implementation of the licensee's decommissioning organization and approved plans
 - Site characterization
 - Construction of site features to support decommissioning

2. **Inspections During Dismantling and Remediation** -- This is the stage when the site is actively being cleaned-up. Key activities include the following:
 - Decontamination and dismantling of structures
 - Decontamination and remediation of soil, sediment, surface waters, and groundwater
 - Waste management and on-site storage
 - Transportation and off-site disposal of wastes
 - On-site disposal of waste
 - Restoration of the site
 - Inspection activities identified during the review of the licensee's decommissioning plan

3. **Inspections After Remediation** -- Key activities in this stage include the following:
 - Licensee final survey
 - MDH confirmatory survey
 - Site maintenance for restricted use

INSPECTION GUIDANCE

Primary indicators of the licensee's overall radiation safety program include the following:

- Observations of licensee decommissioning activities in progress
- Equipment in use
- Facilities and use areas
- The implementation of specific license conditions
- The implementation of approved decommissioning plans and procedures

Review of licensee records will also contribute to the evaluation of the licensee's program. In reviewing records, look for trends, such as increasing doses or effluent releases. The inspector should randomly examine the following records until he or she is satisfied that the records are being maintained and are complete.

- Surveys
- Waste disposal
- Effluent release
- Receipt and transfer of radioactive materials
- Training
- Use logs
- Air sampling

Other records that are more closely related to health and safety (such as personnel dose-monitoring records and incident reports) should be examined in their entirety.

Many of the inspection activities required during decommissioning are similar to inspection activities conducted at operating facilities. The guidance given in this section, therefore, includes references to other sections of the MDH Inspection Procedures Manual that are applicable to materials decommissioning.

A major part of inspection activities will be related to evaluating the licensee's final survey and performing the MDH confirmatory survey for release of the site under MDH regulations. For facilities that will require a final survey, the inspector should begin this activity early in the decommissioning process. Inspections should start during site characterization to ensure that the site will be remediated consistent with MDH requirements and the licensee's approved decommissioning plan.

- A. Inspection Requirements Applicable From Operations** -- Many inspection activities will follow directly from those used during licensee operations. Review the licensee's decommissioning plan and supporting documents for licensee activities that are similar to those performed during operations. Then develop the inspection program to carry over to decommissioning the applicable inspection activities used during operations. Tailor the inspection program to meet licensee-specific conditions.

Some of the requirements that carry over to decommissioning of major licensed activities that require dismantling and remediation are described below:

- 1. Security and Control of Contaminated Material** -- Physical security of the site should be maintained, as necessary, for licensees undergoing decommissioning. Assess licensee security and control of contaminated material throughout the decommissioning process.

Verify that contaminated material is secured and controlled in accordance with 4731.2290, and posted in accordance with 4731.2310. Containers of contaminated materials should be labeled in accordance with 4731.2330. Contaminated materials in buildings should be secured and controlled by locking buildings, rooms, or areas of use. Contaminated materials in outside areas should be secured and controlled by fencing or soil covers. Eight-foot cyclone-type fencing is generally acceptable. Other fencing types, such as barbed wire fences, may be sufficient in low-population, rural areas. Three to four-foot thick soil covers over contaminated soil, slag, or tailing piles are also generally acceptable. Access to buildings, rooms, or outdoor areas having contaminated materials should be limited only to individuals having the licensee's or responsible party's permission for access.

- 2. Radiation Protection for Workers** -- Inspect the licensee's approved health physics procedures, as implemented in the field, to determine that the approved program is being implemented and to establish the degree of potential for exposures. Tailor subsequent inspections to concentrate on identified areas of risk.
- 3. Effluent Releases/Environmental Monitoring** -- Verify that licensee off-site monitoring has been established, and that the following are being met: sampling locations, frequencies, and applicable limits on levels and concentrations of radioactivity. The potential for off-site release may be lower during decommissioning than during operations, but inspections for off-site releases should continue to be performed during decommissioning. Evaluate the need for installing MDH air samplers or TLDs to verify licensee exposure data.
- 4. Management Organization and Controls** -- Review licensee implementation of the following:
 - Approved plans and programs
 - Regulatory requirements

- License conditions for the management and control of decommissioning of the facility
 - The organization in place for the decommissioning project
 - Designation and qualification of the radiation safety officer
 - The QA program and annual review
 - Records control and storage
 - Internal review and audit
 - Safety committee
 - Procedure control for cleanup operations
 - Decommissioning procedures to be implemented
5. **Essential Systems and Services to Support Decommissioning** -- Verify, through observations in the facility and review of licensee records, that the support systems needed for clean-up and dismantling efforts are functional. These systems include the following:
- Electrical power
 - HVAC systems
 - Water supply
 - In-plant communications systems
 - Liquid and solid contaminated waste systems
 - Sewage treatment plant
 - In-plant lighting
6. **Documentation of Inspections** -- Fully document all visits to and inspections of each site undergoing decommissioning. Radioactive materials at the site present potential health and safety hazards until the site is remediated and the license is terminated.
- B. **Inspection of Key Decommissioning Activities** -- Identify all significant or key licensee activities of a particular site undergoing decommissioning, including before, during, and after remediation. Develop an inspection program to focus on activities where potential health and safety problems may occur, especially accounting for high-risk activities. The frequency of inspections should be based on both the inspection frequency used during operations and the particular set of decommissioning activities to be performed by the licensee. Major decommissioning activities are given below. Complete the checklist of key decommissioning activities in Appendix A as part of your inspection report.
1. **Inspections Before Dismantling**
- a. **Pre-decommissioning Conditions** - Verify that all requirements preceding actual facility remediation are in place, including the following:
- Licensed material used during operations has been removed from the site (if required by license condition).
 - Specific license conditions pertaining to the pre-decommissioning stage have been put in place by the licensee.
 - Essential systems and services to support decommissioning activities are in place.
- b. **Timeliness Requirements** - Verify that decommissioning schedules are consistent with decommissioning timeliness requirements in 4731.0600 or that the licensee has submitted an alternative decommissioning schedule for MDH approval.
- c. **Record keeping** - Verify that record keeping for information important to the safe and effective decommissioning of the facility is consistent with the record keeping requirements in 4731.3080 subpart 7.

- d. **Financial Assurance** - Verify that the financial assurance requirements, including financial instruments, are being maintained in accordance with 4731.3080.
- e. **Site Characterization** - Verify that site characterization activities are being conducted according to all applicable radiation protection procedures. Conduct at least one inspection with the licensee while the licensee is performing characterization. Where possible and warranted, conduct side-by-side measurements with the licensee and take independent measurements for comparison with licensee results. Under special circumstances, the inspector should split samples with the licensee during site characterization where necessary to confirm the adequacy and validity of licensee measurements. Evaluate how the results of the planned site characterization will lead to successful site remediation and the licensee's final survey.
- f. **Construction of Site Features to Support Decommissioning** - Verify that the construction of features to support decommissioning is consonant with MDH approved decommissioning plans (if required) and industry standard. Verify that they do not compromise health and safety considerations of workers and the public. Consider such items as:
 - new loading docks
 - roads
 - rail spurs
 - drainage ditches
- g. **Other license conditions and Approved Plans** - Verify that licensee activities conform to specific license conditions and licensee programs and procedures. Audit licensee performance on high-risk activities, as needed.

2. Inspections During Dismantling and Remediation

- a. **Decontamination and Dismantling of Structures** -- Verify, by field observation and record reviews, that licensee activities to decontaminate and dismantle structures are being performed consonant with MDH-approved plans (if required) and industry standards. Structures should include:
 - buildings
 - above and below ground utilities
 - treatment lagoons
 - other man-made structures used or effected by the licensee
- b. **Decontamination and Remediation of Soil, Sediment, Surface Waters, and Groundwater** -- Verify, by field observation and licensee record reviews, that decontamination and remediation of soil, sediment, surface waters, and groundwater are being performed consonant with MDH-approved plans and industry standards. Inspect licensee activities on-site and inspect off-site in areas that may have been contaminated by licensee operations.
- c. **Radioactive Waste Management** -- Confirm that the licensee is maintaining adequate waste management controls related to the release and disposal of liquid, airborne, and solid wastes. Radioactive wastes generated during decommissioning must be disposed of in a manner approved by MDH. Some of the radioactive wastes generated during decommissioning include:
 - building materials
 - process and facility equipment
 - concrete rubble
 - filters

- trash
 - sludge
 - material from the waste treatment lagoons
 - soil and vegetation
 - groundwater
 - surface water
- d. **Low-Level Radioactive Waste Storage** -- During decommissioning, large quantities of low-level waste may be temporarily stored on-site before shipment to a licensed disposal facility. Confirm that the waste is stored in accordance with license conditions.
 - e. **Transportation of Wastes** -- Review the specifics of the licensee's packaging and transportation activities to determine which elements will be inspected. It would be prudent to discuss the regulations and the inspection procedure early with the licensee. For facilities that have large amounts of contaminated materials to ship off-site, transportation of material may continue throughout the decommissioning process. Contaminated materials for off-site disposal must be packaged in accordance with DOT regulations published in 40 CFR Parts 173-178.
 - f. **Restoration of Site** -- Verify that the licensee has restored the site to meet license conditions and specifications in MDH-approved plans.
 - g. **Activities Identified during Review of Decommissioning Plan** -- Plan to inspect any other significant activities or conditions that may have been specified in the licensee's decommissioning plan or license.
3. **Inspections After Remediation**
 - a. **Certification of Waste Disposal** - Verify that the licensee has submitted information regarding the disposition of all licensed material according to 641-39.4(33).
 - b. **Licensee Final Survey Program** - There are many elements of the licensee's final survey program that need to be inspected during the licensee's final survey program to confirm the acceptability of the licensee's survey results. These elements should also be inspected after submittal of the licensee's final survey report. See Appendix B, "Final Survey Program Inspection Field Notes," for detailed guidance on inspecting licensee final surveys, including conducting independent MDH confirmatory surveys where necessary.
 - c. **Site Maintenance for Restricted Use** - If the site is to be released for restricted use, verify that all conditions limiting use of the site conform to license conditions, and that MDH-approved plans and are in place and functional.

LICENSE TERMINATION

As the final step in decommissioning, the licensee shall certify the disposition of all licensed material, including accumulated wastes, and conduct a radiation survey of the premises where the licensed activities were carried out. The licensee must either submit a report of the results of this survey or demonstrate that the premises are suitable for release in some other manner. This information must be submitted within the 24-month period after notification or approval of the decommissioning plan, if required, unless an alternative schedule has been approved.

In addition to maintaining records important to facility decommissioning, licensees are also required to assure that such records are not lost at license transfer or termination. When a license is transferred, records pertinent to decommissioning must be transferred to the new licensee. Before MDH consents to a license transfer, the licensee is responsible for assuring that the appropriate records have been transferred in accordance with MDH regulations. Before MDH terminates a license, a licensee should transfer all decommissioning records to MDH. MDH staff is responsible for verifying that all of these records were received, before termination of the license.

MDH Record Retention Requirements

The decommissioning process can generate a considerable amount of records, particularly in conducting a final status survey. This section provides general record retention guidance for MDH staff responsible for project management of decommissioning nuclear facilities. The guidance is not meant to capture the totality of MDH staff requirements for record retention and document control; therefore, this section provides an overview of the records that, at a minimum, the MDH reviewer should retain.

The MDH reviewer should ensure, at a minimum, that the following records are retained for decommissioned nuclear facilities:

- all license applications, amendment requests, and renewal requests;
- complete license, including all amendments;
- any licensee request for license termination and all supporting documentation, including plans for completion of decommissioning;
- forms dealing with disposition of material and/or letters from licensees dealing with disposition and status of material;
- any documents dealing with the disposition of waste or other material or residual contamination on the site, including records of onsite burials;
- all documents related to financial assurance for decommissioning, including decommissioning funding plans, certifications of financial assurance for decommissioning, related cost estimates, and records of funding methods;
- records of spills and other unusual occurrences involving the spread of contamination and around the facility, equipment, or site;
- as-built drawings and modifications of structures and equipment in restricted areas where radioactive materials were used or stored and locations of possible inaccessible contamination;
- any additional documents that refer to decommissioning, decontamination, or termination of the license, including interim or partial decommissioning of specific facilities at any time during the history of licensed operations;
- any enforcement documents related to decommissioning and decontamination activities;
- a copy of the final status survey plan and decommissioning plan, if required;
- the final survey status report from the licensee, which should include the following:
 - summary measurements for each survey unit in the final status survey,
 - elevated area ("hot-spot") evaluations,
 - survey instrument description and calibration records,
 - records of data reductions and comparisons with guidelines, and
 - the results of any investigations to determine the cause of the failure to meet the decommissioning criteria;
- results of site inspections, meeting reports, and correspondence;
- results of closeout surveys and inspections, including split sample collection and evaluation; and
- any other records provided by the licensee at termination in accordance with the preceding section of this volume.

Transmittal of License Termination

Licenses, including expired licenses, will be terminated by written notice to the licensee when the MDH determines that (a) the radioactive material has been properly disposed of, (b) a reasonable effort has been made to eliminate residual radioactive contamination, and (c) either a radiation survey has been

performed, or other information is submitted by the licensee which demonstrates that the premises are suitable for release in accordance with MDH requirements.

After a comprehensive review of all decommissioning efforts and documentation, a license amendment to terminate the license must be prepared. The amendment, which has the same approval process as any other licensing action, should reference documents essential to the decommissioning process.

APPENDIX A

MINNESOTA DEPARTMENT OF HEALTH
DECOMMISSIONING INSPECTION - FIELD NOTES REPORT

Inspection Report Number: _____ License Number: _____

Licensee (Name and Address):

Licensee Contact: _____

Telephone Number: _____

Last Amendment Number: _____

Date of Amendment: _____

Priority: _____

Category: _____

Date of last inspection: _____

Date of this inspection: _____

Type of inspection:

Announced

Unannounced

Routine

Special

Initial Decommissioning

Re-inspection of Decommissioning

Summary of findings and action:

No Violation, clear Form 516 or letter issued

Violation(s), Form 516 or letter issued

Action on previous Violation(s)

Next inspection date: _____

Inspector: _____
(Signature)

(Date)

Approved: _____
(Signature)

(Date)

Field notes are to be used by the inspector to assist with the performance of the inspection. Note that all areas indicated in the field notes are not required to be addressed during each inspection. However, for those areas not covered during the inspection, the notation "not reviewed" should be made in each section where applicable. Additionally, all areas covered during the inspection should be documented in sufficient detail to describe what activities and/or records the inspector observed. The Decommissioning Procedure for Materials Licensees should be supplemented with the inspection procedures for operating facilities provided in the MDH Inspection Procedures Manual.

1. SUMMARY OF DECOMMISSIONING STATUS

- A. Cessation of licensee operations verified? Yes No
- B. Licensed materials for operations removed from the site? Yes No
- C. Decommissioning plan required? Yes No
- D. Decontamination and dismantling activities required for release of the site? Yes No
- E. Licensee final survey required? Yes No
- F. MDH confirmatory survey required? Yes No
- G. Criteria for release of site finalized? Yes No
- H. Compliance with decommissioning timeliness verified? Yes No
- I. Inspection coordinated with MDH and other parties? Yes No

2. INSPECTION AREAS COVERED UNDER THIS INSPECTION

- A. Site security Yes No
- B. Radiation protection for workers Yes No
- C. Radiological waste generation, storage, transportation, and disposal Yes No
- D. Effluent releases and environmental monitoring Yes No
- E. Management organization and controls Yes No
- F. Essential systems and services to support decommissioning Yes No
- G. Specific license conditions for decommissioning Yes No
- H. Record keeping for decommissioning Yes No
- I. Financial assurance Yes No
- J. Other inspection areas: Yes No

Observations and Remarks:

3. INSPECTION OF KEY DECOMMISSIONING ACTIVITIES

A. Licensee activities inspected before dismantling:

- 1. Off-site removal of licensed material used in operations (if required by license condition) Yes No
- 2. Site characterization Yes No
- 3. Construction of site features to support decommissioning Yes No
- 4. Decommissioning timeliness Yes No
- 5. Other licensee activities: Yes No

Observations and Remarks:

B. Licensee activities inspected during decontamination, dismantling, and site remediation:

- 1. Decontamination and dismantling of buildings Yes No
- 2. Decontamination and dismantling of other structures, such as utilities and roads Yes No
- 3. Decontamination and removal of vegetation, soil, and sediment Yes No
- 4. Decontamination and removal of surface water Yes No
- 5. Decontamination and removal of groundwater Yes No
- 6. Management and on-site storage of radiological waste Yes No
- 7. Transportation of radiological waste to disposal facility Yes No
- 8. On-site disposal of radiological waste from decommissioning site restoration Yes No
- 10. Specific license conditions Yes No
- 11. Activities identified during decommissioning plan review Yes No
- 12. Other licensee activities: Yes No

Observations and Remarks:

C. Activities inspected after completion of site remediation:

- 1. Certification of waste disposal Yes No
- 2. Licensee final survey Yes No
- 3. MDH confirmatory survey Yes No
- 4. Site maintenance (if required for restricted use) Yes No
- 5. Other licensee activities: Yes No

Observations and Remarks:

4. VIOLATIONS, AND OTHER ISSUES

Briefly state (1) the requirements and (2) how and when the licensee violated the requirement. For non-cited violations, indicate why the violation was not cited.

**APPENDIX B
FINAL SURVEY PROGRAM INSPECTION FIELD NOTES**

1. STATUS OF LICENSEE FINAL SURVEY

- A. Final survey report submitted to MDH and approved by license reviewer
- B. Previous inspections of licensee final survey program conducted
- C. Final survey report not submitted, licensee final survey in process
- D. Final survey plan submitted and approved by MDH license reviewer

2. INSPECTION LICENSEE FINAL SURVEYS

Notes:

- (1) For facilities where an approved decommissioning plan is required, the inspector should inspect the commitments in the decommissioning plan and the licensee's final survey plan (which would have been approved during license review). For facilities where a decommissioning plan is not required, inspections should be made using sound industry practices and MDH regulations and guidance.
- (2) Inspection of a licensee's final survey includes independent confirmatory surveys by the inspector or MDH contractor.
- (3) For facilities that require a significant decommissioning effort, all the inspection areas listed below should be inspected while the licensee's final survey program is in progress. For small, licensed facilities that do not require a significant decommissioning effort, only some of the inspection areas below may apply. It may not be practical to inspect these areas until after the licensee's final survey is completed; the final survey report has been submitted; and MDH has reviewed the report.
- (4) The inspector should identify which inspection areas listed below are performed during each inspection.

- | | | |
|--|------------------------------|-----------------------------|
| A. All potential contaminants identified | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| B. Potentially contaminated locations identified, and site areas properly classified as effected or unaffected | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| C. Reclassification of site areas based on survey results | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| D. Release criteria specified and appropriate for site | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| E. Determination of background reaction levels | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| F. Survey instrumentation and calibration | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| G. Survey design appropriate for site, including scanning and sampling for fixed and removable contamination | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| H. Survey procedures and techniques appropriate for site | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| I. Methods and procedures for analyzing samples | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| J. Management organization and controls in place for the final survey | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| K. Qualifications of field survey technicians | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| L. Interpretation of survey results | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| M. Licensee documentation, record keeping, and sample chain of custody | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| N. Independent confirmatory surveys performed by inspector or MDH contractor | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| O. Final survey quality assurance/quality control | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| P. Other: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Observations and Remarks:

✓

✓

✓

Enclosure 6

MINNESOTA DEPARTMENT OF HEALTH



GUIDANCE ABOUT CHANGES OF CONTROL AND BANKRUPTCY INVOLVING RADIOACTIVE MATERIAL

The logo is circular with a stylized animal head (possibly a moose or bear) in the center. The text "Radioactive Materials Group" is written along the top arc, "Minnesota Department of Health" along the bottom arc, and "RAM" in the center.	<p>Radiation Control Unit Asbestos, Lead, Indoor Air & Radiation Section Division of Environmental Health Minnesota Department of Health</p>
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January 2005

Guidance About Changes of Control and Bankruptcy Involving Radioactive Material

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Management Responsibility

MDH recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. MDH believes that consistent compliance with its rules provides reasonable assurance that licensed activities will be conducted safely. MDH also believes that effective management will result in increased safety and compliance. "Management" refers to the processes for conducting and controlling the 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.

It is not the intent of MDH to interfere with the business decisions of licensees. MDH's focus is on the health and safety aspects, not on the financial intricacies, of the proposed transaction. MDH will require licensees to submit only such business information as is necessary to permit the commissioner to determine whether a change of control will take place. MDH is required by statute to ensure that public health and safety is not compromised and to be confident that when a licensee's program is undergoing a change of control, all efforts are made to ensure that the performance of the radiation safety aspects of the program is not degraded.

It is the licensee's obligation to keep the license current. Should a change of control or a bankruptcy action result in a change to the licensee's program, the licensee must amend the license to reflect that change. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 30 days before the expiration date.

Persons applying for an initial license should update and modify their pending applications if they are undergoing a change of control or bankruptcy. Generally, licensee or applicant management has a responsibility for all aspects of the radiation safety program including, but not limited to, the following:

- Radiation safety, security and control of radioactive materials, and compliance with rules;
- Completeness and accuracy of the radiation safety records and all information provided to MDH;
- Knowledge about the contents of the license and application;
- Meticulous compliance with current MDH rules 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 the public and workers are protected from radiation hazards and that meticulous compliance with rules is maintained;
- Selection and assignment of a qualified individual to serve as the Radiation Safety Officer (RSO) for licensed activities;
- Prohibition against discrimination of employees engaged in protected activities;
- Commitment to provide information to employees regarding the employee protection and deliberate misconduct provisions;
- Obtaining MDH's prior written consent before changing control of the license;
- Notifying the appropriate MDH in writing, immediately following filing of petition for voluntary or involuntary bankruptcy.

As discussed above, licensee's management has specific responsibilities with regard to changes of control or bankruptcy. Control of licensed activities cannot be changed without prior written consent from MDH. In addition, licensees must notify MDH immediately upon filing for bankruptcy. Licensees are expected to notify MDH of a proposed change of control in a timely manner, allowing MDH enough time to carry out its statutory mandate of ensuring that licensed materials are adequately safeguarded and that public health and safety is protected.

Licensee management is strongly cautioned that cases where change of control, such as change of ownership, occur without MDH's prior written consent will be considered to be violations of MDH rules. Failure to receive the required MDH approval prior to a change of control of licensed activities may be considered to be a Severity Level III violation warranting escalated enforcement action. Escalated enforcement action may include the issuance of orders, the imposition of monetary civil penalties, or the modification, suspension, or revocation of the license against one or both of the parties involved.

MDH recognizes that information regarding a proposed change of control may be extremely sensitive and that the public release of such information may have an adverse impact on the licensee, as well as other persons potentially involved in the change of control. Licensees, or other persons wishing to protect sensitive information regarding proposed changes of control, should request that sensitive information be protected

Definition of "Control"

Control over licensed activities can be construed as the authority to decide when and how that license (licensed material and/or activities) will be used. A change of ownership may be an example of a change of control, depending on whether the authority over the license has transferred from one person to another. The transfer of stock or other assets is not necessarily a change of control. The central issue is whether the authority over the license has changed.

In all cases, determining whether a change of control has taken place is the MDH's responsibility. Whenever a change in ownership or control may occur, the licensee must so inform MDH.

Changes of ownership or control resulting from legal changes such as mergers, buy-outs, or majority stock transfers require prior consent. In some cases, internal management adjustments and actual changes of control may be difficult to distinguish. Therefore, it is imperative that licensees notify the commissioner of not only actual, but also suspected changes of control so that the agency may make a determination. In general, no MDH license for materials may be transferred, assigned, or disposed of unless MDH gives its prior consent in writing.

In cases where a transferee proposes to purchase a licensed operation, and the transferor continues in business as a separate entity without the license, the transferee must submit notification to the commissioner that reflects both the change in identity of the licensee and any other pertinent changes in the operation. The transferee can always apply for a new license by providing a complete application, for which it may use the transferor's docketed documents as a basis. The transferor is also obligated to notify MDH of the proposed change of control; furthermore, if MDH issues a new license, the transferor must request termination of its license in a separate proceeding.

Description of Transaction

The required description includes, but is not limited to, any transfer of stocks or assets, or mergers. This description will enable MDH to differentiate between name changes and changes of control, when necessary.

The licensee needs to include the new name of the licensed organization or state that there has been no name change. If appropriate, the licensee should include the new licensee contact and telephone number(s) to facilitate communications. See Attachment I for a complete list of information that should be provided.

Changes of Personnel

Changes in personnel that need to be documented include individuals having control over licensed activities. This may include, in some cases, officers of a corporation or other

management individuals who are listed on the license or referred to in the supporting documentation. This would also include any changes in personnel such as the Radiation Safety Officer, authorized users, or any other persons identified on the license or in the license application as having responsibility for radiation safety or authorized to use licensed material. Changes of personnel, as used in this report, do not include notifications regarding new authorized users.

As with any change in personnel listed on a license, pertinent information with regard to training, experience and qualifications applicable to the type of use will be required. The licensee should include applicable information concerning the qualifications, training, and responsibilities of any new individuals not previously listed on the current license or referred to in the supporting documentation. The specific information required will be found in the respective program-specific guidance for the type of operation in which a particular licensee is engaged, or it may be obtained by contacting MDH

Changes of Location, Equipment and/or Procedures

Provide a detailed description of any changes in the licensees' location(s) of use, facility description, equipment or procedures (i.e., changes in operating or emergency procedures) that would normally require a license amendment. Include any changes in organization that may not be identified in "Changes in Personnel."

The location must be described if the licensee is adding a place of use. A description of the contaminated condition of the facility, if any, is required if the licensee is removing a place of use. Any changes in the facilities where licensed material will be used or stored must be described. If equipment used in licensed activities is required to be described by license condition or regulation, or if information regarding this equipment is requested by appropriate licensing guidance, a description of all equipment changes should be provided. Changes in procedures, including routine operating and emergency procedures, must be reviewed to ensure that they are adequate for the types and uses described on the license. Changes in personnel that would require a license amendment, even without the change of ownership, must be submitted as requested by appropriate licensing guidance¹.

Surveillance Records

Typical surveillance requirements include leak tests, physical inventories, ventilation measurements, and conductivity tests. Surveillance requirements specific to the types of use may be found in the license, the rules, the appropriate regulatory guide published by MDH. The licensee must review any and all pertinent surveillance records to determine if they are current and ensure that they will be current at the time of transfer, or include an explanation if this is not to be the case. The licensee may perform the surveillance as authorized by its license. The licensee may also choose to have surveillance items performed by another party such as a contractor or the transferee, as authorized by the license, and if agreeable to both parties. It should be noted that the requirement for surveillance items in the rules or the license is not waived due to a change of control.

Decommissioning and Related Records Transfers

Licensees are required to maintain certain records important to safe and effective decommissioning, including:

- Evaluations concerning waste disposal by release as effluents (either air or water);
- Release to sewers;

¹ As previously stated, this guidance is not program-specific; therefore, any changes in the licensed program should be prepared and reviewed using the program-specific guidance published by MDH specific to the type of use.

- Incineration;
- Disposal of liquid scintillation medium and animal tissue as if it were not radioactive; and
- Disposal by methods specifically allowed through the license.

Subsequent to the transfer, the new licensee will become responsible for maintaining these records until the license is terminated. If licensed activities will continue at the same location, MDH requires confirmation that all the records of the aforementioned evaluations have been transferred to the new licensee. If the license will be terminated, these records must be forwarded to MDH.

No change of control or ownership or license termination will be authorized until all required records have been transferred to the new licensee or to MDH, as appropriate.

These rules require that before licenses are transferred or assigned, all records be transferred to the new licensee. The rules require that all records of measurements and calculations used to evaluate the release of radioactive effluents to the environment and records of certain disposals be transferred to the new licensee prior to the license being transferred or assigned, unless the existing licensee was only authorized to possess and use unsealed material with a half life of less than 65 days or material in a sealed source form.

The current licensee must document ambient radiation levels and the presence or absence of contamination. The documentation must include, as appropriate, the method and sensitivity of the evaluation. If contamination is present, the documentation should describe how and when *decontamination would occur or indicate that the timing and means of decontamination and/or decommissioning have not yet been determined.*

The current licensee must also discuss how the parties agree to assume responsibility for the decontamination and decommissioning of licensed facilities. Those licensees required to provide *evidence of adequate resources to fund any required decommissioning must describe the effect that the change of control will have on financial assurance for decommissioning.* As necessary, documents describing financial assurance must be amended to reflect the change in control. This documentation may refer to decontamination plans, including any required financial assurance arrangements of the transferor, that were previously submitted in support of a decommissioning funding plan.

Transferee's Commitment to Abide by the Transferor's Commitments

The transferee may agree to abide by all constraints, conditions, requirements, representations, and commitments previously made to MDH by the transferor. This would include, but not be limited to, information submitted in support of license amendments (including documents itemized in the tie-down condition of the license) and the maintenance of decommissioning records. Alternatively, the transferee may submit a description of its own program to ensure compliance with the license and rules. This would also include completion of corrective actions for open inspection items and enforcement actions and, if required, implementation of site decontamination and decommissioning activities.

With regard to open inspection items and/or enforcement actions, the transferee should confirm, in writing, that it is knowledgeable of and accepts full responsibility for open inspection items and/or any resulting enforcement actions. Alternatively, the transferee may propose other measures for meeting these requirements, or the transferor may provide a commitment to close out all such actions with MDH before license transfer.

Bankruptcy

A licensee's financial condition could affect its ability to control licensed material. Therefore, MDH must be notified so it can assure that appropriate measures to protect the public health and safety have been or will be taken. These measures include:

- Maintaining security of licensed material and contaminated facilities;
- Assuring that licensed material is transferred only to properly authorized MDH, NRC, or other Agreement State licensees;
- Assuring that properly trained and experienced personnel are retained to implement appropriate radiation safety measures.

MDH may share pertinent information with other involved entities (e.g., trustees) so that health and safety issues can be resolved before bankruptcy actions are completed.

There are different types of bankruptcies described in Title 11 of the United States Code. The following discussion outlines the bankruptcy types that may involve MDH.

- Chapter 7 is used primarily by individuals and by businesses that wish to free themselves from debt simply and inexpensively. The debtor may enter Chapter 7 bankruptcy voluntarily or be forced to enter it involuntarily by creditors. The creditors of a debtor, as well as the debtor, have the right under Chapter 11 to convert to a case under Chapter 7.
- Chapter 9 addresses the adjustments of debts of a municipality.
- Chapter 11 is generally used to reorganize a business and allows the debtor to continue its business operations by a plan of reorganization in the hopes it can be returned to a viable state². As under Chapter 7, the debtor may enter Chapter 11 bankruptcy either voluntarily or involuntarily.
- Chapter 12 is designed to give special relief to a family farmer with regular income.
- Chapter 13 is used as a rehabilitation vehicle for an individual with regular income whose debts do not exceed specified amounts, and is typically used to budget some of the debtor's future earnings under a plan through which creditors are paid in whole or in part.

The filing of a petition in bankruptcy court triggers the automatic stay provision in Section 362(a) of the United States Bankruptcy Code. This provision stays legal actions against the debtor or against the property of the bankruptcy estate, except in certain limited circumstances that include public health, safety, and environmental obligations.

MDH will review and act on bankruptcy notifications when they occur. MDH procedures for reviewing bankruptcy actions ensure that bankruptcy cases are managed in a fully coordinated manner with all involved MDH staff. Key provisions of these procedures may be summarized as follows:

- MDH will promptly verify any bankruptcy information obtained and ensure that the licensee submits the required written notification.
- MDH will promptly verify the adequacy of control of all licensed material possessed by the licensee and, if appropriate, conduct a special inspection.
- MDH will promptly, by telephone or fax, inform:
 - The licensee or trustee, if appointed, that the bankruptcy filing does not relieve the licensee of its obligation to comply with all MDH requirements. Inspections and other MDH regulatory actions will continue after the bankruptcy filing.
 - The Bankruptcy Court that any trustee or receiver in bankruptcy retains the debtor licensee's legal obligations, including public health, safety, and environmental obligations, and must comply with MDH rules and license conditions.

Licensees who have filed for bankruptcy remain responsible for all regulatory requirements. Any person possessing property contaminated with MDH licensed materials, transferred by the

² A reorganized entity emerging from Chapter 11 bankruptcy must receive written MDH approval prior to its assumption of control over licensed activities.

licensee before completion of decommissioning, must comply with all applicable MDH requirements, including obtaining or maintaining an MDH license and completing decommissioning. Furthermore, MDH licenses remain in full effect, even beyond their stated expiration date, until terminated in writing by MDH.

Following the informal contact, MDH staff will provide written notification to the Bankruptcy Court, any trustee or receiver in bankruptcy, or owner of property contaminated by the licensee's activities, regarding the licensee's obligations to control the site, to decontaminate and decommission the site, and to comply with applicable MDH requirements and the conditions of the license.

MDH will assess the current public health and safety situation at the licensee's facility and any impacts that bankruptcy could have on licensed operations. MDH will make an in-house hazard assessment of the extent of contamination and health risks posed by any contamination present. This assessment will be used to:

- Support any petition to the bankruptcy court for priority disbursements of the bankruptcy estate;
- Determine if action is necessary to secure the site or to take any other action required;
- Decide if additional information is needed from the licensee;
- Issue orders to the licensee or other persons;
- Prepare a list of issues to be addressed;
- Make recommendations as to the need to draw on financial assurance instruments that may have been submitted by the licensee;
- Determine the need for additional legal action by MDH that would require the debtor to decontaminate and decommission the site;
- Determine whether there are MDH administrative proceedings or other litigation pending or anticipated (i.e., civil penalties, fee collection) that may affect MDH staff actions in the bankruptcy proceeding.

Licensees requesting amendment of a current license and persons applying for a new materials license as the result of a change of control or bankruptcy should do the following submit an amendment using the appropriate MDH regulatory guide.

Termination of Activities

Persons holding a radioactive materials license must notify MDH in writing within 60 days of the expiration of its license of any of the following:

- A decision to cease licensed activities permanently at the entire site (regardless of contamination levels);
- A decision to cease licensed activities permanently in any separate building or outdoor area if they contain residual radioactivity making them unsuitable for release according to MDH requirements;
- No principal activities having been conducted at the entire site under the license for a period of 24 months;
- No principal activities having been conducted for a period of 24 months in any separate building or outdoor area if they contain residual radioactivity making them unsuitable for release according to MDH requirements.

Prior to a license termination, the licensee must:

- Submit a decommissioning plan, if required.
- Conduct decommissioning as required.
- Submit, to MDH a completed "Certificate of Disposition of Materials" (or equivalent information) and a demonstration that the premises are suitable for release for unrestricted use (e.g., results of final survey).
- Send the records important to decommissioning to the MDH.

- If licensed activities are transferred, assigned, or otherwise disposed of, transfer records important to decommissioning to the new licensee.

The licensee must determine whether residual radioactivity is present. A licensee's determination that a facility is not contaminated is subject to verification by MDH inspection.

