MINNESOTA DEPARTMENT OF HEALTH

AGREEMENT STATE APPLICATION
Volume III

Radiation Control Unit
Asbestos, Lead, Indoor Air & Radiation Section
Division of Environmental Health
Minnesota Department of Health

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MINNESOTA DEPARTMENT OF HEALTH

LICENSING PROCEDURES MANUAL

Radiation Control Unit

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SECTION I – OVERVIEW

INTRODUCTION

This manual provides guidance to license reviewers on administrative licensing procedures. It includes procedures for acknowledging requests for specific licensing actions, tracking the progress of actions, maintaining files electronically, preparing licenses, distributing documents, and other miscellaneous administrative activities.

Much of the information needed by MDH licensing staff is provided in the appendices. Licensing staff should note the following information:

- Appendix A contains standard forms used to complete licensing actions.
- Appendix B contains standard letters that may be edited to meet case-by-case requirements.
- Appendix C contains the list of standard license conditions.

The purpose of this manual is to provide licensing staff and other appropriate staff members with basic administrative procedures for processing, managing, and tracking licensing actions from the time each action is received by the Radioactive Materials Group until the action is completed. The information provided in this chapter is not comprehensive, and it does not describe the major duties of the license reviewer.

AGREEMENT STATES

Minnesota has entered into an agreement with the US Nuclear Regulatory Commission (NRC) that gives the authority to license and inspect radioactive, source, or special nuclear materials used or possessed within its borders. When working at federally controlled sites in Minnesota it is necessary to know the jurisdictional status of the land in order to determine whether MDH or the NRC has regulatory authority.

Licensees are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. MDH recommends that licensees ask their local contact for the Federal Agency controlling the site (e.g., Contract Officer, Base Environmental Health Officer, District Office staff) to help determine the jurisdictional status of the land, so that licensees can comply with MDH or NRC regulatory requirements, as appropriate.[1]

In all cases, the NRC has regulatory authority for licensure of land determined to be "exclusive Federal jurisdiction."

LICENSING TRACKING SYSTEM

The licensing tracking system, called the Radioactive Materials Information System (RAMIS), is the MDH computer system for tracking each license application from its receipt to completion. This system

[1] Additional guidance on determining jurisdictional status is found in All Agreement States Letter, SP-96-022, dated February 16, 1996. This letter is available at <http://www.hsrd.ornl.gov/MDH/home.htm>. Choose "NRC-State Communications," then choose "All of the Above," and follow the directions for submitting a query for "SP96022." As an alternative, interested parties can request the letter from STP by calling NRC toll-free at (800) 368-5642, extension 415-3340.

supports a standardized review process and provides licensing and inspection management reports. RAMIS allows the Radioactive Materials Group to provide timely responses to inquiries and specialized, *ad hoc* queries.

NOTICE OF LICENSE EXPIRATION

A Notice of License Expiration is sent to each licensee 90 days before its license expires. Each month, MDH staff generates a standard form letter. A sample notice is provided in Appendix B. The notices are addressed to the listed contact for that license as well as to the Radiation Safety Officer (RSO). The applicable forms, rules, and guidance for preparing applications for license renewal may be attached to the notices. However, the primary method for obtaining those documents will be by accessing the Radioactive Materials Group website. Therefore, the electronic address for the material will normally be indicated in the notices.

ADMINISTRATIVE PROCEDURES

Initial Processing of Incoming Licensing Actions

All incoming licensing documents shall be entered into the license tracking system. Support staff and the license reviewer are responsible for the timely processing of materials license applications. All materials licenses are assigned unique numbers that are tracked in the RAMIS database for the life of the licenses. (The computer system permits licensee identification using many different queries including a facility name as well as a license number.) Each licensing action is also tracked in the RAMIS database from receipt of a request for licensing action to completion.

For initial applicants, a new license number will be assigned. However, this number will not be referenced in communications with the licensee until the license has been finalized.

Acceptance Review Procedure

The Radioactive Materials Group will complete an acceptance review[2] and take the following actions:

- Issue a "deemed timely" letter (for renewals only) within five working days of the actions receipt. This "deemed timely" letter serves to notify the licensee that their license will not expire until final licensing action has been taken.
- Confirm that all necessary sections of the application are completed and that it has been signed by the applicant's certifying official.
- Confirm that attachments identified by the applicant are, in fact, included in the submittal.
- Identify any requests for expedited review for safety-significant concerns (e.g., change in the Radiation Safety Officer or amendment requests resulting from identification of safety-significant violations) or for business reasons (e.g., change in ownership, bankruptcy).

Follow-up on Expired Materials Licenses

The identification and investigation of licenses that have not been renewed is an important part of the material licensing and inspection program. The licensing staff should coordinate with the inspection staff to take appropriate follow-up action on delinquent licensees. This follow-up action may include a visit to the facility to ensure that radioactive materials are no longer possessed by the licensee, and that significant contamination does not exist in the facilities where radioactive materials were used or stored.

[2] An acceptance review can be completed by any staff member including support staff that has been trained to accomplish this task.

There must be sufficient documentation in the file to demonstrate that one of the following has occurred:

(1) a new license has been issued superseding the previous license; or

(2) the licensee has ceased operations, properly transferred or disposed of all radioactive material, and provided documents demonstrating that the facility is suitable for release for unrestricted use.[3]

PREPARATION AND DISTRIBUTION OF COMPLETED LICENSING DOCUMENTS

Completion Time Objectives

The Group's objective is to complete all licensing actions within 30 days of receipt. Therefore, a well-prepared application (complete and accurate) should be processed, signed, and issued within that time. Likewise, the license reviewer should have identified any need for additional information or clarification and issued a deficiency letter within 30 days of the receiving a licensing action with flaws. When the response to the deficiency letter arrives, the 30-day time frame begins again.

Peer Review Process

The previous discussion established the time constraints for processing a licensing action. Peer review and supervisory review are included in that timeframe. Peer reviews provide the following benefits:

- consistency in licensing actions,
- quality assurance,
- educational opportunities for less experienced licensing staff
- communication between licensing and inspection staff

The 30-day completion objective should always be met when licensing actions involve health and safety related issues. However, the quality review and approval will always take precedence over an arbitrary completion deadline.

A supervisory review of new, amended, and renewed licenses is required. A supervisory review is not required for deficiency letters.

Additional Licensing Procedures

Whenever a licensing modification is requested, the license should be amended in its entirety unless authorized by the Unit supervisor. This process will assist inspectors and provide a complete, up-to-date license.

The license reviewer should ensure that the correct program code is assigned to the license. When it becomes necessary to assign more than one program code to a license, the code with the highest inspection priority (shortest inspection cycle) should be designated the primary code.

Completed licensing documents shall be prepared and distributed to the licensee. At a minimum, the original should be sent to the license contact, a copy should be sent to the Radiation Safety Officer. After the license is mailed to the licensee, the licensing staff must ensure that the license and all supporting documents for the current action are placed into the appropriate electronic and hard copy (paper) file.

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

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[3] Even though a license has expired, the licensee's obligations do not cease until the Department terminates the license. Therefore, licensees cannot terminate licenses merely by allowing the license to expire.

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.

SECTION II - LICENSE REVIEWER GUIDANCE

Introduction
This Section provides guidance and criteria to the license reviewer for processing license applications for new applicants, amendments and renewals. This guidance assumes that applications will be filed and reviewed in accordance with the guidance set forth by the Radioactive Materials Group. If the licensee does not use the appropriate licensing guidance document, the review of the applicant's submittal may take longer to complete.

To standardize and simplify the review process, reviewers should use all available tools, including process, criteria, and checklists, when reviewing license applications. An applicant may request authorization to use licensed materials in more than one program type. In this case, the reviewer needs to use more than one licensing guide to review the application. The reviewer should review and compare the specific licensing criteria for each program type to identify the common criteria and the unique issues. The applicant's radiation safety program must adequately address all of the criteria for each program type to be authorized; however, reviewers should avoid requesting information not identified in the guidance.

The reviewer should identify the highest inspection priority whenever adding new or multiple program types to a license. Inspection Priorities can be found in NRC Inspection Manual Chapter 2800 and Appendix G of NUREG 1556 Volume 20. The program code with the highest inspection priority should be identified as the primary program code. (See Attachment 1.) This program code will dictate the inspection frequency for this license.

Processing New Applications
Applicants for new licenses are expected to provide all the information specified on the *Application for a Minnesota Radioactive Materials License.* All items in the application should be completed in enough detail for the reviewer to determine that the proposed equipment, facilities, training and experience, and radiation safety program satisfy regulatory requirements and are adequate to protect public health and minimize danger to life and property. The reviewer should perform a comprehensive review of the application. This review should consist of a comparison of all of the materials submitted by the applicant to the requirements in the appropriate rules and guidance.[4]

The application should be reviewed against the appropriate checklist. Sections of the application that fail to address areas in the appropriate guidance or do not conform to that guidance become deficiencies.

[4] The reviewer should confirm that none of the staff members is banned from licensed activities by checking the escalated enforcement actions issued to individuals. This can be accomplished by going to the Office of Enforcement page on the NRC web site (www.nrc.gov/OE/). Select "Enforcement Actions" from the buttons on the left side of the screen. Select "Escalated Enforcement Actions Issued to Individuals" from the links at the bottom of the page. Go to the Edit drop-down menu, and select "Find in Frame." Search for the individual's last name. If an order was issued to the individual, read the order and confirm whether the restrictions still apply. Consult with Unit supervisor *before* taking any action for an individual who appears to be banned from activities.

These deficiencies must be resolved before the license is issued. All deficiencies should be clearly documented and communicated to the applicant. Reviewers should apply the guidance to the extent suitable to the applicant's proposed activities. Reviewers should not apply any standards or criteria for which there is no specific regulatory basis. Reviewers should accept only procedures or proposals that result in a level of safety at least equivalent to that provided for in Radioactive Materials Group's guidance.

Processing Amendments
The licensee is responsible for keeping the license current. If any of the information provided in the original application changes in a way that requires an amendment to the license the licensee must submit an application for a license amendment to reflect the change before the change takes place. The amendment request should identify the specific changes and the basis for the changes. The reviewer should focus the evaluation on only those areas that the licensee indicates need revision. If the licensee completely resubmits the entire application, the reviewer should request that the licensee specifically identify the requested changes. The licensee may opt to resubmit the request and only discuss the specific changes, or may identify the changes by marking or highlighting the modified text.

Processing Renewals
Reviewers should conduct the same comprehensive review required for new applications. Please refer to the section on *Processing New Applications* for guidance.