ATTACHMENT I

INFORMATION NEEDED FOR TRANSFER OF CONTROL APPLICATION

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

1. The new name of the licensed organization. If there is no change, the licensee should so state.
2. The new licensee contact and telephone number(s) to facilitate communications.
3. Any changes in personnel having control over licensed activities (e.g., officers of a corporation) and any changes in personnel named in the license such as radiation safety officer, authorized users, or any other persons identified in previous license applications as responsible for radiation safety or use of licensed material. The licensee should include information concerning the qualifications, training, and responsibilities of new individuals.
4. An indication of whether the transferor will remain in non-licensed business without the license.
5. A complete, clear description of the transaction, including any transfer of stocks or assets, mergers, etc., so that legal counsel is able, when necessary, to differentiate between name changes and transferring control.
6. A complete description of any planned changes in organization, location, facility, equipment, or procedures (i.e., changes in operating or emergency procedures).
7. A detailed description of any changes in the use, possession, location, or storage of the licensed materials.
8. Any changes in organization, location, facilities, equipment, procedures, or personnel that would require a license amendment even without transferring control.
9. An indication of whether all surveillance items and records (e.g., calibrations, leak tests, surveys, inventories, and accountability requirements) will be current at the time of transfer. Provide a description of the status of all surveillance requirements and records.
10. Confirmation that all records concerning the safe and effective decommissioning of the facility; public dose; and waste disposal by release to sewers, incineration, radioactive material spills, and on-site burials, have been transferred to the new licensee, if licensed activities will continue at the same location, or to the MDH for license terminations.
11. A description of the status of the facility. Specifically, the presence or absence of contamination should be documented. If contamination is present, will decontamination occur before transfer? If not, does the successor company agree to assume full liability for the decontamination of the facility or site?
12. A description of any decontamination plans, including financial assurance arrangements of the transferee. Include information about how the transferee and transferor propose to divide the transferor's assets and responsibility for any cleanup needed at the time of transfer.
13. Confirmation that the transferee agrees to abide by all commitments and representations previously made to MDH by the transferor. These include, but are not limited to maintaining decommissioning records, implementing decontamination activities and decommissioning of the site, and completing corrective actions for open inspection items and enforcement actions.

With regard to contamination of facilities and equipment, the transferee should confirm, in writing, that it accepts full liability for the site, and should provide evidence of

adequate resources to fund decommissioning. Alternatively, the transferor should provide a commitment to decontaminate the facility before transferring control.

With regard to open inspection items, etc., the transferee should confirm, in writing, that it accepts full responsibility for open inspection items and/or any resulting enforcement actions; or the transferee should propose alternative measures for meeting the requirements; or the transferor should provide a commitment to close out all such actions with MDH before license transfer.

14. Documentation that the transferor and transferee agree to transferring control of the licensed material and activity, and the conditions of transfer; and the transferee is made aware of all open inspection items and its responsibility for possible resulting enforcement actions.
15. A commitment by the transferee to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing license. If not, the transferee must provide a description of its program to ensure compliance with the license and regulations.

Enclosure 7

MINNESOTA DEPARTMENT OF HEALTH



REGULATORY GUIDE FOR CALIBRATING RADIATION SURVEY AND MONITORING INSTRUMENTS

	<p>Radiation Control Unit Asbestos, Lead, Indoor Air & Radiation Section Division of Environmental Health Minnesota Department of Health</p>
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January 2005

**REGULATORY GUIDE FOR CALIBRATING
RADIATION SURVEY AND MONITORING INSTRUMENTS**

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MDH REGULATORY GUIDE FOR CALIBRATING RADIATION SURVEY AND MONITORING INSTRUMENTS

PURPOSE

This guide identifies the information needed by the MDH to evaluate an application for a "Calibrating Radiation Survey and Monitoring Instruments" license and to describe the radioactive material regulations.

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

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. Appendix A provides an outline for a licensee's ALARA program.

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.

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 propriety 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
Snelling Office Park
1645 Energy Park Drive, Suite 300
St. Paul, MN 55108-2970

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 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) At Which 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.

If radiography equipment will be stored and/or used at a field station, give the specific address of each field station.

If radiography 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

Describe the radioactive material by isotope, chemical and/or physical form, and activity, in millicuries or microcuries. Possession limits requested should cover the total anticipated inventory, including stored materials (but not decay-in-storage), and should be based on the applicant's needs and abilities for safe handling.

If the use of sealed or plated sources is being considered, specify the isotope, manufacturer, and model number of each sealed source or plated source. You should consult with your proposed supplier for information to be sure that your sources and devices conform to the sealed source and device designations registered with the US Nuclear Regulatory Commission (NRC) or an Agreement State.

Also list any survey meter or calibration source not exempted under 4731.3040.

Example:

Cesium-137	Sealed rod source XYZ Inc. Model 10	Not to exceed 250 microcuries/source
Cobalt-60	Sealed source XYZ, Inc. Model 351	Not to exceed 20 millicuries/source

NOTE: It is the practice of MDH to provide flexibility in the number of identical sealed source/device combinations you may want to possess at any one time. Therefore, it is not necessary for you to specify the number of identical source/device combinations. You will need to amend your license before you obtain any source other than those listed in Item 6.

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

Specify the purpose for which each type of source listed in Item 6 will be used. If a source is contained in a device, you need to specify the manufacturer and model number of each device (calibrator). For example:

1. To be used for low-range (.01 to 2 mr/hr) calibration of portable survey meters.
2. To be used for medium (1 to 500 m/R/hr) and low-range calibration of survey meters.
3. To be used in a Nuclides, Inc. Model 100 shielded calibrator for the high-range (>1 R/hr) calibration of radiation measuring meters and devices.
4. To be used for calibration of medium- and low-range portable survey meters.

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

Submit a description or chart of the overall organization pertaining to the radioactive materials program that specifies the name and title of each individual who has responsibility for management or supervision of the 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 RSO¹. The duties of the RSO are outlined in Appendix B.

Radiation Safety Officers (RSOs) must have adequate training and experience. The licensee should provide the name of the proposed RSO and information demonstrating that the proposed RSO is qualified by training and experience.

Additional training is required for RSOs of programs that perform non-routine operations. This includes repairs involving or potentially affecting components related to the radiological safety of the calibration equipment (e.g., the source, source holder, source drive mechanism, shutter, shutter control, or shielding)

¹ It is important to notify MDH, as soon as possible, of changes in the designation of the RSO.

and any other activities during which personnel could receive radiation doses exceeding MDH limits (e.g., installation, initial radiation survey, or relocation).

As an alternative, the licensee should state that:

- a. Before obtaining licensed materials, the proposed RSO will have successfully completed training. Provide an outline of the course content or describe the training.
- b. The new RSO will receive training within a specified time after being appointed. Provide an outline of the course content or describe the training.

Authorized Users

An authorized user (AU) is a person whose training and experience meet MDH criteria and who uses or directly supervises the use of licensed material. Authorized users must ensure the proper use, security, and routine maintenance of devices containing licensed material. Therefore, they must attend the formal training and instruction or receive equivalent training and instruction.

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

Before allowing an individual to perform survey instrument calibrations, the RSO will ensure that the AU has sufficient training and experience to perform independent survey instrument calibrations. Classroom training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

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

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

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

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. A model training program is included in Appendix C.

Licensee personnel who work in the vicinity of a device but do not use equipment containing sources (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 device, it is prudent for them to work under the supervision and in the physical presence of an AU or to be provided some basic radiation safety training. Such ancillary staff should be informed of the nature and location of the device and the meaning of the radiation symbol. They should be instructed not to touch the equipment 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 equipment, 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 mSv) in a year (occupationally exposed workers) and ancillary personnel.

Item 9: Facilities and Equipment

Calibration equipment normally has engineering features to protect the user from unnecessary radiation exposure. 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 a sketch or description of the proposed location of each device containing radioactive equipment within your facility. Note the following:

1. The scale. Use the same scale (preferably 1/4 inch = 1 foot) for all drawings.
2. The direction of north.
3. Room numbers and principal use of each room or area (for example, in vitro, hot lab, office, file, fresh materials storage, radioactive waste storage, hallway).
4. Any shielding available, auxiliary shielding and description of use.
5. Additional safety equipment (for example, fume hoods, L-blocks, or fixed area monitors) including manufacturer and model or serial numbers where appropriate.
6. Restricted areas within calibration labs.
7. Location of any beam calibrators and calibration range facilities, including a description of the range facility.
8. Means of minimizing scatter.
9. Location of any self-contained calibration facilities.
10. Source storage facilities.
11. Source handling equipment.
12. Means of preventing entry into high radiation areas.
13. Means of preventing unauthorized use or removal of licensed material.

Sketches and descriptions should show the relationship of material use areas to any adjoining unrestricted areas (e.g., offices, rest rooms, or cafeterias).

In addition, the following precautions should be observed:

- To reduce doses received by individuals not calibrating instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present.
- Individuals conducting calibrations will wear assigned dosimetry. Additional information on monitoring is in Appendix D.
- Individuals conducting calibrations will use a calibrated and operable survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Item 10: Radiation Safety Program

Surveys

Each licensee must make surveys as necessary to evaluate the extent of radiation hazards that may be present during the possession and use of licensed material. List the radiation detection (survey or monitoring) instruments that you will have available for your own use in manipulating the requested sealed sources and in performing your calibration services. Your list must specify both the number of instruments and the following information for each instrument:

- (1) type of instrument
- (2) type of radiation detected
- (3) sensitivity range
- (4) specific use
- (5) calibration interval

Survey instruments should be calibrated at least annually and following servicing.

The following is an example:

Portable thin-window GM survey meter
2 units are available
Radiation detected is beta and gamma
Sensitivity range is 0-500 mR/hr
Used for survey and monitoring

Operating and Emergency Procedures

Each individual who will perform calibration on customers' radiation survey and monitoring instruments should have a set of operating and emergency procedures. You should state in your application that personnel will be provided with operating and emergency procedures. Submit a copy of the procedures listed below.

1. Systematic instructions for performing calibrations of survey and monitoring instruments (including pocket dosimeters, if applicable). For acceptable criteria, see Appendix F as a guide. You should also consider "Radiation Protection Instrumentation Test and Calibration," ANSI N323-1978. Copies are available from the American National Standards Institute, 1430 Broadway, New York, NY 10018.
2. A program for routine area survey. See Appendix J for guidance.
3. The procedures for use of shielding and remote handling equipment when handling hard (high energy) beta- or gamma-emitting materials.
4. Special precautions to be used when handling large sealed calibration sources.
5. Your program for routine personnel monitoring. See Appendix D for guidance.
6. Emergency procedures to be followed in case of fires, equipment malfunction, etc., including notification procedures to the MDH.
7. Leak test procedures.
8. A copy or description of the certificate of instrument calibration that you will provide to customers with each calibrated instrument as part of your documentation of the elements of the radiation protection program and instrument calibration procedure. See Appendix G for guidance.

Annual Audit of Radiation Safety Program

Annually licensees must review the content and implementation of their radiation protection programs at intervals not to exceed 12 months to ensure the following:

- Compliance with MDH and DOT regulations (as applicable), and the terms and conditions of the license.
- Occupational doses and doses to members of the public are ALARA.
- Records of audits and other reviews of program content are maintained for three years.

Currently the MDH's emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of calibration equipment users to determine if, for example, Operating and Emergency Procedures are available and are being followed, etc. It is essential that once identified, problems are corrected comprehensively and in a timely manner.

MDH will review the licensee's audit results and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. If the licensee identifies violations and these steps are taken, the MDH will normally exercise discretion and may elect not to cite a violation. MDH's goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies.

Licensees must maintain records of audits and other reviews of program content and implementation for three years from the date of the record. These audit records should include the following:

- date of audit
- name of person(s) who conducted the audit
- persons contacted by the auditor(s)
- areas audited
- audit findings
- corrective actions
- follow-up

The applicant's program for reviewing the content and implementation of its radiation protection program will be examined during inspections, and should not be submitted in the license application.

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 six-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 E.1 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 E or submit your own procedures.

Inventories

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

Appendices

In addition to Appendix A, review each of the following appendices carefully. Commit to the specific appendix, submit your own procedures using the appendix as a guide, or indicate "not applicable."

Appendix B	Duties and Responsibilities of the RSO
Appendix C	Model Training Program
Appendix D	Personnel Exposure Monitoring Program
Appendix E	Leak Testing Sealed Sources
Appendix F	Calibrating Survey Instruments
Appendix G	Certificate of Instrument Calibration
Appendix H	Guidance for Ordering and Receiving Radioactive Material
Appendix I	Safely Opening Packages Containing Radioactive Material
Appendix J	Area Surveys
Appendix K	Waste Disposal
Appendix L	Calibration Equipment Required
Appendix M	Maintenance of Quality of Calibration

Item 11: Waste Management

Submit your procedures for waste disposal. See Appendix K. Be sure to include a procedure for each material listed in Item 6.

Item 12: License Fees

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. NRC 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 LICENSE

A licensee must receive a license amendment before changing the scope of the program, such as changing the Radiation Safety Officer or adding to the staff of authorized users. An application for an amendment must be signed by the delegated person and must include the appropriate amendment fee.

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

RENEWAL OF 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 MDH has taken the final action on the application. 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 regulations 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 MDH reviews each application to ensure that users of radioactive material are capable of complying with MDH's regulations. This guide provides one set of methods approved by the 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
MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURE ALARA

You may use the text as it appears here, stating on your application, "We will establish and implement the model ALARA program published in Appendix A to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments." Submit the signed commitment in Section 6 of this appendix.

If you prefer, you may develop your own ALARA program for MDH review. If you do so, you should consider for inclusion all the features in the model. State on your application, "We have developed an ALARA program for your review that is appended as Appendix A," and submit your program along with the signed commitment in Section 6 of this appendix.

ALARA PROGRAM

1. Management Commitment

- a. We, the management of this facility, are committed to the program described herein for keeping individual and collective doses as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC), and a Radiation Safety Officer (RSO).
- b. We will perform a formal annual review of the radiation safety program, including ALARA considerations. This will include reviews of operating procedures and past dose records, inspections, etc., and consultations with the radiation safety staff or outside consultants.
- c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, is considered unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been recommended but not implemented, and we will be prepared to describe the reasons for not implementing the changes.
- d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. Review of Proposed Users and Uses

- a. The RSC will thoroughly review the qualifications of each applicant. To ensure that the applicant will be able to maintain ALARA, the review should include the types and quantities of materials used and methods of use.
- b. When considering the use of radioactive material, the RSC will review efforts of the applicant to maintain exposure ALARA.
- c. The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.
- d. The RSC will delegate authority for enforcement of an ALARA program to the RSO.

- e. The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.
- f. The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
- g. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table A-1 are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded.

Table A-1 – Investigational Levels

	Investigational Levels (mrem per year)	
	Level I	Level II
Total Dose Equivalent: whole body; head and trunk; active blood-forming organs; or gonads	500	1500
Skin of whole body, extremities	5,000	15,000
Lens of eye	1,500	4,500

- h. The RSC will evaluate its institution's overall efforts for maintaining doses ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. RADIATION SAFETY OFFICER COMMITMENT

- a. Annual and Quarterly Review
 - The RSC, along with the RSO, will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific methods of use may be conducted on a more frequent basis.
 - The RSC, along with the RSO, will review at least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA in accordance with the provisions of Section 5 of this appendix.
- b. Education Responsibilities for ALARA Program
 - The RSO will schedule briefing and educational sessions to ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy. They should also be informed that management and the RSO are committed to implementing the ALARA concept.
- c. Cooperative Efforts for Development of ALARA Procedures
 - Radiation workers will be given opportunities to participate in formulating the procedures that they will be required to follow.
 - The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

- The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those programs.
 - Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.
- d. Reviewing Instances of Deviation from Good ALARA Practices:
- The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will implement changes in the program to maintain doses ALARA.
- e. The RSO is also responsible for assisting the RSC in the performance of its duties and serving as its secretary.

4. AUTHORIZED USERS COMMITMENT

- a. New methods of Use Involving Potential Radiation Doses
- The authorized user will consult the RSO and/or RSC during the planning stage before using radioactive materials for new uses.
 - The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.
- b. Authorized User's Responsibility to Supervised Individuals
- The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.
 - The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in health physics practices and in maintaining exposures ALARA.

5. ESTABLISHMENT OF INVESTIGATIONAL LEVELS IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION DOSES¹

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table A-1. These levels apply to the exposure of individual workers.

The RSO will review and record on MDH Form, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report) results of personnel monitoring not less than once in any calendar quarter. The following actions will be taken at the investigational levels as stated in Table A-1:

- a. Personnel dose less than Investigational Level I

¹ MDH emphasizes that the investigational levels in this program are not new dose limits but serve as check points above which the results are considered sufficiently important to justify investigations.

- Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's dose is less than Table A-1 values for the investigational Level I.
- b. Personnel doses equal to or greater than Investigational Level I but less than Investigational Level II
- The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter 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 Committee. However, the Committee will review each such dose in comparison with those of others performing similar tasks as an index of ALARA program quality. This review will be recorded in the Committee minutes.
- c. Personnel dose equal to or greater than Investigational Level II
- The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation and any actions taken will be presented to the management following completion of the investigation. The report should include a copy of the individual's "Occupational Exposure Record for Monitoring Period" and "Cumulative Occupational Exposure History," or its equivalent.
- d. Re-establishment of investigational levels to levels above those listed in Table I
- In cases where a worker's or a group of workers' doses need to exceed an investigation level, a new, higher investigational level may be established with good ALARA practices. Justification for new investigational level will be documented.

The RSC will review the justification for and must approve all investigational level revisions.

6. SIGNATURE OF CERTIFYING OFFICIAL¹ Sign and submit as part of Appendix A.

I hereby certify that this institution has implemented the ALARA Program as set forth above.

Signature

Name (Print or type)

Title

¹ The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

APPENDIX B DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER (RSO)

You may use the following model procedure to make commitments for your RSO. If you follow the model procedure, you may state on your application, "We will establish and implement the model procedure for RSO published in Appendix B to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

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 the Minnesota rules. State on your application, "We have developed an RSO procedure for your review that is appended as Appendix B," and submit your procedure.

MODEL PROCEDURE

The RSO is responsible for implementing the radiation safety program and ensuring that radiation safety activities are performed in accordance with approved procedures and regulatory requirements. The RSO's duties and responsibilities include but are not limited to the following:

1. Ensure that licensed material possessed by the licensee is limited to the types, quantities and forms listed on the license.
2. Ensure that individuals using the material are properly trained, are designated by the RSO, have received refresher training at least annually, and are informed of all changes in regulatory requirements and deficiencies identified during annual audits or MDH inspections.
3. Ensure that personnel monitoring devices are used as required, and reports of personnel exposure are reviewed in a timely manner.
4. Ensure that material is properly secured against unauthorized removal at all times when material is not in use.
5. Ensure that proper authorities are notified in case of accident, damage, fire, or theft.
6. Ensure that audits are performed at least annually to make certain that
 - a. The licensee is abiding by MDH and DOT regulations and the terms and conditions of the license (e.g., periodic leak tests, inventories, use limited to trained, approved users).
 - b. The licensee's radiation protection program content and implementation achieve occupational doses and doses to members of the public that are ALARA.
 - c. The licensee maintains required records with all required information (e.g., records of personnel exposure; receipt, transfer, and disposal of licensed material; user training) sufficient to comply with MDH requirements.
7. Ensure that results of audits, identification of deficiencies, and recommendations for change are documented, provided to management for review, and maintained for at least three years. Ensure prompt action is taken to correct deficiencies.
8. Ensure that audit results and corrective actions are communicated to all personnel who use licensed material (regardless of their location or the license under which they normally work).

9. Ensure that all incidents, accidents, and personnel exposure to radiation more than ALARA levels or 4731 limits are investigated and reported to MDH within the required time limits.
10. Ensure that licensed material is transported in accordance with all applicable DOT requirements.
11. Ensure that licensed material is disposed of properly.
12. Ensure that the facility has up-to-date copies of MDH regulations, completes a review of new or amended MDH regulations, and revises licensee procedures to comply with MDH regulations.
13. Ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to MDH in the licensing process.

APPENDIX C
MODEL TRAINING PROGRAM
In addition to 4731.1020

The following guidance may be used to develop a training program. If you use the frequency and subject listings to develop your training program, you may state on your application, "We will establish and implement the model training program published as Appendix C to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments." You may use methods of training that best suit your facility's needs, such as lectures, video presentations, or demonstrations.

If you prefer, you may develop your own training program for review. If you do so, you should consider for inclusion all the features in the model program and carefully review the requirements of 4731.1020. State on your application, "We have developed a training program for your review that is appended as Appendix C." Be sure to include the groups of workers, the method of their training, and the frequency of training.

It may not be assumed that safety instructions have been adequately covered by prior occupational training, board certification, etc. Site-specific training should be provided for all workers. Ancillary personnel (e.g., clerical, housekeeping, security) whose duties may require them to work near radioactive material (whether escorted or not) need to be informed about radiation hazards and appropriate precautions. A training program that provides necessary instruction should be written and implemented.

MODEL PROGRAM

Personnel to be instructed:

1. All workers that might receive an occupational dose.
2. Ancillary personnel (e.g. clerical, housekeeping, security) whose duties may require them to work in the vicinity of radioactive material.

Frequency of instruction:

1. Before assuming duties with, or in the vicinity of, radioactive materials.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or the terms of the license.

Instruction for individuals will include the following subjects in addition to 4731.1020:

1. Applicable regulations and license conditions.
2. Licensee's in-house work rules.
3. Locations where the licensees have posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 4731.1010.

Training will also include a question and answer period. Records will be kept with information regarding the date of the program, subjects covered, and attendees.

**APPENDIX D
MODEL 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 D to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

If you prefer, you may develop your own program for review. If you do, you should consider for inclusion all the features in the model program and carefully review the requirements of 4731.2020. State on your application, "We have developed an exposure monitoring program for your review that is appended as Appendix D," and submit your monitoring program.

If personnel monitoring will not be used, you should submit calculations or documentation from radiation surveys that demonstrate that it is unlikely that any individual will receive a dose equal to or greater than that indicated in 4731.2020.

MODEL PROGRAM FOR EXTERNAL EXPOSURE

1. The RSO will promptly review all exposure records to look for workers or groups of workers whose exposure is unexpectedly high or low. This procedure does not apply to backup monitor records, for example, pocket ionization chambers, when the monitor of record is a film badge, thermoluminescent dosimeter (TLD), or optically stimulated dosimeter (OSD).
2. All individuals who are occupationally exposed to ionizing radiation on a regular basis will be issued a film badge, TLD, or OSD whole body monitor that will be processed by a contract service on a (specify time period) basis.
3. All individuals who, on a regular basis, handle radioactive material that emits ionizing radiation will be issued a film or TLD finger monitor that will be processed by a contract service on a (specify time period) basis.
4. All individuals who are exposed to radiation on an occasional basis such as secretarial personnel and service personnel who deliver packages will not normally be issued exposure monitors.
5. Submit the name, address, and license number of the company who will process the personnel monitoring as part of this procedure.
6. Monitoring devices should be stored in a cool, dry place away from possibility of accidental exposure.
7. Working conditions shall not cause excessive radiation exposure of personnel. Personnel shielding, remote instrument reading and positioning facilities, automatic source handling mechanisms, and other mechanical or remote operations will be used.

APPENDIX E LEAK TESTING SEALED SOURCES

You may use the following model procedure to leak test sealed sources. If you or a contractor follow the model procedure you may state on your application, "We will establish and implement the model procedure for leak testing sealed sources published in Appendix E to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

You may provide leak test analysis as a service. If you wish to analyze leak tests for other licensees, you should indicate in your application that you will be doing so. You may use the model procedure to analyze test samples. If you follow the model procedure, you may state on your application, "We will establish and implement the model procedure for leak testing sealed sources published in Appendix E to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

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 (E.1 and/or E.2)," and submit your leak test procedure.

E.1 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, you should also check for radon leakage. Submerging the source in a vial of fine-grained charcoal or cotton for a day can do this. 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.

E.2 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 (185 Bq) for beta or gamma emitting radionuclides. For alpha emitting radionuclides, select an instrument that is sufficiently sensitive to detect 0.001 microcuries (37 Bq). 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 sodium-iodide crystal with a ratemeter or scaler may be appropriate. Dose calibrators used in nuclear medicine are not sufficiently sensitive. For alpha emitting radionuclides, a zinc-sulfide scintillation detector with a ratemeter or scaler is appropriate.

2. To estimate the detection efficiency of the analyzer used to assay the wipe samples, assay a certified check source that has the same isotope as the sealed source. 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 for beta or gamma emitters or 0.001 microcuries for alpha emitters, 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. Wipes of alpha emitting radionuclides should be dry and the exposed, single layer of the wipe material should face the detector.
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 for beta or gamma emitting radionuclides or 0.001 microcuries for alpha emitting radionuclides, notify the RSO. The source must be withdrawn from use to be repaired or disposed 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 records for three years.

APPENDIX F CALIBRATING SURVEY INSTRUMENTS

You may use the following guidance to calibrate survey instruments. If you follow all the guidance, you may state on your application, "We will establish and implement the model procedure for calibrating survey instruments published in Appendix F to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

If your procedure does not follow the guidance in the model, 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 the Minnesota rules. State on your application, "We have developed a survey instrument calibration procedure for your review that is appended as Appendix F," and append your survey instrument calibration procedure.

Radiation survey meters should be calibrated with a radioactive source. Electronic calibrations alone are not acceptable. Survey meters must be calibrated at least annually and after servicing. (Battery changes are not considered "servicing.")

PRE-CALIBRATION

The following conditions should be established before exposing the instrument to a source for adjustment and calibration:

1. The instrument should be free of significant radioactive contamination.
2. The meter shall be adjusted to zero or the point specified by the manufacturer using the adjustment or adjustments provided.
3. The batteries or power supply should comply with the instrument manufacturer's specification.
4. The instrument shall be turned on and allowed to warm up for the period specified by the manufacturer.
5. Electronic adjustments such as high voltage should be set, as applicable, to the manufacturer's specifications.
6. Geotropism should be known for orientation of the instrument in the three mutually perpendicular planes, and this effect should be taken into account during calibration and performance testing.
7. The performance of any internal sampling time base in digital readout instruments should be verified as being within the manufacturer's specifications.

MODEL PROCEDURE FOR PRIMARY CALIBRATION

1. The source must be approximately a point source.
2. Either the apparent source activity or the exposure rate at a given distance must be traceable by documented measurements to a standard certified within 5 percent accuracy by the National Bureau of Standards.

3. A source that has approximately the same photon energy as the environment in which the calibrated device will be employed should be used for the calibration.
4. The source should be of sufficient strength to give an exposure rate of about 30 mr/hr at 100 cm. Minimum activities of typical sources are 85 millicuries of Cesium-137 or 21 millicuries of Cobalt-60.
5. The inverse square law and the radioactive decay law must be used to correct for change in exposure rate due to changes in distance or source decay.
6. A record must be made of each survey meter calibration.
7. A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than ten percent. A correction chart or graph must be conspicuously attached to the instrument if the difference is greater than ten percent. Any instrument with an exposure rate that differs from the calculated exposure rate by more than 20 percent must be repaired and cannot be considered calibrated.
8. Three kinds of scales are frequently used on survey meters:
 - a. Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be separated by at least 50 percent of scale rating.
 - b. Meters that have a multi-decade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be separated by at least 50 percent of the decade.
 - c. Meters that have an automatically ranging digital display device for indicating rates must be calibrated at no less than one point on each decade and at no less than two points on one of the decades. Those points should be separated by at least 50 percent of the decade.
9. Readings above 1,000 mr/hr need not be calibrated. However, such scales should be checked for operation and approximately correct response.
10. At the time of calibration, the apparent exposure rate from a built-in or owner-supplied check source must be determined and recorded.
11. The report of a survey meter calibration should indicate the procedure used and the data obtained and should be retained for three years. The description of the calibration will include the following:
 - a. The owner or user of the instrument.
 - b. A description of the instrument that includes
 - manufacturer
 - model number
 - serial number
 - type of detector
 -
 - c. A description of the calibration source, including exposure rate at a specified distance on a specified date, and the calibration procedure.
 - d. For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument.

- e. The reading indicated with the instrument in the "battery check" mode (if available on the instrument).
 - f. The angle between the radiation flux field and the detector. For external cylindrical GM or ionization-type detectors, this will usually be parallel or perpendicular indicating photons traveling either parallel or perpendicular to the central axis of the detector. For instruments with internal detectors, this should be the angle between the flux field and a specified surface of the instrument.
 - g. For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure.
 - h. The apparent exposure rate from the check source.
 - i. The name of the person who performed the calibration and the date on which the calibration was performed.
12. The following information will be attached to the instrument as a calibration sticker or tag:
- a. The proper deflection in the battery check mode (unless this is clearly indicated on the instrument).
 - b. The apparent exposure rate from the check source.
 - c. The name of the person who performed the calibration and the date on which the calibration was performed.
 - d. For each scale or decade, one of the following *as appropriate*:
 - (1) The average correction factor;
 - (2) A graph or graphs from which the correction factor for each scale or decade may be deduced; or
 - (3) An indication that the scale was checked for function but not calibrated or an indication that the scale was inoperative;
13. To check reproducibility, the instrument should be exposed to a radiation field three or more times under identical conditions. The readings obtained should normally not deviate from the mean value by more than ± 10 percent.
14. The response of an instrument may vary as a function of such parameters as energy, temperature, pressure, humidity, and source/detector geometry. Primary calibration should be accomplished with known values of these parameters and under the conditions specified by the manufacturer. Any of these parameters may be fixed to the condition in which the instrument is to be used routinely, and notation will be made of these values.
15. Readout Scale and Linearity Calibration and Adjustment:
- a. Linear Readout Instruments
 - (1) Linear instruments usually have a scale selection switch. If controls are provided for each scale, adjustment of each shall be made according to the manufacturer's specifications or at the midpoint of each scale. If only one control is provided, adjustment shall be made
 - at the point specified by the manufacturer,

- near the midpoint of the middle scale, or
 - near the midpoint of a scale that is particularly important to the user's requirements.
 -
- (2) After adjustment, calibration shall be checked near the ends of each scale (approximately 20 percent and 80 percent of full scale). After an adjustment has been completed, instrument readings shall be within ± 10 percent of known radiation values at these two points. However, readings between 10 and 20 percent are acceptable if a calibration chart or graph is prepared and attached to the instrument.
- b. Logarithmic readout instruments
- (1) These instruments commonly have a single readout scale spanning several decades with two or more adjustments. The instrument should be adjusted for each scale according to the manufacturer's specifications, or, alternatively, at points of particular importance to the user.
- (2) As a minimum, calibration shall be performed at one point near the midpoint of each decade after adjustment. Instrument readings shall be within ± 10 percent of known radiation values at these points. Readings between 10 and 20 percent are acceptable if a calibration chart or graph is prepared and attached to the instrument.
- c. Digital readout instruments
- These may have manual scale switching (auto ranging) or no scale switching. For instruments with either manual or automatic scale switching, the calibration shall be performed according to 15.a. above. For instruments without scale switching, the calibration shall be performed as in 15.b. above.

MODEL PROCEDURES FOR SPECIAL CONDITIONS

1. If the instrument is to be used under conditions that vary significantly from those for which the instrument is designed, the instrument should be adjusted, calibrated, and used only for the special conditions. (Examples of such conditions are radiation energy, temperature and pressure, and source/detector geometry). When an instrument is calibrated for special conditions, an identification label shall be attached, in addition to any required calibration labels, to indicate its restriction to the special use. If the instrument is also to be used within its design limits, the adjustments made during primary calibration shall remain the same and instrument readings for the special conditions shall be corrected using correction factors obtained from appropriate tables or graphs. Only one parameter should be varied at a time during calibration for the special conditions, but the interrelationships of the variables should be known.
2. Radiation Energy
 - a. Calibration shall be performed with a standard source or source-providing radiation fields similar to those in which the instrument will be used. Where instruments will be used in radiation fields of widely differing energies, the response of the instrument at several energies over the energy range shall be determined.
 - b. The response of the instrument to various energies of radiation shall be
 - (1) plotted as a function of energy, or otherwise called out;
 - (2) normalized to the response to a specific energy obtained during primary calibration; and
 - (3) provided with the instrument.

This type of graph is commonly called an energy dependence or spectral sensitivity curve.

3. Temperature, Pressure, and Humidity

a. Instruments to be used outside the manufacturer's recommended temperature range or at temperatures that differ by more than 30 degrees from the calibration temperature shall be calibrated over the temperature range at which they will be used. Care should be taken to ensure that instruments are not exposed to temperatures that will damage the detector or electronic components.

b. If the manufacturer has not stated operating limits for humidity or atmospheric pressures, the instruments shall be calibrated at the approximate humidity or pressure expected to be encountered in use. Care should be taken to ensure that an instrument is not damaged by exceeding its pressure or humidity limits.

4. Detector Directional Dependence

If an instrument is to be used in a detector orientation relative to the source that is different from that used during primary calibration, correction factors should be developed.

DISCRIMINATION AGAINST UNWANTED RADIATION

If adjustments or changes are made which might alter the instrument response to unwanted ionizing and non-ionizing radiation, the discrimination against unwanted radiation should be determined for all unwanted radiation that may be encountered.

PERIODIC PERFORMANCE TEST

To assure proper operation of the instrument between calibrations, the instrument shall be tested with the check source during operation and before each intermittent use.

Reference readings shall be obtained on each instrument when exposed to a check source in a constant and reproducible manner at the time of, or promptly after, primary calibration. If at any time the instrument response to the check source differs from the reference reading by more than ± 20 percent, the instrument shall be returned to the calibration facility for calibration or for maintenance, repair, and re-calibration, as required. Reference readings should be obtained for one point on each scale or decade normally used. The check source should accompany the instrument if it is specific to that instrument.

PRIMARY CALIBRATION FREQUENCY

All instruments shall receive a pre-calibration inspection and the primary calibration prior to first use. Primary calibration will be required at least annually even when the performance test requirements outlined above are met. Where instruments are subjected to extreme operational conditions, hard usage, or corrosive environments, calibration should be scheduled more frequently.

Re-calibration shall be scheduled after any maintenance or adjustment of any kind has been performed on the instrument. For this requirement, battery change is not normally considered maintenance.

CALIBRATION FREQUENCY FOR SPECIAL CONDITIONS

Calibration for special conditions need be performed only once unless

- (1) the instrument is modified or physically altered,
- (2) the special conditions are changed, or
- (3) the primary calibration is altered, providing that the conditions above are met.

PERFORMANCE TEST FREQUENCY

A performance check shall be made prior to each use, during intermittent use conditions, and several times a day during continuous use.

NOTE: One-word reminders or symbols that are explained on the Survey Meter Calibration Report may be used on the calibration sticker.

APPENDIX G CERTIFICATE OF INSTRUMENT CALIBRATION

The following guidance may be used to develop a procedure for the certificate of instrument calibration to be given to the customer with each calibrated instrument. If you use this procedure, you may state on your application, "We will establish and implement the model procedure for instrument calibration certificates as published in Appendix G to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

If you prefer, you may develop your own procedures for review. If you do so, you should consider for inclusion all the feature in the model procedure. State on your application, "We have developed a procedure that is appended as Appendix G," and submit your procedures.

MODEL PROCEDURE

Certificates to be issued to the customer with a calibrated instrument will include the following information:

1. The customer's name, address, and person to be contacted.
2. Identification of the instrument by manufacturer, type, and model and serial number.
3. Calibration data, such as instrument readings at a point on a given scale.
4. Any specific comments on the calibration or calibration data.
5. Identification of the calibration source or sources used in calibrating nuclide and exposure rates at specified distances (include calibration accuracy).
6. Identification of the individual performing the calibration.
7. The date of the calibration.
8. Energy correction factors, where required.
9. Unusual or special use conditions or limitations.
10. Date that primary calibration is again required.
11. Special condition identification label, if applicable. See special condition model procedures in Appendix F.