Deficiency Letters, Calls, Faxes, and E-mails
Once application issues and deficiencies have been identified, the license reviewer should use the most efficient process available to fully communicate issues to licensees, document the request, and elicit the appropriate applicant response. The reviewer should use the telephone, facsimile, and email to communicate with licensees, thereby reducing reliance on formal letters. All substantive communications must be clearly documented and dated. Efforts should also be aimed at educating licensees to improve the quality of future submittals. The reviewer should ensure that each requested item for additional information is clear (i.e., provides a description of the deficiency and a statement of what is needed), is essential to protect safety, and is linked to regulatory requirements and appropriate guidance documents. Once a request for information (deficiency letter, telephone call, facsimile or e-mail) is sent to the licensee, the action should be entered into and tracked by RAMIS. The time parameters can be extended, if necessary, as approved by the Unit supervisor.

APPLICATION FOR A NEW LICENSE OR FOR AN AMENDMENT

Complex Deficiencies
Any significant or complex deficiencies in an application for either a new license or license amendment should be described in a deficiency letter to the applicant. A sample deficiency letter is provided in Appendix B. Deficiency letters can be sent by regular mail, e-mail, or facsimile. The letter to the applicant should contain a statement that specifies that MDH will assume the applicant does not wish to pursue its application if MDH does not receive a reply within 30 calendar days from the date of the letter. The database must be updated to track the specific licensing action.

If a response to the deficiency letter is received within 35 calendar days from the date of the letter, the license reviewer should proceed with review of the response.

If a response to the deficiency letter is not received within 35 calendar days from the date of the letter, the licensing staff should consider the application as abandoned for failure to provide the requested information. This abandonment is without prejudice to the resubmission of the application. Prompt action (5 working days) should be taken to void the application.

If a response to the deficiency letter is received after the application has been voided, and the response is received not more than 60 days from the date of the letter, review should proceed. Typically, no additional fee is necessary unless the application was subject to full cost recovery.

Simple Deficiencies
To expedite the issuance of a license or license amendment, reviewers are encouraged to use the telephone or e-mail to obtain clarifying information from an applicant and to notify an applicant of the existence of simple deficiencies in their application. The applicant should be informed that the request would be considered void or abandoned without prejudice if they fail to respond. Simple deficiencies can include such items as a model number for a source, model number of a leak test kit, need for a commitment for frequency of change of personnel monitoring equipment, etc. Simple deficiencies do not typically include training and experience of individuals, descriptions of radiation safety programs, etc.

The reviewer should document the telephone call or e-mail, including the warning about failure to respond. Documentation of the telephone call or e-mail should be entered into RAMIS. A copy of the conversation record should be provided to the applicant.

APPLICATION FOR LICENSE RENEWAL

Complex Deficiencies
The reviewer is encouraged to use the most expedient process available to communicate significant or complex deficiencies to licensees. This likely will also include sending a deficiency letter to the applicant. A sample deficiency letter is provided in Appendix B. The letter should request the applicant to respond within 30 calendar days from the date of the letter, but the letter should not include a formal warning.

The licensing goal is to have no more than one request for additional information for each renewal application. If a second request is needed, the licensee's management should be contacted to resolve open issues. If the applicant does not provide adequate information after such an exchange, the license reviewer should complete the licensing action that can be completed, inform the licensee of issues that cannot be approved, and explain the reason. The reviewer should avoid multiple rounds of requests for additional information.

If a response to the deficiency letter has not been received within 35 calendar days from the date of the letter, a denial warning (second letter) should be sent. This letter will notify the applicant that unless a response to the deficiency letter (first letter) is received within the next 30 calendar days, it may be cause for denial of the application. Such a denial would require the applicant's divestiture of all material.

The reviewer should proceed to deny the application if a response to the denial warning is not received within 35 calendar days.

Simple Deficiencies
Reviewers are encouraged to first use the telephone, facsimile, or e-mail, as described above, for new applications and amendments to accelerate issuance of a renewal. If the licensee does not respond to the formal confirmatory letter, the reviewer should proceed to deny the renewal.

Extensions
An oral or written request from an applicant for an extension of time to respond to any correspondence about its application may be granted if it is determined that there is good cause to grant an extension. Appropriate computer entries should be made to track each application properly and record extensions of time for responses. The reviewer should keep the Unit supervisor informed of licensees' continued requests for extensions.

CREATING THE LICENSE

Standard Licenses and Standard License Conditions

Some instances may exist where the reviewer may need to customize a license. Because an applicant may request authorization to use licensed materials in more than one program type, the reviewer may need to review the sample licenses in more than one licensing guide and combine the pertinent license conditions into a single license, where appropriate. In some complex licensing cases, it may be best to issue separate licenses. The reviewer should refer to Attachment 1, which is based on the NRC Inspection Manual Chapter 2800, to identify the program code with the highest priority for inspection. The program code that identifies the highest inspection priority (shortest inspection cycle) will dictate the inspection frequency for the license.

In some specific instances, an applicant may request authorization to conduct special activities in a program that is non-routine and not included in the sample license. The reviewer should refer to the approved list of standard license conditions in Appendix C. The standard conditions are organized in categories of authorization. Use of standard license conditions should not substitute for obtaining situation specific information from applicants and licensees. Reviewers should first try to obtain commitments that will be captured by the tie-down condition rather than creating new conditions.

Non-Standard License Conditions

When reviewing applications, if there are simple issues that the licensee did not address, even after being asked to provide the information in a deficiency request, the reviewer should use custom license conditions to achieve closure rather than engage in protracted negotiations with the applicant. The reviewer should use standard license conditions whenever possible; however, custom conditions may be used when necessary. The license reviewer should write the custom license condition to state the requirement clearly and simply. Custom conditions should be approved by the Unit supervisor. In addition, license reviewers should explain these conditions to inspection staff and licensees to ensure that all parties have the same understanding, especially those unique to a specific type of licensee. It is anticipated that license reviewers will provide an explanation in the cover letter issuing the license or call the licensee before issuing a license with non-standard license conditions.

If the need for a custom licensing condition recurs it should be considered for inclusion as a new standard licensing condition.

Establishing License Expiration Dates

All of these materials licenses have the same five-year license term limit.

Issuance of Final Licensing Action

A cover letter and the original license should be sent for all completed licensing actions. The cover letter may be a form letter or individual letter. A sample cover letter is provided in Appendix B.

Many licensing actions require specific information to be included in the cover letter related to the individual case. All information may be combined into a single cover letter, or license reviewers may elect to use attachments. For licenses that are amended frequently, it is acceptable to include the standard information with every licensing action; or, if deemed appropriate, the information may be deleted if it was provided in a recent previous communication.

GUIDANCE FOR MULTI-SITE LICENSES

On occasion, MDH will receive applications for new licenses, amendments, and renewals ("applications") that request authorization for use of licensed material at multiple sites under one license. Many of these applications represent categories of licensees for which multiple locations of use have not been routinely authorized. The purpose of this section is to ensure that applications requesting authorization for multiple sites of use under one license (including amendment requests that expand a licensed program to multi-site) are identified and have radiation safety programs that are adequate, both in scope and in depth, to

oversee safe use of licensed material at each facility. This section does not apply to certain categories of licenses that, by specific license condition, routinely authorize multiple locations of use (i.e., broad-scope and mobile medical service licenses) or licenses authorizing temporary job sites. Furthermore, this section highlights general radiation safety management concerns specific to multi-site licenses. It does not attempt to define the necessary structures for radiation safety management in every type of licensed activity. The license reviewer will need to tailor the review to the type of license under consideration.

Focus of Review
During the review of the licensee's radiation safety program and management oversight, the license reviewer should pay particular attention to delegation of responsibility and established, reciprocal lines of communication between users and management. Regardless of the number of sites authorized under one license or the geographic distance between these sites, the adequacy of the overall radiation safety management structure must be reviewed to ensure safe operations at each site.

Description of Multi-Site
A multi-site license is one that authorizes two or more locations of use that are specifically identified on the license. Such authorized locations will typically include either: (1) stand-alone facilities that would otherwise be licensed individually; or (2) satellite facilities that are not located within the principal job site and for which licensed activities are ongoing, with the exception of temporary job sites, broad scope licensees, or mobile nuclear medicine services. A multi-site facility may also include those groups of licensees for which the addresses of use are geographically separated. These facilities may each be under the direction of a single corporate Radiation Safety Officer, or they may have site RSOs who report to a corporate RSO. The corporate RSO is usually the RSO of record on the license.

The nature of licensed material use and licensed operations (e.g., medical versus industrial) should be the same at each site. Licensed material uses currently licensed separately by policy should continue to be licensed separately (e.g., teletherapy).

Multi-Site Examples:

- Radiopharmacy licensees with multiple radiopharmacy locations on one license;
- Radiographers or moisture density gauge users with multiple permanent work sites on one license (e.g., branch offices);
- Medical licensees with facilities at more than one geographic location;
- Large manufacturers with facilities at more than one geographic location.

Number of Sites
A specific limit to the number of sites permitted on a multi-site license is not practical for generic application to all licensees; rather, the reviewer should assess applications on a case-by-case basis. The basis for determining the appropriate number of sites for a specific licensee should include the following considerations: (1) past inspection history; and (2) adequacy of licensee management structure for the type, scope, and geographic distribution of the program. All sites approved for use should be identified on the license when issued.

Communication
In those cases where there are multiple oversight levels proposed, the applicant should clearly address communication and accountability systems, including:

- Delegation of clear and appropriate levels of authority within the licensed entity, indicating that sufficient organizational freedom exists and management has established prerogative to communicate with, train, and direct personnel according to MDH rules and license conditions;

- To ensure consistency, MDH requires that multiple site licensees appoint one Radiation Safety Officer (RSO) to oversee operations. It is therefore imperative that the licensee's management provides sufficient time and resources for the RSO to oversee the radiological programs at all sites. The application should address the time commitment and staff assignments, which assist in the administration of the radiological program.

- Descriptions of program reviews or audits and the reporting of such activities on a regular basis;

- Mechanisms for addressing urgent situations;

- Mechanisms in place to inform all personnel of radiation safety program changes;

- Provisions and techniques in the application to make personnel aware of the appropriate representatives to contact at each level of authority;
- Assurance provided in the application that each level of oversight is available to interact with other levels, authorized users, and supervised workers, both as needed and on a regular basis.

Records
After receiving reasonable notice from the Department, each licensee is required to make its radiation safety records available for an inspector's review. The license application should specify point-of-contact information for MDH notification and inquiry about records. The licensee may also choose to identify locations where the records will be maintained for review.