APPENDIX H
GUIDANCE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL
In addition to 4731.2350

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 published in Appendix H to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

If your procedure does not follow all the guidance in the model, you may develop your own procedure for review. If you do so, you should include 4731.2350. State on your application, "We have developed a procedure for ordering and receiving radioactive material that is appended as Appendix H," and submit your procedure.

MODEL GUIDANCE

1. The Radiation Safety Officer (RSO) or a designee must 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 the authorized user or department, isotope, chemical form, activity, and 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.
4. For deliveries during off-duty hours, the RSO shall instruct security personnel or other designated persons to accept delivery of radioactive packages in accordance with procedures outlined in the sample memorandum below.

SAMPLE MEMORANDUM

MEMO TO: Chief of Security

FROM: Radiation Safety Officer

SUBJECT: Receipt of Packages Containing Radioactive Material

The security guard on duty shall accept delivery of packages containing radioactive material that arrives during other than normal working hours. Packages should be placed on a cart or wheelchair and taken immediately to the Radioactive Materials Department, Room _____. Unlock the door, place the package on top of the counter, and re-lock the door.

If the package appears damaged or leaking, you should immediately contact one of the individuals identified below. Ask the carrier to remain at the hospital until it can be determined that the driver and the delivery vehicle are not contaminated.

If you have any questions concerning this memorandum, please call our hospital Radiation Safety Officer,

_____, at _____
Name Home Telephone

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

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 that was published in Appendix I to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

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 I," and submit your procedure. The response should address the requirements of 4731.2350.

MODEL PROCEDURE

1. All shipping packages received and known to contain radioactive material must be monitored for radiation levels and radioactive surface contamination in accordance with 4731.2350.
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 one (1) meter and at the package surface. If it is more than 10 millirem per hour at three (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 one (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 ²
All other alpha-emitting radionuclides	2.2 dpm/cm ²
 - 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) 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 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 J 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 was published in Appendix J to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

You may develop your own procedure for review. State on your application, "We have developed survey procedures for your review that are appended as Appendix J" and submit your survey procedures.

MODEL PROCEDURE

Surveys will be repeated when quantity or type of radioactive material changes or changes occur in containment systems or methods of use.

AMBIENT DOSE RATE SURVEYS

1. Survey Areas: restricted areas

- a. In areas 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. Survey areas: unrestricted

Quarterly surveys should be completed in areas

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

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

REMOVABLE CONTAMINATION SURVEYS

1. Survey Areas: unrestricted

In any area where the potential for spreading contamination is likely to occur, (in cafeterias and snack bars, or on furniture and equipment), survey at least quarterly. Random wipe testing of floors alone is acceptable for most unrestricted areas. If such surveys reveal that radioactive contamination is being transferred out of restricted areas, immediate corrective action should be

taken to eliminate such transfers. Surveys that are more frequent should be conducted until a trend of negative results is again established.

2. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 2000 dpm/100 cm² of removable contamination (200 dpm/100 cm² for isotopes of iodine). You must use a radioactive source with a known amount of activity to convert sample measurements (usually in counts per minute to disintegrations per minute).
3. Immediately notify the RSO if you find levels that exceed the established action levels. See Table J-1 below for guidance in establishing your action levels.

RECORDS

1. Records must include the information in required for normal package receipt as well as actions taken in the case of excessive dose rates or contamination and follow-up survey information.
2. The RSO will review and initial the record at least monthly and promptly in those cases in which action levels were exceeded.

Table J-1

RECOMMENDED ACTION LEVELS IN DPM/100 CM² FOR SURFACE CONTAMINATION		
	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, In-111, I-123, I-125, I-131, Yb-169, Au-198	Cr-51, Co-57, Ga-67, Tc-99^m, Hg-197, Tl-201
1. Unrestricted areas, personal clothing	200	2,000
2. Restricted areas, protective clothing used only in restricted areas, skin	2,000	20,000

APPENDIX K WASTE DISPOSAL

The following general guidance and procedure may be used for disposal of radioactive waste. If you follow all the general guidance and procedures, you may state on your application, "We will establish and implement the general guidance and model procedures for waste disposal published in Appendix K to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the general guidance and models, and carefully review requirements for waste disposal. State on your application, "We have developed a procedure for waste disposal for your review that is appended as Appendix K," and attach your procedure.

OVERVIEW

There are four commonly used methods of waste disposal: release to the environment through the sanitary sewer or by evaporative release; decay-in-storage (DIS); transfer to a burial site or back to the manufacturer; and release to in-house waste. Nothing in these guidelines relieves the licensee from maintaining records of the disposal of licensed material. (See 4731.2410 through 4731.2450.)

GENERAL GUIDANCE

1. All radioactivity labels must be defaced or removed from containers and packages prior to disposal. If waste is compacted, all labels that are visible in the compacted mass must be defaced or removed.
2. Remind employees that non-radioactive waste, such as leftover reagents, boxes, and packing material, should not be mixed with radioactive waste.
3. Occasionally monitor all procedures to ensure that unnecessary radioactive waste is not created. Review all new procedures to ensure that waste is handled in a manner consistent with established procedures.
4. In all cases, consider the entire impact of various available disposal routes. Consider occupational and public exposure to radiation, other hazards associated with the material and routes of disposal (e.g., toxicity, carcinogenicity, pathogenicity), and expense.

MODEL PROCEDURE FOR DISPOSAL OF LIQUIDS AND GASES

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere. This does not relieve licensees from complying with other regulations regarding toxic or hazardous properties of these materials.

1. Regulations for disposal in the sanitary sewer appear in 4731.2420. There are monthly limits based on the total sanitary sewerage release of your facility. Make a record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries), and the sink or toilet at which the material was released.
2. Limits on permissible concentrations in effluents to unrestricted areas are enumerated in 4731.2750(4). These limits normally apply at the boundary of the restricted area. Make a

record of the date, radionuclide, estimated activity that was released (in millicuries or microcuries) and estimated concentration, and the vent site at which the material was released.

3. Liquid scintillation-counting media containing 0.05 microcuries per gram of H-3 or C-14 may be disposed of without regard to its radioactivity. Make a record of the date, radionuclide, estimated activity (in millicuries or microcuries), calculated concentration in microcuries per gram, and how the material was disposed of.

MODEL PROCEDURE FOR DISPOSAL BY DECAY-IN-STORAGE (DIS)

Short-lived material (with physical half-life less than 120 days) may be disposed of by decay-in-storage. If you use this procedure, keep material separated according to half-life.

1. Consider using separate containers for different types of waste (e.g., capped needles and syringes in one container, other injection paraphernalia such as swabs and gauze in another, and unused dosages in a third container). Smaller departments may find it easier to use just one container for all decay-in-storage waste. Because the waste will be surveyed with all shielding removed, the containers in which waste will be disposed of must not provide any radiation shielding for material.
2. When the container is full, seal it with string or tape and attach an identification tag that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container. The container may then be transferred to the decay-in-storage area.
3. Decay the material for at least ten half-lives. If the material is not segregated by isotope, decay the material for at least ten half-lives of the longest-lived radionuclide.
4. Before disposal as in-house waste, monitor each container as follows:
 - a. Check your radiation detection survey meter for proper operation.
 - b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area.
 - c. Remove any shielding from around the container.
 - d. Monitor all surfaces of each container.
 - e. Discard as in-house waste only those containers with radiation levels that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and the type of material (e.g., paraphernalia, unused dosages). Check to be that sure no radiation labels are visible.
 - f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay or transferred for burial.
5. If possible, Mo-99/Tc-99^m generators should be held 60 days before being dismantled because of the occasional presence of a long-lived contaminant. When dismantling generators, keep a radiation detection survey meter (preferably with a speaker) at the work area. Dismantle the oldest generator first, then work forward chronologically. Hold each column in contact with the radiation detection survey meter in a low-background (less than 0.05 mr/hr) area. Record the generator date and disposal date for your waste disposal records. Remove or deface the radiation labels on the generator shield.

MODEL PROCEDURE FOR TRANSFER FOR BURIAL

Except for material suitable for decay-in-storage and some animal carcasses, solids must be transferred to a burial site. Follow the packaging instructions you received from the transfer agent and the burial site operator. For your record of disposal, keep the consignment sheet given to you by the transfer agent.

MODEL PROCEDURE FOR RELEASE TO IN-HOUSE WASTE

Waste from in vitro kits that are generally licensed pursuant to 4731.3245 is exempt from waste disposal regulations. Radioactive labels should be defaced or removed. There is no need to keep any record of release or make any measurement.

APPENDIX L REQUIRED CALIBRATION EQUIPMENT

The following general guidance and procedure may be used for the requirements for calibration equipment. If you follow all the general guidance and procedures, you may state on your application, "We will establish and implement the general guidance and model procedures for the requirements for calibration equipment published in Appendix L to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the general guidance and models and carefully review requirements of the Minnesota rules. State on your application, "We have developed a procedure for the requirements for calibration equipment for your review that is appended as Appendix L," and attach your procedure.

MODEL PROCEDURE

Calibration Standards. Instruments should be calibrated either against National Standards or with Derived Standards. If National or Derived Standards are not available, Laboratory Standards may be used. Procedures for Laboratory Standards are demonstrated in ANSI N323-1978.

Calibration Assemblies. Instrument calibration assemblies shall be mechanically precise to ensure that positioning errors of either instruments or radiation sources do not affect the radiation field values by more than ± 2 percent. A sufficient range of radiation fields shall be available to satisfy calibration requirements.

Standard Instruments. An instrument used as a Derived Standard shall have an uncertainty no greater than ± 10 percent. Calibration shall be reestablished after maintenance or repair, or at intervals specified by the manufacturer, but in no case at intervals greater than three years.

A periodic instrument check procedure shall be established by the licensee to assure proper operation.

Check Sources. Check sources should provide radiation of the same type or types as provided by those sources used in instrument calibration. Check sources may provide radiation different than that used for calibration if:

1. the source instrument geometry is well understood and easily reproduced, or
2. the instrument response to this radiation is well understood and is not critically dependent on instrument adjustment. For example, the use of a photon source to check instruments sensitive to beta radiation may be acceptable; the use of a photon source to check a detector utilizing a BF_3 response to neutrons is not acceptable.

A reproducible source detector geometry shall be established and used for all performance test measurements.

APPENDIX M MAINTAINING QUALITY OF CALIBRATION

The following general guidance and procedures may be used for the maintaining quality of calibration. If you follow all the general guidance and procedures, you may state on your application, "We will establish and implement the general guidance and model procedures for the maintenance of quality of calibration published in Appendix M to the MDH Regulatory Guide for Calibrating Radiation Survey and Monitoring Instruments."

If you prefer, you may develop your own procedure for review. If you do so, you should consider for inclusion all the features in the general guidance and models and carefully review requirements of the Minnesota rules. State on your application, "We have developed a procedure for the maintenance of quality of calibration for your review that is appended as Appendix M" and attach your procedure.

MODEL PROCEDURE

Radiation Field

Either narrow or broad beam geometry may be used to compare the response of similar instruments with that of a standardized instrument.

For calibration of X-ray machines or particle accelerators, a calibrated instrument shall be used. If a continuous monitor is available, it can be calibrated simultaneously and used in subsequent work with periodic checks on its constancy.

Alpha radiation sources shall be standardized in terms of activity per unit area of the source, or both. The reference geometry 2π or 4π shall be stated.

Beta radiation sources shall be standardized in terms of air or soft tissue absorbed dose rate at the surface or specified distance from the source, or in terms of activity.

Photon-emitting radionuclide sources shall be standardized in terms of exposure rate (roentgens per hour) at a specified distance from the source.

Neutron sources shall be standardized in terms of (1) the number of neutrons emitted per unit time and (2) the effective or average neutron energy. The concomitant photon exposure-rate should be known and stated.

For photon and neutron monitoring instrument calibrations, the source-to-detector distance shall be the distance measured between the effective center of the radioactive source and the effective center of the radiation detector. Either this distance shall be greater than seven times the maximum dimension of the source or detector, whichever is larger, or suitable corrections shall be used.

Calibration Facility

Free-space geometry should be achieved for photon and neutron instrument calibration. The distance to scattering objects from the source and from the detector should be at least twice the distance between the detector and the source. Where scattering contributions to instrument readings are significant, they shall be included in stating the value of the radiation field for all detector positions used for calibration purposes.

The radiation background at the calibration facility shall be low, known, and stable, and shall be accounted for during calibration.

Temperature, relative humidity, and atmospheric pressure shall be noted at the time of instrument calibrations. Calibrations should be performed within the temperature range $25 \pm 10^\circ\text{C}$, except when the instrument is to be used outside this temperature range.

Other

If an instrument may exhibit an incremental response, the entire instrument should be placed in the radiation field during calibration and the results compared to calibration with just the detector in the field. The fractional contribution, if any, to the instrument reading due to an incremental response should be determined and noted on the instrument.

A reasonable delay should occur before reading to allow warm-up, and to accommodate switching transients and the time constant of the instrument.

ATTACHMENT I

US DEPARTMENT OF TRANSPORTATION REQUIREMENTS FOR THE SAFE TRANSPORTATION OF HAZARDOUS MATERIALS

The Federal hazardous materials transportation law (49 U.S.C. 5101 et seq.) is the basic statute pertaining to the transportation of hazardous materials (HAZMAT) in the United States. This law requires the training of all HAZMAT employees. The purposes are to increase a HAZMAT employee's safety awareness and to be an essential element in reducing HAZMAT incidents. The Hazardous Materials Regulations (HMR) include training requirements in several sections of Title 49 Code of Federal Regulations (CFR) as follows:

General	§ 173.1
Specific	§ 172.704
Modal	
Air	§ 175.20
Vessel	§ 176.13
Highway	§§ 177.800, 177.816

Each HAZMAT employer must:

- train and test,
- certify; and
- develop and retain records of current training (inclusive of preceding three years) for each HAZMAT employee (during the period of employment and 90 days thereafter).

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 conducted by OSHA, EPA and other Federal or international agencies, may be used to satisfy the training requirements in 172.704(a) to the extent that such training addresses the training components specified in paragraph (a) of this section.

Training records must include:

- 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.

DEFINITIONS

Hazardous Material means a substance or material capable of posing an unreasonable risk to health, safety, or property when transported in commerce.

HAZMAT Employer means a person who uses one or more employees in connection with:

- transporting HAZMAT in commerce;
- causing HAZMAT to be transported or shipped in commerce; or
- representing, marking, certifying, selling, offering, reconditioning, testing, repairing, or modifying packagings as qualified for use in the transportation of HAZMAT.

The term "HAZMAT employer" also includes any department, agency or instrumentality of the United States, a State, a political subdivision of a State, or an Indian tribe engaged in offering or transporting HAZMAT in commerce. This term includes an owner-operator of a motor vehicle, which transports hazardous materials in commerce.

HAZMAT Employee means a person who is employed by a HAZMAT employer and who directly affects HAZMAT transportation safety including;

- an owner-operator of a motor vehicle which transports HAZMAT;
- a person (including a self-employed person) who:
 - loads, unloads, or handles HAZMAT;
 - tests, reconditions, repairs, modifies, marks, or otherwise represents packagings as qualified for use in the transportation HAZMAT;
 - prepares HAZMAT for transportation;
 - is responsible for safety of transporting HAZMAT; or
 - operates a vehicle used to transport HAZMAT.

Training means a systematic program (consistent approach, testing, and documentation) that ensures that a HAZMAT employee has knowledge of hazardous materials and the HMR, and can perform assigned HAZMAT functions properly. See §172.700 through §172.704.

ATTACHMENT II

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.

Enclosure 8

MINNESOTA DEPARTMENT OF HEALTH



REGULATORY GUIDE FOR INDUSTRIAL RADIOGRAPHY

	<p>Radiation Control Unit Asbestos, Lead, Indoor Air & Radiation Section Division of Environmental Health Minnesota Department of Health</p>
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January 2005

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REGULATORY GUIDE FOR INDUSTRIAL RADIOGRAPHY

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 the use of sealed sources used in industrial radiography. The term radiography as used in this guide means the examination of the structure of materials by nondestructive methods that use gamma-emitting radionuclides. The radionuclides most commonly used are Cobalt-60 and Iridium-192.

The information in this guide is not a substitute for training in radiation safety 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 by-product material program to ensure the continued safe use of by-product material. The RSO is also responsible for the day-to-day operations of the radiation safety program.

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 propriety 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
Snelling Office Park
1645 Energy Park Drive, Suite 300
St. Paul, MN 55108-2970

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 NRC, MDH, or other Agreement State licenses.
- Materials are properly handled and secured.
- Persons using these materials are competent and committed to implementing appropriate radiological controls.
- A clear chain of custody is established to identify who is responsible for final disposal of 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 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.

If radiography equipment will be stored and/or used at a field station, give the specific address of each field station.

If radiography 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

Sealed Sources and Devices

Applicants must provide the manufacturer's (or distributor's) name and model number for each requested source assembly (sealed source), exposure device, and source changer. Licensees will only be authorized for radiographic exposure devices, source assemblies or sealed sources containing radioactive material and associated equipment meeting MDH requirements and specifically approved or registered by the US Nuclear Regulatory Commission (NRC) or an Agreement State. Also, identify any depleted uranium that is used as shielding material. (Radiographic exposure devices, source changers and some collimators contain depleted uranium).

The NRC or an Agreement State performs a safety evaluation of radiography source assemblies (sealed sources) exposure devices and source changers before distribution of these sources/devices to specific licensees. The safety evaluation is documented in a Sealed Source and Device (SSD) Registration Certificate issued to the manufacturer (or distributor). Therefore, if the source assemblies, exposure

devices, or source changers are approved for use by the NRC or an Agreement State, the applicant need only note the manufacturer's (or distributor's) name and model number of the sources or devices in its license application to demonstrate that the requirements are met.

Consult with the proposed supplier to ensure that sources and devices conform to the sealed source and device designations registered with the NRC or an Agreement State. To ensure that radiographic equipment is used in accordance with registration certificates, licensees may want to review the certificate, discuss with the manufacturer, or obtain a copy of the certificate. Licensees may not make modifications to exposure devices, source changers, source assemblies and associated equipment unless the design of any replacement component would not compromise the safety features of the system.

Consult with the manufacturer of the associated equipment (i.e., equipment that is used in conjunction with the exposure device that drives, guides, or comes in contact with the source) to be sure that the associated equipment is compatible with the sources and devices.

Identify each radionuclide that will be used. Identify the manufacturer (or distributor) and model number of each sealed source, source assembly, exposure device, and/or source changer to be possessed. Identify any depleted uranium that is used as shielding material.

Confirm that each sealed source, device, and source/device combination possessed is registered as an approved sealed source or device by MDH and will be possessed and used in accordance with the conditions specified in the registration certificate.

Confirm that associated equipment is compatible with the exposure devices, source changers, and sealed sources containing radioactive material.

Identify by radioisotope, manufacturer (or distributor), and model number any other sealed sources containing radioactive material (i.e., any source that will not be used for performing radiography).

Confirm that all radiographic exposure devices, source assemblies or sealed sources, and all associated equipment which meet the requirements specified in 4731.4030.¹

¹ 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.

**Table 1: Industrial Nuclear Model Ir-100 Exposure Device
(Maximum Authorization – 120 Ci)**

Element	Sealed Source	Curies	Source Changer Meeting 10 CFR 34 Requirements	Maximum Curies Authorized
Ir-192	• IN Model 32	120 Ci	• Amersham 550-SU • IN IR-50	120 Ci 120 Ci
Ir-192	• IN Model 33	120 Ci	• Amersham 550-SU • IN IR-50	120 Ci 120 Ci
Ir-192	• Amersham 87703	120 Ci	• Amersham 550-SU • Amersham 650L • Amersham 820 • Amersham 855 • IN IR-50	120 Ci 240 Ci 1,000 Ci 960 Ci 120 Ci
Ir-192	• Amersham 87704	120 Ci	• Amersham 550-SU • Amersham 650 • Amersham 820 • Amersham 855	120 Ci 240 Ci 1,000 Ci 960 Ci
Ir-192	• SPEC G-40F	120 Ci	• Amersham 550-SU • SPEC C-1 • IN IR-50	120 Ci 150 Ci 120 Ci
Ir-192	• SPEC G-40T	120 Ci	• Amersham 550-SU • SPEC C-1 • IN IR-50	120 Ci 150 Ci 120 Ci

**Table 2. Spec Model 150 Exposure Device
(Maximum Authorization – 150 Ci)**

Element	Sealed Source	Curies	Source Changer	Curie Authorization
Ir-192	• SPEC G-60	240 Ci	• SPEC C-1	150 Ci

**Table 3: Amersham Model 680 System Exposure Device
(Maximum Authorization – 110 Ci)**

Element	Sealed Source	Curies	Source Changer	Curie Authorization
Co-60	• Amersham A424-14	110 Ci	• Amersham 770 • Amersham 771	550 Ci 110 Ci
Co-60	• Amersham 943	110 Ci	• Amersham 770 • Amersham 771	550 Ci 110 Ci

**Table 4: Amersham Model 660 System Exposure Device
(Maximum Authorization -- 140 Ci)**

Element	Sealed Source	Curies	Source Changer	Curie Authorization
Ir-192	IN Model 7	100 Ci	Amersham 550 -SU	120 Ci
			Amersham 650L	240 Ci
			Amersham 820	1,000 Ci
			Amersham 855	960 Ci
			IN IR-50	120 Ci
			SPEC C-1	150 Ci
Ir-192	CIS-US-702	120 Ci	Amersham 550 -SU	120 Ci
			IN IR-50	120 Ci
			SPEC C-1	150 Ci
Ir-192	Amersham 91813	20 Ci	Amersham 650L	240 Ci
Ir-192	Amersham A424-22	240 Ci	Amersham 550 -SU	120 Ci
			Amersham 650L	240 Ci
			Amersham 820	1,000 Ci
			Amersham 855	960 Ci
Ir-192	Amersham A424-9	240 Ci	Amersham 550 -SU	120 Ci
			Amersham 650L	240 Ci
			Amersham 820	1,000 Ci
			Amersham 855	960 Ci
			IN IR-50	120 Ci
			SPEC C-1	150 Ci

Financial Assurance and Recordkeeping for Decommissioning

Licensees are required to maintain decommissioning records related to structures where devices are used or stored. Records relating to leaking sources must also be maintained. Licensees must transfer these records important to decommissioning either to any new licensee before licensed activities are transferred or assigned, or to MDH before the license is terminated.

The requirements for financial assurance are specific to the types and quantities of byproduct material authorized on a license. Most industrial radiography applicants and licensees do not need to comply with the financial assurance requirements because the thresholds for sealed sources containing radioactive material are 3.7×10^5 Bq (10,000 curies) of Cobalt-60 and 3.7×10^6 Bq (100,000 curies) of Cesium-137 or radioactive material with half-lives less than 120 days (e.g., Iridium-192). Thus, a licensee would need to possess hundreds of sources before the financial assurance requirements would apply. Since the standard industrial radiography license does not specify the maximum number of sources that the licensee may possess (allowing the licensee flexibility in obtaining sources/devices as needed without amending its license), it contains a condition requiring the licensee to limit its possession of sources to quantities not requiring financial assurance for decommissioning. Applicants and licensees desiring to possess sources exceeding the threshold amounts must submit evidence of financial assurance.

The same regulation also requires that licensees maintain records important to decommissioning in identified locations other than at any temporary jobsite. All industrial radiography licensees need to maintain records of structures and equipment where devices are used or stored. As-built drawings showing modifications to structures and equipment fulfill this requirement. If drawings are not available, licensees may substitute appropriate records (e.g., a sketch of the room and building, or a narrative description of the area) concerning the areas and locations. In addition, industrial radiography licensees who have experienced unusual occurrences (e.g., leaking sources or other incidents that involve spread of contamination, such as S-tube breakthrough) also need to maintain records about contamination that remains after cleanup or contamination that may have spread to inaccessible areas.

State the following in your application: "We shall maintain drawings records important to decommissioning. These records will be provided to a new licensee before licensed activities are transferred, or to MDH before the license is terminated."

If financial assurance is required, submit evidence.

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

Sources and devices will be used only for the purposes for which they were designed and in accordance with the manufacturer's recommendations for use as specified in an approved Sealed Source and Device (SSD) Registration Certificate.

The typical license authorizes persons to perform source exchanges and to conduct industrial radiography at temporary jobsites, field stations, and/or permanent radiographic installations. Unusual uses will be evaluated on a case-by-case basis and the authorized use condition will reflect approved uses. Applicants who plan to perform radiographic operations on lay-barges or underwater must specifically request these operations.

Specify the purposes for which the sources and device(s) will be used other than those included in the manufacturer's recommendations, as specified on the SSD Registration Certificate.

In addition, specify any plans to perform radiography underwater or on lay-barges.

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

Radiation Safety Officer (RSO)

RSOs and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures must have adequate training and experience.

The person responsible for the radiation protection program is called the RSO. MDH believes the RSO is the key to overseeing and ensuring safe operation of the licensee's radiography program. 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.

The RSO may delegate certain day-to-day tasks of the radiation protection program to other responsible individuals (potential designees). For example, a large testing company with multiple field stations may appoint individuals designated as site RSOs who assist the RSO and are responsible for the day-to-day activities at the field stations. Licensees may also appoint other individuals who may step in as an emergency contact when the RSO is unavailable. The potential designees do not need to meet the required RSO qualifications; however, these individuals should be qualified, experienced radiographers who are adequately knowledgeable of the activities to which they are assigned. Applicants do not have to identify other responsible individuals if day-to-day tasks, etc. will not be delegated.

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. Provide MDH with a copy of an organizational chart showing the RSO (and other designated responsible individuals) to demonstrate that he or she has sufficient independence and direct communication with responsible management officials. In addition, show in the organizational chart the position of the individual who signs the application.

To be considered eligible for the RSO position, an individual must be a qualified radiographer, have a minimum of 2,000 hours (one year full-time field experience) of hands-on experience as a qualified

radiographer, and have formal training in establishing and maintaining a radiation protection program². This should be a course specifically designed to provide training in running a radiation safety program, a basic radiation safety course is not acceptable. While a course particular to industrial radiography would be highly encouraged, this is not required. Acceptable training programs would be a classroom course typical of those provided through universities or commercial training facilities. Hands-on experience means experience in all areas considered to be directly involved in the radiography process. This includes taking radiographs, surveying device and radiation areas, transporting the radiography equipment to temporary jobsites, posting, work sites, radiation area surveillance, completing and maintaining records, etc. Excessive time spent in only one or two of these operations (film development and/or area surveillance) should not be counted toward the 2,000 hours. Experience with radiography using x-rays can be included; however, the majority of experience should be in isotope radiography.

Provide the name of the proposed RSO and other potential designees who will be responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures³. Demonstrate that the RSO has sufficient independence and direct communication with responsible management officials by providing a copy of an organizational chart by position, demonstrating day-to-day oversight of the radiation safety activities.

Provide the following:

- The specific training and experience of the RSO and other potential designees.
- Include the specific dates of certification and/or training in radiation safety.
- Documentation to show that the RSO has a minimum of 2,000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations.
- Documentation to show that the RSO has obtained formal training in the establishment and maintenance of a radiation protection program.

OR

- Alternative information demonstrating that the proposed RSO is qualified by training and experience (e.g., Board Certification by the American Board of Health Physicists, completion of a bachelor's and/or master's degree in the sciences with at least one year of experience in the conduct of a radiation safety program of comparable size and scope).
- Documentation to show that the RSO has obtained formal training in the establishment and maintenance of a radiation protection program.

² MDH will consider individuals with alternative training and experience as RSOs. For example, a person certified in health physics or industrial hygiene with previous experience in managing a radiation safety program of comparable size and scope could be considered as an individual case. The qualifications, training, and experience required of the RSO may vary depending upon the complexity of the applicant's operations and number of radiography personnel.

³ It is important to notify MDH and obtain a license amendment before making changes in the designation of the RSO responsible for the radiation safety program. If the RSO leaves the organization before an amendment is approved by the MDH, a potential designee, who meets the RSO qualification requirements, is responsible for ensuring that the licensee's radiation safety program is implemented in accordance with the license and MDH regulations. Alternative responses will be reviewed against the criteria listed above.

Item 8: Training for Individuals Working in or Frequenting Restricted Areas (Radiographers and Radiographers' Assistants)

Radiographers and radiographer's assistants must have adequate training and experience. A radiographer is a person who performs or personally supervises industrial radiography. This person is responsible for ensuring compliance with MDH regulations and the safe use of radioactive materials.

A radiographer is an individual who has been certified by a certifying entity to ensure he/she has met established radiation safety, testing, and experience criteria.

A radiographer's assistant is an individual who, under the direct supervision (in the physical presence) of the radiographer, uses radiographic equipment (sealed sources containing radioactive material or related handling tools, exposure devices, and radiation survey instruments) in performing industrial radiographic operations.

4731.4140 describes specific training requirements for radiographers and radiographer's assistants. It requires that all radiographers are certified. It also addresses annual refresher training and semiannual audits of radiographers and radiographer's assistants.

The applicant must submit a description of its training program for radiographers and radiographers assistants.

Because 4731.4140 contains different requirements for radiographers and radiographer's assistants, include training programs for each. When describing the training programs for these positions, include the sequence of events from the time of hiring through the designation of individuals as radiographers or radiographer's assistants. Experienced radiographers who have worked for another licensee should receive formal instruction similar to that given to prospective radiographer's assistants. This instruction must include training in your operating and emergency procedures, in the use of your exposure devices and associated equipment, and in the use of survey meters and other radiation monitoring devices.

Instructors who provide classroom training to individuals in the principles of radiation and radiation safety should have knowledge and understanding of these principles beyond those obtainable in a course similar to the one given to prospective radiographers. Individuals who provide instruction in the hands-on use of radiography equipment should be qualified radiographers with at least one year of experience in performing radiography, or should possess a thorough understanding of the operation of radiographic equipment (e.g., a manufacturer's service representative).

An internal inspection program (audit program) of the job performance of each radiographer and radiographer's assistant ensures that MDH rules, license requirements, and the licensee's operating and emergency procedures are followed. The audit must include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation at intervals not to exceed 6 months. If a radiographer or radiographer's assistant has not participated in an industrial radiographic operation for more than 6 months, the individual must demonstrate knowledge of the training requirements by practical examination before participating in a radiographic operation. The person conducting internal inspections should have a minimum of one year of actual experience as a radiographer.

Submit an outline of the training to be given to prospective radiographers and radiographer's assistants. Submit your procedures for experienced radiographers who have worked for another licensee.

Provide a copy of a typical examination and the correct answers to the examination questions. Indicate the passing grade.

Specify the qualifications of your instructors in radiation safety principles and describe their experience with radiography. If training will be conducted by someone outside the applicant's organization, identify the course by title and provide the name and address of the company providing the training.

Describe the field (practical) examination that will be given to prospective radiographers and radiographer's assistants. The MDH suggests using the checklist in Appendix B as a source of potential areas to review during the field examination.

Describe the annual refresher training program, including topics to be covered and how the training will be conducted.

Submit your procedures for verifying and documenting the certification status of radiographers and for verifying that their certification remains valid. As a minimum your procedures for newly hired, previously certified individuals should require documentation that you contacted the certifying entity and confirmed the certification. Your procedures should also ensure you are aware of certification expiration dates, and that individuals with expired certifications do not act as radiographers.

Submit a description of your program for inspecting the job performance of each radiographer and radiographers' assistant at intervals not to exceed six months.

Item 9: Facilities and Equipment

Annotated Drawing for Storage of Devices

Submit an annotated drawing of the room or rooms and adjacent areas where the radiographic exposure device will be stored. Include the following:

1. The scale. Use the same scale (preferably 1/4 inch = 1 foot) for all drawings.
2. The type, thickness, and density of shielding materials on all sides of the storage area, including the floor and roof.
3. Types of posting and their locations.
4. The locations of entrances and other points of access into the installation.
5. Security controls to prevent unauthorized access.
6. A description of the nature of the areas adjacent to the installation, and the distance to these areas.
7. The results of dose calculations or actual radiation measurements adjacent to, above, and below the installation.

Annotated drawing for permanent installation

Submit an annotated drawing of the room or rooms and adjacent areas where the radiographic exposure device will be stored. Include the following:

1. Identify its location and describe the visible and audible signal system.
2. Submit the results of radiation level calculation or actual radiation measurements adjacent to, above, and below the installation. For determination of installation adequacy, provide information showing that the radiation level in all directions around the installation, including the roof, will not exceed 2.0 mrem (0.02 mSv) in any one hour. Identify the type of source, including isotope, amount, and the location of the source within the facility for the calculations or measurements. Take into account the highest quantity of radioactive material that will be used in the facility and any limitations on source positioning.

Variations will be considered if construction requirements preclude shielding the roof to meet the 2.0 millirem (0.02 mSv) in any one hour. Provide the following information to obtain approval for a variance:

- a. Means of access to the roof.
- b. Procedures for ensuring that no individual is on the roof or could gain access to the roof during performance of radiography.
- c. A commitment that the roof will be posted with "Caution (or Danger) Radiation Area" signs.
- d. Steps taken to minimize radiation on the roof.

A radiation level on the roof that exceeds 100 millirem (1.0 mSv) per hour at 30 cm from the surface will not be considered acceptable. This level constitutes a high radiation area and requires special precautions, such as a visible and/or audible signal system.

- 3. Identify limitations on positioning of sources or type and amount of radioactive material that may be used in the installation to ensure that areas adjacent to, above, and below the installation will be unrestricted areas during performance of radiography.

Survey Equipment

Describe your survey instruments. Instrumentation must include the range from 2.0 milliroentgens (0.02 mSv) per hour to 1.0 roentgen (10 mSv) per hour and must be calibrated every six months. Electronic calibrations alone are not acceptable. Records of equipment problems and maintenance performed must be retained for three years. Battery changes are not considered "maintenance."

In order to assure that the radiation surveys are accomplished, you must maintain an adequate number of appropriate radiation survey instruments that are both calibrated and operable at each location where radioactive material is present.

If you are using an outside contractor to calibrate your survey instruments, provide the name, address, and license number of the company or individual. If you are calibrating your own instruments, request the specific regulatory guide for calibrating instruments from MDH.

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. In addition to the information in this regulatory guide, the following appendices may be useful in developing your program:

Appendix A	Training
Appendix B	Model Six-Month Radiographer/Radiographer Trainee Inspection Checklist
Appendix C	Model Annual Audit Checklist
Appendix D	Model Procedure for Leak Testing Sealed Sources
Appendix E	Daily Maintenance Check of Radiographic Equipment
Appendix F	Transportation
Appendix G	Operating and Emergency Procedures

Leak Testing of Sealed Sources

Each sealed source must be tested for leakage at intervals not to exceed six months. The leak test should be performed at six-month intervals. The instrumentation should be sufficiently sensitive to detect 0.005 microcuries 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 reports 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 organization.

For Option 2, specify the kit model number and 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. Commit to Appendix D.1.

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. Commit to Appendices D.1 and D.2.

Maintenance

Each licensee must inspect radiographic exposure devices, storage containers, and source changers before each day or shift of use. The licensee must also conduct a program of inspection and maintenance of radiographic exposure devices, storage containers, and source changers to ensure proper functioning of components important to safety. Inspections and maintenance should be accomplished at intervals not to exceed three months. If instruments are stored for longer than three months, maintenance should be performed before use. You must commit to a program of inspection and maintenance and submit the procedures.