Additional Program Areas for Review
The licensee should provide specific information, including the following:

- Transportation of licensed material (including radioactive waste) between authorized sites;

- Applicability of decommissioning requirements;

- Sharing of safety equipment between sites; and

- Coordination among sites for inventory control of licensed material, with the intended focus of continually monitoring types and quantities of material to ensure that the total possession limits specified in the license are not exceeded.

LICENSING SITE VISITS

Licensing visits should be conducted for all new material applications involving large programs or programs that present significant or unique technical issues. Licensing site visits are conducted by the license reviewer or an inspection staff member to accomplish one or more of the following objectives:

- Evaluate the applicant's ability to conduct safe operations and comply with requirements;

- Evaluate safety and technical issues that are not easily understood through correspondence or telephone conversations;

- Expedite resolution of issues and concerns through discussions with the applicant;

- Verify statements and commitments in the license application; and

- Provide a first-hand review of the applicant's staff, site, and facilities.

Licensing Visits for New License Applications
Licensing visits should be conducted for the following types of new license applications:

- Type A licenses of broad scope
- Manufacturers or distributors using unsealed radioactive material or significant quantities of sealed material
- Radioactive waste brokers
- Radioactive waste incinerators
- Commercial nuclear laundries
- Any other application that involves complex technical issues, complex safety questions, or unprecedented issues warranting a site visit

Licensing Visits for Amendments
Licensing visits should be conducted for any license amendment requesting a new authorization for the types of operations listed above. Licensing visits are also encouraged by NMSS for amendments involving significant modification to the types of operations listed above.

Licensing Visits for Renewals
Licensing visits are encouraged for renewals involving the types of activities listed above; however, in many cases, resource limitations can make this difficult to support. For each significant renewal, an evaluation of proposed licensee program changes and inspection history should be performed. If there are no significant program changes or unresolved licensing issues, a licensing visit need not be performed.

SIGNIFICANT LICENSING ACTIONS THAT WARRANT ONSITE INSPECTION

Staff should conduct inspections of licensees whose programs have significantly changed or expanded since the last routine inspection. A checklist is provided in Appendix A for determining when a significant licensing action has taken place that may warrant a pre-license on-site inspection. The selection criteria should not be considered all-inclusive, as there may be unique indicators that suggest that a licensed program has changed significantly. All license reviewers should understand the elements of the checklist and complete it for significant amendment or renewal licensing actions.

CRITERIA FOR DENYING APPLICATIONS - MATERIAL LICENSES

Applications for material licenses should only be denied if the applicant does not satisfy the substantive requirements for receiving a license (even after the licensee has provided information on which the staff can make a decision); or the applicant has not submitted adequate information. Denial presupposes that:

- The staff has requested the additional information needed to make the required findings;
- The applicant has had at least 30 days in which to provide the needed information; and
- The applicant has failed to respond and provide information or the response is not considered adequate.

To ensure that denials, where appropriate, are issued in a timely manner, it is important for the licensing staff to perform follow-up on oral and written communications with applicants. In special situations, staff may grant extensions for replies and prepare denial correspondence.

Early identification and coordination is needed to ensure that the staff promptly prepares a letter of denial, if appropriate, or that an appropriate strategy for handling the application is established. Therefore, as early in the review process as possible, the license reviewer should identify and consult with supervision on any application:

- In which the staff has any question about the applicant's suitability; integrity (e.g., lack of candor or submission of inaccurate or misleading information); or ability or commitment to comply with the NRC regulations (e.g., financial instability or past inspection and enforcement history); or
- Containing an unusual request; or
- Raising novel legal or technical issues.

FEES

The application fee must accompany the application. MDH has no renewal or inspection fees. These are included in the annual fees. (See Attachment 2.) However, fees are charged for amendments.

The annual fees are due on the anniversary date of the license approval at the rate in effect on the license anniversary date. The anniversary date of the materials license is considered the first day of the month in which the original materials license was issued. For example, if the original materials license was issued on June 17, then for annual fee purposes, the anniversary date of the material license is June 1, and the licensee will continue to be billed each year 30 days prior to the due date. Procedures for processing fees have been developed to assure that licensees receive the invoices for annual fees before the due date.

If a licensee fails to respond to notices of payment due, the Radioactive Materials Group staff will attempt to locate the licensee by telephone or other means to determine if it has received the notices of payment; to determine the licensee's status; and intentions with respect to compliance.

Licensees must immediately:

- Restrict activity involving licensed material to only decommissioning and safe, secure storage or transfer of material;
- Continue to control entry into restricted areas until the licensee has determined and MDH has confirmed that such areas are suitable for release.
- Arrange for disposal of any licensed material, either by return to the manufacturer or transfer to an authorized recipient. The licensee must notify MDH, in writing, of such disposal.
- Notify each customer or client in writing that authorization to provide any support has been revoked and that customers and clients may need to amend their licenses to comply with MDH requirements.
- Conduct an adequate termination survey of the premises and report results of the survey in writing to MDH.
- Submit a written report to MDH on the status of materials.

Upon determination that the steps above have been satisfactorily completed, as necessary, MDH will terminate the license.

APPENDIX A - FORMS

Radioactive Materials Group
Minnesota Department of Health
1645 Energy Park Drive, Suite 300
St. Paul, Minnesota 55108-2970

Phone: (651) 643-2151 ***Fax: (651) 643-2152***

APPLICATION FOR A MINNESOTA RADIOACTIVE MATERIALS LICENSE

INSTRUCTIONS: COMPLETE ALL ITEMS IF THIS IS AN INITIAL APPLICATION OR RENEWAL. USE SUPPLEMENTAL SHEETS WHERE NECESSARY. MINNESOTA DEPARTMENT OF HEALTH (MDH) REGULATORY GUIDES FOR LICENSES CAN BE FOUND ON THE INTERNET AT **[INSERT ADDRESS]**. A LINK TO THE MINNESOTA RADIOACTIVE MATERIALS RULES CAN BE FOUND AT THAT WEB SITE. TO ENSURE A COMPLETE AND ACCURATE APPLICATION, PLEASE USE THE APPROPRIATE REGULATORY GUIDE AS A REFERENCE WHILE COMPLETING THIS APPLICATION.

1. THIS IS AN APPLICATION FOR: *(Check appropriate item)* ☐ A. NEW LICENSE ☐ B. AMENDMENT TO LICENSE NO. _____ ☐ C. RENEWAL OF LICENSE NO. _____	2. NAME AND MAILING ADDRESS OF APPLICANT *(INCLUDING ZIP CODE)*
3. ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED OR POSSESSED	4. PERSON TO CONTACT REGARDING THIS APPLICATION TELEPHONE NUMBER:

SUBMIT ITEMS 5 THROUGH 11 ON ADDITIONAL SHEETS. THE TYPE AND SCOPE OF THE REQUIRED INFORMATION IS DESCRIBED IN THE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL a. Element and mass number b. Chemical and/or physical form c. Maximum amount to be possessed at any one time	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS
9. FACILITIES AND EQUIPMENT	10. RADIATION SAFETY PROGRAM
11. WASTE MANAGEMENT	12. LICENSE FEE - AMOUNT ENCLOSED

13. CERTIFICATION *(Must be completed by applicant.)*

THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION (INCLUDING ATTACHMENTS) ARE BINDING UPON THE APPLICANT.

CERTIFYING OFFICER *(TYPED/PRINTED NAME AND TITLE)*	SIGNATURE	DATE

CHECKLIST FOR DETERMINING WHEN SIGNIFICANT LICENSING ACTION HAS TAKEN PLACE THAT MAY REQUIRE AN ADDITIONAL ONSITE INSPECTION

If recent licensing actions have resulted in one of the following, Radioactive Materials Group staff should determine the need for performing an onsite inspection before the next routine inspection:

1. Does the licensing action result in increased authorization for types and quantities of radioactive material that could result in a significant potential for increased radiation exposure to the public and occupational workers?

   ☐ No
   ☐ Yes *(Describe)*

   Note: This can be identified by a change to a higher priority (i.e., from a Priority 2 to a Priority 1 license) or an increase in the authorized quantity from a millicurie amount to a curie amount.

2. Does the licensing action authorize a physical move of a facility or authorize use at a temporary job site(s)?

   ☐ No
   ☐ Yes *(Describe)*

3. Does the licensing action authorize satellite facilities where material will be used or stored?

   ☐ No
   ☐ Yes *(Describe)*

4. Does the licensing action increase the types of uses or disposal (incineration) of radioactive materials?

   ☐ No
   ☐ Yes *(Describe)*

5. Does the licensing action significantly increase the number of authorized users?

   ☐ No
   ☐ Yes *(Describe)*

Licensing and Inspection Tracking Form

Originator:	☐ New License ☐ Renewal ☐ Amendment No.: _____	☐ Deficiency Letter ☐ Inspection Report ☐ 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 – SAMPLE LETTERS

Sample of License Expiration Letter

[INSERT DATE]

[INSERT NAME AND ADDRESS]

License Number: **[Number]**
Expiration Date: **[Date]**
Program Code: **[Number]**

SUBJECT: NOTICE OF LICENSE EXPIRATION

[INSERT SALUTATION]:

Your Minnesota Department of Health (MDH) Radioactive Materials License, specified above, will expire on the date shown. If you wish to continue your licensed program, you should prepare and submit a renewal application on "Application for Radioactive Materials License," following the instructions in the regulatory guide that can be found at **[web address]**. If the application reflects any significant changes in your licensed program, those changes must be clearly indicated.

You must submit an application for the renewal of your license at least 30 days before the expiration date on the license. If your renewal application is filed (delivered or postmarked) before the expiration date, MDH will use discretion and your license will remain in effect until MDH takes final action on your application. However, if your renewal application cannot be filed before the expiration date, you should contact MDH immediately to obtain a temporary extension of the expiration date. Without approval of that extension request, your license expires on the expiration date stated on the license. If your license expires, you no longer have a valid license. You are required to maintain all licensed materials in safe, locked storage until your application for a license or request for termination is submitted and approved. Use of the licensed material after the expiration of your license may subject you to criminal and/or civil sanctions.

If you do not wish to renew your license, you must dispose of or transfer all licensed radioactive material in your possession in an authorized manner. You must also complete a "Certificate of Disposition of Materials" or equivalent and return it before the expiration date of your license, with a request that your license be terminated. If you cannot dispose of or transfer all licensed radioactive material in your license before the expiration date, you must request a license renewal for storage-only of the radioactive material, to avoid enforcement action for violations involving the possession of licensable material without a valid license. Enforcement action may include a substantial monetary civil penalty that could also include daily civil penalties until you achieve compliance.