Transportation of Devices

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

It is your obligation to obtain a copy of the DOT regulations on transportation of radioactive materials. The requirements for package labeling are in 49 CFR Part 172, subpart E of the DOT regulations. General requirements for shipping and packaging radioactive material are in 49 CFR Part 173, subpart I. Write to the following address for a copy of these regulations:

US Government Bookstore
120 Bannister Road
Kansas City, MO 64137
(816) 765-2256

You should state that packaging and transport of the device will be carried out in accordance with the applicable DOT regulations.

The following items should be covered in the instructions to personnel:

- Labeling containers appropriately (i.e., when to use labels Radioactive White I, Radioactive Yellow II, or Radioactive Yellow III.)
- Securing the exposure device or storage container within the transport vehicle.
- Preparation of shipping papers. The instructions should specify that the papers must be completed before transporting licensed material and must be accessible in the driver's compartment at all times.
- Placarding both sides, the front, and the back of the vehicle with "RADIOACTIVE" placards if the package being transported requires a Radioactive Yellow III label.
- If an exposure device is transported in an overpack, the procedures should include instructions that the overpack must be properly marked with the shipping name and identification number, and labeled (Radioactive White I or Radioactive Yellow II).

Inventories

State that you will conduct inventories at intervals not to exceed three months to account for all sealed sources and devices containing depleted uranium received and possessed under your license. You should maintain records of the inventories for at least two 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 device containing depleted uranium or radioactive material; and the location of each device and date of inventory.

Operating and Emergency Procedures

You should state on your application that you will provide the operating and emergency procedures to each person who uses the device. Submit the detailed operating and emergency procedures to MDH for review. See Appendix G for sample operating and emergency procedures.

Item 11: Waste Management

The only option for disposal of the licensed material contained in industrial radiography devices 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 include 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. NRC 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.

RENEWAL OF A LICENSE

An application for the renewal of a license should be filed at least 30 days before the license expiration date. This will ensure that the license does not expire before MDH has taken the final action on the application. 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 byproduct 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 TRAINING

The following guidance may be used to develop a training program. If you use the frequency and subject listings to develop your training program, the application should state, "We will establish and implement the model training program published in Appendix A to MDH Regulatory Guide for Industrial Radiography."

If you prefer, you may develop your own training program. If you do so, carefully review the requirements of 4731.4000. State in your application, "We have established a training program for your review that is appended as Appendix A." Provide a detailed outline of each topic covered in the course.

The safety course for prospective radiographers requires at least 40 hours of classroom instruction. Regardless of whether you choose to implement the model program or one of your own, you should do the following:

- Identify the course segments by title and instructor.
- Submit a description of each demonstration provided in the course.
- If any equipment or visual aids are used, provide a description. These may include filmstrips, videotapes, movies, dummy sources, survey instruments, and handling equipment.
- Provide a copy of books, training manuals, workbooks, and handouts used in the course. If these resources are available commercially, you may instead provide the title, author(s), and publishing companies.
- Submit a copy of a typical examination together with the correct answers to the examination questions. Indicate the passing grade and describe the re-instruction to be given in areas in which individuals are found deficient. Indicate the frequency at which the test will be periodically changed. Provide the security measures taken to protect the examination and the answers.

Records of training will include the date of training. These records will be retained for three years.

INSTRUCTOR QUALIFICATIONS

Identify the instructor who will instruct in the classroom, and the topics in which they will provide instruction.

Submit specific information about the qualifications of the instructors. Include the location and date of their training in the principles of radiation and radiation safety, and identify their industrial radiography experience. The person who instructs individuals in the classroom on the principles of radiation and radiation safety should have a knowledge and understanding beyond that obtainable in a course similar to the one provided to the radiographers. Alternatively, that person should possess a thorough understanding of the operation of radiographic equipment (e.g., a manufacturer's service representative).

MODEL PROCEDURE

Personnel will be instructed

1. Before assuming duties in the vicinity of radioactive material,
2. During annual refresher training, and
3. Whenever there is a significant change in duties, regulations, or terms of the license.

Instruction for individuals in attendance will include the following subjects:

1. Applicable regulations and license conditions.
2. Areas where radioactive material is used or stored.
3. Potential hazards associated with radioactive material in each area where the employee will work.
4. Appropriate radiation safety procedures.
5. Licensee's in-house work rules.
6. Each individual's obligation to report unsafe conditions to the RSO.
7. Appropriate response to emergencies or unsafe conditions.
8. Worker's right to be informed of occupational radiation exposure.
9. Locations of notices, copies of pertinent regulations, and copies of the current license (including applications and applicable correspondence).
10. Review of operating procedures.
11. Question and answer period.

**APPENDIX B
MODEL SIX-MONTH RADIOGRAPHER/RADIOGRAPHER TRAINEE INSPECTION CHECKLIST**

Date:	Time:
Radiographic Location:	
Radiographer/Radiographer's Assistant:	
Device Model Number:	Serial Number:

Survey Meter Functionality Yes No

Calibrated (date): Yes No

Daily source check Yes No

Dosimetry Yes No

- OSD
- TLD
- Film Badge
- Pocket Dosimeter

Calibrated (date): Yes No

Alarming Dosimeter: Yes No

Calibrated (date): Yes No

- Were other individuals working within the restricted area wearing film badges/TLDs/OSDs dosimeters and alarm dosimeters?
- Was the restricted area posted with the appropriate "CAUTION (or DANGER): RADIATION AREA" sign(s)?
- Was the restricted area properly controlled to prevent unauthorized entry?
- Was the high-radiation area posted with the appropriate "CAUTION (or DANGER): HIGH RADIATION AREA" sign(s)?
- Was the utilization log properly filled out?
- Did the radiographer/radiographer's assistant have sufficient knowledge of safety rules? (Ascertained by oral questions.)
- Was the radiographer working with proper inspected and operable equipment?
- Did the radiographer/radiographer's assistant properly survey the source projector?
- Did the radiographer properly supervise the radiographer assistant?

- Was the source projector properly locked and secured to prevent unauthorized removal?
- Was the restricted area properly controlled?
- Was the high radiation area under continuous direct observation except where entry had been prevented?
- Were radioactive isotopes stored properly and kept locked to prevent removal?
- Was the storage area posted with the appropriate "CAUTION (or DANGER): RADIOACTIVE MATERIAL" sign(s)?
- Did the radiographer/radiographer assistant possess and use a copy of the operating and emergency procedures and MDH rules and regulations for protection against radiation?
- Were there any other safety items found to be lacking? If yes, explain in Remarks.

Remarks:

**APPENDIX C
MODEL ANNUAL AUDIT CHECKLIST**

ORGANIZATIONAL STRUCTURE

- a. Matches license conditions N/A Yes No
- b. Temporary sites authorized N/A Yes No

RADIATION SAFETY OFFICER

- a. Named on license N/A Yes No
- b. Fulfills duties as RSO N/A Yes No
- c. Meets requirements N/A Yes No

RADIOGRAPHER TRAINERS

- a. Trainers listed in license N/A Yes No
- b. Have appropriate ID card N/A Yes No
- c. Radiographers have ID card N/A Yes No
- d. Radiographer Trainees have trainee status card N/A Yes No

AUDIT HISTORY

- a. Last audit conducted on:
- b. Deficiencies identified? N/A Yes No
- c. Were they corrected? N/A Yes No

SCOPE OF PROGRAM

- a. Are there multiple authorized locations of use?
If multiple locations authorized, list locations audited. N/A Yes No
- b. Have there been radiation safety program changes?
If yes, list changes. N/A Yes No

TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS

- a. Instructions to workers provided. N/A Yes No
- b. Training program conducted according to license commitments. N/A Yes No
- c. Radiographers are familiar with:
 - 1. The rules contained in 4731.2000 and 4731.4000 N/A Yes No
 - 2. The appropriate conditions of the license or registration N/A Yes No
 - 3. The operating and emergency procedures N/A Yes No
- d. Copies are furnished to radiographer trainees and radiographers N/A Yes No
- e. Specific training
 - 1. Written tests completed by all radiographers and radiographer trainees N/A Yes No
 - 2. Oral tests N/A Yes No
 - 3. All radiographers completed on-the-job training N/A Yes No
 - 4. Periodic training program implemented N/A Yes No
 - 5. Records maintained N/A Yes No

OPERATING AND EMERGENCY PROCEDURES

- a. Procedures are current N/A Yes No
b. Procedures contain all required information N/A Yes No

INTERNAL AUDITS

- a. Audits/inspections of each radiographer and radiographer trainees conducted at six-month intervals or after as appropriate N/A Yes No
b. Equipment check before use each day N/A Yes No
c. Equipment inspection and maintenance performed at three-month intervals N/A Yes No
d. Records maintained N/A Yes No

FACILITIES

- a. Facilities are as described in the license application. N/A Yes No
b. Permanent radiographic installations meet MDH requirements N/A Yes No
1. Visible and audible radiation signals N/A Yes No
2. Visible signal actuates if entry is attempted when source is exposed N/A Yes No
3. Audible signal actuates if entry is attempted when source is exposed N/A Yes No
4. System tested daily with radiation source N/A Yes No
5. Records maintained for two years N/A Yes No
c. Entrance controls are as described 4731 part 2000 N/A Yes No
d. High radiation areas posted N/A Yes No
e. Storage and use of radioactive material N/A Yes No
(1) Adequate method to prevent unauthorized individuals from entering restricted area. N/A Yes No
(2) Radioactive material secured to prevent unauthorized removal or access. N/A Yes No
f. Sources locked in devices N/A Yes No
g. Devices secured to prevent tampering or unauthorized removal N/A Yes No

EQUIPMENT

- a. Radiography devices, source assemblies and source changers in use meet requirements N/A Yes No
b. Associated equipment in use complies with N/A Yes No
c. Source changers and storage containers have radiation level less than 200 hr/hr (2 mSv) on surface and 10 mrem/hr (0.1 mSv) at one meter N/A Yes No
d. Equipment exempted by specific license condition is used in accordance with license commitments and authorization N/A Yes No

MATERIAL

- a. Isotope, chemical/physical form, quantity and use as authorized N/A Yes No
b. All sealed sources not fastened to or contained in an exposure device are tagged N/A Yes No
c. During radiographic operations, sources are secured in shielded position each time source is returned to that position N/A Yes No
d. Leakage and contamination tests N/A Yes No
e. Sealed sources N/A Yes No
1. Leak test method approved N/A Yes No
2. Leak tests performed at 6-month interval N/A Yes No
3. Leakage is less than 0.005 microcuries (185 Becquerels (Bq)) N/A Yes No
f. Depleted uranium (DU) shielding with S-tubes N/A Yes No

- | | | | |
|--|------------------------------|------------------------------|-----------------------------|
| 1. Test every 12 months [34.27] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. DU is less than 0.005 microcuries (185 Bq) | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| g. Records maintained for 3 years | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| h. Inventories | | | |
| 1. Conducted quarterly (not to exceed 3 months) | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. Contain all required information | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 3. Most recent inventory conducted on: | | | |
| i. Utilization Logs | | | |
| 1. Utilization logs maintained | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. Contain all required information | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| j. Survey instruments | | | |
| (1) Appropriate operable survey instruments available and used | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (2) Calibration every six (6) months | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (3) Records maintained for three years | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

RADIOLOGICAL PROTECTION PROCEDURES

- | | | | |
|---|------------------------------|------------------------------|-----------------------------|
| a. Individual has understanding of procedures | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (1) In general, rules for safe use | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| (2) Emergency procedures | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

- | | | | |
|---|------------------------------|------------------------------|-----------------------------|
| a. Procedure for opening packages adequate | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Incoming packages monitored for external radiation levels | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. Transfers performed, as required | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. Records of receipt surveys | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e. Records of receipt, transfer, & disposal of radioactive material | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

AREA SURVEYS

- | | | | |
|---|------------------------------|------------------------------|-----------------------------|
| a. Area or facility surveys conducted | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Records maintained | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. Survey after each exposure, including device, guide tube, ensuring source has returned to the shielded position | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. Survey of device when place in storage to ensure source is in shielded position | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e. Protection of members of the public | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| f. Adequate surveys made to demonstrate | | | |
| 1. The TEDE to the individual likely to receive the highest dose does not exceed 100 mrem (0.1 mSv) in a year, or | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. That if an individual were continuously present in an unrestricted area, the external dose would not exceed 2 mrem (0.02 mSv) in any hour and 100 mrem (1.0 mSv) in a year | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| g. Unrestricted area radiation levels do not exceed 2 mrem (0.02 mSv) in any one hour | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| h. Records maintained | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

PERSONNEL RADIATION MONITORING

- | | | | |
|---|------------------------------|------------------------------|-----------------------------|
| a. Film badges, TLDs, OSDs | | | |
| 1. Supplier NVLAP approved | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. Dosimeters exchanged at required frequency | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 3. Dosimetry records maintained | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

- b. Dosimeters
- | | | | |
|--|------------------------------|------------------------------|-----------------------------|
| 1. Read and recorded at start of each shift | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. Daily readings recorded | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 3. Dosimeters checked for response ($\pm 20\%$) at intervals not to exceed 12 months | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 4. Off-scale dosimeter procedure and records | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
- c. Alarm Ratemeters
- | | | | |
|--|------------------------------|------------------------------|-----------------------------|
| 1. Checked that alarm functions properly at start of each shift | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 2. Preset at 500 mrem (5 mSv) per hour | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 3. Calibrated to $\pm 20\%$ at intervals not to exceed 12 months | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 4. Records maintained | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
- d. Dose(s) exceeded regulatory limits. N/A Yes No
- e. ALARA program implemented. N/A Yes No
- f. Written description of ALARA program available. N/A Yes No
- g. Workers monitored as required N/A Yes No

WASTE DISPOSAL

- a. Radioactive material disposed of as authorized. N/A Yes No

NOTIFICATION AND REPORTS

- | | | | |
|--|------------------------------|------------------------------|-----------------------------|
| a. Notifications and reports provided to individuals. [| <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Reporting theft or loss compliant with rules. [| <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. Compliant regarding overexposures and notification of incidents. | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. Compliant regarding reporting of excessive levels and concentrations. | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e. Termination reports furnished, if requested by workers. | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

POSTING AND LABELING

- | | | | |
|--|------------------------------|------------------------------|-----------------------------|
| a. Radiation Areas posted | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. High Radiation Areas posted | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. Use or storage areas posted "Caution: Radioactive Material" | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. Containers or devices labeled | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e. Notice to Workers posted | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| f. Notice to Employees posted | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

TRANSPORTATION (10 CFR 49)

- | | | | |
|--|------------------------------|------------------------------|-----------------------------|
| a. Authorized packages used. | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. DOT-7A performance test records on file. [173.415(a)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. Valid Certificate of Compliance available for all Type B packages | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. For special form sources, performance test records on file. [173.476(a)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. Packages properly labeled. [172.403(b)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e. Packages properly marked. [172.301(a)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| f. Proper shipping papers prepared. [172.200] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| g. Shipping paper contains emergency response telephone number. [172.201(d)] | <input type="checkbox"/> N/A | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

APPENDIX D MODEL PROCEDURE FOR LEAK TESTING SEALED SOURCES

You may use the following model procedure to leak test sealed sources. If you follow the model procedure for taking leak test samples for analysis by a contractor, you may state on your application, "We will establish and implement the model procedure for leak testing sealed sources published in Appendix (D.1 and/or D.2) to the MDH Regulatory Guide for Industrial Radiography."

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.

D.1 MODEL PROCEDURE FOR TAKING LEAK 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 greater 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.
 - b. For larger sealed sources and devices, 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. Submerging the source in a vial of fine-grained charcoal or cotton for a day can do this. 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.

D.2. MODEL PROCEDURE FOR ANALYZING LEAK TEST SAMPLES

The samples will be analyzed as follows:

1. Select an instrument that is sufficiently sensitive to detect the 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 and whose activity the supplier certifies. 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 records for three years.

**APPENDIX E
DAILY MAINTENANCE CHECK OF RADIOGRAPHIC EQUIPMENT**

The radiographer or radiographer's assistant shall perform a daily maintenance check of the exposure device and related radiographic equipment. This inspection will be performed before using the equipment on each day the equipment is to be used. Report defective equipment to the RSO immediately. Do not attempt to use defective equipment. After the inspection, document the results of the inspection.

1. Inspect the survey meter. If batteries are low, replace, then check for operability. If you are not able to correct a problem with the survey meter, obtain another meter and start over.
2. Check the survey meter with a check source (or check with camera) as indicated on the survey meter⁴. If the reading is not acceptable, obtain another meter and start again.
3. Inspect the remote-control radiographic equipment as follows:

Inspect the cables for cuts, breaks, and broken fittings.

Carefully inspect approximately one foot of the drive cable immediately next to the male connector. Take care not to introduce any dirt or dust on the drive cable during this inspection. In addition to the previously mentioned items, the examination of the cable should look for any of the following:

- excessive or uneven wearing
- fraying
- unraveling
- nicks
- kinks or bends
- loss of flexibility (abnormal stiffness)
- excessive grit or dirt
- stretching

Inspect the crank unit for damage and loose hardware.

Check operation of the control for freedom of drive cable movement.

Inspect the guide tube for cuts, crimps, and broken fittings.

Survey for radiation levels and record readings. The radiation levels should be about the same as those in the previous day's inspection, unless there has been a source change.

Check that all safety plugs are in place.

Inspect the exposure device for damage to fittings, lock, fasteners, and labels.

Check for any impairment of the locking mechanism.

4. Record the results of the daily inspection.

⁴ The RSO or calibration vendor should determine the acceptable meter reading for each survey meter and post the expected reading on each instrument. This reading shall be obtained and noted at the time of calibration

APPENDIX F TRANSPORTATION

The following are the major areas in DOT regulations most relevant for transporting radiographic exposure devices and source exchangers that are shipped as Type B quantities:

- A. Table of Hazardous Materials and Special Provisions - 49 CFR 172.101
 - 1. 49 CFR 172. 101 - Hazardous Materials Table [proper shipping name, hazard class, identification number]
 - 2. Table 2, Appendix A, 49 CFR 172.101 - List of Hazardous Substances and Reportable Quantities [for radionuclides]
- B. Shipping Papers - 49 CFR 172.200
 - 1. 49 CFR 172.201 - General entries [on shipping papers]
 - 2. 49 CFR 172.202 - Description of hazardous material on shipping papers
 - 3. 49 CFR 172.203 - Additional description requirements
 - 4. 49 CFR 172.204 - Shipper's certification [if applicable]
- C. Package Markings - 49 CFR 172.300
 - 1. 49 CFR 172.301 - General marking requirements for non-bulk packaging
 - 2. 49 CFR 172.304 - Marking requirements
 - 3. 49 CFR 172.310 - Radioactive material [Type B]
 - 4. 49 CFR 172.324 - Hazardous substances in non-bulk packaging [designation of "reportable quantities" with the letters "RQ"]
- D. Package Labeling - 49 CFR 172.400
 - 1. 49 CFR 172.400(a) - General labeling requirements
 - 2. 49 CFR 172.403 - Radioactive materials [types and contents of labels]
 - 3. 49 CFR 172.406 - Placement of labels
- E. Placarding of Vehicles - 49 CFR 172.500
 - 1. 49 CFR 172.504 - General placarding requirements
 - 2. 49 CFR 172.516 - Visibility and display of placards
 - 3. 49 CFR 172.556 - RADIOACTIVE placard
- F. Emergency Response Information - Subpart G
 - 1. 49 CFR 172.600 - Applicability and general requirements
 - 2. 49 CFR 172.602 - Emergency response information

3. 49 CFR 172.604 - Emergency response telephone number

G. Training - Subpart H

1. 49 CFR 172.702 - Applicability and responsibility for training and testing [for HAZMAT employees]
2. 49 CFR 172.702 - Training requirements (includes types of training, when it must be conducted, need for refresher training every 3 years, record keeping)

H. Shippers - General Requirements for Shipments and Packaging - 49 CFR 173

1. 49 CFR 173.25 - Requirements for use and labeling of overpacks
2. 49 CFR 173.403 - Definitions
3. 49 CFR 173.411 - General design requirements
4. 49 CFR 173.413 - Additional design requirements for Type B packages
5. 49 CFR 173.416 - Authorized Type B packages [includes packaging certification requirements]
6. 49 CFR 173.441 - Radiation levels
7. 49 CFR 173.471 - Additional requirements for Type B packages approved by NRC
8. 49 CFR 173.476 - Approval of special form radioactive materials [includes requirement for documentation of special form status]

I. Carriage by Public Highway - 49 CFR 177

1. 49 CFR 177.817 - Shipping paper [location of shipping papers during transport]
2. 49 CFR 177.842 - Class 7 (radioactive) material [includes requirement for blocking and bracing during transport]

APPENDIX G OPERATING AND EMERGENCY PROCEDURES

You may use the following model procedure to leak test sealed sources. If you follow the model procedure for Operating and Emergency Procedures, you may state on your application, "We will establish and implement the model procedure for Operating and Emergency Procedures published in Appendix G to the MDH Regulatory Guide for Industrial Radiography."

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 the Minnesota Rules. State on your application, "We have developed operating and emergency procedures for your review that is appended as Appendix G," and submit your operating and emergency procedures.

MODEL OPERATING AND EMERGENCY PROCEDURES

A. Handling and Use of Sources of Radiation

Procedures should include systematic procedures for the handling and use of devices containing sources of radiation so that an individual will not receive an exposure in excess of the limits specified in 4731.2000.

B. Methods and Occasions for Conducting Radiation Surveys

The procedures should identify

- when surveys will be made.
- what should be surveyed.
- acceptable radiation levels.

Necessary surveys include the following:

1. Surveys that verify that the source has been returned to the shielded position. These surveys are conducted after each exposure. This survey should include both the source tube, if one is used, and the device.
2. Surveys of the restricted area perimeter. NOTE: It is not necessary to perform a survey of the perimeter of the high radiation area. Exposure levels may be determined by calculation, in keeping with the ALARA concept.
3. Determination of radiation levels at the external surfaces of temporary storage facilities.
4. Determination of radiation levels in the cab of transportation vehicles and around vehicles used for transporting sources and devices.
5. Determination that sources are in safe storage positions before securing radiographic exposure devices or storage containers.
6. Determinations that the containers prepared for shipment comply with the regulations of the Department of Transportation.

C. Methods of Controlling Access to Radiographic Areas

1. Procedures should ensure that a second radiographer observes the operations and is capable of providing immediate assistance to prevent unauthorized entry.
2. Include procedures to control access to areas in which radiographic operations are being performed such as posting, constant surveillance of perimeter of the restricted area, and steps to follow when unauthorized personnel enter the restricted area.

D. Methods and Occasions for Locking and Securing Radiographic Exposure Devices, Storage Containers and Sealed Sources

1. The procedures should contain instructions for securing the source at the time of the survey to determine that the source has been returned to the shielded position after each exposure. This is usually accomplished by locking the device. However, other methods may be preferred.
2. You should state that the radiographic exposure device will be stored in a locked enclosure (transport vehicle, store room, closet, shed, etc.) in a way that will prevent access by unauthorized persons. You should keep in mind that the radiographic exposure device needs to be in storage or physically watched by an authorized user at all times. It is not acceptable for a radiographic exposure device to be chained to a post or left lying unattended at the place of use during lunch or breaks, because the radiographic exposure device would then be accessible to unauthorized persons.
3. Provide instructions and procedures for storage of sources and devices at both permanent and temporary job sites including posting of storage areas, and surveys around the storage area. Any area outside the storage area should be considered an unrestricted area.

E. Personnel Monitoring

1. Procedures should state that personnel are required to wear direct-reading pocket dosimeters, alarm rate-meters, and personnel monitoring devices (film badges, TLDs, or OSDs) when they are engaged in radiographic operations. Personnel should be instructed to charge pocket dosimeters at the start of each workday so the dosimeters are capable of reading full scale. Readings should be recorded at the beginning and end of each workday. Alarm rate-meters should be tested at the start of each shift to ensure that the alarm functions properly (audibly). Include instructions regarding how and where dosimetry devices are to be stored when not in use.
2. Include instructions for action taken in the case of a lost, damaged, or off-scale pocket dosimeter.

F. Transportation to Field Locations, Including Packaging of Sources of Radiation in the Vehicles, Posting of Vehicles, and Control of Sources of Radiation During Transportation

1. The transportation of radioactive material over public highways in exposure devices or storage containers is subject to US Department of Transportation regulations (DOT).
2. The procedures should contain instructions on how exposure devices and storage containers should be secured within a transporting vehicle to prevent movement and possible damage to, or loss of, the exposure device or storage container.

3. Instructions for surveys should be available in and around the vehicle. For the passenger compartment, it is recommended that the radiation level not exceed 2 milliroentgens (mR) per hour. Although it is not specifically required for transport, there are occasions when the vehicle may be used for storage. In that case, the area outside the vehicle should be considered an unrestricted area so that a specification of the radiation level of 2 mR per hour at any external surface of the vehicle should be provided. When a vehicle is used for storage, it must be posted with a "Caution, Radioactive Material" sign.

G. Minimizing Exposure of Individuals in the Event of an Accident

These procedures must contain clear and specific instructions concerning emergencies. In general, the steps to be taken by radiography personnel should be limited to:

1. Surveying the area;
2. Establishing the restricted area;
3. Notifying appropriate persons; and
4. Maintaining direct surveillance and control over the area until the situation is corrected.

H. The Procedure for Notifying Proper Personnel in the Event of an Accident or Unusual Occurrence

Procedures should be provided with the name of appropriate personnel to contact in case of an accident or unusual occurrence. MDH telephone numbers should be included.

I. Maintenance of Records

Procedures should contain instructions to radiography personnel, outlining the records that must be maintained during the course of their work. This would include, but not necessarily be limited to, the following:

1. Dosimeter records;
2. Utilization records;
3. Survey records; and
4. Records of the daily inspection and maintenance of radiographic equipment.

J. The Daily Inspection and Maintenance of Radiographic Exposure Devices, Storage Containers, Survey Meters and Personnel Monitoring Devices

These procedures should contain specific instructions for the radiographer to perform daily inspections of radiographic equipment. These checks may not be as detailed as the quarterly inspection and preventive maintenance, but should follow the guidelines recommended by the manufacturer of the equipment. A checklist should be provided for the radiographer, listing the items to be covered in the daily inspection. If the equipment manufacturer's procedures are to be followed, this should be included as a part of the operating procedures, not merely referenced.

K. Identifying and Reporting Defects and Noncompliance

If radiography personnel discover any malfunction or defect in radiography equipment, instructions should require management notification so it can take appropriate reporting action.

ATTACHMENT I

US DEPARTMENT OF TRANSPORTATION REQUIREMENTS FOR THE SAFE TRANSPORTATION OF HAZARDOUS MATERIALS

The Federal hazardous materials transportation law (49 U.S.C. 5101 et seq.) is the basic statute pertaining to the transportation of hazardous materials (HAZMAT) in the United States. This law requires the training of all HAZMAT employees. The purposes are to increase a HAZMAT employee's safety awareness and to be an essential element in reducing HAZMAT incidents. The Hazardous Materials Regulations (HMR) include training requirements in several sections of Title 49 Code of Federal Regulations (CFR) as follows:

General	§ 173.1
Specific	§ 172.704
Modal	
Air	§ 175.20
Vessel	§ 176.13
Highway	§§ 177.800, 177.816

Each HAZMAT employer must:

- train and test,
- certify; and
- develop and retain records of current training (inclusive of preceding three years) for each HAZMAT employee (during the period of employment and 90 days thereafter).

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 conducted by OSHA, EPA and other Federal or international agencies, may be used to satisfy the training requirements in 172.704(a) to the extent that such training addresses the training components specified in paragraph (a) of this section.

Training records must include:

- 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.

DEFINITIONS

Hazardous Material means a substance or material capable of posing an unreasonable risk to health, safety, or property when transported in commerce.

HAZMAT Employer means a person who uses one or more employees in connection with:

- transporting HAZMAT in commerce;
- causing HAZMAT to be transported or shipped in commerce; or
- representing, marking, certifying, selling, offering, reconditioning, testing, repairing, or modifying packagings as qualified for use in the transportation of HAZMAT.

The term "HAZMAT employer" also includes any department, agency or instrumentality of the United States, a State, a political subdivision of a State, or an Indian tribe engaged in offering or transporting HAZMAT in commerce. This term includes an owner-operator of a motor vehicle, which transports hazardous materials in commerce.

HAZMAT Employee means a person who is employed by a HAZMAT employer and who directly affects HAZMAT transportation safety including;

- an owner-operator of a motor vehicle which transports HAZMAT;
- a person (including a self-employed person) who:
 - loads, unloads, or handles HAZMAT;
 - tests, reconditions, repairs, modifies, marks, or otherwise represents packagings as qualified for use in the transportation HAZMAT;
 - prepares HAZMAT for transportation;
 - is responsible for safety of transporting HAZMAT; or
 - operates a vehicle used to transport HAZMAT.

Training means a systematic program (consistent approach, testing, and documentation) that ensures that a HAZMAT employee has knowledge of hazardous materials and the HMR, and can perform assigned HAZMAT functions properly. See §172.700 through §172.704.

ATTACHMENT II

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.

Enclosure 9

Radioactive Materials Instrument Inventory

TAB	INSTRUMENT MFGR.	MODEL	SERIAL NO.	LAST CAL. DATE	NEXT CAL. DATE
1	ICN	DMC2000X	254690	07/16/04	10/01/05 ¹
2	ICN	DMC2000X	267295	11/14/04	10/01/05
3	ICN	DMC2000X	258846	07/16/04	07/01/05
4	ICN	DMC2000X	258862	07/16/04	07/01/05
5	Eberline	RO-2A	1159	08/03/03	Unservicable
6	Eberline	PAC 1SA	5004	07/09/04	07/01/05
7	Eberline	E-520 w/ HP 270 probe	4115	07/09/04	07/01/05
8	Eberline	E-520 w/ HP 270 probe	2242	07/09/04	07/01/05
9	Eberline	E-520 w/ HP 270 probe	4117	07/09/04	07/01/05
10	Eberline	E-520 w/ HP 270 probe	4112	03/01/04	07/01/05
11	Eberline	E-520 w/ HP 270 probe	4113	03/01/04	04/01/05
12	Eberline	E-520 w/ HP 270 probe	4114	03/01/04	04/01/05
13	Eberline	E-520 w/ HP 270 probe	2233	03/01/04	04/01/05
14	Eberline	E-520 w/ HP 270 probe	2245	03/01/04	04/01/05
15					
16	Eberline	ASP-1 w/ 2" Scintillation probe	332	09/27/04	10/01/05
17	Eberline	ASP-1 w/ alpha probe	2890	11/09/04	10/01/05
18	Exploranium	GR-135 MINISPECT	2595	12/13/03	04/01/05 ¹
19	Exploranium	GR-135 MINISPECT	2596	11/18/04	10/01/05
20	Exploranium	GR-130 MINISPECT	9612	12/12/03	04/01/05 ¹
21	Exploranium	GR-130 MINISPECT	9913	11/17/04	10/01/05
22	NDS Products	RA-500	44036	06/11/04	04/01/05
23	NDS Products	RA-500	44037	06/11/04	04/01/05
24	NDS Products	RA-500	44038	06/11/04	07/01/05
25	NDS Products	RA-500	44039	06/11/04	07/01/05
26	Radiation Alert	Inspector	05588	07/09/04	07/01/05
27	Victoreen	190	107367	07/09/04	07/01/05
28	Victoreen	190	107737	07/09/04	07/01/05
29	Victoreen	190	107738	10/27/04	10/01/05
30	Victoreen	450P	1126	10/27/04	07/01/05
31	Victoreen	450P	2363	07/09/04	07/01/05
32	Victoreen	450P	2378	06/15/04	04/01/05
33	Victoreen	450P	2381	06/15/04	04/01/05
34	Reuter-Stokes	100 mR/hr HPIC	N-4510	11/10/00	---
35	Reuter-Stokes	100 mR/hr HPIC	N-4518	02/01/99	---
36	Eberline	NRD with Eberline ASP-1 Meter	RN 014279 277	09/22/04	10/01/05

¹ Calibration deferred to facilitate future scheduling

TAB	INSTRUMENT MFGR.	MODEL	SERIAL NO.	LAST RESPONSE TEST	NEXT RESPONSE TEST
39a	Dosimeter Corp.	862	4010818	10/24/05	10/01/05
b	Dosimeter Corp.	862	4010820	10/24/05	10/01/05
c	Dosimeter Corp.	862	4010831	10/24/05	10/01/05
d	Dosimeter Corp.	862	4010832	10/24/05	10/01/05
e	Dosimeter Corp.	862	4010833	10/24/05	10/01/05
f	Dosimeter Corp.	862	4010835	10/24/05	10/01/05
g	Dosimeter Corp.	862	4010838	10/24/05	10/01/05
40a	Dosimeter Corp.	611	9124754	10/24/05	10/01/05
b	Dosimeter Corp.	611	9124767	10/24/05	10/01/05
c	Dosimeter Corp.	611	9124783	10/24/05	10/01/05
d	Dosimeter Corp.	611	9124781	10/24/05	04/01/05
e	Dosimeter Corp.	611	9124787	10/24/05	04/01/05
f	Dosimeter Corp.	611	9124795	10/24/05	04/01/05
41a	Dosimeter Corp.	862	8101121	03/09/04	04/01/05
b	Dosimeter Corp.	862	8101122	03/09/04	04/01/05
c	Dosimeter Corp.	862	8101123	03/09/04	04/01/05
d	Dosimeter Corp.	862	8101124	03/09/04	04/01/05
e	Dosimeter Corp.	862	8101125	03/09/04	04/01/05
f	Dosimeter Corp.	862	8101126	03/09/04	04/01/05
g	Dosimeter Corp.	862	8101127	03/09/04	04/01/05
h	Dosimeter Corp.	862	8101128	03/09/04	04/01/05
I	Dosimeter Corp.	862	8101130	03/09/04	04/01/05
j	Dosimeter Corp.	862	8101131	03/09/04	04/01/05
k	Dosimeter Corp.	862	8101132	03/09/04	04/01/05
l	Dosimeter Corp.	862	8101133	03/09/04	04/01/05
m	Dosimeter Corp.	862	8101134	03/09/04	04/01/05
n	Dosimeter Corp.	862	8101135	03/09/04	04/01/05
o	Dosimeter Corp.	862	8101136	03/09/04	04/01/05
p	Dosimeter Corp.	862	8101137	03/09/04	04/01/05
q	Dosimeter Corp.	862	8101138	03/09/04	04/01/05
r	Dosimeter Corp.	862	8101139	03/09/04	04/01/05
s	Dosimeter Corp.	862	8101140	03/09/04	04/01/05
t	Dosimeter Corp.	862	9101882	03/09/04	04/01/05

Enclosure 10

MINNESOTA DEPARTMENT OF HEALTH



INSPECTION PROCEDURES MANUAL

	<p>Radiation Control Unit Asbestos, Lead, Indoor Air & Radiation Section Division of Environmental Health Minnesota Department of Health</p>
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January 2005

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INSPECTION PROCEDURES

SECTION I - INSPECTION PROGRAM

PURPOSE

To establish an inspection program for licensees authorized to possess and use licensed material for radiography, medical programs, academic and industrial uses, waste disposal operations, manufacturing and distribution of products, leak testing and calibration, other types of services, and related transportation activities. The focus of these Inspection Procedures relates mainly to the activities described above; however, the principles discussed apply equally to the inspection of all activities licensed or registered by the Minnesota Department of Health.

INSPECTION OBJECTIVES

Two important objectives that can be accomplished by inspections are:

- (1) Determining if licensed activities are being conducted in a way that will ensure the health and safety of workers and the general public.
- (2) Determining if licensed activities are being conducted in accordance with the regulatory requirements of the Minnesota Department of Health.