If you have any questions about this notice or license expiration/renewal, please contact **[INSERT NAME AND TELEPHONE NUMBERS]**.

[INSERT WRITER'S IDENTIFICATION]

Sample Deficiency Letter

[INSERT DATE]

[INSERT NAME AND ADDRESS] **[INSERT LICENSE NUMBER]**

SUBJECT: **[INSERT APPROPRIATE DESCRIPTIVE TEXT]**

[INSERT SALUTATION]:

The Radioactive Materials Group of the Minnesota Department of Health (MDH) has reviewed your request dated **[INSERT DATE OF SUBMITTAL]**. Before we can take further action, we will need the following additional information:

1. **[DESCRIBE THE DEFICIENCY AND INCLUDE A CLEAR STATEMENT SPECIFYING THE INFORMATION NEEDED]**

To continue review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter. Please refer to the license number specified above. Failure to provide the requested information within 30 days may lead to the termination of your license or enforcement action.

If you have questions or require clarification on any of the information stated above, we encourage you to contact **[INSERT THE APPROPRIATE STAFF AND PHONE NUMBERS]**.

Sincerely,

[INSERT WRITER'S IDENTIFICATION]

Materials License Cover Letter for Licensing Actions, Except Terminations

[INSERT DATE]

[INSERT NAME AND ADDRESS] **[INSERT LICENSE NUMBER]**

SUBJECT: **[INSERT APPROPRIATE DESCRIPTIVE TEXT - NEW LICENSE, LICENSE AMENDMENT, LICENSE RENEWAL]**

[INSERT SALUTATION]:

Please find enclosed Amendment Number **[INSERT NUMBER]** to your Minnesota Department of Health (MDH) Radioactive Materials License Number **[INSERT LICENSE NUMBER]** or please find enclosed License Number **[INSERT LICENSE NUMBER]** authorizing **[INSERT AUTHORIZATION]**. You should review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please contact the Radioactive Materials Group.

The Minnesota Department of Health expects licensees to conduct their programs with meticulous attention to detail and high standard of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with MDH requirements, you must conduct your radiation safety program according to the condition of your license, representations made in your license application, and MDH rules. In particular, note that you must:

1. Operate in accordance with "Notices, Instructions and Reports to Workers; Inspections," "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify MDH in writing of any change in mailing address.

3. Promptly notify MDH, in writing, and request termination of the license:

   a) When you decide to terminate all activities involving materials authorized by the license; or

   b) If you decide not to acquire or possess and use authorized material.

4. Request and obtain a license amendment before you:

   a) Change Radiation Safety Officer;

   b) Order radioactive material in excess of the amount, radionuclide, or form authorized on the license;

   c) Add or change the areas of use or address(es) of use identified in the license application or on the license; or

   d) Change the name or ownership of your organization.

5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of MDH regulations.

In addition, please note that the " Application for a Minnesota Radioactive Materials License" requires the applicant, by signature, verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. Failure to conduct your program in accordance with MDH rules, license conditions, and representations made in your license application and supplemental correspondence with MDH may result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying, or revoking your license.

If you have questions or require clarification on any of the information stated above, please contact **[INSERT THE APPROPRIATE STAFF AND PHONE NUMBERS].**

Sincerely,

[INSERT WRITER'S IDENTIFICATION]

Reciprocity Procedures Letter

[INSERT DATE]

[INSERT NAME & ADDRESS]

SUBJECT: RECIPROCITY PROCEDURES

[INSERT SALUTATION]:

Radioactive Materials Licensees seeking to conduct activities under reciprocity in Minnesota for the first time in a calendar year, must submit a copy of the current US Nuclear Regulatory Commission (NRC) or Agreement State specific license; and the reciprocity fee, which is **[INSERT FEE]**. The Minnesota Department of Health (MDH) must receive this filing at least three days before the licensee engages in activities. For areas of exclusive federal jurisdiction, licensees must contact the NRC and cannot perform without either: (a) filing NRC Form 241 for reciprocity in accordance with 10 CFR 150.20(b); or (b) applying for a specific NRC license.

A general license authorizes persons holding a specific license from the NRC or another Agreement State to conduct the same activity in Minnesota if the specific license issued by the NRC or Agreement State does not limit the authorized activity to specified locations or facilities. Under this general license, licensees conducting reciprocity activities, including storage (usage), are limited to a total of 180 days in any calendar year. MDH tracks reciprocity usage based on approved usage days and will not approve any activity, under the general license, that causes the total usage days to exceed 180 days. It is important that licensees track the days of use and clarify or delete dates of work when applicable.

Licensees operating under reciprocity where MDH maintains jurisdiction must conduct activities involving radioactive materials in accordance with the conditions specified in the licensee's NRC or Agreement State license and Minnesota's Radioactive Materials Rules. MDH may perform inspections of activities by NRC or other Agreement State licensees operating under a general license. These inspections will occur at the listed work site location(s). Failure to comply to conduct the radiation safety program in compliance established rules and license conditions while operating under reciprocity may result in MDH enforcement action(s) against the licensee.

If you have any questions about the regulations or the application process, please feel free to contact **[INSERT THE APPROPRIATE STAFF AND PHONE NUMBERS].**

Sincerely,

[INSERT WRITER'S IDENTIFICATION]

Internal Communications

RADIOACTIVE MATERIALS GROUP
DIVISION OF ENVIRONMENTAL HEALTH
MINNESOTA DEPARTMENT OF HEALTH

MEMORANDUM TO LICENSE REVIEWER DESIGNATING 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

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:

APPENDIX C – STANDARD LICENSE CONDITIONS

PLACE OF USE

1. Licensed material shall be used only at the licensee's facilities located at .

5. Licensed material may be used or stored at the licensee's facilities located at and at temporary job sites of the licensee anywhere in the State of Minnesota where the Minnesota Department of Health maintains jurisdiction for regulating the use of licensed material.

10. Licensed material may be stored at the licensee's facilities located at and may be used at temporary job sites of the licensee anywhere in the State of Minnesota where the Minnesota Department of Health maintains jurisdiction for regulating the use of licensed material.

15. Licensed material may be used only at temporary job sites of the licensee anywhere in the State of Minnesota where the Minnesota Department of Health maintains jurisdiction for regulating the use of licensed material.

20. Licensed material shall be stored only at the licensee's facilities located at .

25. The licensee shall use licensed material only at the licensee's facilities located at .

Note: This condition should be used for distribution, redistribution, and/or dispensing licensees.

SUPERVISION -- GENERAL

30. Licensed material shall be used by, or under the supervision of .

35. Licensed material shall be used by, or under the supervision and in the physical presence of .

40. Licensed material shall be used only by .

45. Licensed material shall be used by, or under the supervision of, individuals who have received:

A. A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering;

B. At least 40 hours of training or experience in the safe handling of radioactive material, the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and the biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

C. The Radiation Safety Officer's written approval for the use of each specific isotope.

50. Authorization for specific isotope use for each individual user listed in License Condition 10 shall be approved in writing by the Radiation Safety Officer.

SUPERVISION -- LIMITED MEDICAL

55. The following individuals are authorized users for the materials and uses indicated:

Authorized Users	Material and Use

60. Licensed material is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users	Material and Use

SUPERVISION -- BROADSCOPE MEDICAL

65. The use of licensed material in or on humans shall be by an authorized user as defined in 4731.0100 Subp. 24.

70. Individuals designated to work as authorized users as defined in 4731.0100 Subp.24, shall meet the training criteria established for the discipline that the authorized user is trained. Individuals designated to work as authorized nuclear pharmacists defined in 4731.0100 Subp.23, shall meet the training criteria established in 4731.4413. The licensee's Radiation Safety Committee shall also designate each use.

[Reviewer Note: License Conditions 60 and 65 are used together]

75. Licensed material for other than human use shall be used by or under the supervision of individuals designated by the Radiation Safety Committee.

80. The licensee's Radiation Safety Committee may approve medical physicists for their HDR brachytherapy program. Authorizations are limited to naming those physicists that meet the training criteria in 4731.4412 or who are named on a current US Nuclear Regulatory Commission or Agreement State license, or a permit issued by another US Nuclear Regulatory Commission or Agreement State licensee of broad scope as an HDR medical physicist. In addition to these requirements, the physicist must possess recent, device specific training and experience for each make and model of HDR device used by the licensee.

SUPERVISION -- CARDIAC PACEMAKERS

85. The physicians responsible for implantation, follow-up, explanation, and return of nuclear-powered pacemakers to the manufacturer for proper disposal are .

SUPERVISION -- NUCLEAR PHARMACY

90. At least one individual named in License Condition 10 shall be physically present at the authorized place of use whenever licensed material is being used.

[Reviewer Note: Use License Condition 85 with License Condition 30 or 90]

95. The individuals listed in License Condition 10 shall maintain a current pharmacist license issued by the State of Minnesota. The licensee shall maintain a copy of the current pharmacist license on file.

SUPERVISION – BROAD SCOPE

100. Licensed material shall only be used by, or under the supervision of, individuals designated by the Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.

[Reviewer Note: Authorized user for a Type A Broad Scope]

105. Licensed material shall be used by or under the supervision of individuals designated in writing by the Radiation Safety Officer. The licensee shall maintain records of these individual users for three years after the individual's last use of licensed material.

[Reviewer Note: Authorized user for a Type B Broad Scope]

110. Licensed material shall be used by or under the supervision of individuals meeting the requirements stated in 4731.3550. The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.

[Reviewer Note: Authorized user for a Type C Broad Scope]

SUPERVISION – PORTABLE GAUGES

115. Licensed material shall only be used by, or under the supervision and in the physical presence of individuals who have received the training described in application dated and have been approved in writing by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for three years following the last use of licensed material.

120. Licensed material shall only be used by, or under the supervision and in the physical presence of, or individuals who have successfully completed a manufacturer's training program for gauge users; have been instructed in the licensee's routine and emergency operating procedures; and who have been designated by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for three years following the last use of licensed material.

125. Licensed material shall only be used by, or under the supervision and in the physical presence of, individuals who have successfully completed a manufacturer's training program for gauge users or an equivalent course approved by the U.S. Nuclear Regulatory Commission or an Agreement State.

A. Individuals must be instructed in the licensee's routine and emergency operating procedures and designated in writing by the Radiation Safety Officer.