The most important of these objectives is to determine if licensed activities are being conducted in a way that will ensure the health and safety of workers and the general public. However, there is no easy way to reach this conclusion. One way to measure the safety of a regulated program is to determine if there are violations of regulatory requirements. This method only identifies symptoms of what might be an unsafe program. The identification of violations does not necessarily mean a program is unsafe.

These Inspection Procedures will focus on those elements of an inspection that are most useful in determining the overall safety of a program.

PROGRAM OBJECTIVES

- (1) To establish a general policy for an inspection program, including priorities for conducting inspections.
- (2) To define requirements for conducting inspections.
- (3) To achieve a consistent method of conducting inspections.

INSPECTION PRIORITIES

The inspection priority assigned to a license is based on the potential hazard of the regulated activities. For example, a license with Priority 1 inspection is one in which there exists the greatest potential for health and safety hazards. Inspections must be conducted more frequently for this type of license.

At the other end of the scale is Inspection Priority 6. This type of license involves very limited potential health and safety hazards. Therefore, the interval between inspections can be much greater.

Determining Inspection Priorities

Inspections of licensees in all priorities are conducted at intervals in years corresponding to the priority.

- Priority 1 = every year
- Priority 2 = 2 years
- Priority 3 = 3 years
- Priority 4 = 4 years
- Priority 5 = 5 years
- Priority 6 = 6 years

In addition, some inspection priorities are "Priority T." These are contacts, made by telephone and documented in the file, to determine the status of the licensees' activities, to assess compliance of priority T licensees, or to exchange information with the licensee. Examples such as reminding a licensee that its license is near expiration, calling to determine whether there are sufficient licensee operations to conduct an inspection, or calling to determine whether the licensee actively possesses licensed material are types of telephonic contacts. Telephonic contacts are not inspections.

The US Nuclear Regulatory Commission determines the inspection priority for each type of license. The priorities are published in NRC Inspection Manual Chapter 2800. (Additional guidance concerning uses of radioactive materials can be found in Volume 20 Appendix G of NUREG 1556.) Because inspection frequencies are a matter of compatibility, they can be completed more frequently than the published intervals but should not be conducted less often.

Currently, General Licenses do not have an inspection frequency. However, because of the potential impact on health and safety (albeit diminished due to the supposed safety of the devices) at some time in the future, this is expected to change.

Assignment of Inspection Priority

When a new license is issued, it is assigned an inspection priority and scheduled for an initial inspection. In some cases, a license will authorize a variety of activities. If a license authorizes more than one kind of activity, the activity associated with the highest priority (most frequent inspection) shall be the one used to determine the initial inspection priority. However, if the inspection frequency is significantly different a separate license should be created (e.g., an HDR should not be incorporated in a medical private practice license).

Reduction of Inspection Interval

The interval between inspections may be reduced (shortened) and inspections conducted more often than specified by the priority system based on minimally satisfactory performance by a licensee. The main consideration in reducing the inspection interval should be a lack of confidence in the licensee's level of performance. The inspection must show that the licensee will not provide adequate protection of workers and the public without increased Department attention.

TYPES OF ROUTINE INSPECTIONS

Initial Inspections

Normally, initial inspections shall be conducted between six months and one year after a new radioactive materials program has been licensed. Inspections may be scheduled within the first six months if the licensed operations have a higher potential impact on health and safety. Because initial inspections are unannounced, the inspector may find that radioactive material is not being used. A new inspection date

should be determined and scheduled. The new date should be between six months and one year from the date of the initial attempt to inspect.

Periodic Inspections

Inspections of licenses in all priorities shall be conducted at intervals in years corresponding to the inspection priority.

Follow-up Inspections

Follow-up inspections should be conducted when violations result in significant enforcement action (Severity Level I, II, or III), for repeated poor performance, or, where there has been a significant breakdown in management control. These inspections should occur no later than six months after the most recent inspection.

SCHEDULING INSPECTIONS

Basis for Scheduling

The month in which an inspection is actually performed may be earlier or later than scheduled (by its placement in the priority system) for scheduling and cost effectiveness. The cost effectiveness should be balanced against the basic purpose of the inspection priorities, that is, effective use of an inspector's time versus the potential hazards in a licensee's operation. A low priority license should not be over inspected just because an inspector happens to be in the area. Conversely, the inspection of a high-priority license should not be delayed merely to be cost effective.

Intervals between Inspections

To achieve the goal of cost saving and efficient use of staff time, routine periodic inspections (other than initial inspections) may be performed at a frequency other than that defined by the priority system. However, the frequency of inspection of a licensee cannot fall outside the following points:

<u>Type of Inspection</u>	<u>Acceptable Frequency</u>
Initial Inspection	Within one year after operations have begun.
Inspection of licenses in Priorities 1, 2, and 3	Interval between inspections may vary by no more than 25 percent.
Inspection of licenses in Priorities 4, 5, and 6.	Interval between inspections may vary by a year.

Routine Inspection Not Required

Inspections of General Licenses are not required on a routine basis. However, inspections should be made to resolve allegations, complaints, or other indications of an unsafe practice, or when the inspection is directly pertinent to an inspection involving a specific license.

TYPES OF NON-ROUTINE INSPECTIONS

Telephone Contacts

Contact by telephone is a good way of keeping in touch with licensees who have never been inspected or are inspected infrequently. Telephone contacts should be limited to General Licensees and Priority T licensees. A telephone questionnaire may be useful during this type of communication. After such contact, a licensee should be sent written documentation describing the findings.

MDH has established telephone contact procedures to maintain safety for materials possessed by certain licensees (Priority T) after the initial inspection has been completed and the inspector has determined that the licensee is satisfactorily implementing the radiation protection program. Thereafter, an inspector will interview the Priority T licensee at five-year intervals for the duration of the license. See Appendix C for further detail.

Telephone Inquiries

Telephone inquiries are made for a variety of reasons. These may include: (a) reminding a licensee that its license is about to expire; (b) determining if a licensee has an active program that would warrant an inspection. A previous visit may have determined that no licensed material had been received or, (c) determining if a licensee is still maintaining its licensed material in secure storage.

Expired or Terminated Licenses

Notification that a license has expired or is being processed for termination will require prompt action to ensure that licensed material has been properly disposed and areas where material was used can be safely released for unrestricted use. For unsealed radioactive material, final action should be conducted as soon as possible, but no later than six months after the notification has been received or the Department has determined that a previously licensed program is no longer covered by a valid license. The final action should include an inspection and a confirmatory survey, if one is necessary.

Abandonment of Licensed Material or Licensed Activities

Often, the fact that a licensee has moved from the location specified in the license is first discovered when the post office returns mail. On other occasions, inspectors have gone to the designated location and found it abandoned.

It is important to find missing licensees to determine if they still possess licensed material or if it has been properly transferred or disposed. This is necessary to ensure that licensed material presents no danger to the public health and safety. The first step is to try to contact the licensee by telephone. If contact cannot be made, an inspector should be sent to the site to determine the status of the program. The next step might involve contacting the local postmaster and asking for his or her help in locating the licensee. Also, interview persons who are in the same building or area and who might have information about what happened and where the licensee might have gone.

Occasionally, contact with a licensee is lost because the licensee is not familiar with the requirements of the Department and moves to another location without first getting authorization from the Department to make such a move.

Allegations

Occasionally, the Department will receive telephone calls or written communication from individuals who claim they are being exposed to hazardous radioactive materials at work. In other cases, they claim someone is releasing radioactive material into the environment or a company that works with radioactive material was involved in a serious radiation incident and did not report it. The possible scenarios are endless. Some of the calls are clearly the imagination of an overly concerned person. However, it is important to listen carefully to these allegations because the persons making them are not acquainted with the rules that govern the use of radioactive material in the State of Minnesota. Therefore, they do not have the ability to define a situation the way a trained scientific person would.

Allegations can be a valuable source of information and can bring to the Department's attention things that would not usually be identified during a routine inspection. For example, a spouse of a worker at a licensed facility may learn that the worker is being exposed to radiation but because of a fear of being fired, that worker will not report the situation. In other cases, workers who have been terminated for a variety of reasons will inform the Department that records are being falsified, untrained persons are

permitted to use radioactive material, or licensee management refuses to inform workers of hazardous working conditions.

In some cases, *allegers* have a valid complaint but it is not within the jurisdiction of the Department. In those cases, the individual should be referred to a Department that does have jurisdiction over the matter.

Reactive Inspections

Because these inspections are reactive, they cannot be scheduled on a routine basis. They typically result in response to a licensee's report of an incident. In such cases, an onsite inspection is needed to determine the facts of the case, the cause of the incident, and adequacy of the licensee's actions to correct the cause of the incident, mitigate its consequences, and prevent recurrence.

RECIPROCITY INSPECTIONS

It is the Radioactive Materials Group's objective to inspect 50 percent of all Priority 1, 2, and 3 licensees entering the state under reciprocal recognition of an NRC or another Agreement State's license each calendar year. Industrial radiography operations, which have a Priority 1 inspection frequency, represent the greatest potential threat to health and safety if not performed in accordance with approved operating procedures and MDH rules.

INSPECTION REQUIREMENTS

The depth of review of licensed activities should be commensurate with the scope of a licensee's program. To the extent possible, a determination regarding compliance with the Department's regulatory requirements should be based on observations of work activities, on interviews with workers, on demonstrations by workers of how they perform various tasks that are regulated by the Department, and on making a series of independent measurements of radiation conditions at the facility. An inspector's conclusion regarding the safety of a licensed program should never be based solely on a review of a licensee's records.

Program Administration

The following elements should be reviewed in sufficient detail to verify if a licensee's organizational and administrative systems have been established; if they are functioning in a manner that will ensure the safety of workers; and if they represent the safe implementation of licensed activities.

(1) Organization

A licensee's organizational structure will be found in the license application. An inspector should examine any changes that have occurred in the licensee's organization with respect to personnel, functions, responsibilities, and authorities since the last inspection. If an initial inspection is being conducted, it is even more important to carefully review this information.

It should be noted that in many instances the license application is nothing more than a template document that has been prepared by the manufacturer or distributor of the device. In other instances such as medical licenses, a consultant has prepared the documentation and the licensee's only input was signing the application and submitting it to the Department for approval. This is important because a license application may be comprehensive and say all the right things but, in fact, licensee management personnel have little understanding of what they have committed to do.

When individuals are named in a license application, a request for an amendment must be submitted and approved before changes in personnel are authorized (except for some broadscope licenses and radiography licenses, in which case only an individual's responsibilities are defined). If there have been no changes in the organizational structure since the last inspection, there is no need to pursue this element further. However, licensee management does not always inform the Department of the status of personnel changes. Therefore, during an inspection it is advisable to ask other workers to identify any changes in the staff over the last few years.

If an inspector determines that changes have occurred, it is important to evaluate the qualifications of new personnel and to determine whether adequate training and supervision exist. If the inspector determines unapproved users are not qualified to engage in licensed activities, the inspector should direct licensee management to immediately terminate such activity until the unqualified individuals have been properly trained, approved by Department, and added to the license as authorized users. If the use of licensed material by unqualified persons involves medical procedures, it may compromise the well being of a patient if the procedure is terminated. In such cases, and in any case about which the inspector is unsure, it is always advisable to contact the Radioactive Materials Group supervisor and discuss the matter before recommending that the licensee terminate the activity. However, if an individual is at great risk or is placing a member of the public at risk, the activity must be immediately stopped.

The method of accomplishing this immediate termination of activity may be a matter of serious concern for an inspector. However, there are several options available to accomplish this goal, depending on where the activity is taking place. If the unsafe activity is being conducted at a fixed facility, it is usually possible for the inspector to get to a telephone, contact the Radioactive Materials Group supervisor or the Department's management and then discuss available options. The inspector may be authorized to pursue the matter with licensee management or, more likely, the inspector's supervisor would contact licensee management and try to resolve the matter. If the inspector is authorized to proceed, a high-level licensee manager at the site should be immediately contacted. The inspector should point out to the licensee's management representative that continuation of the hazardous activity may be considered by the Department as "willfully" violating safety practices or, more likely, of violating regulatory requirements. This could result in issuing an *Order to Cease and Desist* from this activity and probably suspension of all licensed activities until the matter could be resolved. It is unlikely licensee's management would refuse to terminate the unsafe activity; however, if it does, the inspector should get back in touch with the Unit supervisor.

If an unsafe activity is taking place at a remote field site, for example industrial radiography, it may be more difficult to resolve the matter. However, an inspector should be aware that, once an unsafe condition has been identified, it is the inspector's responsibility to do whatever is necessary to stop that unsafe activity. One problem with a remote field site is there is usually no telephone available to contact the office or licensee's management. As a result, it may be necessary to travel many miles to find a telephone. At this point, the inspector has a number of options available:

- (a) The inspector can explain to the radiographer the basis of the concern and the regulatory significance of the unsafe activity. If the radiographer is unwilling to stop the unsafe activity, the inspector could inform the radiographer that any radiographer who violates the Department's rules may be required to show cause at a formal hearing why the radiographer's I.D. card should not be revoked or suspended. If the radiographer has a serious attitude problem, the inspector may be in danger of physical harm. If it appears this may be the case, the inspector should pursue another option.

- (b) If the work is being conducted at a large construction site or a large pipeline operation, an inspector should attempt to find someone, such as a construction foreman, who is in charge of the overall operations. After providing proper identification, the inspector should explain the cause for concern and the real or potential danger to workers at the site. If the supervisor has the authority to stop the radiographer, the inspector should ask him or her to do so until the appropriate personnel can be contacted to resolve the matter.
- (c) If no one is available at the site to offer assistance, the inspector should call the city, county, or state police. The law enforcement agency should be requested to come to the field site and take possession of the radiographer's equipment until the matter can be resolved. The appropriate surveys should be completed to ensure that the radioactive source is properly shielded and is locked to prevent accidental exposure. As soon as the radioactive material has been properly secured, the inspector should contact the Unit supervisor or Department management for any further instructions.
- (d) It is important to note that a regulatory Department has the authority to take possession of licensed equipment and radioactive material. However, such activities could lead to legal complications. The inspector must also weigh the possibility of injury if the material were to be transported.

(2) QA Program and Licensee Audits

The quality assurance program usually consists of procedures that are referenced in the license and which cover a variety of activities and methodologies. Generally these procedures specify various limitations, things to do and things not to do, as well as how to carry out various tasks. The licensee is required to follow its procedures, which are contained in the license application and are usually referenced in one or more license conditions. The inspector should attempt to verify, preferably by direct observation, the implementation of a random selection of the QA procedures. The inspector should avoid asking licensee personnel if procedures are being followed. Instead, individuals should be asked to explain the QA program and how it is implemented. Such probing questions will reveal those individuals who merely fill out check sheets and spend little time implementing the QA program.

The required internal audits should be verified. The results of all licensee audits should be documented. These records should be reviewed with particular attention to deficiencies found by the auditor. If appropriate and timely corrective actions were taken in response to identified deficiencies, they should be noted. If no corrective actions were shown after deficiencies were found, licensee management should be questioned to see if any actions were taken and, if they were, why they were not documented in the audit records.

The inspector should use judgment when asking a licensee to describe its QA and audit programs. If it is obvious to the inspector that the licensee is conducting an outstanding program, it is not necessary to go into detail.

Audits of field radiography sites are especially important. If possible, accompany a licensee auditor to a field site (this may require special scheduling). Other kinds of internal audits for different categories of licenses may involve determinations about the proper use of syringe shields (hospitals), whether technetium generators are properly shielded (hospitals), and whether established ALARA programs are being implemented. These are only a few examples. The inspector should review the license and application before making an inspection to become familiar with the licensee's commitments regarding its audit program.

(3) Training

Certain kinds of training and instruction are regulatory requirements; how they are implemented will be found in the license. The inspector should verify that proper training and initial instructions are being given, as specified in the license or rules. To do so, licensee personnel must communicate how and by whom the training is conducted and the content of the training. A detailed description of the training program can usually be found in the license application.

The inspector should determine that initial instructions have been given to workers who enter restricted areas. Under the basic instruction requirement, it is licensee management's responsibility to inform workers of precautions to take when entering a restricted area, kinds and uses of radioactive materials in that area, exposure levels, and the types of equipment to be used. The workers should also be informed of the pertinent provisions of Department rules, the license, and the requirement to notify licensee management of any conditions the workers observe which, if not corrected, could result in a violation of Department requirements.

Training of authorized users is of primary importance. At least one and preferably several users should be interviewed to determine if they have received the required training, both the basic instructions and any that is specified in the license application. For medical licensees, this includes specific training needed to perform routine and non-routine medical procedures as well as how to prepare and use radioactive material in medical research studies.

No person, other than a licensed professional, shall operate equipment or use materials for medical treatment or diagnostic purposes unless that person has completed a course of instruction approved by the Department or has otherwise met the minimum training established by the Department. In addition, a person, other than a licensed professional, who operates equipment or uses materials for medical treatment or diagnostic purposes shall display the credentials which indicate that person's qualifications to operate equipment or use materials in the immediate vicinity of the equipment or where the materials are stored.

A person who owns or controls the materials is also responsible for the proper display of the user's credentials. The licensee or registrant shall not employ a person to operate equipment or use materials for medical treatment or diagnostic purposes except as provided in this section. For radiographers, the training must cover instruction in the topics listed in the rules.

The inspector should randomly select and review a sufficient number of records of training given to licensee personnel and applicable tests or examinations (if applicable) to reach a conclusion that the training program is being implemented, as required. If written examinations have been given, the inspector should review a random sample of the test questions to ensure that the material covered in the test is appropriate to demonstrate what a worker should know to carry out his/her responsibilities.

An inspector will frequently ask licensee management, as well as users of radioactive material, if a training program has been implemented and if all users have been properly trained. Licensee personnel will rarely respond to this question in the negative. The only way to determine if individuals are trained is by asking them, for example: (a) when was the training program conducted, (b) who was the instructor, (c) what was the scope of the training, and (d) how was their performance or understanding of the material evaluated. Finally, the inspector should ask the individuals to explain how they perform or would perform certain tasks. For example: (a) how are direct reading surveys and surveys for removable contamination conducted; (b) how is radioactive material ordered, received, and stored; (c) how do they perform the required calibrations and checks on a dose calibrator; (d) how are instruments calibrated; and (e) how would they react or who would they contact if an unusual event occurred.

If an inspector concludes an individual is unable to respond to such questions in an acceptable manner, it may be necessary to interview additional persons to determine if this is an isolated occurrence or a widespread problem. Determining if licensee personnel are qualified is one of the inspector's most important tasks.

(4) Operating and Emergency Procedures, Safety Component Defects

Operating and emergency procedures will be found in license applications. They may vary from the systematic procedures for radiography programs to more generalized procedures for lower priority licenses. The procedures are approved by the Department and updated by the licensee. Any revisions require an amendment to the license except in the case of broadscope licenses.

The inspector should examine the emergency procedures to determine if they are as approved by the Department. The examination may be a discussion with the licensee or observation (for the higher priority licensees) of the periodic tests and drills. In addition, the inspector should verify that operational procedures are being followed by observing personnel performing tasks at various workstations.

Larger licensees may have agreements with other agencies to respond to emergencies. Such agreements may be in writing and include state regulatory commissions (or their equivalent) and hospitals. Generally, there are no written agreements with fire departments. The licensee representatives should be asked what has been done to ensure that agencies (with whom the licensee has made agreements) understand their roles in emergency responses.

The inspector may meet with other agencies or departments to determine their understanding of their roles if called upon to respond to an emergency.

(5) Reports and Notifications

The inspector should examine records to determine if reports regarding theft or loss of sources of radiation were made immediately upon discovery. An evaluation of the corrective actions taken to address the events leading to the incident should also be made. This regulatory requirement states, "Each licensee or registrant shall report by telephone to the Department the theft or loss of any source of radiation immediately after such occurrence becomes known." However, the regulation makes no stipulation regarding the quantity of lost material. For enforcement purposes, the inspector should use some discretion when reviewing the theft or loss of sources of radiation. The inspector should ask the question, "Did the theft or loss of licensed material occur in such quantities and under such circumstances that a substantial hazard may result to persons in unrestricted areas?" If a licensee reported the theft or loss of 100 microcuries of tritium, it would clearly present no significant hazard to anyone in an unrestricted area. Therefore, a prompt inspection of the licensee would be neither reasonable nor cost effective. It is advisable, nevertheless, to insist that licensees report all stolen or lost material. The inspection staff can then decide how to proceed.

Prompt follow-up should always be made if a report describes an incident in which excessive personnel exposures or releases of radioactive material have occurred. Prompt follow-up is needed to determine if adequate medical care is being provided to licensee personnel or in some cases to members of the public. Has the licensee taken adequate steps to control the incident? Other essential information that is missing from a report (initially received by telephone, FAX, etc.) may be obtained by making telephone contact with the licensee or by sending an inspector to the site.

In the case of high personnel exposures, if the exposure is believed to be valid, an inspector should be sent to the site to conduct an inspection. The inspection findings may be used to support possible escalated enforcement action. In such cases, an inspection should be scheduled as soon as possible. This will ensure that information is obtained while it is fresh in everyone's mind. In addition, it will give the inspector a chance to make meaningful independent measurements and gather samples for later analysis.

(6) Records

During the course of an inspection, most items examined will have supporting records. Records should be randomly examined in sufficient detail to conclude that the required records are being maintained and are complete. Other records, more closely related to health and safety (such as bioassay and personnel monitoring records), should be reviewed in detail.

A licensee who keeps records that are completely filled out and up to date is not necessarily running a safe program. An inspector must know whether the information stated in the licensee's records is appropriate for the activities that are being conducted. For example, a radiographer may correctly state in the utilization log that radiation surveys are being performed with a CDV-700 survey meter. The record may also state that the instrument is being calibrated at the required interval. The information stated is correct; however, the Inspector should know that a CDV-700 survey meter is a low range civil defense GM survey meter (0-50 mR/hr) and does not meet the requirements for use in a radiography program. If an inspector finds inconsistencies such as this, it indicates a more detailed review of a licensee's records is needed.

An examination of records, while important, should not be the principal focus of an inspection effort. Instead, most of the time should be spent observing areas where licensed material is used, examining equipment, talking to persons who handle licensed material, and making independent measurements.

Records that should be examined in detail include:

- ✓ Management audits
- ✓ Safety committee minutes
- ✓ Environmental releases
- ✓ Personnel monitoring
- ✓ Leak tests of sealed sources
- ✓ Instrument calibration
- ✓ Radiography quarterly inventory of devices and sources
- ✓ Inspection and maintenance of radiographic exposure devices
- ✓ Receipt and transfer records
- ✓ Final radiation surveys of radiographic exposure devices
- ✓ Pocket dosimeter readings and calibration
- ✓ Calibration tests and checks of dose calibrators
- ✓ Full calibration and spot-check measurements for teletherapy units

The scope of records reviews, either randomly or in their entirety, will depend on the category of the license as well as the enforcement history of the licensee inspected. The inspector will need to use judgment and continue with the record review until it can be concluded that the licensed program is being operated in a manner that will protect the health and safety of radiation workers and the general public.

In general, an inspector should review records as far back in time as is necessary but need not search back more than three years or back to the last inspection. Records older than three years may be inspected if circumstances indicate, such as a history of non-compliance, lack of management control, or high radiation exposures.

An inspector should use good judgment when citing for recordkeeping deficiencies. If a licensee failed to document a leak test or a daily radiation survey several years ago but since that time all records have been accurate and up to date, there is no benefit in issuing a citation. The current good record keeping performance indicates that whatever the problem was, it has been corrected.

Authorized Materials, Uses and Users

Determine, by reviewing records, observing the use of radioactive material, and discussing the program with licensee personnel, if the type, quantity, and use of radioactive material at a licensee's facility is as authorized by the license. Specific records and areas to be reviewed include the following:

(1) Receipts, Transfers, and Package-handling Procedures

Depending on the size of the licensed program, the procedures (a few or many) will be found in the license application. The procedures should be carefully reviewed before an inspection is conducted. The reason for such a review is to determine completeness, procedures that may be contradictory, and procedures that should be in the application but are missing. It should be noted that once a license or authorization has been issued, the Department cannot insist that additional procedures be submitted and adopted. If a licensee volunteers to submit additional procedures, a license can be amended to incorporate these additional procedures. If a licensee chooses not to expand the scope of its procedures, a memo should be placed in the license file to flag the deficiency. Then, when the licensee submits a license renewal application, the license reviewer will see the memo and can ask that the additional information be provided as a condition for renewing the license.

There is one instance in which the Department can unilaterally modify a license or an authorization. If a licensee is involved in a significant escalated enforcement action and the Department determines that additional requirements are needed to ensure a safe program, an Order Modifying a License or Authorization may be issued.

(2) Authorized Users

Authorized users are usually named in a license application, and are designated in the license as authorized users. If the license is a broadscope license, the radiation safety committee or the committee that has authority over the use of radioactive materials will appoint authorized users.

The inspector should determine whether authorized users are the ones actually using licensed material rather than someone who is not named in the license or approved by the safety committee. The license document should be read carefully to determine if individuals are permitted to work under the supervision of approved users and, if so, is the supervision actually being given.

In general, authorized users are specifically licensed by the Department or otherwise listed in the license application or in a license condition for specific tasks that only the named individuals can perform. This includes such activities as: leak testing of sealed sources, replacement of sealed sources, modification and opening for the purpose of repairing or replacing sealed sources in teletherapy units and radiography equipment, and changing sources from source changers or containers. Such individuals may not be authorized by the license that is being inspected. They

may, however, be employed by a service firm or manufacturer that is licensed by the Department, another Agreement State, or by the U. S. Nuclear Regulatory Commission.

There are a number of terms used in license conditions to describe the level of oversight that is required for individuals who are not authorized users but do use licensed radioactive material. These terms are: (a) under the supervision of, (b) by or under the supervision of, and (c) in the physical presence of. These oversight requirements are most often found in nuclear medicine licenses and in academic licenses.

- (a) Under the supervision of - This means that an individual who is essentially academically qualified but is not named on the license as an authorized user can work under the supervision of an authorized user while gaining the necessary clinical experience to qualify as an authorized user. In this situation, a supervised physician can prescribe diagnostic procedures, can prescribe the amount of radioactive material to be administered to a patient, and after the test has been completed can evaluate the results of the test. Based on this evaluation, the individual being supervised can prescribe an appropriate treatment for the patient. The essential element is that an authorized user (in this example an authorized physician) must periodically review the procedures used by the individual being supervised; must find that the dosages prescribed by the supervised individual are appropriate; and evaluate the diagnostic data to assure it has lead to a proper diagnosis and treatment of a patient's condition. It is not necessary that an authorized user confirm a patient's test data before a patient receives treatment.
- (b) By or under the supervision of - This means essentially the same as paragraph (a) above. The main difference is that paragraph (a) would be more appropriate for a large medical complex where an authorized user is supervising a number of physicians while they are gaining appropriate clinical experience. The statement "by or under the supervision of" is more appropriate for a small medical facility where the authorized user normally is responsible for personally evaluating patient's test data but occasionally may have assistance from an individual who is not yet qualified to be an authorized user. This might occur when the authorized user is away on vacation.
- (c) Physical presence of - This means that an authorized user must be physically present and essentially maintain direct supervision over anyone who uses licensed material but who is not named on a license as an authorized user.

(3) Authorized Uses

Authorized uses of radioactive materials, excluding broadscope licenses, will be found in the license or in the license application. Most specific licenses list isotopes, physical or chemical forms, and the maximum quantity that may be possessed at one time. Purchase, receipt, and inventory records should be reviewed to verify that material received is the kind and quantity that was ordered from the supplier and is authorized by the license.

The inspector should determine that radioactive material is used as authorized, particularly for human use. If the wrong isotope or wrong quantity is administered to a patient, it could result in a misadministration.

(4) Material Control

Storage areas in unrestricted and restricted areas should be examined. All storage areas should be locked and should have controlled access. There are usually procedures for access control. Additional controls may include logging out radioactive material from storage areas and logging it

in after use. This is especially important for medical programs in which very small radioactive sources (seeds or tubes) are implanted during therapy procedures. Occasionally, seeds or tubes have been lost because a licensee failed to follow its control procedures. Determine whether radioactive storage devices and source changers are locked when in storage and that storage areas are locked when not in use.

(5) Area Radiation and Contamination Control

By independent measurements, the inspector should ensure that the radiation levels in unrestricted areas are within the limits specified in the rules. A licensee shall not allow radiation levels in any unrestricted area that, if an individual were continuously present in the area, could result in the individual receiving a dose in excess of 2 millirems in any one hour or 100 millirems in any seven consecutive days, whichever is more restrictive.

It should be noted that occupancy is *not* a factor when evaluating radiation levels and the potential exposures from radioactive materials. Since a licensee has no control over access to an unrestricted area, an individual could be present in the area for 24 hours per day and 7 days per week (168 hours total). If one considers the most restrictive requirement, 100 millirems in any seven consecutive days, it means that any continuous radiation level in an unrestricted area which is in excess of 0.6 mR/hr would constitute a violation of this requirement. This can be significant if one considers radiation levels that result from large gamma sources such as irradiators, radiography sources, and calibration sources. To support a violation of this requirement, independent measurements should be made with a calibrated survey meter. If significant radiation levels are identified and the violation could result in escalated enforcement action, the calibration of the survey meter should be verified when the inspector returns to the office.

The licensee should complete surveys for radioactive materials in restricted areas to verify that there are no abnormal exposure levels. If possible, the inspector should observe how a licensee conducts surveys to determine their adequacy. This is of particular importance in radiographic operations. Also, note the type of instrument being used and determine whether it is appropriate for the type of radiation being measured.

During the physical operations review (facility walkthrough), appropriate caution signs at access points to areas containing radioactive materials, radiation areas, and areas containing airborne radioactive materials should be observed. Labeling on packages or other containers should be randomly checked to determine that proper information is recorded such as isotope, quantity, and the date of measurement. Note that certain exceptions exist from these requirements.

Some types of licenses, such as those for teletherapy rooms, radiography (fixed or permanent facilities), and irradiator facilities also require visible and audible alarm systems. The inspector should examine these to determine operability. When determining the operability of devices that retract sources, sound alarms, or perform other safety functions, the inspector should not test the devices personally. The licensee should demonstrate the operability of the system being inspected. This eliminates any liability on the part of the inspector. It also eliminates the possibility of a licensee later stating that the reason a particular safety device failed to function as designed, was because the inspector did not initiate the test properly.

Also during the walkthrough, the inspector should note if "Notices to Workers" are posted so that individuals engaged in work authorized by the license can observe them on the way to or from their work location.

(6) Packaging and Transportation

Requirements for shipping papers constitute an important part of hazardous materials regulatory concerns. Other important areas are labeling, marking, and vehicle placarding. In some cases, identification of shipping paper deficiencies may be symptomatic of serious packing deficiencies. Therefore, inspectors should be reasonably familiar with shipping paper requirements. A shipping paper can be any kind of transportation document, i.e., bill of lading, shipping invoice, radioactive waste shipment record, etc, but it must contain at least the following elements of *applicable* information (see 49 CFR 172.203(d)):

- (a) The proper DOT shipping name and the hazard class, "Radioactive Material," 49 CFR 172.101 (unless the words "Radioactive Material" are already contained in the name).
- (b) The applicable identification number (UNXXXX or NAXXXX) from 49 CFR 172.101.
- (c) The name of each radionuclide. Abbreviations taken from 49 CFR 173.435 are authorized.
- (d) A description of the physical and chemical form of the material. (For special form sources this description is "SPECIAL FORM".)
- (e) The activity contained in each package measured in SI units (e.g., Becquerel, Terabecquerel) or SI units followed by the customary units (e.g., Curies, millicuries). See 49 CFR 172.203"d"(4).
- (f) The category of label applied to each package (RADIOACTIVE WHITE-I, RADIOACTIVE YELLOW-II, or RADIOACTIVE YELLOW-III).
- (g) The transport index (dose rate at one meter) assigned to each package bearing "RADIOACTIVE YELLOW-III" or "RADIOACTIVE YELLOW-III" labels.
- (h) For packages delivered to a common carrier for shipment, the appropriate signed shipper's certification; and for shipments by aircraft, the additional statement as to acceptability for either passenger or cargo only aircraft. For shipments by passenger-carrying aircraft, the additional statement of intended use in research or medical diagnosis or treatment must also be included, as described in 49 CFR 172.204(a), 49 CFR 204(c)(3), 49 CFR 172.204(c)(4), and 49 CFR 172.204(d).
- (i) Any other descriptive information following the basic description provided it is not inconsistent with 49 CFR 172.201(a)(4).

In shipments where both non-hazardous and radioactive materials are described on the same shipping paper, the radioactive materials must appear as the first entry; or be designated by an "X" in columnar fashion, or be highlighted in a contrasting or other distinguishing fashion from the non-hazardous materials.

Special Form vs. Normal Form - For transportation purposes, radioactive materials are classified either as "special form" or "normal form" as defined in 49 CFR 173.403 (s) and (z). Radioactive materials classified as "special form" such as sealed sources may be transported with fewer restrictions than other materials with equal radioactivity. However, sealed sources must meet the physical integrity requirements defined in 49 CFR 173.469. All other radioactive materials are considered "normal form." For a particular shipping package specification, the activity limits for special form material usually are greater than for normal form materials (49 CFR 173.435). That

is, if the material is in special form, a greater quantity of material usually is permitted in the package.

Type A vs. Type B Packages - Normal form materials in quantities no greater than applicable A₂ limits (curies), specified in 49 CFR 173.435, may be shipped in a package called a "Type A" package (i.e., one which is expected to maintain its integrity only during normal conditions of transport). Similarly, special form materials may be shipped in larger quantities up to the A₁ limit, in a Type A package. Shipment of materials in a single package in excess of these limits requires the use of the higher quality "Type B" package. (i.e., one that is expected to maintain its integrity during both normal and severe accident conditions of transport).

Examples of A₁ and A₂ limits (in curies) from 49 CFR 173.435 are as follows:

RADIONUCLIDE	A ₁ (SPECIAL FORM)	A ₂ (NORMAL FORM)
Am-241 (in Am:Be sources)	20	0.008
Co-60	7	7
Cs-137	30	10
Ir-192	20	10
Mo-99	100	20

Labeling - Each package must be labeled with one of the three "RADIOACTIVE" labels described in 49 CFR 172.403. The three labels are referred to as RADIOACTIVE WHITE-I, RADIOACTIVE YELLOW-II, and RADIOACTIVE YELLOW-III. RADIOACTIVE WHITE-I is the lowest category label and RADIOACTIVE YELLOW-III is the highest. Labels must be affixed on two opposite sides of the package (49 CFR 172.406) and must be 4 inches square (49 CFR 172.407). DOT rules display the formats of these labels in 49 CFR 172.436 - 440.

All labels include spaces for marking the contents (the name of the radionuclide) and the activity. The YELLOW labels also include spaces for marking the Transport Index (TI). The TI is the number expressing the maximum radiation level in millirem per hour at one meter (3.3 feet) from the external surface of the package.

The appropriate label is selected based on the measured radiation levels anywhere on the external surface of the package and based on the package TI. A WHITE-I label may be used if the radiation level at any point on the surface of the package does not exceed 0.5 mR/hr. A YELLOW-II label indicates that the surface rate does not exceed 50 mR/hr and the TI does not exceed 1.0. Higher radiation levels require use of the YELLOW-III label. Pursuant to 49 CFR 173.441, package radiation levels are limited to 200 mR/hr at the surface and 10 mR/hr at one meter (i.e., a TI of 10).

When reviewing packaging and transportation requirements, the inspector should consider such factors as the volume, quantity, types of radioactive material, inherent radiological hazards, and the number of shipments made and received. Smaller programs require complete but less complex and extensive controls than larger programs. The scope of the inspection effort can be adjusted accordingly.

Placarding - The outside of the transport vehicle must be placarded by the carrier on the front, rear, and each side with the RADIOACTIVE placard (identified in 49 CFR 172.556) only if any package in the vehicle bears the RADIOACTIVE-III label. The licensee (shipper) is required to furnish the placards to a common or contract carrier at the time the packages are delivered to

(picked up) by the carrier. In the case of a licensee acting as a shipper/private carrier, the licensee must apply the placards. Vehicles are not required to be placarded when the shipment includes only WHITE-I or YELLOW-II packages.

Package Marking - The outside of each package must be marked with the following:

- (a) Applicable DOT Proper shipping name (see 49 CFR 172.101 List of Hazardous Materials), and "RQ" if a "reportable quantity" is present (see 49 CFR 172.101, Table 2 to Appendix A for radionuclide reportable quantities);
- (b) Identification number (49 CFR 172.101);
- (c) Applicable DOT specification, (e.g., "DOT-7A," "Type A");
- (d) Gross Weight (for packages in excess of 110 lbs);
- (e) The marking "USA," if the package is destined for export;
- (f) The name and address of the consignee or consignor.

Blocking, Bracing, and Securing of Packages - Licensees who transport packages in their own vehicles must provide for adequate blocking, bracing, or tie-down of the packages to prevent shifting or movement during normal transport. Licensees also are required to provide security measures adequate to prevent the unauthorized removal of materials from the place of storage during transport. This may involve locking the packages within an external, permanently attached compartment of the vehicle, or within the cargo compartment itself. In either case, it is necessary to remove the keys from the vehicle and to lock it when leaving the vehicle unattended.

(7) Physical Plant Facilities and Equipment

The equipment and the physical facility should be reviewed and verified. All components should be as described in the license application. Systems, subsystems, and equipment important to the safe handling of licensed materials and protection of operating personnel and the public should be examined to verify that it is working and to determine that it is meeting its intended functions.

The inspector should examine records of the most recent five-year teletherapy maintenance program. Have any malfunctions occurred and what, if any, routine maintenance work has been done on the unit? In addition, the inspector should verify that all required spot checks have been performed. The review should also attempt to identify if any unusual patterns of component failures were apparent. If problems were noted, were they corrected promptly? In addition, were defects reported?

(8) Radioactive Effluents and Waste Disposal

The inspector should verify that waste handling equipment, monitoring equipment, and administrative controls are adequate to keep radioactive effluents within the limits established by the license, other applicable regulatory requirements, and are ALARA.

The licensee's records should be reviewed for obvious mistakes, anomalous measurements, trends, missing data (compare the recorded data with regulatory requirements), and verify the accuracy of the data in the report or record with the licensee if there are any discrepancies noted.

(9) Confirmatory Measurements

Confirmatory measurements, when properly conducted, accomplish two goals. They produce an objective assessment of a licensee's radiological hazards. More importantly, confirmatory measurements evaluate the results of a licensee's measurements. Each time an inspector makes an independent measurement, using accepted techniques, the results of those measurements can be compared with the results obtained by the licensee. If agreement between the measurements is reasonably close, one can assume the licensee's techniques and equipment are producing a meaningful evaluation of radiological hazards.

If the confirmatory measurements do not agree with those of the licensee, can one assume the licensee is doing something wrong? Not necessarily. If an inspector wants to compare independent measurements with measurements made by a licensee, it is essential that the techniques are similar and that the instrumentation are equal or similar. For example, if one is comparing direct reading radiation measurements, the instruments used by the licensee and the inspector must have similar characteristics, such as sensitivity, range, window or wall thickness, response time, and type of detector (GM vs. ionization chamber), etc.

Onsite confirmatory measurements include direct reading radiation measurements and airflow measurements. Other important confirmatory measurements include wipe surveys, collecting liquid samples, and collecting air samples. The last three require that samples be returned to the Department's laboratory for analysis.

If, after making independent measurements, the inspector concludes that there is a real problem with the licensee's methods or equipment, it is essential to have the Department's instruments checked to verify they are still in calibration. It is not sufficient to rely on the fact that the Department's instruments were calibrated at proper intervals. Such findings may be necessary to support the decision to proceed with escalated enforcement action.

(10) Required Documentation of Selected Materials Inspections

There are two methods of documenting inspection findings and the one selected will, in great measure, determine the scope and detail of the inspection effort. The two methods include:

- (1) Inspection Field Note Reports
- (2) Narrative Inspection Reports

The format used most often is the Inspection Field Note Report. The alternative format is the Narrative Inspection Report. It is used principally for an initial and in some cases for a follow-up inspection of larger licensed programs. It is usually used for large manufacturers, distributors, and larger university programs. It would also be used if a licensee was involved in a serious radiological event and it became necessary to document inspection findings in sufficient detail to support a possible escalated enforcement action. The Narrative Inspection Report format is included in a separate section of this Manual.

SECTION II - INSPECTION PROCEDURES

PREPARING FOR AN INSPECTION

No matter how skilled an inspector might be, a quality inspection can *never* be performed without an in-depth preparation for that inspection. This applies equally to both entry level and senior inspectors. An in-depth preparation includes:

- (1) having a good understanding of Minnesota's regulatory requirements;
- (2) careful study of the license document, to be aware of regulatory requirements, as well as specific licensee commitments which have been incorporated into the license;
- (3) review of the license application to gain an understanding of what a licensee has committed to do and how these commitments will be carried out; and
- (4) review of the last several inspection reports, with particular emphasis on:
 - a. enforcement actions, if any,
 - b. the corrective steps the licensee has taken or
 - c. the corrective steps the licensee has committed to take
- (5) discussions with the Radioactive Materials Group supervisor and other inspectors who have accumulated first-hand knowledge of the licensee's program

To be effective, the inspector should take notes during the review process to ensure that reviewed information can be quickly recalled during the inspection. Many inspectors believe that if they have a copy of the license, the correspondence file, and the enforcement file in their possession during an inspection, it will be an easy matter to refer to these documents during the inspection. Unfortunately, this does not work. If licensee concludes that an inspector has not made adequate preparation for the inspection, his or her image as a professional may be in jeopardy. It cannot be emphasized too strongly that licensees expect and deserve to have all inspections carried out in a thorough and professional manner. In most cases, the inspector provides the only independent audit that is ever made of the licensee's program.

Inspectors should ensure that they have the appropriate documents to conduct the inspection, including inspection forms and informational fact sheets that may be helpful to the regulated party. Ensure that necessary equipment or safety gear is available and in good repair. If sampling is part of the inspector's inspection process, coordinate the inspector's inspection schedule with the laboratory that will analyze the samples.

The inspector will need to develop a plan that defines the inspector's objectives, tasks and procedures, and the resources the inspector will need to fulfill the inspection objectives. A comprehensive checklist is essential to conducting a thorough inspection. As the inspector develops the inspection plan, the following should be considered:

Objectives

- What is the inspector's purpose for conducting the inspection?
- What does the inspector intend to accomplish by conducting the inspection?

Tasks

- What does the inspector intend to do while at the facility or site? What information and/or samples are to be obtained?

Procedures

- What methods will the inspector use to accomplish the inspector's objectives?
- Will the inspector need to review special procedures?

Resources

- Will additional inspection personnel be required?
- What equipment will be needed?
- What records does the inspector intend to review during the inspection?

Schedule

- How much time will the inspector need to conduct the inspection?
- In what order will the inspector conduct various aspects of the inspection?
- Will this be an announced or unannounced inspection?
- If announced, who will the inspector contact?
- Does the inspector have a vehicle reserved for the inspection?
- Can the inspector arrange to conduct several inspections during one trip?

Coordination

- If sampling is part of the inspection, has the inspector arranged with the laboratory to receive the samples?

ANNOUNCED VS. UNANNOUNCED INSPECTIONS

One of the questions that must be answered even before the review process begins is, "Should this inspection be conducted on an announced or unannounced basis?" The answer depends on the type of inspection that is going to be conducted and why the inspection is being conducted.

The general policy regarding this matter is as follows:

Initial Inspections

Opponents of the announced inspection concept suggest that announced inspections give a licensee a chance to fix the problems. Therefore, the inspection will not give a true picture of the licensed program as it is actually conducted. If one takes a reasonable approach to this question, one can conclude that a new licensee has no idea what an inspector will be looking for during the inspection. Moreover, if the licensee is smart enough to fix all existing problems before the inspector arrives, that licensee probably will already have a good program.

Re-inspections

Most re-inspections should be conducted on an unannounced basis. This will eliminate any concern that the licensee time has time to fix existing problems before an inspector arrives.

One question that is frequently asked by inspectors is, "Does a licensee have to submit to an unannounced inspection?" The answer is not necessarily. This matter is addressed in Minnesota Department of Health rules 4731.0250, which state, "Each licensee and registrant shall afford the Commissioner at all reasonable times an opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored."

When an inspector tries to make an unannounced inspection, it may be possible that a licensee is involved in an activity that cannot be interrupted at the exact time the inspector arrives on site. For example, a patient may be undergoing a therapy treatment or an industrial process may require the total attention of the individual who is designated on the license as the authorized user or the RSO. It would be unreasonable for an inspector to insist that a licensee immediately stop whatever it was doing and submit

to an unannounced inspection. If one considers that a space of several years exists between re-inspections, it would be difficult, if the Department were challenged in court, to justify that a compelling safety concern existed which would make an immediate inspection necessary.

A related matter deals with the availability of records at the site where an inspection is being conducted. In some instances, a licensee will maintain a master copy of all records at its corporate headquarters or district office instead of at the site where the licensed material is actually used. In such cases, the licensee might have available at the place of use only those records that are of immediate use in the conduct of licensed activities. This practice is permitted by the rules. The rules require that "Each licensee and registrant shall make available to the Department for inspection, upon reasonable notice, records maintained pursuant to these rules."

If an inspector is confronted with either of these situations (a licensee refuses to permit an unannounced inspection or does not have on hand records that are needed to complete the inspection), it is essential that prompt action is taken to resolve the matter. What options does an inspector have?

- (a) Explain to the licensee that the Department policy is to conduct all re-inspections, except very large programs, on an unannounced basis.
- (b) It is likely the licensee representative is not refusing to permit an inspection, but instead is saying now is not a good time. It is not suggested that an inspector give up too easily and leave a licensee's premises in such a situation. The inspector can be forceful, yet professional, and should explain that a short delay is acceptable to give the licensee representative a chance to finish an important task. The inspector should ask the licensee representative how soon he or she will be available and return promptly at that time. Once a licensee representative understands the inspector is not going to leave the area without conducting the inspection, an agreeable time can usually be negotiated.
- (c) If a licensee is unwilling to cooperate or is acting unreasonably, the inspector should ask for the name of an immediate supervisor and contact that supervisor. If possible, the inspector should have the licensee representative present when meeting with the supervisor.
- (d) If a licensee representative and all licensee management refuse to cooperate and to permit an inspection to be made promptly or within a reasonable time, the inspector should inform the licensee that the Radioactive Materials Group supervisor will be contacted immediately.

During a review of the license and inspection files, it may have been noted that this licensee had a poor enforcement history as well as poor management control over its program. If such is the case, it would be proper for the inspector to tell the licensee an Order may be issued requiring immediate suspension of all licensed activities until an inspection and evaluation of the program has been completed. This information should never be conveyed to the licensee as a threat.

- (e) In some cases, licensees do not maintain a full set of required records at field sites or at branch offices. The licensee's rationale could be that the "official" or complete set of records is maintained at corporate headquarters by the corporate RSO. Although this method of record keeping delays completion of an inspection, it is acceptable for a licensee to operate in this manner. An alternative is to request that copies of records be made and sent to the inspector for review. If a licensee refuses to duplicate its records, the inspector may need to visit the corporate headquarters to complete the inspection. If the licensee's headquarters is in another state, it may be necessary to ask for an assist

inspection from the other state, if it is an Agreement State, or from the Nuclear Regulatory Commission.

ENTRANCE MEETING

Licensee management has a right to know when an inspection is being conducted at its facility. Inspectors generally choose one of two options for making licensee management aware of an inspection. The first option suggests that a high-level management representative be contacted as soon as the inspector arrives at the site. For example, if a hospital is to be inspected, the inspector will go to the administrator's office. If an inspector meets with top-level management before starting an inspection, appropriate personnel are aware of the inspector's presence. Then, if any problems arise, the inspector already has a direct line of communication with top management. It is unlikely that a hospital employee will challenge an inspector in this situation.

The second option suggests it is better to go to the nuclear medicine department, and meet with a nuclear medicine technologist. If an inspector meets with the nuclear medicine technologist and then runs into difficulty, he or she will probably ask to meet with the RSO. If the RSO is unable to mediate the matter, the inspector will try the next higher level and have to explain at each step of the way what the problem is and why resolution has been unsuccessful. In most cases, an inspector does not go directly from meeting with a technologist to meeting with a hospital administrator.

A third option is available that uses the best of both methods to accomplish our goal. If an inspector goes directly to the office of the administrator, there may be considerable delay before the administrator is available to meet with the inspector. If instead, the inspector meets with an actual user of the licensed material, that individual can call the administrator's office, announce the inspection, and schedule an exit meeting with the administrator's office. In many cases, the administrator will call the inspector back within a short time and offer the full cooperation of his or her staff. Option three usually results in the most efficient use of Department resources.

An entrance meeting with management should be brief but explicit. A good entrance meeting requires and demonstrates that the inspector be well prepared for the inspection. A discussion of the inspection scope should include the following:

- (1) Records, procedures, or documents that will be reviewed.
- (2) Personnel that the inspector will need to interview. It may be necessary for the inspector to identify the subject of interest and have the licensee identify the appropriate contact for further information.
- (3) The kinds of activities the inspector wants to witness.

There are certain kinds of inspection activities for which limited details should be given. These are instances where an event has occurred and the inspector needs to rely on experience rather than a review of a license file to determine what should be discussed. As the inspection progresses, the scope may change many times.

Another kind of inspection activity for which licensee management should be given minimum details is one in which an allegation is being investigated. Management should be told only that a matter has been brought to the Department's attention and the inspection is to determine if the matter has substance. Licensee management should be told that they will be informed of any

conclusions that are reached. They should also be told it may require some discussion with management before conclusions can be discussed with them.

EXIT MEETING

The purpose of an exit meeting is to communicate by discussion inspection findings and provide the licensee an opportunity to provide additional information that could change or even refute an inspector's findings. The exit meeting is just as important as the inspection; and adequate preparation is essential. Before meeting with licensee management, the inspector may find it beneficial to find a quiet area and carefully go over all inspection findings particularly when the findings appear to be violations of regulatory requirements. The inspector should arrange the findings in decreasing order of significance with the most important ones first and the least important last. Once this effort has been completed, the inspector is ready to meet with licensee management and should cover the following areas.

- (1) Scope of inspection effort. Briefly summarize what was inspected and how it was inspected.
- (2) State the inspection conclusion, as appropriate.
 - (a) Clear - No apparent discrepancy identified.
 - (b) Unresolved Items - Identify apparent problems including the requirements or commitments that the licensee is not meeting.
 - (c) Noncompliance - Identify the specific requirements violated and the supporting facts. Explain what the licensee is doing or is not doing and why this does not meet regulatory requirements.
- (3) If negative findings are identified that involve continuing operation of a licensed facility contrary to regulatory requirements or if operations are being carried out in an unsafe manner, they should be resolved before the inspector leaves the site.

CONFRONTATIONS WITH A LICENSEE

If a licensee disagrees with the inspector's findings and/or becomes hostile, it is important that the inspector not engage in an argument. The inspector must maintain control over the meeting. When this situation comes up, the inspector should restate the findings and then allow the licensee representative to state their position. If it is obvious that agreement over the findings cannot be reached, the inspector should request a senior licensee management representative, who can speak for the licensee, to state the licensee's official position. Resolution of the differences will then be worked out through inspection correspondence and/or direct communication between Department and licensee management.

INDEPENDENT MEASUREMENTS

Occasionally violations identified during an inspection are based on independent measurements made by the inspector or samples that were collected during an inspection. Typical examples include radiation levels in excess of regulatory requirements, removable contamination in excess of regulatory limits, or airflow in a hood that does not meet commitments made by a licensee in its

license application. In order to ensure that independent measurements can legally support violations, the inspector must take measurements, collect samples, and ensure that the methods are scientifically acceptable and the equipment is properly calibrated.

- (1) **Survey Meters** - All instrumentation must be calibrated by an approved calibration facility. In addition, whenever an inspector makes measurements that are grossly inconsistent with those of the licensee, the instruments should be re-checked for proper calibration as soon as the inspection has been completed.
- (2) **Laboratory Support** - An approved laboratory facility should be available to ensure that the full spectrum of radiological samples can be evaluated when necessary.
- (3) **Sample Collection and Preparation** - The laboratory that analyzes an inspector's independent samples should be asked to describe exactly how it wants the samples collected, preserved, and transported. If the samples are not handled properly, any resulting analytical information can be suspect.
- (4) **Assessment of surface contamination from tritiated compounds** is customarily done by smearing with filter paper or cotton swabs with subsequent analyses in the laboratory by liquid scintillation counting (LSC). An essential part of this process is preserving the sample to ensure that it survives to be counted. This is most important with volatile compounds such as tritiated water.

One method of preserving such samples is to place each one into an LSC bottle containing three-milliliter (3 ml) of distilled or demineralized water. Tightly cap the bottle and tilt it to ensure that the smear is thoroughly wetted. LSC cocktail should be added to the samples only after they are returned to the laboratory for counting in order to avoid any problem with carrying chemicals.

Vials and demineralized water may be obtained from the chemistry laboratory that will be analyzing the samples. An adequate supply of clean vials should be kept on hand along with a supply of demineralized water.

SECTION III – FORMAT FOR NARRATIVE REPORTS

GENERAL INFORMATION

1. Type of Inspection - Announced or unannounced.
2. Notification of, and accompaniment by, representatives from other agencies. Give name, title, and organization.
3. Persons interviewed. Give names, titles, and responsibility within the organization and licensed program.

INSPECTION HISTORY

4. Brief resume of results of previous inspections.

PROGRAM

5. Type of program - For what purpose is licensed material used? Are these uses permitted by the license?
6. Radioisotopes presently in use.
 - (a) Physical inventory of isotopes, quantity and forms. Show quantities on a specific date. If used in a device, show device model number and manufacturer.
 - (b) Rate of procurement and use. A statement should be made regarding compliance with possession limits, forms, and specific radioisotopes.
 - (c) Method of inventory control.

ORGANIZATION

7. Management organization of licensee and location of licensed program within this organizational structure.
8. Radiation Safety Committee
 - (a) Location within organizational structure.
 - (b) Members with titles and specialties.
 - (c) Functions, responsibility, and authority.
 - (d) Title of management person who appoints committee and to whom the committee is responsible.
 - (e) Meetings - Frequency and recording of minutes.

9. Radiation Safety Officer (RSO)

- (a) Name - Is it the same as in license application?
- (b) Full or part time? Other position if part time.
- (c) Position within licensee organization.
- (d) Authority and responsibility.
- (e) Title of individual to whom responsible.
- (f) RSO assistants for control of program.

ADMINISTRATIVE CONTROL

- 10. Does licensee management participate directly in control of licensed program?
- 11. Management review of committee, RSO, and/or individual users' actions with regard to control of the licensed program.
- 12. Method used to determine individual user's competency.
- 13. Control of procurement of licensed material. Specific action taken to assure that possession limits are not exceeded.
- 14. Instructions to individuals within licensed program.
 - (a) Written instructions.
 - Distribution – copy posted?
 - When and by whom given?
 - (b) Oral instructions.
 - Contents
 - (c) Training programs and meetings.
- 15. Instructions given to other than individuals within licensed program.
 - (a) Instructions to patients and/or customers.
 - (b) Instructions to visitors.
 - (c) Instructions to other employees.
- 16. Procedures used.

A description of procedures and techniques used by the licensee. These should be as observed by the inspector. If no operation is observed, the licensee should describe his or her techniques and these should be reported. The licensee should not be asked whether he is following procedures, but the inspector should evaluate for him/herself the licensee's level of compliance.

17. Emergency procedures - Provided? Posted?

FACILITIES

18. Location of facilities - Make sketch if appropriate.

19. Control exercised by licensee over facilities. Are facilities used exclusively by licensee? Are living quarters located in the facilities?

20. Storage facilities.

(a) Description.

(b) Physical security.

(c) Control of keys.

(d) Used for other than storage of radioisotopes.

(e) Construction - Materials, thickness, shielding.

21. Utilization facilities.

(a) Description.

(b) Security.

(c) Control of entry.

(d) Control devices and alarms. Are these controls required and do they satisfy requirements?

(e) Special finishes, replaceable tile, waxed surfaces, and stainless steel surfaces.

(f) Construction - Material, thickness, shielding.

EQUIPMENT

22. Special equipment.

(a) Utilization devices.

(b) Hoods, glove boxes, remote handling devices, filters, holding tanks, shielding.

(c) Storage containers - Method of locking.

23. Instrumentation.

(a) Portable - Number, type, model number, manufacturer, range of instrument.

(b) Systems - Number, type, model number, sensitivity, operability.

- (c) Calibration and maintenance - Is method adequate and is calibration by authorized person?
- (d) Is instrumentation possessed the same as or comparable to that listed in license application?

PERSONNEL MONITORING AND EXPOSURE DETERMINATION

24. Film badges / TLD/OSD.

- (a) Requirements for use of film badge / TLD.
- (b) Persons monitored.
- (c) Number used.
- (d) Supplier.
- (e) Period worn.
- (f) Handling of film supplier's report by licensee.
- (g) Action taken if above licensee's normal reading.
- (h) Action taken if regulatory limit is exceeded.

25. Pocket dosimeters or chambers.

- (a) Persons monitored.
- (b) Number used and number available.
- (c) Manufacturer's name, model number, and dosimeter range.
- (d) Period worn.
- (e) Results recorded.
- (f) Action taken if above licensee's normal reading.
- (g) Licensee action if dosimeter is off-scale.

26. Licensee's reliance on TLD versus dosimeters for determination of doses.

27. Personnel doses determined by instrument readings or calculations - Are these adequate?

28. Bioassay program.

29. Air Sampling.

- (a) Engineering controls.

- (b) Respiratory protective equipment. Is equipment used as stipulated in U.S. Nuclear Regulatory Commission Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection?"

30. Action taken in the event of an overexposure.

RADIATION SURVEYS AND/OR EVALUATIONS

31. Types of surveys and/or evaluations and frequency (direct reading; removable contamination; airborne; etc.).
- (a) In storage areas.
 - (b) In restricted areas.
 - (c) In unrestricted areas.
 - (d) In determination of concentrations of effluents to unrestricted areas.
 - (e) In determination of need for personnel monitoring.
 - (f) In determination of quantities of material disposed or transferred.
 - (g) During and after use.

POSTING AND LABELING (Give precise wording of signs and labels)

- 32. Restricted Areas.
- 33. Radiation Areas.
- 34. High Radiation Areas.
- 35. Storage areas.
- 36. Transportation vehicle.
- 37. Storage and use containers.
- 38. Reading at 12 inches from sealed sources for determination of exemption under 4731.2000.
- 39. Wording on tags on sealed sources.
- 40. License, procedures, and rules, posted or available.

TRANSPORTATION

- 41. Within and outside facilities; method used; precautions taken.

LEAK TESTS

42. Method used.
43. Is method approved or adequate?

WASTE DISPOSAL

44. Method used.
45. Amounts, frequency, isotopes disposed by each method.
46. Surveys performed. How?
47. Is method authorized?

REPORTS OF THEFT AND LOSS

48. Has any material been lost or stolen? Was a report made?
49. Has any incident occurred?
50. Was a report made?
51. Was the report timely?

REPORTS OF OVEREXPOSURES AND EXCESSIVE LEVELS OR CONCENTRATIONS

52. Has any overexposure occurred? Was a timely report made? Was employee or individual notified in writing within 30 days?
53. Have radiation levels or concentrations in excess of limits existed? Was a report made? Was the report timely?

RECORDS

54. Receipt of material.
 - (a) Isotopes, dates, and amounts.
 - (b) Vendor.
 - (c) Compliance with possession limits.
55. Transfer of material.
 - (a) Isotope, dates, and amounts.
 - (b) To whom transferred.

(c) Determination of license status of recipient.

56. Surveys.

(a) Frequency of record.

(b) Content - Instrument used; Units recorded (dose rate or exposure rates; d/m per area for any contamination measurements); area surveyed.

(c) Storage area.

(d) At boundary of restricted area.

(e) Storage and/or utilization devices.

(f) Contamination survey after use.

(g) During use.

(h) Airborne radioactivity.

(i) Waste Disposal.

(j) If other than instruments used, describe evaluation and adequacy of evaluation.

57. Personnel exposure.

(a) Show how personnel exposure determined.

(b) Bioassay Give highest results and range of results.

(c) Film badge/TLD/OSD.

(1) Dates and amounts of doses.

(2) Highest results and range of results.

(3) Frequency of service.

(4) Name of supplier.

(d) Pocket dosimeters or chambers.

(1) Manufacturer's name and model number.

(2) Maximum range.

(3) Number available.

INDEPENDENT MEASUREMENTS

58. If licensee possesses licensed material during the inspection, an independent survey should be made by the inspector.

LICENSE CONDITIONS

59. Is licensee in compliance with license conditions?

MANAGEMENT DISCUSSION

60. State the name and title of all individuals who participated in the exit interview. If violations were identified and discussed with the licensee management, did licensee propose or commit to any corrective actions? If so, describe proposed corrective actions and the licensee's proposed time of completion.

SECTION IV - Processing Inspection Reports

To be an effective enforcement tool, an inspection report must be completed in a timely manner. This is especially true if violations have been identified. The Radioactive Materials Group's objective is to have all Administrative Penalty Orders issued within 30 days of the inspection date. In some cases, the inspector may have to obtain additional information from the licensee, which may extend the completion period. Regardless of the circumstances, however, any APOs issued later than 30 days should be documented.

NARRATIVE REPORTS

If the narrative report is the result of a team effort, the team leader is responsible for preparing the draft report following an inspection. The members of the inspection team shall complete their portions of the draft report and submit them to the team leader within five working days of the exit meeting. The team members should include any citations that pertain specifically to the issues identified during their portion of the inspection.

The team leader is responsible for integrating the information from the team members. Within 30 days of the exit briefing, the team leader should submit the draft narrative report and the cover letter requesting factual comments to the Unit Supervisor. Before submittal, all members of the team should review the draft report.

The licensee will have 15 days for review of the draft report. Any factual errors or misstatements should be addressed to Minnesota Department of Health in writing.

The team leader will be responsible for making any appropriate corrections and for submitting the final report to the other team members and the Unit Supervisor for final review. All team members should concur with the findings of the report and signify by signature.

PEER REVIEW PROCESS

The previous discussion established the time constraints for processing an inspection report. Peer review and supervisory review are included in that timeframe. Reviews provide the following benefits:

- *inspection consistency*
- *quality assurance*
- *educational opportunities for less experienced inspection staff*
- *communication between staff*

Completion of the report within 30 days should always be the objective; however, preparing an accurate and complete inspection report and ensuring adequate reviews are paramount.

COMMUNICATIONS

One of the essential preparatory elements for an inspection is the discussion with the Radioactive Materials Group supervisor and other inspectors who have accumulated first-hand knowledge of the licensee's program. Licensing and inspection issues that need to be communicated to other staff should be documented on an appropriate form and placed in the licensee's file. Appendix A has examples of the documents used to communicate the licensing or inspection issues.

INFORMATION NOTICES

Periodically, the Radiation Control Unit publishes Information Notices that contain clarification, provide additional information about regulations and licensing and promulgate regulatory deadlines. Much of the subject matter originates from other regulatory agencies such as the U.S. Nuclear Regulatory Commission (NRC) or the US Department of Transportation (DOT). However, Information Notices may be prepared to address inspection, licensing, or incident response issues identified by the Minnesota Department of Health Staff.

RECORD RETENTION

Paper and electronic records of inspection reports, enforcement actions, licensing documents, and routine correspondence are kept on the premises of the Minnesota Department of Health Radiation Unit. Paper documents are saved and filed according to license number and are stored in a secured entry resource room. Electronic files are kept in the radioactive materials database and on a network accessible to the Unit. All records are periodically archived to effectively utilize space.

APPENDIX A - FORMS

**RADIOACTIVE MATERIALS GROUP
DIVISION OF ENVIRONMENTAL HEALTH
MINNESOTA DEPARTMENT OF HEALTH**

**MEMORANDUM TO LICENSE REVIEWER
AREA(S) THAT SHOULD BE ADDRESSED DURING THE NEXT LICENSE REVIEW**

Inspector:

Date:

Licensee:

License Number:

Specific license condition, application, or letter that needs to be reviewed. Identify type and date of document.

Provide a brief description of the issue associated with the license. If there are numerous issues, the items should be numbered. Use additional sheets if necessary.

**RADIOACTIVE MATERIALS GROUP
DIVISION OF ENVIRONMENTAL HEALTH
MINNESOTA DEPARTMENT OF HEALTH**

**MEMORANDUM TO LICENSE INSPECTOR
MATTER(S) TO BE REVIEWED DURING THE NEXT INSPECTION**

Staff Member:

Date:

Licensee:

License Number:

Type of matter to be reviewed during the next inspection:

Instructions or comments:

**RADIOACTIVE MATERIALS GROUP
DIVISION OF ENVIRONMENTAL HEALTH
MINNESOTA DEPARTMENT OF HEALTH**

CONVERSATION RECORD

- Outgoing call
- Incoming call

Date:

Licensee:

License Number:

Summary of Discussion:

Required actions:

Inspector:

Date:

Licensing and Inspection Tracking Form

Originator: _____	<input type="checkbox"/> New License <input type="checkbox"/> Renewal <input type="checkbox"/> Amendment	No.: _____	<input type="checkbox"/> Deficiency Letter <input type="checkbox"/> Inspection Report <input type="checkbox"/> Other _____
-------------------	--	------------	--

Facility: _____

License Number: _____

	Initials	Date
Draft Completed		
Draft Typed		
Originator		
First Reviewer		
Originator		
Final Typed		
To GFJ for Review		

Notes: _____

Inspections	Date of Inspection:
Number of non-compliance items:	
Pre-inspection preparation time:	
On-site time:	
Travel time:	
Off-site report preparation time:	
Review plan of correction:	
Total hours:	

Licensing Activities				
New License				
Amendment				
Renewal				

APPENDIX B

Program Codes and Inspection Frequencies

PROGRAM CODE	PRIORITY	TYPE
1100	3	Academic - Type A Broad Scope
1110	5	Academic - Type B Broad Scope
1120	5	Academic - Type C Broad Scope
2110	2	Medical - Type A Broad Scope
2120	3	Medical Institution - Diagnostic and Therapeutic
2121	5	Medical Institution - Diagnostic (No Written Directives)
2200	3	Medical Private Practice - Diagnostic and Therapeutic
2201	5	Medical Private Practice - Diagnostic (No Written Directives)
2210	3	Eye Applicators
2220	3	Nuclear Medical Vans
2230	2	High Dose Rate Afterloader
2231	2	Mobile High Dose Rate Afterloader
2240	2	Medical Therapy - Other Evolving Technology
2300	5	Teletherapy
2310	2	Gamma Knife
2400	5	Veterinary Medicine
2410	5	In Vitro Testing Lab
2500	2	Nuclear Pharmacy
2511A	5	Radiopharmaceutical Distribution (10 CFR 32.72)
2511B	5	Radiopharmaceutical Processing & Distribution (10 CFR 32.72)
2513A	5	Medical Sealed Sources Distribution (10 CFR 32.74)
2513B	5	Medical Sealed Sources Processing & Distribution (10 CFR 32.74)
3111	3	Well Logging - Sealed Sources
3120	5	Measuring Systems - Fixed Gauge
3121	5	Measuring Systems - Portable Gauge
3122	T	X-Ray Fluorescent Analyzer
3123	T	Measuring Systems - Gas Chromatograph

3124	T	Measuring Systems - Other
3211	2	Manufacturing and Distribution - Type A Broad Scope
3212	5	Manufacturing and Distribution - Type B Broad Scope
3213	5	Manufacturing and Distribution - Type C Broad Scope
3214	5	Manufacturing and Distribution - Other
3218	3	Nuclear Laundry
3219	2	Decontamination Services
3220	T	Leak Test Services Only
3221	5	Instrument Calibration Service Only Less Than 100 Curies
3222	5	Instrument Calibration Service Only 100 Curies and Greater
3225	5	Services/maintenance, installation, source changes, etc.
3232	3	Waste Disposal Service Prepackaged Only
3234	2	Waste Disposal
3240	5	Distribution - General Licensed Devices (Sealed Sources)
3244	5	Distribution - General Licensed Material (Unsealed Sources)
3310	2	Industrial Radiography - Fixed Location
3320	1	Industrial Radiography - Temporary Job Sites
3510	5	Irradiators, Self-Shielding - Less Than 10,000 Curies
3511	5	Irradiators, Other - Less Than 10,000 Curies
3520	5	Irradiators, Self-Shielding - 10,000 Curies or Greater
3610	3	Research & Development - Type A Broad Scope
3611	5	Research & Development - Type B Broad Scope
3612	5	Research & Development - Type C Broad Scope
3620	5	Research & Development - Other
3810	3	Storage - No Operations
11210	T	Source Material - Shielding
22120	5	SNM Plutonium - Neutron Source in Device
22160	T	Pacemaker Byproduct and/or SNM - Medical
22162	2	Pacemaker Byproduct and/or SNM Manufacturing & Distribution

99100	2	Accelerator-Produced RAM
99200	5	Nonprofit Educational Institutions

APPENDIX C
Telephone Contact Procedures for
Priority T Licensees

TELEPHONE CONTACT PROCEDURES FOR PRIORITY T LICENSEES

OBJECTIVES

MDH has established telephone contact procedures to maintain safety for materials possessed by certain licensees (Priority T) after the initial inspection was completed and the inspector determined that the licensee had satisfactorily implemented the radiation protection program. Thereafter, an inspector will interview the Priority T licensee at five-year intervals for the duration of the license.

PROCEDURES

Using the tracking system, select a Priority T licensee to interview by telephone.

- Obtain the license file and identify the licensee's point of contact and review pertinent details of the license that will be needed to evaluate the licensee's responses to the interview questionnaire (Enclosure 3.)
- Telephone the licensee and complete each item of Telephone Contact Questionnaire as appropriate for the type of use authorized by the license. If a question is not applicable for the type of use, then indicate "N.A." for the answer.

The interviewer should promptly notify their supervisor if the licensee describes any problem listed below:

- licensee is unaware of licensed material or MDH rules for possession, use, transfer, and disposal
- change in ownership or bankruptcy proceedings
- a qualified radiation safety officer or authorized user was not routinely involved
- unsecured or unshielded material
- doses in excess of 4731.2020 limits
- excessive radiation levels or leaking sources
- lost, stolen, or missing licensed material
- any non-routine event (i.e., special maintenance or handling; fires, explosions, or natural disasters resulting in decommissioning)

The supervisor should determine if an inspection of the facility is required, or if a letter transmitting regulatory concerns is needed. If an inspection is required, the inspector should note that decision and provide the completed questionnaire and license file to the supervisor for further action.