B. The licensee shall maintain records of training for three years following the last use of licensed material.

SUPERVISION – RADIOGRAPHY

130. Only individuals who have met the requirements of 4731.4140 shall use license material.

135. The individuals listed below are the only persons authorized by this license to act as radiographer trainers:

SUPERVISION -- WELL-LOGGING

140. The individuals listed below are the only persons authorized by this license to act as logging supervisors or logging assistants:

Logging Supervisors	Logging Assistants

SUPERVISION -- IRRADIATOR

145. (RESERVED)

RADIATION SAFETY OFFICER

150. The Radiation Safety Officer for this license is .

155. A. The Radiation Safety Officer for this license is .

B. Before assuming duties as the Radiation Safety Officer for this license, shall have successfully completed the training course outlined in of the application dated .

LEAK TESTS

160. Each sealed source containing Radium-226 shall be leak tested at intervals not to exceed six (6) months while in storage.

165. The licensee is authorized to perform leak tests on the sealed source(s) listed in Item(s) 5. at intervals not to exceed .

"TIE DOWN"

170. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Minnesota Department of Health rules shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the rules.

A.

B. (Documents should be listed chronologically)

175. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below except for minor changes in the medical use radiation safety procedures as provided by 4731.4405 Subpart 2. The Minnesota Department of Health rules shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the rules.

A.

B. (Documents should be listed chronologically)

C.

GAS CHROMATOGRAPHS

180. Maintenance, repair, cleaning, replacement and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

185. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210 or equivalent registration form an Agreement State.

190. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

[Reviewer Note: License Condition 190 should not be used with portable field devices.]

FEMA

195. Each sealed source containing licensed material to be used outside of a shielded exposure device shall have a durable, legible, and visible tag permanently attached by a durable ring. The tag shall be at least one inch square, shall bear a conventional radiation symbol prescribed in 4731.0900 and a minimum of the following instructions: DANGER – RADIOACTIVE MATERIAL – DO NOT HANDLE – NOTIFY CIVIL AUTHORITIES IF FOUND.

200. Replacement of tags and rings shall be carried out by the licensee in accordance with instructions contained in procedures provided by the Federal Emergency Management Agency.

PORTABLE GAUGES

205. Sealed sources or source rods containing licensed radioactive material shall not be opened or removed or detached from the source rods or gauges by the licensee, except as specifically authorized.

210. Each portable nuclear gauge shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The gauge or its container must be locked when in transport, storage or when not under the direct surveillance of an authorized user.

215. The licensee may remove the source rod from model numbers for the purpose of cleaning, maintenance, or repair of the gauge(s) in accordance with procedures outlined in letter dated .

220. Any cleaning, maintenance, or repair of the gauge(s) that requires removal of the source shall be performed only by the manufacturer or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

225. Any cleaning, maintenance, or repair of the gauge(s) that requires removal of the source rod shall be performed only by the manufacturer or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

230. When performing tests at temporary job sites, the authorized user shall not leave the nuclear gauge unattended. Upon completion of tests, the device shall be secured in the licensee's vehicle or a secure building to prevent loss, theft, or unauthorized use.

235.

A. If the licensee uses unshielded sealed sources extended more than three (3) feet below the surface, a surface casting that extends from the lowest depth to one (1) foot above the surface and other appropriate procedures to reduce the probability of the source or probe becoming lodged below the surface. If it is not feasible to extend the casing one (1) foot above the surface, procedures to ensure that the cased hole is free of obstruction shall be implemented.

B. If a sealed source or a probe containing a sealed source becomes lodged below the surface and it becomes apparent that all efforts to for recovery may be unsuccessful, the licensee shall notify, by telephone, the Minnesota Department of Health and submit a written report within 24 hours.

RADIOGRAPHY

245. No sealed source or device containing licensed material shall be stored for a period more than three years without being leak tested.

250. The licensee is authorized to analyze leak test samples in according with the letter dated .

255. The licensee is authorized to possess, use, transfer, and import the uranium contained in the radiography exposure devices and source changers authorized by this license as outlined in 4731.0750.

260. Sealed Iridium-192/ Cobalt-60/ Cesium-137 sources and exposure devices authorized for use are as follows:

Manufacturer & Model No. of Exposure Devices	Manufacturer and Model No. of Source	Maximum Activity per Source

265. The licensee is authorized to receive, possess, and use sealed sources of Iridium-192 where the radioactivity exceeds the maximum amount of radioactivity specified in this license provided:

A. Such possession does not exceed the quantity per source specified in by more than 20 percent.

B. Records of the licensee show that no more than the maximum amount of radioactivity per source specified in this license was ordered from the supplier or transferor of the byproduct material; and

C. The levels of radiation for radiographic exposure devices and storage containers do not exceed those specified in 4731.4040.

270. The following source changers may be used with the listed Iridium-192/ Cobalt-60/ Cesium-137 sources:

Manufacturer and Model No. of Source Changers	Manufacturer and Model No. of Source Assemblies

275. The licensee is required to notify the Minnesota Department of Health three days prior to commencement of any radiography assignments beginning of each year. Such notification shall be in writing and may be faxed. The notification shall include the date the licensee was notified, the date(s) that the radiography will be performed, location of the assignment, and client contact and telephone number. This requirement shall remain in effect each year until completion of a field inspection by the Minnesota Department of Health.

WELL-LOGGING

280. Sealed sources authorized for a use other than well logging shall be tested for leakage and inventoried in accordance with 4731.7070 and 4731.7080.

285. The licensee shall not vacate or release to unrestricted use a field office or storage location whose address is identified in License Condition 10, without prior approval from the Minnesota Department of Health.

290. The licensee is authorized to analyze leak tests samples in accordance with the letter dated

295. The opening, repair, or modification of any Energy Compensation Source must be performed by persons specifically approved to do so by the Commission or an Agreement State.

300. Notwithstanding the periodic leak test required by 4731.7070, the requirement does not apply to sources, except sources containing plutonium, that are stored and not being used. The sources exempted from this periodic test shall be tested for leakage before use or transfer to another person. No sealed source shall be stored for a period of more than ten years without being tested for leakage and/or contamination.

305. The licensee shall not vacate or release to unrestricted use a field office or storage location whose address is identified in Condition , without prior approval from the Minnesota Department of Health.

FIXED GAUGES

310. Each gauge shall be tested for the proper operation of the on-off mechanism and indicator, if any, at intervals not to exceed six months or at such longer intervals as specified by the manufacturer, the US Nuclear Regulatory Commission, or an Agreement State. The requirement does not apply to gauges that are stored, not being used, and have the shutter lock mechanism in the locked position. Gauges exempted from this periodic test shall be tested before use.

315. The following services shall not be performed by the licensee: Installation, initial radiation surveys, relocation, removal from service, dismantling, alignment, replacement, disposal of the source and non-routine maintenance or repair of components related to the radiological safety of the gauge (i.e., the sealed source, source holder, source drive mechanism, on-off mechanism [shutter], shutter control, shielding). Only persons specifically licensed by the US Nuclear Regulatory Commission or an Agreement State to perform such services shall perform these services.

320.

A. Installation, initial radiation survey, relocation, removal from service, maintenance, and repair of devices containing sealed sources shall be performed by or by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

B. Sealed source installation, replacement, or disposal shall be performed only by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.

325.

A. Installation, initial radiation survey, relocation, or removal from service of devices containing sealed sources shall be performed by or by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

B. Only persons specifically licensed by the US Nuclear Regulatory Commission or an Agreement State shall perform maintenance and repair of devices and installation, replacement, and disposal of sealed sources.

330. The licensee may initially mount a gauge, if permitted by the certificate of registration by the US Nuclear Regulatory Commission or an Agreement State, under the following conditions:

A. The gauge must be mounted in accordance with written instructions provided by the manufacturer;

B. The gauge must be mounted in a location compatible with the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" in the certificate of registration issued by the US Nuclear Regulatory Commission or Agreement State.

C. The on-off mechanism (shutter) must be locked in the off position, if applicable, or the source must be otherwise fully shielded;

D. The gauge must be received in good condition (package not damaged) and;

E. The gauge must not require any modification to fit in the proposed location of use.

Mounting does not include electrical connection, activation or operation of the gauge. The source must remain fully shielded and may not be used until it is fully installed and made operational by a person specifically licensed by the US Nuclear Regulatory Commission or an Agreement State to perform such operations.

335. Prior to initial use and after installation, relocation, dismantling, alignment, or any other activity involving the source or removal of the shielding, the licensee shall assure that a radiological survey is performed to determine radiation levels in accessible areas around, above, and below the gauge with the shutter open. Only persons authorized to perform such services by the U.S. Nuclear Regulatory Commission or an Agreement State shall perform this survey.

340. The licensee shall operate each gauge within the manufacturer's specified temperature and/or environmental limits such that the shielding and shutter mechanism of the source holder are not compromised.

345. The licensee shall operate each gauge within the manufacturer's specified temperature and/or environmental limits such that the shielding and shutter mechanism of the source holder are not compromised. The source housing shall not be subjected to vibration that exceeds a vibration standard (MIL-STD-202F METHOD 201A).

[To be used for 7062B/BP source housings manufactured by Kay-Ray/Sensall, Inc. (KSI).]

350. The licensee shall assure that the shutter mechanism is locked in the closed position during periods when a portion of an individual's body may be subject to the direct radiation beam. The licensee shall review and modify as appropriate its "lock-out" procedures whenever a new gauge is obtained to incorporate the device manufacturer's recommendations.

355.

A. The licensee may maintain, repair, or replace device components not related to the radiological safety of the gauge (i.e., sealed source, source holder, source drive mechanism, source control) and which do not result in the potential for any portion of the body to come in contact with the primary beam or in increased radiation levels in accessible areas.

B. The licensee may not maintain, repair, replace, or alter any of the following device components: the sealed source, source holder, source drive mechanism, on-off mechanism [shutter], shutter control, shielding, or any other component related to the radiological safety of the device except as provided otherwise by specific condition of this license.

IRRADIATORS – SELF SHIELDED

360. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to licensed material. Persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services shall perform removal, replacement and disposal of sealed sources in the irradiator.

365. The licensee shall not perform repairs, remove, replace, or alter electrical and mechanical systems that control source and shielding movement, the irradiator's shielding or safety interlocks, or any component that may affect the safe operation of the irradiator. A person specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services shall perform these activities.

370. Except for the repair and maintenance operations described in the letter dated , the licensee shall not perform repairs, remove, replace, or alter electrical and mechanical systems

that control source and shielding movement, the irradiator's shielding or safety interlocks, or any component that may effect the safe operation of the irradiator. A person specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services shall perform these activities.