MINNESOTA DEPARTMENT OF HEALTH
TELEPHONE CONTACT QUESTIONNAIRE

Date of this inspection:

License Number:

Licensee (Name and Address):

Address letter to:

cc:

Licensee Contact:

Telephone Number:

Fax Number:

Last Amendment Number:

Date of Amendment:

1. Name of person responsible for the radiation safety program.
2. Describe how the licensee prevents the following:
 - a. Use by unauthorized personnel:
 - b. Prevents loss or theft:
3. Describe how the licensee accomplishes the following:
 - a. Maintains shielding:
 - b. Restricted access:
 - c. Contamination control from unsealed material:
4. Describe how the licensee determines radiation does to workers and members of the public.
5. What was the maximum dose received since the last MDH contact?
6. Describe the radiation surveys around the licensed activities.

- a. What survey instrument was used?
 - b. Date of last calibration
 - c. Typical radiation levels.
 - d. At what distance?
7. Describe the leak testing of sealed sources.
- a. How often are leak tests conducted?
 - b. Who analyzes the samples?
 - c. What were the most recent results?
8. Describe the provisions for repair and maintenance of the device(s) or source(s).
9. Describe any unusual events involving the radioactive material (i.e., fire, explosion, natural disaster).

Inspector Signature:	Date:
Approval Signature:	Date:

MINNESOTA DEPARTMENT OF HEALTH



LICENSING AND INSPECTION QUALIFICATION JOURNAL

	<p>Radiation Control Unit Asbestos, Lead, Indoor Air & Radiation Section Division of Environmental Health Minnesota Department of Health</p>
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January 2005

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MINNESOTA DEPARTMENT OF HEALTH LICENSING AND INSPECTION QUALIFICATION JOURNAL

INTRODUCTION

The combination of the Licensing Procedures Manual, Inspection Procedures Manual, Enforcement Applications Manual, and the Qualification Journal form the nucleus of the Unit's Licensing and Inspection program. They provide the basic information necessary to review applications, issue licenses, conduct inspections, and implement any enforcement actions.

POLICY STATEMENT

The Qualification Journal is the tool that documents the license reviewer's and the inspector's qualification progress as well as the steps taken to qualify that individual. This Journal contains an outline of the *minimum* activities expected by the Radiation Control Supervisor and the Section Manager. These activities are classified as the following:

1. Formal training
2. Self-study
3. Accompanied inspections
4. Licensing audits

Additional activities may be assigned to augment an employee's professional development.

With the concurrence of the Section Manager, the Radiation Control Unit Supervisor will schedule attendance at the job related NRC sponsored training courses. No person will be expected to attend all the courses in a twelve-month period. However, each employee will have the opportunity to attend all courses. The Section Manager reserves the right to waive the requirement for attendance at any course based on availability and program workload.

US Nuclear Regulatory Commission establishes the content of MDH staff training. The current policy states: "although Agreement States need not follow NRC Inspection Manual, Chapter 1246, they should have an equivalent program for training and qualification of personnel, and it should be present and adhered to in Agreement State programs.¹" Formal training consists of the "core courses" indicated in Sections I and II of the NRC Inspection Manual. These courses represent the minimum formal training requirements established for staff personnel who license and inspect radioactive materials programs.

In addition to the core courses, several "specialized training" courses may be scheduled to expand the staff's technical knowledge. Attendance, which is normally scheduled after employees have completed the core courses and functioned in the job position for a significant period, will be based on the availability of funds; the previous experience of personnel; and on the anticipated requirements of assigned work. The Section Manager will make the determination on an individual basis. For example, a staff member should attend the training if assigned activities in one of the areas for which a formal training course is available. As an alternative, management should ensure that the individual has had equivalent experience.

The self-study portion of this journal consists of a series of questions on each section of the Minnesota Department of Health's rules pertaining to the use of licensed material. These questions test the employee's knowledge of the rules and the thought process needed to effectively review licensing action requests and conduct inspections.

¹ *Integrated Materials Performance Evaluation Program (IMPEP) Directive 5.6, Common Performance Indicator 3 - Technical Staff and Training*

After completing a self-study quiz, the supervisor will review the answers and assign a grade. If the grade is less than a passing grade (80%), the supervisor should assign remedial actions. Once this program is satisfactorily completed, the supervisor will sign the appropriate block in the journal. The original quiz and any relevant documentation will become a part of the Qualification Journal.

The accompanied inspections have been divided into categories. At a minimum, the inspector candidate must complete two accompanied inspections. During the first accompaniment, the candidate will observe a qualified inspector in all phases of the inspection. In the second, the candidate will conduct all phases of the inspection under the supervision of a qualified inspector. At the discretion of the Unit supervisor, a candidate may be required to perform more than one of either type of accompaniment. Once a candidate has received a signature, he or she will be able to conduct that type of inspection independently in all but broadscope program areas.

RADIOACTIVE MATERIAL LICENSE REVIEWER AND INSPECTOR QUALIFICATION JOURNAL

Webster's Collegiate Dictionary defines "journal" as, "A record of current transactions and an account of day-to-day events." Clearly, a journal should not be a massive reference manual. The Qualification Journal used by the State of Minnesota for its radioactive materials license reviewers and inspectors defines areas in which an individual must demonstrate competence. It also provides a record to show how and when this competence was measured or demonstrated. Although this Journal does not include reference material, in some cases it does describe various reference materials employees should study to satisfactorily complete the Journal.

The agreement between the State of Minnesota and the U.S. Nuclear Regulatory Commission (NRC) in accordance with the provisions of subsection 274b of the Atomic Energy Act of 1954 (Act), as amended, determines the minimum training requirements for a radioactive materials inspector. Under the provisions of the Act, the Minnesota Legislature must certify that the State has a program for the control of radiation hazards adequate to protect the public health and safety. The legislature must also affirm the desire to assume regulatory responsibility for those hazards (i.e., become an Agreement State). The Act also requires that the State's program be compatible with the NRC's program for the regulation of such material and the State's program must be adequate to protect the public health and safety with respect to the materials covered by the Agreement. To implement the requirements of the Act, the NRC routinely interacts with each Agreement State; verifies that compatibility is being maintained; and evaluates the State's program to determine that it is adequate to protect the public health and safety.

One of the important criteria reviewed by the NRC is the level of technical competence of each Agreement State radioactive materials license reviewer and inspector. Since technology and the uses of radioactive material are not static, it is necessary to continually evaluate the skills of Agreement State personnel based on current perceived hazards that exist throughout the radioactive material industry. Hazards exist now that did not exist ten years ago. Both the license reviewer and the inspector should recognize that as industry practices and activities change, there will be additions and revisions to this journal. These changes will require a corresponding update of skills.

PURPOSE

This Qualification Journal establishes the current minimum training requirements required to license and inspect radioactive material facilities in the State of Minnesota. The Journal also is a record that documents the training requirements of the individuals completing those tasks. It is important to note that subsequent training may be required to retain or update those skills.

FORMAT

The Journal documents that various administrative and technical tasks required of the license reviewer and the inspector have been accomplished. It shows that:

1. The license reviewer/inspector received an administrative orientation that explains administrative actions of the Department.
2. The license reviewer/inspector demonstrated a basic understanding of Information Notices issued by the U.S. Nuclear Regulatory Commission.
3. The license reviewer/inspector completed required formal training courses.

4. The license reviewer/inspector demonstrated by a series of self-study quizzes an understanding of State of Minnesota Rules.²

In addition to the above, the radioactive materials inspector complete the following actions:

1. The inspector accompanied a qualified senior inspector during inspections.
2. The inspector independently performed radioactive materials inspections while being observed by a senior inspector.
3. The inspector was interviewed, evaluated, and approved by the Radiation Control Unit Supervisor and the Section Manager.
4. The inspector was qualified in writing as having met all the specific training requirements.

EXPECTATIONS FOR A LICENSE REVIEWER AND/OR INSPECTOR:

The primary role of a license reviewer or inspector is to gather information that can be used to determine a licensee's level of understanding of, and compliance with, applicable statutes, laws, rules, and license conditions. Beyond this responsibility, the personnel are expected to provide technical support for the regulated community. To successfully fulfill these roles, individuals will need to be aware of the proper procedures for the following:

- safety practices
- quality assurance standards
- documentation
- sampling techniques (where required)
- evidence collection

Explaining the rationale behind a rule helps the regulated party understand its importance. This also enables the inspector to effectively communicate the rules to regulated parties. Many of the radioactive materials rules coincide with federal regulations. The rationale behind the enactment of a federal regulation may be found in the Statements of Consideration prepared as part of the U.S. Nuclear Regulatory Commission's rulemaking process.

SKILLS

An effective radioactive materials license reviewer or inspector possesses many skills. Some can be learned but others seem to be innate and are difficult to quantify. In this training program, the developed skills will be measured or objectively verified. The following list sets forth the more important basic skills that should be possessed by competent and effective radioactive materials license reviewer or inspector:

1. Academically Qualified
2. Effective Communicator
3. Competent Technical Writer

² Some of the questions pertain to the enforcement policy that has been provided to each employee. In addition, answers to questions pertaining to transportation of radioactive material can be found in 49 CFR 172-184.

TRAINING POLICY

An individual can be qualified to perform license and inspection functions for certain types of licenses while working toward full qualification of all types of licenses issued by MDH. When an individual has demonstrated competency in a particular training area, their training record will be updated to document that competency. An individual will not serve as lead inspector or senior license reviewer unless that individual has demonstrated competency in the program areas applicable to that type of license.

Normally, staff is expected to complete the Core Courses within the two years. Specialized training courses will be scheduled based on employee's schedules, program requirements, and availability of funds.

Refresher training will be provided as needed. Providing refresher training is in recognition that inspector and license reviewer training does not stop with initial qualification. Training will be made available for inspectors and reviewers on a basis of need and availability. Needs assessment should include training necessary to keep current with inspection and licensing program changes as well as changes in technology.

ACADEMIC QUALIFICATIONS

The usual criteria for evaluating technical personnel are academic qualifications. Most assume that more degrees equal greater ability to perform complex technical tasks. Unfortunately, most resumes and job interviewers focus almost entirely on academic qualifications. Little effort is made to evaluate the other areas listed above. This does not imply academic excellence is not important, it obviously is. However, academic excellence without collateral skills (those listed above) will not result in a competent and effective radioactive materials license reviewer or inspector. The qualification objectives³ for entry-level license reviewers and inspectors are:

- Graduation from an accredited college or university with major coursework in a natural science; or
- An equivalent combination of the required education and experience, substituting one year of full-time professional experience in a radiation or environmental control program for thirty semester hours of education; or
- An equivalent combination of education and full-time experience in radiological technology, nuclear medicine technology or radiation therapy, substituting thirty semester hours or equivalent or one year of full-time experience for one year or thirty semester hours of the required education or experience.

COMMUNICATION SKILLS

Communication is an essential element in the licensing and inspection processes. It is imperative that employees understand the licensee's policies and procedures. However, it is just as important that employees effectively communicate any issues identified during a review or inspection. The license reviewer and the inspector must be able to adequately converse with licensees and transfer information. Good communication skills are essential in the evaluation and assurance of radiological safety programs licensed by MDH.

³ The specific education and experience requirements for employees are included in the position descriptions.

TECHNICAL WRITING SKILLS

The ability to accurately document licensing issues and inspection findings cannot be emphasized too strongly. Each licensing action or inspection report provides the legal basis for enforcement sanctions. That documentation also helps the license reviewer during the next license review as well as the inspector on the next inspection.

ADDITIONAL CONSIDERATIONS

Persistence means that the license is not issued or the inspection is not finished until all the facts and information needed have been obtained. Sometimes, it may be more important to delay issuing a license or to reschedule other inspections until all necessary information is obtained.

Treating others fairly. It is essential that reviewers and inspectors assist the licensees in understanding all the identified problems. In some cases, a licensee might need to contemplate the various options and issues. The license reviewer and the inspector must ensure that the licensee has the appropriate time to identify and implement actions. Finally, if licensee's management does not agree that there is a problem, the reviewer or inspector should take another look at the conclusions.

Awareness of the inspector's Own Emotions. Employees experience a range of emotions. Sometimes interaction with the licensee can be intense. Inspectors should recognize that they might experience strong emotions while doing their job. Licensees may respond in a defensive, argumentative way, or even be verbally abusive. In these situations, the personnel should not let inappropriate behavior trigger a similar response.

Ethics for a State Employee. Employees will be faced with decisions that concern ethics throughout their career. The ethical behavior expected of state employees ranges from areas of conflict of interest, acceptance of advantages, use of state equipment, use of confidential information, and acceptance of gifts, meals and other items of financial value. Beyond these, management expects employees to use common sense, conduct themselves professionally, and to seek guidance from a supervisor if a situation arises where the ethical choice is unclear.

Personnel must not act (or fail to act) for reasons of personal gain. In fact, any actions that may be construed as such must be avoided. Employees cannot accept favors under circumstances that may be construed as having an influence on the performance of their duties. For example, if an inspector and the regulated party have lunch together during the course of the inspection, the inspector must pay for his or her own lunch.

Other Inspection Guidelines. A positive, supportive demeanor promotes good will. A positive rapport with the regulated party will more likely result in a cooperative, productive inspection than will an arrogant, heavy-handed approach. It is important to be courteous and respectful. To do so creates an atmosphere of cooperation, reduces the responsible party's anxiety level, and encourages an exchange of information.

Proper personal appearance is also important and contributes significantly to the professional image. Under no circumstances should the employees wear clothing that bears emblems advertising a business or business-related product. Inspectors should wear attire appropriate for the type of inspection being conducted, including proper safety equipment.

INFORMATION NOTICES

In order to keep licensees, as well as NRC and Agreement State inspectors, informed about various concerns involving radioactive material that were identified throughout the country, the NRC began

issuing Information Notices. Each Notice describes a problem or concern that relates to equipment failure, design problems, loss of control over radioactive material, etc. More importantly, the Notices describe various solutions and corrective actions that were taken or can be taken to resolve identified problems.

During training, the license reviewers and inspectors may need to refer to some of these Notices. Employees are not expected to review every Notice. However, as a minimum, they should know where to look if a question or concern arises.

LICENSING AND INSPECTION QUALIFICATION JOURNAL

MASTER LOG SHEET

Employee:

The following log verifies you have received various documents and have completed required learning objectives in a satisfactory manner.

	Signature When Issued Or Completed	Date
1. Administrative orientation and Department Policy Explained	_____ (Unit Supervisor)	_____
2. Inspection Manual	_____ (Unit Supervisor)	_____
3. Enforcement Manual	_____ (Unit Supervisor)	_____
4. Information Notices	_____ (Unit Supervisor)	_____
5. Required Formal Training Courses	_____ (Unit Supervisor)	_____
6. Self-Study Quizzes	_____ (Unit Supervisor)	_____
7. Accompanied a Qualified Senior Inspector	_____ (Unit Supervisor)	_____
8. Accompaniment by a Qualified Senior Inspector	_____ (Unit Supervisor)	_____

RADIOACTIVE MATERIALS LICENSING AND INSPECTION QUALIFICATION JOURNAL

CORE COURSE TRAINING LOG

This log verifies that you have satisfactorily completed the following "core courses."

	Signature When Completed	Date
1. Inspection Procedures (G-108) Date:	 _____ (Unit Supervisor)	
2. Licensing Practicing and Procedures (G-109) Date:	 _____ (Unit Supervisor)	
3. Applied Health Physics (H-109) Date:	 _____ (Unit Supervisor)	
4. Root Cause/Incident Workshop (G-205) Date:	 _____ (Unit Supervisor)	
5. Inspecting for Performance – Materials Version (G-304) Date:	 _____ (Unit Supervisor)	
6. Diagnostic and Therapeutic Nuclear Medicine (H-304) Date:	 _____ (Unit Supervisor)	
7. Safety Aspects of Industrial Radiography (H-305) Date:	 _____ (Unit Supervisor)	
8. Transportation of Radioactive Material (H-308) Date:	 _____ (Unit Supervisor)	
9. Teletherapy and Brachytherapy (H-313) Date:	 _____ (Unit Supervisor)	
10. Radiological Emergency Response Operations (RERO) Date:	 _____ (Unit Supervisor)	
11. Health Physics in Radiation Accidents (REAC/TS) Date:	 _____ (Unit Supervisor)	

RADIOACTIVE MATERIALS LICENSING AND INSPECTION QUALIFICATION JOURNAL

SPECIALIZED TRAINING COURSES LOG

This log verifies that you have satisfactorily completed the following specialized training courses.

	Signature When Completed	Date
1. Environmental Monitoring for Radioactivity (H-111) Date:	 _____ (Unit Supervisor)	
2. Air Sampling for Radioactive Material (H-119) Date:	 _____ (Unit Supervisor)	
3. Multi-Department Radiation Survey and Site Investigation Manual (MARSSIM) (H-121) Date:	 _____ (Unit Supervisor)	
4. Internal Dosimetry (H-312) Date:	 _____ (Unit Supervisor)	
5. Safety Aspects of Well Logging (H-314) Date:	 _____ (Unit Supervisor)	
6. Advanced Radiological Incident Operations (ARIO) Date:	 _____ (Unit Supervisor)	
7. Health Physics Technology (H-210) Date:	 _____ (Unit Supervisor)	

RADIOACTIVE MATERIALS LICENSING AND INSPECTION QUALIFICATION JOURNAL

RADIOLOGICAL SAFETY INSPECTION ACCOMPANIMENTS

As part of your on-the-job training, you will accompany other inspectors and observe how they conduct inspections. You will probably have an opportunity to accompany more than one inspector. In this way, you will be able to learn those techniques and methods that best suit your personality and technical skills.

After you have participated in inspections, principally as an observer, you will have an opportunity to prepare for, perform, and document the results of actual inspections while being observed by the Radiation Control Unit Supervisor or a qualified inspector. If it is determined that you are capable of performing a quality inspection for a particular type of licensed program, you will be granted approval for performing that type of inspection without accompaniment. The Inspector Fieldwork Evaluation Report (Appendix A) must be completed and a copy included in this Journal.

As you demonstrate the ability to perform additional types of inspections, these will be added to the types of inspections you can perform without accompaniment. The following kinds of inspections are included in this qualification program:

1. Measuring Systems - Fixed and Portable Gauges
2. Medical Institution - Diagnostic Only
3. Medical Institution - Diagnostic & Therapy
4. Research and Development
5. Broadscope
6. Industrial Radiography

In addition to the accompaniments indicated above, the Radiation Control Unit Supervisor or another qualified inspector will make periodic evaluations. These evaluations are to assure consistency within the program. The Inspector Fieldwork Evaluation Report must be completed and a copy incorporated into this Journal.

RADIOACTIVE MATERIALS LICENSING AND INSPECTION QUALIFICATION JOURNAL

RADIOLOGICAL SAFETY INSPECTION ACCOMPANIMENTS WITH PARTICIPATION

This log verifies that you have accompanied a qualified inspector on a series of inspections principally as an observer with some participation. This accompaniment included at least one of each type of licensed program described on the previous page.

Licensee	License Number	Inspection Date	Qualified Inspector
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			

RADIOACTIVE MATERIALS LICENSING AND INSPECTION QUALIFICATION JOURNAL

EVALUATED RADIOLOGICAL SAFETY INSPECTION ACCOMPANIMENTS

This log verifies that you have performed a series of inspections while being observed and evaluated by a qualified inspector. Your effort included a review of the license files while preparing for the inspection, the conduct of the inspection (while being observed by a qualified inspector), written documentation of the inspection findings, and any enforcement correspondence of findings that resulted from your inspection. This accompaniment included at least one of each type of licensed program described in the Radiological Safety Inspection Accompaniments.

Licensee	License Number	Inspection Date	Qualified Inspector
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			

RADIOACTIVE MATERIALS LICENSING AND INSPECTION QUALIFICATION JOURNAL

EVALUATED RADIOLOGICAL SAFETY INSPECTIONS - ANNUAL ACCOMPANIMENTS

This log documents accompaniments and subsequent evaluation by the Radiation Control Unit Supervisor. Your effort included a review of the license files while preparing for the inspection, the conduct of the inspection, written documentation of the inspection findings, and any enforcement correspondence of findings that resulted from your inspection. A copy of the Inspector Evaluation Form (included in Appendix A) has been completed and placed in this manual.

Licensee	License Number	Inspection Date	Supervisor's Signature
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			

RADIOACTIVE MATERIALS LICENSING AND INSPECTION QUALIFICATION JOURNAL

SELF-STUDY QUIZZES – FINAL SCORES

This log verifies that you have satisfactorily completed the following self-study quizzes. A grade of 80% is required to pass each quiz. In some instances, you are required to explain how you arrived at your answer. This requires that you analyze a situation that might be identified during an inspection before you are able to determine what, if any, regulatory requirement has been violated.

	<u>Final Score</u>	<u>Date</u>
Regulatory Requirements, Administrative	_____	_____
Regulatory Requirements, Licensing Procedures	_____	_____
Regulatory Requirements, Radiation Protection Standards	_____	_____
Regulatory Requirements, Medical Uses	_____	_____
Regulatory Requirements, Industrial Radiography	_____	_____

**APPENDIX A
INSPECTOR FIELDWORK EVALUATION REPORT**

**MINNESOTA DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS GROUP**

Inspector Fieldwork Evaluation Report

DATE:

INSPECTOR:

EVALUATOR:

LICENSEE:

LICENSE NUMBER:

LOCATION:

ANNOUNCED

UNANNOUNCED

DATE OF INSPECTION:

INSPECTION TYPE:

I. PRELIMINARY DISCUSSION WITH INSPECTOR

Done

1. Explain the extent of the reviewer's participation in the inspection.
2. Discuss the procedure for introducing the reviewer to the licensee and explaining his/her presence during the inspection.
3. Explain the method that will be used for evaluating the inspector's performance.

II. SUMMARY OF EVALUATION

1. Inspector's performance rating: Meets the Guidelines
 Needs Improvement

2. Comments:

3. The inspector would benefit from additional training in:

4. The evaluation was discussed with me.

Inspector's Signature

Date

Qualified Inspector's Signature

Date

III. INSPECTOR'S PREPARATION

- 1. Has the inspector reviewed the license and prior compliance history? Yes No N/A
- 2. Has the inspector planned the inspection? Yes No N/A
- 3. Does the inspector have the appropriate instruments? Yes No N/A
- 4. Are the instruments in calibration? Yes No N/A
- 5. Does the inspector have the necessary supplemental materials? (Regulations, inspection forms, personal dosimetry, ID, wipe materials, smoke tubes and bombs, thermal anemometer, dose calibrator sources, instrument check sources, etc.) Yes No N/A

Comments:

IV. OPENING

- 1. Was the opening interview conducted with management? Yes No N/A
- 2. Were incidents or overexposures discussed? Yes No N/A
- 3. Did licensee understand the purpose, scope and techniques? Yes No N/A

Comments:

V. INSPECTION

- 1. Did the inspector use appropriate form or checklist? Yes No N/A
- 2. Did the inspector perform a "walk through" at the beginning of the inspection? Yes No N/A
- 3. Were licensee operations and use and handling of materials observed? Yes No N/A
- 4. Were the facilities checked for proper posting? Yes No N/A
- 5. Was security verified? Yes No N/A
- 6. Were workers checked for personal dosimetry? Yes No N/A
- 7. Were workers interviewed to verify their understanding of safety procedures? Yes No N/A
- 8. Were ancillary workers also interviewed? Yes No N/A
- 9. Were adequate wipes, surveys, and measurements taken? Yes No N/A
- 10. Did inspector check for adherence to ALARA? Yes No N/A
- 11. Were records verified against oral statements for
 - a. procurement and inventory Yes No N/A
 - b. receipt and transfer of materials Yes No N/A
 - c. internal audits Yes No N/A
 - d. qualification and training of users Yes No N/A
 - e. emergency plan and procedures Yes No N/A
 - f. committee meetings and minutes Yes No N/A
 - g. authorized users Yes No N/A
 - h. instrument calibration Yes No N/A
 - i. dose calibrator tests Yes No N/A
 - j. surveys and monitoring Yes No N/A
 - k. personnel dosimetry and bioassay Yes No N/A
 - l. leak tests Yes No N/A
 - m. generator-assay, moly breakthrough and logs Yes No N/A
 - n. release of effluents, sewer and air Yes No N/A
 - o. management and disposal Yes No N/A

12. Did the inspector safely handle radioactive material? Yes No N/A
13. Did the inspector address all necessary elements of the licensee's program? Yes No N/A
If not, explain:

14. Were hazards or potential problems discovered and given follow-up? Yes No N/A
If not, explain:

Comments:

VI. CLOSING

1. Was there careful assembly of supporting information prior to the exit interview? Yes No N/A
2. Did the inspector close with appropriate level of management or make every effort to do so? Yes No N/A
3. Were recommendations clearly distinguished from items of noncompliance? Yes No N/A
4. Were items of noncompliance fully explained with regulation or license condition cited? Yes No N/A
5. Did the inspector explain what follow-up actions would occur? (enforcement letter, etc.) Yes No N/A
6. Was the licensee advised of any requirements? Yes No N/A
7. Did the inspector properly decide if certain practices or operations should cease immediately? Yes No N/A
8. Were previous items of noncompliance discussed? Yes No N/A

Comments:

VII. PROFESSIONALISM

1. Did the inspector use proper judgment in evaluating radiation safety? Yes No N/A
2. Did the inspector demonstrate an adequate knowledge of health physics and regulations? Yes No N/A
3. Was the inspector's appearance appropriate for the type of licensee? Yes No N/A
4. Was rapport with management and workers sufficient for free exchange of information? Yes No N/A
5. Were the inspector's questions phrased appropriately? Yes No N/A

VIII. INSPECTION REPORT

1. Did the inspector document all items in the Inspection Report? Yes No N/A
2. Were all deficiencies addressed? Yes No N/A
3. Was the inspection report generated in a timely manner? Yes No N/A

Comments:

REVIEWED:

Evaluator

Date

Unit Supervisor

Date

Revisions

<u>REVISION</u>	<u>SECTION</u>	<u>DESCRIPTION</u>

Enclosure 11

MINNESOTA DEPARTMENT OF HEALTH



LICENSING AND INSPECTION QUALIFICATION JOURNAL

	<p>Radiation Control Unit Asbestos, Lead, Indoor Air & Radiation Section Division of Environmental Health Minnesota Department of Health</p>
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January 2005

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MINNESOTA DEPARTMENT OF HEALTH LICENSING AND INSPECTION QUALIFICATION JOURNAL

INTRODUCTION

The combination of the Licensing Procedures Manual, Inspection Procedures Manual, Enforcement Applications Manual, and the Qualification Journal form the nucleus of the Unit's Licensing and Inspection program. They provide the basic information necessary to review applications, issue licenses, conduct inspections, and implement any enforcement actions.

POLICY STATEMENT

The Qualification Journal is the tool that documents the license reviewer's and the inspector's qualification progress as well as the steps taken to qualify that individual. This Journal contains an outline of the *minimum* activities expected by the Radiation Control Supervisor and the Section Manager. These activities are classified as the following:

1. Formal training
2. Self-study
3. Accompanied inspections
4. Licensing audits

Additional activities may be assigned to augment an employee's professional development.

With the concurrence of the Section Manager, the Radiation Control Unit Supervisor will schedule attendance at the job related NRC sponsored training courses. No person will be expected to attend all the courses in a twelve-month period. However, each employee will have the opportunity to attend all courses. The Section Manager reserves the right to waive the requirement for attendance at any course based on availability and program workload.

US Nuclear Regulatory Commission establishes the content of MDH staff training. The current policy states: "although Agreement States need not follow NRC Inspection Manual, Chapter 1246, they should have an equivalent program for training and qualification of personnel, and it should be present and adhered to in Agreement State programs.¹" Formal training consists of the "core courses" indicated in Sections I and II of the NRC Inspection Manual. These courses represent the minimum formal training requirements established for staff personnel who license and inspect radioactive materials programs.

In addition to the core courses, several "specialized training" courses may be scheduled to expand the staff's technical knowledge. Attendance, which is normally scheduled after employees have completed the core courses and functioned in the job position for a significant period, will be based on the availability of funds; the previous experience of personnel; and on the anticipated requirements of assigned work. The Section Manager will make the determination on an individual basis. For example, a staff member should attend the training if assigned activities in one of the areas for which a formal training course is available. As an alternative, management should ensure that the individual has had equivalent experience.

The self-study portion of this journal consists of a series of questions on each section of the Minnesota Department of Health's rules pertaining to the use of licensed material. These questions test the employee's knowledge of the rules and the thought process needed to effectively review licensing action requests and conduct inspections.

¹ *Integrated Materials Performance Evaluation Program (IMPEP) Directive 5.6, Common Performance Indicator 3 – Technical Staff and Training*

After completing a self-study quiz, the supervisor will review the answers and assign a grade. If the grade is less than a passing grade (80%), the supervisor should assign remedial actions. Once this program is satisfactorily completed, the supervisor will sign the appropriate block in the journal. The original quiz and any relevant documentation will become a part of the Qualification Journal.

The accompanied inspections have been divided into categories. At a minimum, the inspector candidate must complete two accompanied inspections. During the first accompaniment, the candidate will observe a qualified inspector in all phases of the inspection. In the second, the candidate will conduct all phases of the inspection under the supervision of a qualified inspector. At the discretion of the Unit supervisor, a candidate may be required to perform more than one of either type of accompaniment. Once a candidate has received a signature, he or she will be able to conduct that type of inspection independently in all but broadscope program areas.

RADIOACTIVE MATERIAL LICENSE REVIEWER AND INSPECTOR QUALIFICATION JOURNAL

Webster's Collegiate Dictionary defines "journal" as, "A record of current transactions and an account of day-to-day events." Clearly, a journal should not be a massive reference manual. The Qualification Journal used by the State of Minnesota for its radioactive materials license reviewers and inspectors defines areas in which an individual must demonstrate competence. It also provides a record to show how and when this competence was measured or demonstrated. Although this Journal does not include reference material, in some cases it does describe various reference materials employees should study to satisfactorily complete the Journal.

The agreement between the State of Minnesota and the U.S. Nuclear Regulatory Commission (NRC) in accordance with the provisions of subsection 274b of the Atomic Energy Act of 1954 (Act), as amended, determines the minimum training requirements for a radioactive materials inspector. Under the provisions of the Act, the Minnesota Legislature must certify that the State has a program for the control of radiation hazards adequate to protect the public health and safety. The legislature must also affirm the desire to assume regulatory responsibility for those hazards (i.e., become an Agreement State). The Act also requires that the State's program be compatible with the NRC's program for the regulation of such material and the State's program must be adequate to protect the public health and safety with respect to the materials covered by the Agreement. To implement the requirements of the Act, the NRC routinely interacts with each Agreement State; verifies that compatibility is being maintained; and evaluates the State's program to determine that it is adequate to protect the public health and safety.

One of the important criteria reviewed by the NRC is the level of technical competence of each Agreement State radioactive materials license reviewer and inspector. Since technology and the uses of radioactive material are not static, it is necessary to continually evaluate the skills of Agreement State personnel based on current perceived hazards that exist throughout the radioactive material industry. Hazards exist now that did not exist ten years ago. Both the license reviewer and the inspector should recognize that as industry practices and activities change, there will be additions and revisions to this journal. These changes will require a corresponding update of skills.

PURPOSE

This Qualification Journal establishes the current minimum training requirements required to license and inspect radioactive material facilities in the State of Minnesota. The Journal also is a record that documents the training requirements of the individuals completing those tasks. It is important to note that subsequent training may be required to retain or update those skills.

FORMAT

The Journal documents that various administrative and technical tasks required of the license reviewer and the inspector have been accomplished. It shows that:

1. The license reviewer/inspector received an administrative orientation that explains administrative actions of the Department.
2. The license reviewer/inspector demonstrated a basic understanding of Information Notices issued by the U.S. Nuclear Regulatory Commission.
3. The license reviewer/inspector completed required formal training courses.

4. The license reviewer/inspector demonstrated by a series of self-study quizzes an understanding of State of Minnesota Rules.²

In addition to the above, the radioactive materials inspector complete the following actions:

1. The inspector accompanied a qualified senior inspector during inspections.
2. The inspector independently performed radioactive materials inspections while being observed by a senior inspector.
3. The inspector was interviewed, evaluated, and approved by the Radiation Control Unit Supervisor and the Section Manager.
4. The inspector was qualified in writing as having met all the specific training requirements.

EXPECTATIONS FOR A LICENSE REVIEWER AND/OR INSPECTOR:

The primary role of a license reviewer or inspector is to gather information that can be used to determine a licensee's level of understanding of, and compliance with, applicable statutes, laws, rules, and license conditions. Beyond this responsibility, the personnel are expected to provide technical support for the regulated community. To successfully fulfill these roles, individuals will need to be aware of the proper procedures for the following:

- safety practices
- quality assurance standards
- documentation
- sampling techniques (where required)
- evidence collection

Explaining the rationale behind a rule helps the regulated party understand its importance. This also enables the inspector to effectively communicate the rules to regulated parties. Many of the radioactive materials rules coincide with federal regulations. The rationale behind the enactment of a federal regulation may be found in the Statements of Consideration prepared as part of the U.S. Nuclear Regulatory Commission's rulemaking process.

SKILLS

An effective radioactive materials license reviewer or inspector possesses many skills. Some can be learned but others seem to be innate and are difficult to quantify. In this training program, the developed skills will be measured or objectively verified. The following list sets forth the more important basic skills that should be possessed by competent and effective radioactive materials license reviewer or inspector:

1. Academically Qualified
2. Effective Communicator
3. Competent Technical Writer

² Some of the questions pertain to the enforcement policy that has been provided to each employee. In addition, answers to questions pertaining to transportation of radioactive material can be found in 49 CFR 172-184.

TRAINING POLICY

An individual can be qualified to perform license and inspection functions for certain types of licenses while working toward full qualification of all types of licenses issued by MDH. When an individual has demonstrated competency in a particular training area, their training record will be updated to document that competency. An individual will not serve as lead inspector or senior license reviewer unless that individual has demonstrated competency in the program areas applicable to that type of license.

Normally, staff is expected to complete the Core Courses within the two years. Specialized training courses will be scheduled based on employee's schedules, program requirements, and availability of funds.

Refresher training will be provided as needed. Providing refresher training is in recognition that inspector and license reviewer training does not stop with initial qualification. Training will be made available for inspectors and reviewers on a basis of need and availability. Needs assessment should include training necessary to keep current with inspection and licensing program changes as well as changes in technology.

ACADEMIC QUALIFICATIONS

The usual criteria for evaluating technical personnel are academic qualifications. Most assume that more degrees equal greater ability to perform complex technical tasks. Unfortunately, most resumes and job interviewers focus almost entirely on academic qualifications. Little effort is made to evaluate the other areas listed above. This does not imply academic excellence is not important, it obviously is. However, academic excellence without collateral skills (those listed above) will not result in a competent and effective radioactive materials license reviewer or inspector. The qualification objectives³ for entry-level license reviewers and inspectors are:

- Graduation from an accredited college or university with major coursework in a natural science; or
- An equivalent combination of the required education and experience, substituting one year of full-time professional experience in a radiation or environmental control program for thirty semester hours of education; or
- An equivalent combination of education and full-time experience in radiological technology, nuclear medicine technology or radiation therapy, substituting thirty semester hours or equivalent or one year of full-time experience for one year or thirty semester hours of the required education or experience.

COMMUNICATION SKILLS

Communication is an essential element in the licensing and inspection processes. It is imperative that employees understand the licensee's policies and procedures. However, it is just as important that employees effectively communicate any issues identified during a review or inspection. The license reviewer and the inspector must be able to adequately converse with licensees and transfer information. Good communication skills are essential in the evaluation and assurance of radiological safety programs licensed by MDH.

³ The specific education and experience requirements for employees are included in the position descriptions.

TECHNICAL WRITING SKILLS

The ability to accurately document licensing issues and inspection findings cannot be emphasized too strongly. Each licensing action or inspection report provides the legal basis for enforcement sanctions. That documentation also helps the license reviewer during the next license review as well as the inspector on the next inspection.

ADDITIONAL CONSIDERATIONS

Persistence means that the license is not issued or the inspection is not finished until all the facts and information needed have been obtained. Sometimes, it may be more important to delay issuing a license or to reschedule other inspections until all necessary information is obtained.

Treating others fairly. It is essential that reviewers and inspectors assist the licensees in understanding all the identified problems. In some cases, a licensee might need to contemplate the various options and issues. The license reviewer and the inspector must ensure that the licensee has the appropriate time to identify and implement actions. Finally, if licensee's management does not agree that there is a problem, the reviewer or inspector should take another look at the conclusions.

Awareness of the inspector's Own Emotions. Employees experience a range of emotions. Sometimes interaction with the licensee can be intense. Inspectors should recognize that they might experience strong emotions while doing their job. Licensees may respond in a defensive, argumentative way, or even be verbally abusive. In these situations, the personnel should not let inappropriate behavior trigger a similar response.

Ethics for a State Employee. Employees will be faced with decisions that concern ethics throughout their career. The ethical behavior expected of state employees ranges from areas of conflict of interest, acceptance of advantages, use of state equipment, use of confidential information, and acceptance of gifts, meals and other items of financial value. Beyond these, management expects employees to use common sense, conduct themselves professionally, and to seek guidance from a supervisor if a situation arises where the ethical choice is unclear.

Personnel must not act (or fail to act) for reasons of personal gain. In fact, any actions that may be construed as such must be avoided. Employees cannot accept favors under circumstances that may be construed as having an influence on the performance of their duties. For example, if an inspector and the regulated party have lunch together during the course of the inspection, the inspector must pay for his or her own lunch.

Other Inspection Guidelines. A positive, supportive demeanor promotes good will. A positive rapport with the regulated party will more likely result in a cooperative, productive inspection than will an arrogant, heavy-handed approach. It is important to be courteous and respectful. To do so creates an atmosphere of cooperation, reduces the responsible party's anxiety level, and encourages an exchange of information.

Proper personal appearance is also important and contributes significantly to the professional image. Under no circumstances should the employees wear clothing that bears emblems advertising a business or business-related product. Inspectors should wear attire appropriate for the type of inspection being conducted, including proper safety equipment.

INFORMATION NOTICES

In order to keep licensees, as well as NRC and Agreement State inspectors, informed about various concerns involving radioactive material that were identified throughout the country, the NRC began

issuing Information Notices. Each Notice describes a problem or concern that relates to equipment failure, design problems, loss of control over radioactive material, etc. More importantly, the Notices describe various solutions and corrective actions that were taken or can be taken to resolve identified problems.

During training, the license reviewers and inspectors may need to refer to some of these Notices. Employees are not expected to review every Notice. However, as a minimum, they should know where to look if a question or concern arises.

LICENSING AND INSPECTION QUALIFICATION JOURNAL

MASTER LOG SHEET

Employee:

The following log verifies you have received various documents and have completed required learning objectives in a satisfactory manner.

	Signature When Issued Or Completed	Date
1. Administrative orientation and Department Policy Explained	_____ (Unit Supervisor)	_____
2. Inspection Manual	_____ (Unit Supervisor)	_____
3. Enforcement Manual	_____ (Unit Supervisor)	_____
4. Information Notices	_____ (Unit Supervisor)	_____
5. Required Formal Training Courses	_____ (Unit Supervisor)	_____
6. Self-Study Quizzes	_____ (Unit Supervisor)	_____
7. Accompanied a Qualified Senior Inspector	_____ (Unit Supervisor)	_____
8. Accompaniment by a Qualified Senior Inspector	_____ (Unit Supervisor)	_____

RADIOACTIVE MATERIALS LICENSING AND INSPECTION QUALIFICATION JOURNAL

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RADIOACTIVE MATERIALS LICENSING AND INSPECTION QUALIFICATION JOURNAL

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RADIOACTIVE MATERIALS LICENSING AND INSPECTION QUALIFICATION JOURNAL

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In addition to the accompaniments indicated above, the Radiation Control Unit Supervisor or another qualified inspector will make periodic evaluations. These evaluations are to assure consistency within the program. The Inspector Fieldwork Evaluation Report must be completed and a copy incorporated into this Journal.

RADIOACTIVE MATERIALS LICENSING AND INSPECTION QUALIFICATION JOURNAL

RADIOLOGICAL SAFETY INSPECTION ACCOMPANIMENTS WITH PARTICIPATION

This log verifies that you have accompanied a qualified inspector on a series of inspections principally as an observer with some participation. This accompaniment included at least one of each type of licensed program described on the previous page.

Licensee	License Number	Inspection Date	Qualified Inspector
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			

RADIOACTIVE MATERIALS LICENSING AND INSPECTION QUALIFICATION JOURNAL

EVALUATED RADIOLOGICAL SAFETY INSPECTION ACCOMPANIMENTS

This log verifies that you have performed a series of inspections while being observed and evaluated by a qualified inspector. Your effort included a review of the license files while preparing for the inspection, the conduct of the inspection (while being observed by a qualified inspector), written documentation of the inspection findings, and any enforcement correspondence of findings that resulted from your inspection. This accompaniment included at least one of each type of licensed program described in the Radiological Safety Inspection Accompaniments.

Licensee	License Number	Inspection Date	Qualified Inspector
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			

RADIOACTIVE MATERIALS LICENSING AND INSPECTION QUALIFICATION JOURNAL

EVALUATED RADIOLOGICAL SAFETY INSPECTIONS - ANNUAL ACCOMPANIMENTS

This log documents accompaniments and subsequent evaluation by the Radiation Control Unit Supervisor. Your effort included a review of the license files while preparing for the inspection, the conduct of the inspection, written documentation of the inspection findings, and any enforcement correspondence of findings that resulted from your inspection. A copy of the Inspector Evaluation Form (included in Appendix A) has been completed and placed in this manual.

Licensee	License Number	Inspection Date	Supervisor's Signature
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			

RADIOACTIVE MATERIALS LICENSING AND INSPECTION QUALIFICATION JOURNAL

SELF-STUDY QUIZZES – FINAL SCORES

This log verifies that you have satisfactorily completed the following self-study quizzes. A grade of 80% is required to pass each quiz. In some instances, you are required to explain how you arrived at your answer. This requires that you analyze a situation that might be identified during an inspection before you are able to determine what, if any, regulatory requirement has been violated.

	<u>Final Score</u>	<u>Date</u>
Regulatory Requirements, Administrative	_____	_____
Regulatory Requirements, Licensing Procedures	_____	_____
Regulatory Requirements, Radiation Protection Standards	_____	_____
Regulatory Requirements, Medical Uses	_____	_____
Regulatory Requirements, Industrial Radiography	_____	_____

**APPENDIX A
INSPECTOR FIELDWORK EVALUATION REPORT**

**MINNESOTA DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS GROUP**

Inspector Fieldwork Evaluation Report

DATE:

INSPECTOR:

EVALUATOR:

LICENSEE:

LICENSE NUMBER:

LOCATION:

ANNOUNCED

UNANNOUNCED

DATE OF INSPECTION:

INSPECTION TYPE:

I. PRELIMINARY DISCUSSION WITH INSPECTOR

Done

1. Explain the extent of the reviewer's participation in the inspection.
2. Discuss the procedure for introducing the reviewer to the licensee and explaining his/her presence during the inspection.
3. Explain the method that will be used for evaluating the inspector's performance.

II. SUMMARY OF EVALUATION

1. Inspector's performance rating: Meets the Guidelines
 Needs Improvement
2. Comments:
3. The inspector would benefit from additional training in:
4. The evaluation was discussed with me.

Inspector's Signature

Date

Qualified Inspector's Signature

Date

III. INSPECTOR'S PREPARATION

- 1. Has the inspector reviewed the license and prior compliance history? Yes No N/A
- 2. Has the inspector planned the inspection? Yes No N/A
- 3. Does the inspector have the appropriate instruments? Yes No N/A
- 4. Are the instruments in calibration? Yes No N/A
- 5. Does the inspector have the necessary supplemental materials? (Regulations, inspection forms, personal dosimetry, ID, wipe materials, smoke tubes and bombs, thermal anemometer, dose calibrator sources, instrument check sources, etc.) Yes No N/A

Comments:

IV. OPENING

- 1. Was the opening interview conducted with management? Yes No N/A
- 2. Were incidents or overexposures discussed? Yes No N/A
- 3. Did licensee understand the purpose, scope and techniques? Yes No N/A

Comments:

V. INSPECTION

- 1. Did the inspector use appropriate form or checklist? Yes No N/A
- 2. Did the inspector perform a "walk through" at the beginning of the inspection? Yes No N/A
- 3. Were licensee operations and use and handling of materials observed? Yes No N/A
- 4. Were the facilities checked for proper posting? Yes No N/A
- 5. Was security verified? Yes No N/A
- 6. Were workers checked for personal dosimetry? Yes No N/A
- 7. Were workers interviewed to verify their understanding of safety procedures? Yes No N/A
- 8. Were ancillary workers also interviewed? Yes No N/A
- 9. Were adequate wipes, surveys, and measurements taken? Yes No N/A
- 10. Did inspector check for adherence to ALARA? Yes No N/A
- 11. Were records verified against oral statements for
 - a. procurement and inventory Yes No N/A
 - b. receipt and transfer of materials Yes No N/A
 - c. internal audits Yes No N/A
 - d. qualification and training of users Yes No N/A
 - e. emergency plan and procedures Yes No N/A
 - f. committee meetings and minutes Yes No N/A
 - g. authorized users Yes No N/A
 - h. instrument calibration Yes No N/A
 - i. dose calibrator tests Yes No N/A
 - j. surveys and monitoring Yes No N/A
 - k. personnel dosimetry and bioassay Yes No N/A
 - l. leak tests Yes No N/A
 - m. generator-assay, moly breakthrough and logs Yes No N/A
 - n. release of effluents, sewer and air Yes No N/A
 - o. management and disposal Yes No N/A

12. Did the inspector safely handle radioactive material? Yes No N/A
13. Did the inspector address all necessary elements of the licensee's program?
If not, explain: Yes No N/A

14. Were hazards or potential problems discovered and given follow-up?
If not, explain: Yes No N/A

Comments:

VI. CLOSING

1. Was there careful assembly of supporting information prior to the exit interview? Yes No N/A
2. Did the inspector close with appropriate level of management or make every effort to do so? Yes No N/A
3. Were recommendations clearly distinguished from items of noncompliance? Yes No N/A
4. Were items of noncompliance fully explained with regulation or license condition cited? Yes No N/A
5. Did the inspector explain what follow-up actions would occur? (enforcement letter, etc.) Yes No N/A
6. Was the licensee advised of any requirements? Yes No N/A
7. Did the inspector properly decide if certain practices or operations should cease immediately? Yes No N/A
8. Were previous items of noncompliance discussed? Yes No N/A

Comments:

VII. PROFESSIONALISM

1. Did the inspector use proper judgment in evaluating radiation safety? Yes No N/A
2. Did the inspector demonstrate an adequate knowledge of health physics and regulations? Yes No N/A
3. Was the inspector's appearance appropriate for the type of licensee? Yes No N/A
4. Was rapport with management and workers sufficient for free exchange of information? Yes No N/A
5. Were the inspector's questions phrased appropriately? Yes No N/A

VIII. INSPECTION REPORT

1. Did the inspector document all items in the Inspection Report? Yes No N/A
2. Were all deficiencies addressed? Yes No N/A
3. Was the inspection report generated in a timely manner? Yes No N/A

Comments:

REVIEWED:

Evaluator

Date

Unit Supervisor

Date

Revisions

<u>REVISION</u>	<u>SECTION</u>	<u>DESCRIPTION</u>

Enclosure 12

**Asbestos, Indoor Air, Lead and Radiation
Minnesota Department of Health
Division of Environmental Health**

**Linda Bruemmer
Environ. Health Manager**

Radiation Control Unit

**George Johns
Environ. Health Supervisor**

**Asbestos and Lead
Compliance Unit**

Indoor Air Unit

**Radioactive Materials
Group**

X-Ray Group

- Tom Hogan
Environ. Health Supervisor**
- Nancyjo LaPlante
Industrial Hygienist 3**
- Dan Locher
Industrial Hygienist 3**
- Greg Boole
Industrial Hygienist 2**
- Daniel Miller
Industrial Hygienist 2**
- Bruce Lange
Industrial Hygienist 1**
- Bob Miles
Public Health Sanitarian 2**

- Dale Dorschner
Environ. Health Supervisor**
- Kathy Norlien
Environ. Research Scientist**
- Elizabeth Croteau-Kallestad
Research Scientist 2**
- Daniel Tranter
Research Scientist 2**
- Joshua Kerber
Research Scientist 2**
- Vacant
Health Physicist 1**
- Amanda Wobbema
Project Analyst**

- Sue McClanahan
Radiation Specialist 3**
- Tim Donakowski
Health Physicist 1**
- John Goepferd
Radiation Specialist 2**
- Craig Verke
Radiation Specialist 2**
- Brandon Juran
Radiation Specialist 1**
- Tina Leland
Office & Admin.
Specialist Sr.**

- Vacant
Radiation Specialist 3**
- Darrel Holtz
Radiation Specialist 2**
- Marge Shaw
Radiation Specialist 2**
- Charles Doerr
Radiation Specialist 2**
- Ronald Peterson
Radiation Specialist 2**
- Michael Cimaglio
Radiation Specialist 1**
- Lisa Schuck
Office & Admin.
Specialist**

Brandon N. Juran

5132 William Avenue

Edina, MN 55436

(952) 922-9277

bnjuran@hotmail.com

Education

University of Florida, Graduated December 2003

Master of Science in Materials Science and Engineering

- Teaching Assistant for Mechanical Metallurgy.
- Experience with Instron and MTS mechanical testing systems, Rockwell hardness, microhardness (Knoop and Vickers), heat-treatment, mechanical polishing, electro-polishing, Charpy impact testing, optical microscopy, and scanning electron microscopy.
- Research into deformation behavior of a nickel-based single-crystal superalloy.
- Studies focused on Mechanical Metallurgy, Fracture of Brittle Materials, Surface Science, Mechanical Properties of Polymers, Structure and Defects of Materials, and Scanning Electron Microscopy.

GPA 3.8/4.0

University of Minnesota Duluth, Graduated May 1998

Bachelor of Chemical Engineering

Bachelor of Arts in Chemistry, cum laude

Minor in Mathematics

GPA 3.5/4.0

Work Experience

Radiographic and Data Solutions: Engineer (Contract), January 2004 - present

- Assisted in building and testing of industrial x-ray machines.
- Served as the math resource for the software developer.
- Extracted data on angulation and displacement of spinal cord movement from fluoroscopic images for a clinical research study.

Bay West: Environmental Engineer, March 2000 – June 2002

- Responsible for vendor contracts, bid preparation, writing reports, preparing technical specifications, estimating costs and contractor oversight.
- Operated and maintained a large groundwater treatment system on budget. Duties included repairing the treatment system, routine maintenance, water quality sampling, report preparation, and regular performance presentations to the client and regulatory agencies.
- Hazardous material emergency response team member.

EnecoTech Midwest: Staff Engineer, June 1999 – March 2000

- Ensured remediation systems were operating properly, water sampling was performed, and reports were completed on time for contaminated sites.
- Inspected condemned homes for asbestos and hazardous materials.
- Supervised work of Field Technicians.

Institute for Environmental Assessment: Field Engineer, September 1998 – June 1999

- Performed oversight for asbestos and mold abatement projects, asbestos inspections, and asbestos air sampling and analysis.

Certifications and Memberships

Engineer-in-Training in the State of Minnesota

American Institute of Chemical Engineers member

ASM International member

Omega Chi Epsilon Honor Society member (undergraduate)

Enclosure 13

STAFF BALANCE ANALYSIS

LICENSE CATEGORY	LICENSING STAFF DAYS		INSPECTION STAFF DAYS	
	NEEDED	AVAILABLE	NEEDED	AVAILABLE
Nuclear Medicine – Diagnostic	12	19	12	16
Nuclear Medicine – Therapy	32	50	40	55
HDR	12	19	21	30
Gamma Knife	4	7	3	4
Mobile Nuclear Van	5	8	8	12
Medical – Broad Scope	15	24	80	115
Nuclear Pharmacy	7	9	8	12
Fixed Gauge	16	25	12	17
Portable Gauge	10	16	10	15
Industrial – Other	24	29	20	28
Broad Scope – Industrial	20	30	120	176
Industrial Radiography	10	15	30	44
PET	5	8	4	7
Total	172	259	368	531

STAFF RESOURCE ANALYSIS¹

LICENSE CATEGORY	TIMOTHY DONAKOWSKI		CRAIG VERKE		JOHN GOEPFERD		BRANDON JURAN		TOTAL	
	LIC	INSP	LIC	INSP	LIC	INSP	LIC	INSP	LIC	INSP
Nuclear Medicine – Diagnostic	7	0	0	5	0	5	7	3	14	13
Nuclear Medicine – Therapy	19	0	0	20	0	20	19	4	38	44
HDR	7	0	0	10	0	10	7	3	14	23
Gamma Knife	4	0	0	2	0	1	1	0	5	3
Mobile Nuclear Van	4	0	0	4	0	4	2	1	6	9
Medical – Broad Scope	9	10	0	30	9	30	0	18	18	88
Nuclear Pharmacy	5	0	0	4	0	4	2	1	7	9
Fixed Gauge	15	0	0	6	0	6	4	1	19	13
Portable Gauge	10	0	0	5	0	5	2	1	12	11

¹ Assumes 0.8 FTE for each employee dedicated to the Agreement State Program. Other duties include Radiological Response, instructional opportunities, and training.

Industrial - Other	14	0	5	10	5	10	4	2	28	22
Broad Scope - Industrial	10	15	12	55	0	55	2	7	24	132
Industrial Radiography	10	0	0	15	0	15	2	4	12	34
PET	5	0	0	2	0	2	1	1	6	5
	119	25	17	168	14	167	53	46	203	406

PROFESSIONAL STAFF ASSIGNMENTS

STAFF MEMBER	PRIMARY ASSIGNMENT	SECONDARY ASSIGNMENT
Susan McClanahan Radiation Specialist 3	<ul style="list-style-type: none">• Radiological Response Program Coordinator	<ul style="list-style-type: none">• Incident and Allegation Coordinator• Rules Coordinator• Radiological Training Coordinator• Positron Emission Tomography (PET) License Inspection• License Reviewer
Timothy Donakowski Health Physicist	<ul style="list-style-type: none">• License Reviewer	<ul style="list-style-type: none">• License Inspector• Emerging Technologies Specialist• Environmental Issues Specialist
John Goepferd Radiation Specialist 2	<ul style="list-style-type: none">• License Inspector	<ul style="list-style-type: none">• License Reviewer
Craig Verke Radiation Specialist 2	<ul style="list-style-type: none">• License Inspector	<ul style="list-style-type: none">• License Reviewer
Brandon Juran Radiation Specialist 1	<ul style="list-style-type: none">• License Reviewer	<ul style="list-style-type: none">• License Inspector• Technical Documents Administrator• Radiological Trainer

OVERALL FTE FOR MINNESOTA AGREEMENT STATE PROGRAM

NAME	FTE
Susan McClanahan Radiation Specialist 3	0.25
Timothy Donakowski Health Physicist	0.80
John Goepferd Radiation Specialist 2	0.80
Craig Verke Radiation Specialist 2	0.80
Brandon Juran Radiation Specialist 1	0.80
George F. Johns, Jr. Supervisor	0.50
Tina Leland Support Staff	1.00

Enclosure 14

TIMOTHY DONAKOWSKI

DATE	FACILITY	FACILITY TYPE	QUALIFIED INSPECTOR
03/04/98	University of Minnesota	Iridium-192 Brachytherapy Incident	James Cameron Geoff Wright
03/06/98	University of Minnesota	Cesium-137 Brachytherapy Misadministration	John Jones
08/27/98	University of Minnesota	Cobalt-60 Irradiator Incident	John Jones
01/20/99	University of Minnesota	HDR Allegation	John Jones
02/26/99	Mayo Clinic	Misadministration	Darrel Wiedemann
12/01/99	Fairview Southdale	Misadministration	John Jones Deborah Piskura
02/15/01	Hennepin County Medical Center	Nuclear Medicine	James Cameron Chris Martin
04/18/01 04/19/04	Alliant Integrated Defense (ATK)	Decommissioning	George (Mike) McCann Michael LaFranzo
04/20/01	Syncor	Nuclear Pharmacy	Michael LaFranzo
09/05/01	St. Mary's Hospital	Misadministration	Robert Hayes Chris Martin
09/20/01	University of Minnesota	Broad Scope – Irradiators and Teletherapy	Chris Martin Darrel Wiedemann
10/18/01	Health Partners Riverside Nuclear Cardiology	Nuclear Medicine	Robert Hayes
10/18/01	Fairview University	Nuclear Medicine	Robert Hayes
10/30/01	American Engineering and Testing	Industrial Radiography	Robert Hayes
11/02/01	Minnesota Department of Agriculture	Gas Chromatograph	Robert Hayes
01/30/02	St. Joseph's Hospital	Nuclear Medicine	Deborah Piskura
04/15/02	Cardiology Partners	Nuclear Medicine	Robert Gattone

05/21/02	GME Consultants	Portable Gauge – Incident Investigation	Robert Hayes
07/28/02	Iowa State University	Broad Scope	George F. Johns, Jr.
07/23/02	Alliant Integrated Defense (ATK)	Decommissioning	Jim Persoon
07/23/02	Imation	Fixed Gauge	Robert Hayes
08/08/02	St. Cloud Hospital	Nuclear Medicine	Deborah Piskura
01/28/03	Alliant Integrated Defense (ATK)	Decommissioning	Michael LaFranzo
04/12/04	Imaging Solutions	Nuclear Medicine – Initial Inspection	Deborah Piskura

JOHN GOEPFERD

DATE	FACILITY	FACILITY TYPE	NRC INSPECTOR
01/18/01	Riverside University Campus Nuclear Medicine	Nuclear Medicine	Robert Hayes
02/13/01	Woodwinds Hospital	Nuclear Medicine	Jim Lyons
02/13/01	Syncor	Nuclear Pharmacy	Jim Lyons
10/29/01	Health Partners	Nuclear Cardiology	Robert Hayes
01/31/02	Braun Intertec	Industrial Radiography	Deborah Piskura
08/07/02	DiaSorin	Research and Development	Deborah Piskura
08/27/02	Braun Intertec	Industrial Radiography	Deborah Piskura
08/28/02	Mayo Clinic	Gamma Knife	Deborah Piskura
02/25/04	Braun Intertec	Industrial Radiography	Deborah Piskura
02/26/04	Cooperheat MQS	Industrial Radiography	Deborah Piskura
02/26/04	Mercy Hospital	Nuclear Medicine	Deborah Piskura

CRAIG VERKE

DATE	FACILITY	FACILITY TYPE	NRC INSPECTOR
02/12/01	Arrow Tank	Industrial Radiography	James Cameron Christopher Martin
09/20/01	University of Minnesota	Broad Scope – Irradiators and Teletherapy	Chris Martin Darrel Wiedemann
05/15/02	Mercy Hospital	Nuclear Medicine – IVB	Sam Mulay
05/15/05	Unity Hospital	Nuclear Medicine	Sam Mulay
06/19/02	Alliant Integrated Defense (ATK)	Decommissioning	Michael LaFranzo
08/06/02	Chart Industries	Industrial Radiography	Deborah Piskura
06/19/02	Hitchcock Industries	Decommissioning	Michael LaFranzo

Enclosure 15

MINNESOTA DEPARTMENT OF HEALTH



RESPONSE MANUAL FOR ALLEGATIONS

The logo is circular with a stylized animal head (possibly a moose or bear) in the center. The text "Radioactive Materials Group" is written along the top arc, "Minnesota Department of Health" along the bottom arc, and "RMG" in the center.	<p>Radiation Control Unit</p> <p>Asbestos, Lead, Indoor Air & Radiation Section</p> <p>Division of Environmental Health</p> <p>Minnesota Department of Health</p>
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January 2005

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- GENERAL DOCUMENTATION OF AN ALLEGATION 9

This document provides general information on the MDH allegation program, for receipt of an allegation until closure. It is important to note that there is no threshold for the acceptance of allegations. Even vague, general, or hearsay allegations require a reasonable effort on the part of the staff to support a determination to close an allegation.

INITIAL CONTACT

Receipt of an Allegation

An "alleger" is any individual or organization that makes an allegation to MDH. Any MDH employee may receive an allegation, either by telephone, in person, via the Internet¹; during an inspection, investigation, or enforcement conference; or in the mail. The alleger should be treated courteously in all contacts and be responsive to the alleger, irrespective of the reason the alleger came to the MDH. The safety significance of an allegation should not affect the treatment of the alleger, although it may affect the timing of MDH follow-up actions. The way MDH staff treat an alleger is an important indicator of how the alleger, MDH staff, and the public view the allegation process.

Questions To Be Asked During Contact With the Alleger

First obtain as much information as possible from the alleger, including—

- The alleger's full name, position or relationship to the facility or activity involved, home mailing address (not business), telephone number
- The alleger's employer, the facility, and activity involved
- Nature and details of the allegation
- Potential safety impact
- How the alleger found out about the concern(s)
- Other individuals MDH should contact for additional information
- Records MDH should review
- Whether the alleger raised the concerns with his or her management—
 - If not, why not
 - If yes, what action has been taken
- Whether the alleger objects to having his or her identity released
- The alleger's preference for method and time of contact
- The reason the alleger contacted the MDH (e.g., licensee's corrective action program is unresponsive, individual fears retaliation)

¹ Because of the current lack of security in Internet communications between the public and MDH, the inability to verify the identity of the sender, and the possibility that messages sent to company e-mail addresses can be read by the company, all allegations received via the Internet will be treated as anonymous.

- Whether the alleged has contacted the Department of Labor (DOL) regarding this discrimination allegation

If the alleged attempts to provide off-the-record information, advise him or her that MDH does not recognize off-the-record information and that all information received will be accepted officially and appropriately acted upon.

If the alleged does not object to being contacted again, inform the alleged that he or she will be contacted again, either by telephone, a personal visit, or a letter, usually within 30 days of the allegation. Inform the alleged that he or she will be contacted when the allegation is resolved. All contacts should be documented in the appropriate allegation file.

If the MDH contact does not have the capability to evaluate the information, determine follow-up action, or establish MDH jurisdiction, the contact should inform the alleged that it might be necessary for someone else to contact him or her for additional information.

If during contact with an alleged, the alleged becomes hostile and/or abusive, the MDH employee should politely end the conversation and either offer to re-contact the alleged, or provide the alleged the opportunity to re-contact MDH, after he or she has had an opportunity to regain composure.

Protecting an Alleged's Identity

It is MDH's practice to neither confirm nor deny to the licensee or the public that an individual is an alleged or confidential source, except when necessary in the furtherance of an investigation. Whether confidentiality has been granted or not, the following points apply:

- Do not tell a licensee (even if the licensee asks) that an inspection is based on an allegation, except when deemed necessary during the conduct of an inspection requested by a worker. Inspection-related documents should address relevant issues without acknowledging that the issue was raised in the context of an allegation.
- Do not include information that could lead to the identification of the alleged or confidential source in MDH-generated documents related to an allegation, except in cases in which the alleged has indicated that he or she has no objection to the release of his or her name to the licensee and this lack of objection has been documented in writing.
- If necessary, to protect the identity of an alleged or confidential source, reword and retype an alleged's written allegation before it is made available to a licensee.
- Do not reproduce allegation files and documents that could reveal the identity of an alleged or confidential source.

For more information on privacy issues, refer to the Data Privacy Standards and Guidelines for Environmental Health Staff.

Disclosing an Alleger's Identity

Inform an allegor of the limitations on the protection of his or her identity. Tell the allegor that his or her identity will not be disclosed outside MDH, except as follows:

- The allegor has clearly indicated no objection to being identified.
- Disclosure is necessary because of an overriding health or safety issue.
- Disclosure is necessary pursuant to an order of a court.
- Disclosure is necessary in furtherance of a wrongdoing investigation.
- Disclosure is necessary to support a hearing on an enforcement matter.
- The allegor has taken actions that are inconsistent with and override the purpose of protecting the allegor's identity.
- Disclosure is mandated by the Freedom of Information Act (FOIA).

For allegations involving discrimination, MDH will disclose an allegor's identity to the licensee and/or the employer during an MDH investigation if the allegor claims he or she is the victim of the discrimination.

For allegations involving wrongdoing (e.g., allegations involving record falsification, willful violations, or other deliberate conduct in violation of MDH regulatory requirements), an allegor's identity may be disclosed at the MDH's discretion in order to pursue the investigation.

Notify the allegor if his or her name or other personal identifier is to be, or has been, released.

For allegations concerning radiological working conditions, for which an allegor specifically requests an inspection, it is required that a worker's request for an inspection be in writing, setting forth the specific grounds for the request, and that it be signed. The request for inspection shall be made available to the licensee, and if requested by the worker giving this notice, the names of the requestor and other individuals shall not appear in the request or any record published except for good cause. If an allegor simply provides a radiological safety issue and does not specifically request an inspection, treat the issue like any other allegation.

Department of Labor (DOL) Information

If the allegation involves discrimination under the Energy Reorganization Act of 1974 (ERA), Section 211, inform the allegor that—

- Section 211 affords remedies such as reinstatement and compensation for lost wages to an allegor when an employer is found to have discriminated against an employee for engaging in any protected activity, including contacting the MDH.
- He or she may obtain personal remedies through the DOL for any retaliatory or discriminatory practices by his or her employer, if filed timely, and the employer does not have another legitimate reason for the adverse action.
- He or she must file a written complain with DOL within 180 days of the occurrence of the discriminatory act to ensure that his or her personal employee rights are protected. In situations where the employee receives written notice of a proposed lay-off or other

adverse action, the 180 days begin on the day the employee is notified of the action, not the day the action is effective.

- Complaints should be filed with the regional DOL office in Kansas City. The address is:

Department of Labor
City Center Square
1100 Main Street, Suite 800
Kansas City, MO 64105
(816) 426-5866

ACTIONS TO ADDRESS AN ALLEGATION

Actions of the MDH Supervisor

The supervisor should screen the allegation for safety significance and determine the method of follow-up. An allegation having relatively high safety significance should be addressed and resolved expeditiously. Occasionally, an allegation may be too general for follow-up and further information cannot be obtained from the allexer. Nonetheless, the supervisor should ensure that the allegation is documented so that it could be pursued if additional information is obtained from other sources that clarify the allegation.

The supervisor should assign appropriate staff to respond to the allegation and assist the technical staff in identifying the issues involved in an allegation using the following categories:

- Allegations that involve inadequate technical issues such as:
 - operation of devices
 - procedures or implementation of procedures
 - qualifications
 - training
 - corrective actions
- Allegations the involve overexposure to radiation
- Allegations that provide a reasonable suspicion of wrongdoing such as:
 - record falsification
 - willful violation of rules or license conditions
 - other conduct in violation of MDH regulatory requirements
- Allegations that involve matters outside MDH jurisdiction, which includes OSHA, other Agreement States, or NRC

Actions of the Technical Staff

The technical staff, in coordination with the supervisor, should review the documentation and determine the actions necessary to properly address the allegation. Implementation of follow-up actions should consider not only the particular allegation, but also the overall area of concern, which includes the potential for more generic issues. When allegations indicate a broader problem, action should be taken to expand the scope of the inquiry to determine the extent of the problem.

Technical staff should document the final resolution of an allegation in a final report or other appropriate correspondence

General Documentation of an Allegation

The allegation file will include all correspondence (including drawings, maps, etc. provided by the allegor), memorandums to file, interviews, and summaries of telephone conversations, discussions, and meetings.

If the information is determined to be insufficient to determine the safety and regulatory significance, the staff should make additional contact with the allegor.

ALLEGATION FOLLOWUP AND RESOLUTION

Evaluation by Technical Staff

The allegation should be screened using the following questions:

- Is there an immediate safety concern that must be quickly addressed?
- Is the allegation a specific safety or quality issue or a generalized concern?
- Has the staff previously addressed the issue?
- Have there been a substantial number of allegations on similar concerns?
- What is the time sensitivity of the allegation, and what immediate actions are necessary?
- What is the potential for wrongdoing and will investigative assistance be needed?
- Does the allegation package contain sufficient information for a thorough evaluation? If not, identify the additional information needed.
- Is the identity of an allegor necessary for a thorough evaluation?
- Can the issues be adequately addressed by a technical inspection? If not, determine the best way to address the issues.
- Identify any peripheral issues that could develop.
- Are any licensing actions, enforcement actions, or other allegations pending that could be affected by the allegation?
- Can inspection resources be effectively utilized pursuing the issue or is the allegation too vague or frivolous?
- Is further consideration of the allegation required? If not, inform the allegor or confidential source in a courteous and diplomatic manner of the rationale for not considering it further.

- Can license resources reasonably be used in resolving the allegation to conserve staff resources? Consider potential problems associated with involving the licensee in the resolution process?
- Does the allegation have the potential to require escalated enforcement action?

Referrals

Any time there is a referral to another organization the allegor must be notified. However, for an allegation not within the jurisdiction of MDH, tell the allegor that the allegation will be forwarded to the appropriate organization(s) and that he or she, subsequently, should directly contact the organization(s). The allegor should be told to contact the new organization(s) directly, and MDH will terminate its involvement in the case. When MDH forwards an allegation not within its jurisdiction to another organization(s), MDH should not act as a middleman between the allegor and the other organization(s).

CLOSURE OF ALLEGATIONS

Staff Action

The supervisor shall review and concur with closing an allegation.

Documentation of Resolution of the Allegation

A final report will be prepared to set forth the facts about the allegation and its resolution. This report can be a memorandum for a relatively minor matter, a report of an investigation, an inspection report, material inspection field notes, or a technical paper for a complex or major generic issue. The report can be a supplement to a safety evaluation report for multiple allegations occurring close to the issuance of a license.

The final closure report should include a summary of the concern, a description of the evaluation performed, and the conclusions drawn. It also should inform the allegor which concerns were substantiated and which were not. However, if the closure document is an inspection report, it will address the relevant issue without acknowledging that the issue was raised in the context of an allegation.

The closure report officially closes the allegation and must be placed in the allegation file.

Distribution of the Final Report

Send to the allegor or confidential source a copy of the final report. Do not send materials inspector field notes, instead, summarize the information in the closure letter.

Notification of Results of Investigations

When an enforcement action is pending, the allegor cannot normally be informed of the results of the investigation unless the licensee is informed. The licensee is informed of the results through the issuance of a letter informing the licensee that MDH is considering an issue for escalated enforcement and inviting the licensee to an enforcement conference or offering the licensee the choice of responding in writing. A copy of the letter to the licensee and the synopsis of the report shall be sent to the allegor at the time it is sent to the licensee.

ACTION BY THE RECEIVING MDH EMPLOYEE

General Documentation of an Allegation

Occasionally, an allegation may be too general for follow-up and further information cannot be obtained from an alleger. Nonetheless, the allegation should be documented so that it could be pursued if additional information is obtained from other sources that clarify the allegation.