375. For each J. L. Shepherd and Associates, Mark I Cesium-137 Irradiator installed and used, the licensee shall:

A. Permit the use of the irradiator only when a calibrated and operable radiation survey meter or room monitor is available; and

B. Permit the irradiator door to be opened only after the operator has checked visual indicators to verify that the source has returned to its safe storage position; and

C. Have room monitors installed that will:

(i) Operate at all times when the irradiator is in use; and

(ii) Activate a visible and audible alarm when radiation exceeds two (2) millirems per hour; and

(iii) Detect any radiation leaking from the irradiator door; and

(iv) Be visible to the irradiator user when he is next to the irradiator; or

D. If a room monitor is not installed, have available a calibrated and operable survey meter which will be used to:

(i) Determine the radiation level at the irradiation door when the door is closed; and

(ii) Check for any increase in radiation levels each time the irradiator door is opened.

E. If abnormal radiation levels or any malfunctions of the irradiator are detected at anytime, the licensee shall cease using the irradiator, restrict access to the area housing the irradiator, and immediately notify the Radiation Safety Officer.

F. Not repair or authorize repairs of the irradiator except by the manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

380. The procedures contained in the manufacturer's instruction manual for the Model device shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.

385. The licensee is authorized to use the following sealed sources in the irradiator:

Manufacturer	Model Number

IRRADIATORS

390. Nothing in this license relieves the licensee from complying with the rules and regulations of the U.S. Food and Drug Administration, or any requirements governing the irradiation of foods for human consumption.

355. Notwithstanding the requirements of 4731.6060, the licensee may use separate keys to operate the lock on the personnel entrance door or barrier and to move the sources in accordance with procedures described in the letter dated .

400. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Persons specifically licensed by the Commission or an Agreement State to perform such services shall perform removal, replacement, and disposal of sealed sources in the irradiator.

405. The licensee shall implement the material accountability program described in letter dated , to account for all sealed sources containing licensed material received and possessed under the license.

NUCLEAR PHARMACIES

410. The licensee is authorized to retrieve, receive, and dispose of radioactive waste from its customers limited to radiopharmacy supplied syringes, vials and their contents.

415. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements, and representations in the letter dated .

420. When redistributing material listed in Item , the manufacturer's packaging, labeling, and shielding shall not be altered. The packaged, redistributed material shall be accompanied by the manufacturer-supplied document that provides radiation safety instructions for handling and storage.

425. The licensee may perform services for their clients that include in accordance with the letter dated .

MEDICAL – GENERAL

430. Needles or standard medical applicator cells containing licensed material as wire shall not be opened by the licensee.

435. The licensee shall possess and use byproduct material for human research use in accordance with the prescriptive and performance criteria in all sections of 4731.4400.

[Reviewer Note: Use License Condition 475 for limited medical use programs that have non-broad human research programs.]

440. The licensee may use Iridium-192 as seeds encased in nylon ribbon and Palladium-103 seeds for topical, interstitial, and intracavitary treatment of cancer. The licensee may deviate from manufacturer's radiation safety and handling instructions only to the extent that the instructions are not applicable to the type of use proposed by the licensee.

445. The licensee may use the alternate method for maintaining records as described in the letter dated .

MEDICAL BROADSCOPE

450. The licensee shall possess and use radioactive material for medical use in accordance with the prescriptive and performance criteria in 4731.4400. This does not relieve the licensee from complying with applicable United States Food and Drug Administration (FDA) and other Federal and State requirements.

455. Notwithstanding the requirements of License Condition Number , the licensee is authorized to make program changes and changes to procedures specifically identified in the (application dated or letter dated), which were previously approved by the Commissioner and incorporated into the license, without prior Commissioner approval, as long as:

A. The proposed revision is documented, reviewed, and approved by the licensee's Radiation Safety Committee in accordance with established procedures prior to implementation;

B. The revised program is in accordance with regulatory requirements, will not change license conditions, and will not decrease the effectiveness of the Radiation Safety Program;

C. The licensees staff is trained in the revised procedures prior to implementation; and

D. The licensees audit program evaluates the effectiveness of the change and its implementation.

REMOTE AFTERLOADERS

460. The Medical Physicist(s) is/are:

INTRAVASCULAR BRACHYTHERAPY

465. To be used in the (Novoste™ Beta-Cath™ System A1000 Series Model A1732/ Cordis® Checkmate™ System) for intraluminal beta radiation treatments in accordance with the Food and Drug Administration's Pre-market Approval.

470. Training for the use of licensed material in Item 5. shall be as described in (Novoste™/Cordis®/Guidant®) Clinical Training Program. The Radiation Safety Officer shall approve all individuals in writing. The licensee shall maintain records of the training for five (5) years following the last use of licensed material.

475. Nothing in this license relieves the licensee from complying with the rules and regulations of the U.S. Food and Drug Administration.

LIQUID BRACHYTHERAPY SOURCES AND DEVICES

480. For brachytherapy using the Proxima Therapeutics' GliaSite® RTS, "prescribed dose" means the total dose documented in the written directive.

A. Prior to implantation the written directive should include the treatment site and the radionuclide (including chemical and physical form Iotrex™).

B. After implantation but prior to the completion of the procedure the written directive should include the treatment site and the total dose.

485. The licensee shall report a leaking source to MDH within five (5) days of the leakage test. Source leakage for the Iotrex™ implanted in the GliaSite® RTS means leakage of Iodine-125 that results in a dose that exceeds 50 rem (0.5 Sv) dose equivalent to any organ other than the treatment site.

MICROSPHERE BRACHYTHERAPY SOURCES AND DEVICES

490. For Yttrium-90 microspheres, "prescribed dose" means the total dose documented in the written directive.

A. Prior to implantation the written directive should include the treatment site and the radionuclide (including chemical and physical form – Yttrium-90 microspheres).

B. After implantation but prior to the completion of the procedure the written directive should include the treatment site and the total dose.

C. The written directive should specify the maximum dose that would be acceptable for the specified site or sites outside the primary treatment site to which the microspheres could be shunted.

495. The licensee shall complete quarterly physical inventories that include the radioisotope, the total activity of the aggregate, the container in which the aggregate is stored, and the location of the container.

TELETHERAPY

500. The teletherapy physicist for this license is .

505. The licensee is exempted from decommissioning financial assurance requirements for possession of licensed material in sealed sources in quantities greater than the limits in 4731.3080 for the purpose of source changes only. This exemption is granted for no more than 30 days for any one-source change.

[Reviewer Note: Possession Limit Exemption for Teletherapy Licensees.]

MOBLIE NUCLEAR MEDICINE

510. The licensee shall not receive, store, prepare or administer radiopharmaceuticals in the PET imaging van.

515. All records pertaining to licensed activities in Minnesota shall be maintained for inspection on the mobile imaging van.

520. The licensee shall retain a current copy of each client's radioactive materials license.

525. Prior to using sealed sources for diagnosis, the licensee shall verify that licensed material is prescribed by a physician meeting the requirements of 4731.4461.

530. Licensed material shall be received and stored only in the mobile imaging vehicles that may be located at temporary job sites within Minnesota where the Minnesota Department of Health maintains jurisdiction for regulating the use of radioactive materials.

CARDIAC PACEMAKERS

535. The specified possession limit includes all licensed material possessed by the licensee under this license whether in storage, implanted in patients, or otherwise in use.

540. The licensee shall continue patient follow-up and replacement procedures for the nuclear pacemaker during the life of the patient. Procedures for recovery and authorized disposal of the nuclear pacemaker by return to the manufacturer shall be followed upon the death of the patient.

545. The licensee shall report to the Minnesota Department of Health within 10 days after discovery of loss of contact with a nuclear-powered pacemaker patient.

BROAD SCOPES

550. The licensee is authorized to make program changes and changes to procedures specifically identified in the letter dated , which were previously approved by the Commission and incorporated into the license without prior Commission approval provided:

A. The proposed revision is documented, reviewed, and approved by the licensee's Radiation Safety Committee in accordance with established procedures prior to implementation;

B. The revised program is in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the Radiation Safety Program;

C. The licensee's staff is trained in the revised procedures prior to implementation; and

D. The licensee's audit program evaluates the effectiveness of the change and its implementation.

WASTE DISPOSAL

625. A record of each disposal of licensed material shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

630. Radioactive waste possessed under this license shall be stored in accordance with the statements, representations, and procedures included with the licensee's waste storage plan described in the licensee's letter dated .

[Reviewer Note: Use this License Condition when a waste storage plan has been submitted.]

635. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided:

A. Waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

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

C. A record of each such disposal permitted under this license condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

INCINERATION

640. The licensee is authorized to dispose of licensed material by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in 4731.2750, Subp. 4.

TRANSPORTATION

645. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Materials."

DISTRIBUTION

650. The licensee may distribute material from .

[Reviewer note: For use on distribution only licenses]

655. The following may be distributed provided the amount of contained in the device does not exceed the amounts specified in the following table:

Device Model Number	Isotope	Source Model Number	Maximum Activity per Source

660. Each device distributed under this license shall be manufactured, tested, and labeled in accordance with the statements, representations, and procedures contained in the letter dated .

665. This license does not authorize commercial distribution of licensed material to persons generally licensed or to persons exempt from licensing pursuant to 4731.3040.

MISCELLANEOUS

670. Licensed material shall not be used in or on human beings.

675. This license does not authorize commercial distribution of licensed material.

680. This license does not authorize possession or use of licensed material.

685. The licensee shall not use licensed material in or on human beings except as provided otherwise by specific license condition of this license.

690. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific license condition of this license.

695. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

700. The licensee shall conduct a physical inventory every six (6) months to account for all sources and/or devices received and possessed under the license.

710. Experimental animals or the products from experimental animals that have been administered licensed materials shall not be used for human consumption.

715. Pursuant to 4731.2090 and in reliance on statements, procedures and representations made by the licensee in the letter dated , the following maximum radiation levels are hereby authorized in the following unrestricted areas:

Maximum Radiation Level	Unrestricted Area

720. The licensee shall not acquire licensed material in a sealed source or device that contains a sealed source unless the source or device has been registered with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.

[Reviewer Note: This license condition may be used when the reviewer doesn't specify manufacturer's or model numbers (e.g., gas chromatographs, bone mineral analyzers).]

725. The licensee shall conduct a physical inventory of all sealed sources received and possessed under the license at intervals not to exceed six months and retain each inventory record for three years. The inventory record shall contain the identity and estimated activity of each radionuclide, the model number of each source, and serial number if one has been assigned, the location of each source, date of the inventory, and the signature of the Radiation Safety Officer.

[Reviewer Note: Use License Condition 715 on non-medical and non-radiography licenses]

730. The licensee is only authorized to calibrate radiation detection instruments for use at its facility.

EMERGENCY PLANS/DECOMMISSIONING

735. In addition to the possession limits in Item 7, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 4731.3150, which require consideration of the need for an emergency plan for responding to a release of licensed material.

740. In addition to the possession limits in Item 7, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 4731.3080 for establishing decommissioning financial assurance.

[Reviewer Note: This is a general possession limit for no decommissioning financial assurance for cases where the possession limit is not explicit.]

745. In addition to the possession limits in Item 7, the licensee shall further restrict the possession of to quantities less than .

750. If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 4731.3580. If two or more radionuclides are possessed, the possession limit is determined as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 4731.3580 for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

[Reviewer Note: To limit the possession limit for a Type C Broad License to eliminate the need for financial assurance for decommissioning also use standard license condition no. 745.]

755. If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 4731.3580 Column I. If two or more radionuclides are possessed, the possession limit is determined as follows: for each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 4731.3580 Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

[Reviewer note: To limit the possession limit for a Type B Broad License to eliminate the need for a decommissioning funding plan also use standard license condition no. 735.]

760. The licensee is exempt from decommissioning financial assurance for possession of licensed material in sealed sources for the purpose of source changes only. This exemption is granted for no more than 30 days for source changes.

SERVICES

765. Sealed source leakage or contamination tests provided as a commercial service to licensees of this Minnesota Department of Health, other Agreement States, or the US Nuclear Regulatory Commission shall be conducted in accordance with the procedures approved by the Minnesota Department of Health.

770. Sealed source leak test certificates shall identify the following:

A. The radionuclide, estimated activity, model, and serial number of each isotope tested.

B. The date of sample collection.

C. The name of the individual who collected the sample.

D. The date of leak test sample analysis.

E. The name of the individual who performed the leak test sample analysis.

F. The results of each test analysis in units of microcuries (μCi) or becquerels (Bq).

775. Radiation survey instrument calibration provided as a commercial service to licensees of this Minnesota Department of Health, other Agreement States, or the US Nuclear Regulatory Commission shall be conducted in accordance with statements, representations, and procedures approved by the Minnesota Department of Health.

POSSESSION ONLY

770.

A. The licensee will take appropriate actions to dispose of all radioactive material as soon as practical.

B. Within 30 of all radioactive material disposal, the licensee will notify the Minnesota Department of Health.

ATTACHMENT 1

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

ATTACHMENT 2

Fee Schedule

PROGRAM CODE	TYPE	APPLICATION FEE	ANNUAL FEE
1100	Academic - Type A Broad Scope	$5920	$19920
1110	Academic - Type B Broad Scope	5920	19920
1120	Academic - Type C Broad Scope	5920	19920
2110	Medical - Type A Broad Scope	3920	19920
2120	Medical Institution - Diagnostic and Therapeutic	1520	3680
2121	Medical Institution – Diagnostic (No Written Directives)	1520	3680
2200	Medical Private Practice - Diagnostic and Therapeutic	1520	3680
2201	Medical Private Practice – Diagnostic (No Written Directives)	1520	3680
2210	Eye Applicators	1520	3680
2220	Nuclear Medical Vans	1520	3680
2230	High Dose Rate Afterloader	1520	3680
2231	Mobile High Dose Rate Afterloader	1520	3680
2240	Medical Therapy – Other Evolving Technology	1520	3680
2300	Teletherapy	5520	8960
2310	Gamma Knife	5520	8960
2400	Veterinary Medicine	960	2000
2410	In Vitro Testing Lab	960	2000
2500	Nuclear Pharmacy	4880	8800
2511A	Radiopharmaceutical Distribution (10 CFR 32.72)	2160	3840
2511B	Radiopharmaceutical Processing & Distribution (10 CFR 32.72)	4880	8800
2513A	Medical Sealed Sources Distribution (10 CFR 32.74)	2160	3840
2513B	Medical Sealed Sources Processing & Distribution (10 CFR 32.74)	4880	8800
3111	Well Logging - Sealed Sources	1600	3760
3120	Measuring Systems - Fixed Gauge	960	2000
3121	Measuring Systems - Portable Gauge	960	2000
3122	X-Ray Fluorescent Analyzer	584	1520
3123	Measuring Systems - Gas Chromatograph	960	2000
3124	Measuring Systems - Other	960	2000

3211	Manufacturing and Distribution - Type A Broad Scope	5920	19920
3212	Manufacturing and Distribution - Type B Broad Scope	5920	17600
3213	Manufacturing and Distribution - Type C Broad Scope	5920	17600
3214	Manufacturing and Distribution - Other	2320	5280
3218	Nuclear Laundry	10080	18640
3219	Decontamination Services	2640	4960
3220	Leak Test Services Only	960	2000
3221	Instrument Calibration Service Only Less Than 100 Curies	960	2000
3222	Instrument Calibration Service Only 100 Curies and Greater	960	2000
3225	Services/maintenance, installation, source changes, etc.	2640	4960
3232	Waste Disposal Service Prepackaged Only	2240	6000
3234	Waste Disposal	1520	8320
3240	Distribution - General Licensed Devices (Sealed Sources)	880	1760
3244	Distribution - General Licensed Material (Unsealed Sources)	520	1120
3310	Industrial Radiography - Fixed Location	2640	9840
3320	Industrial Radiography - Temporary Job Sites	2640	9840
3510	Irradiators, Self –Shielding – Less Than 10,000 Curies	1440	2880
3511	Irradiators, Other – Less Than 10,000 Curies	2960	5360
3520	Irradiators, Self-Shielding - 10,000 Curies or Greater	1440	2880
3610	Research & Development - Type A Broad Scope	4960	9520
3611	Research & Development - Type B Broad Scope	4960	9520
3612	Research & Development - Type C Broad Scope	4960	9520
3620	Research & Development - Other	2400	4480
3810	Storage - No Operations	960	2000
11210	Source Material - Shielding	136	584
22120	SNM Plutonium - Neutron Source in Device	1200	3680
22160	Pacemaker Byproduct and/or SNM - Medical	1200	3680
22162	Pacemaker Byproduct and/or SNM Manufacturing & Distribution	2300	5280
99100	Accelerator-Produced RAM	4100	3840

99200	Nonprofit Educational Institutions	300	300
99300	General License Registration	---	150
	Amendments	300	

ATTACHMENT 3

MDH License

RADIOACTIVE MATERIALS LICENSE

Pursuant to Minnesota Statute 144.12 and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer radioactive materials designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the rules. This license is subject to all applicable rules and orders of the Minnesota Department of Health including the Minnesota Radioactive Materials Rules, Chapter 4731, now or hereafter in effect, and to any conditions specified below.

Licensee	In accordance with the application dated , the Minnesota Department of Health Radioactive Materials License is issued to read as follows:
1.	3. License Number:
2.	4. Expiration Date:
	Program Code Primary: Secondary:

5. Byproduct, Source Special Nuclear and/or Natural Occurring or Accelerator Produced Radioactive Material	6. Chemical and/or Physical Form	7. Maximum Amount that Licensee May Possess At Any One Time Under This License
A.	A.	A.
B.	B.	B.
C.	C.	C.
D.	D.	D.

8. **AUTHORIZED USE**

A.

B.

C.

D.

CONDITIONS

RADIOACTIVE MATERIALS LICENSE

SUPPLEMENTARY SHEET LICENSE NO.

11.

12.

13.

14.

15.

16.

17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Minnesota Department of Health's rules shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the rules.

    A. Application dated .

    B. Letter dated .

For the Minnesota Department of Health

Date: _____ By: _____
Radioactive Materials Group

Concurrence

Date: _____ By: _____
Radiation Control Unit Supervisor

ATTACHMENT 4

License Transition from NRC to MDH

LICENSE TRANSITION FROM NRC TO MDH

Upon completion of the Agreement, all active NRC licenses[5] issued to facilities in Minnesota will be recognized as Minnesota Department of Health licenses.

MDH will issue a one-page licensing document with all information in items 1 through 4 completed. A new license number (if appropriate) and expiration date will be included.

The document will contain the following statements:

> This license authorizes receipt, acquisition, possession, and transfer of byproduct, source, and/or special nuclear material; the authorized use(s); purposes; and the places of use as designated on the NRC license.
>
> The licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed in the NRC license. The Minnesota Department of Health rules shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the rules.

Electronic copies of the licenses shall be transferred and stored on the Radioactive Materials Group site. Hard copies of licenses shall be stored in file cabinets.

[5] Nuclear power plants and licenses for facilities in areas of exclusive federal jurisdiction (e.g., Veterans Administration Hospitals) will remain NRC licenses.

B

MINNESOTA DEPARTMENT OF HEALTH

INSPECTION PROCEDURES MANUAL

Radiation Control Unit

Asbestos, Lead, Indoor Air & Radiation Section

Division of Environmental Health

Minnesota Department of Health

January 2005

Table of Contents

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 7. 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).

Extension of Inspection Interval
The interval between inspections may be extended (lengthened) beyond that specified by the priority system based on exemplary performance by the licensee. Extensions are not normally granted because of the liability that might be incurred by MDH should a degradation of the licensee's radiological program occur. Therefore, the decision to extend the inspection interval should be made considering current and prior findings. The governing consideration in extending the inspection interval should be evidence of a consistent level of performance that provides a greater than normal assurance of a well-managed, safe operation.

An extension shall be valid only until the next inspection. At that time, it may be renewed. The extension shall be limited to a maximum of six months for licensees in Priorities 1 and 2. The extension shall be limited to two years for licensees in other priorities.

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

These shall be conducted between six months and one year after licensed material is received and operations have begun. 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, which should occur within six months of the most recent inspection, should be conducted when numerous violations were identified during a previous inspection, for repeated poor performance, or, where there has been a significant breakdown in management control.

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, 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 should not fall outside the following points:

Type of Inspection	Acceptable Frequency
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, 6, and 7	Interval between inspections may vary by a year.

If escalated enforcement action has taken place, an inspection should be conducted within one year following closeout of the escalated enforcement action.

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 attachment

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 safety 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 I, 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 a patient's test data be confirmed by an authorized user 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 a number of physicians are being supervised by an authorized user 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 A_2 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 A_1 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 A_1 and A_2 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 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 a licensing action. Peer review and supervisory review are included in that timeframe. Peer reviews provide the following benefits:

- consistency in licensing actions,
- quality assurance,
- educational opportunities for less experienced licensing staff
- communication between licensing and inspection staff

The 30-day completion objective should always be met when licensing actions involve health and safety related issues. However, the quality review and approval will always take precedence over an arbitrary completion deadline.

A supervisory review of new, amended, and renewed licenses is required. A supervisory review is not required for deficiency letters.

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:	☐ New License ☐ Renewal ☐ Amendment No.: _____	☐ Deficiency Letter ☐ Inspection Report ☐ 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 QUESTIONAIRE

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

Minnesota Department of Health - Radioactive Materials Group - RAM	Radiation Control Unit Asbestos, Lead, Indoor Air & Radiation Section Division of Environmental Health Minnesota Department of Health

January 2005

Table of Contents

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.

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[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.

POLICY

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. 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.

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, special circumstances, and the need 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 objectives[3] 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.

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.

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[3] The specific education and experience requirements for employees are included in the position descriptions.

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 - SEMI-ANNUAL ACCOMPANIMENTS

This log documents accompaniments and subsequent evaluation by the Radiation Control Unit Supervisor or another 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. A copy of the Inspector Evaluation Form (included in Appendix A) has been completed and placed in this manual.

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

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.

	Final Score	Date
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

REVISION	SECTION	DESCRIPTION

MINNESOTA DEPARTMENT OF HEALTH

RESPONSE MANUAL FOR INCIDENTS INVOLVING RADIOACTIVE MATERIAL

Radiation Control Unit

Asbestos, Lead, Indoor Air & Radiation Section

Division of Environmental Health

Minnesota Department of Health

January 2005

Table of Contents

SECTION I – OFFICE PROCEDURES

PURPOSE

The purpose of this Manual is to provide a general outline for MDH staff to follow when incidents involving radioactive material occur. Because every incident has unique circumstances, the intention of the Manual is to provide a generalized structure to be followed for the sake of consistency.

GUIDANCE

What is an incident?
Incidents are unusual occurrences that have an impact on public health and safety. They include, but are not limited to the following:

- Misuse, loss of control over, or loss of licensed radioactive material
- Medical misadministrations
- Overexposures to radiation

Who reports incidents?
According to MDH rules, licensees are required to report incidents on specific occasions, including the following:

- "Reports of Stolen, Lost, or Missing Licensed Material"
- "Notification of Incidents"
- "Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits"
- "Reports of Leaking or Contaminated Sealed Sources"
- "Records and Reports of Misadministrations"
- "Notification of Incidents Involving Industrial Radiography"
- "Notification of Incidents, Abandonment, and Lost Well-Logging Sources"

Members of the public can also report incidents. The majority of these calls are from scrap metal processors that identify radioactive material that set off radiation monitors in a load of scrap metal. Other calls come from individuals who are concerned with something they saw, or have knowledge of, that is radiation related.

What steps should be taken in response to an incident call?

Incident Call
Routinely, all incident calls should be routed to the Radioactive Materials Group. If Radioactive Material Staff are unavailable, the call should be routed to a member of the Senior Staff.

Radioactive Materials Group Documents
The MDH staff member who takes the call should complete the "Incident Reporting Form" (Attachment 1). Additionally, in instances where a DOT exemption is necessary, a Department of Transportation Form E10656 "Shipment Approval for Scrap Metal or Related Recycling Material" will need to be filled out. (See Attachments 2 and 3.)

Assessment
Upon completing the "Incident Reporting Form" the MDH staff member should determine if the situation is an incident required to be reported by the Chapter 4731. Regardless of the situation, the Radiation Control Supervisor should be informed as soon as possible. If the supervisor is unavailable, the Section Manager should be notified.

Ideally, MDH staff should work together to assess the situation. However, there may be times in which a MDH staff member must use his/her judgment assessing the situation. The first and foremost consideration is to determine if an immediate threat to public health and safety exists. Once this has been determined, consideration should be given to the following questions:

- What was the caller's comfort level with the situation?
- What resources does the caller have at his/her disposal?
- Is this an incident that might attract the media?

The Radiation Control Supervisor, or the Section Manager has final authority on what the response will be. In the rare circumstance when both are absent, individual staff member will formulate a response plan and consult with the Assistant Division Director or the Division Director before implementing that plan.

Call Back
After assessment is made, at a minimum, the MDH staff member must contact the caller to inform him/her of what actions will be taken. At this time, a decision to inform the Nuclear Regulatory Commission's Regional State Agreement Officer (RSAO) must be made. The RSAO is an excellent source of information and can assist in resolving questions or concerns about the specific reporting requirements.

Response
An immediate physical response is required for the following:

- Lost, stolen, or missing radioactive material that threatens public health and safety.
- An exposed source that will cause or threatens to cause overexposure of people.
- A leaking source that can not be contained.

All other response time is to be determined by the Radioactive Materials Group Supervisor. Consideration must be made to the number of MDH staff members that will be needed to carry out the appropriate response. The personal protective gear, equipment and instrumentation must be appropriate to the situation. This includes the following:

Personal protective gear/equipment

- ✓ Hard hat
- ✓ Steel-toed shoes
- ✓ Gloves
- ✓ Eye and Ear protection
- ✓ Protective clothing
- ✓ Personnel dosimetry

Instrumentation/Equipment

- ✓ Appropriate survey instrumentation
- ✓ Counting equipment
- ✓ Wipe test kit
- ✓ Camera
- ✓ Plastic baggies

Once on-site it will be necessary for the MDH staff to make a field assessment. If this assessment changes the response, the Radiation Control Supervisor should be notified and the changes documented.

Follow-up
Follow-up actions will depend on the situation. These actions are taken to resolve and close the incident. It also includes, implementing corrective actions to prevent recurrence. Follow-up actions may be:

- Debriefing the affected parties
- MDH Investigation
- Enforcement Action(s)
- Updating the incident file

Incident Closure
After the information is gathered and determined to be adequate, the information will be presented to the Radiation Control Supervisor. Once the Radiation Control Supervisor determines that closure is appropriate, the MDH staff will prepare information for the incident file.

The MDH staff that documents the incident must prepare a chronological report. This report and any supporting documentation will be routed to all radioactive materials personnel and filed in the incident file.

Privacy Information
Most information the department holds is public data and can be reviewed and copied by members of the public upon proper request and payment of copying costs. As a public agency, the law requires us to provide the public and media all information collected or generated by staff as quickly as is reasonably possible. There are exceptions.

Please read "The Data Privacy Puzzle," a guide the division has developed to help you.

Nuclear Materials Events Database (NMED)
For uniformity in reporting, incidents should be entered into NMED. Entry into this system will also provide information to other regulatory entities. The licensee or persons involved in the incident should be informed that the information will be made available to parties outside MDH. However, they should be assured that individuals will not be mentioned by name.

The Appendix to this document, *The Handbook on Nuclear Material Event Reporting in Agreement States* provides specific guidance including reporting requirements, which should be followed. An edited copy of that document is incorporated in this Manual as Attachment 4. A complete text of the NRC *Reporting Materials Events Procedure Number: SA-300*, can be found electronically at:

http://www.hsrd.ornl.gov/nrc/procedures/sa300.pdf

MDH staff should ensure that the information is included in NMED as soon as practicable. In addition, the database should promptly be updated to indicate any status changes. Obviously, response operations have priority over the data entry. However, it is imperative that NMED information be kept as current as possible.

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.

ATTACHMENT 1
INCIDENT REPORTING FORM

MDH RADIATION INCIDENT/EMERGENCY FORM

Call received

DATE: TIME: BY:

INCIDENT INFORMATION

Reported by: Phone number(s):	Affiliation/Location:

Description of the incident (including individuals, sources, locations, times, site involved).
(If more room is needed, please use back of sheet.)

Source involved (type of object, container). *Be specific.*

Radiation Safety Officer or other contact person:

Phone number(s):

Media at incident site: Yes ☐ *(inform Division Director immediately)* No ☐

FOLLOW-UP INFORMATION

Follow- up conducted by Inspection ☐ Phone ☐ Date:

Brief description of results of follow up (corrective actions taken):
(If more room is needed, please use back of sheet.)

Additional follow-up N/A ☐ Inspection ☐ Phone ☐ Date:

Incident closed date:	Closed by (name):

ADDENDUM FOR RADIOACTIVE MATERIALS

RADIOLOGICAL INFORMATION

ISOTOPE	ACTIVITY	READINGS

DEVICES

ISOTOPE	ACTIVITY	MANUFACTURER	MODEL	SERIAL NO.

INCIDENT STATUS

Status of the event:	☐ OVER ☐ ONGOING
Does the caller have assessment capability? If so, explain:	☐ Yes ☐ No
What are the exposure readings?	
What is the background reading?	

Does the event pose an immediate threat to health and public safety? If so, explain:	☐ YES ☐ NO
Are other hazards or hazardous materials involved? If so, what are they?	☐ Yes ☐ No ☐ Unknown
Are other hazards or hazardous materials involved? If yes, explain:	☐ Yes ☐ No ☐ Unknown
Has anyone been injured (non-radiological)?	☐ Yes ☐ No ☐ Unknown
Has anyone been radioactively contaminated? If so, where are they now?	☐ Yes ☐ No ☐ Unknown
Has anyone been injured do to radiation exposure? If so, explain:	☐ Yes ☐ No ☐ Unknown
Does the incident involve a shipment of scrap metal or other recycling material? If so, fill out the appropriate DOT exemption form (Attachments 1 and 2):	☐ Yes ☐ No

Directions given to Caller:

ATTACHMENT 2:
DOT FORM FOR SCRAP METAL
OR RELATED RECYCLABLE MATERIAL

Annex A

DOT-E 10656 SHIPMENT APPROVAL FORM

Approval Number: **MN - - 03 -** (Refer to E 10656, para. 8a)

This shipment of scrap metal or related materials for recycle contains unidentified radioactive material causing low level radiation outside the vehicle. Shipment is under Exemption DOT-E 10656 without a determination of materials meeting or not meeting the regulatory definition of radioactive material. The shipment is a minor radiological concern based on considerations of the U.S. Dept. of Transportation and the state official signing this shipment approval document.

DETAILS OF DETECTION SITE, MATERIALS, AND ORIGIN

FACILITY: Name: Type:

Address:

(1) Contact Person: Ph. : Fax.:

☐ Highway or ☐ Rail Vehicle type: ID. No.:

Owner: Operator:

(2) Contact Person: Ph. : Fax.:

Description of waste and release risk factors:

Radiation Measurement: Date/Time Performed:

mrem/hr (max): Location on vehicle:

Inst. Mfgr./Type/Model: Background mrem/hr:

Surveyor Name: Ph.:

Shipment Origin: Company: Address:

(3) Contact person: Ph.: Fax.:

RADIATION CONTROL OFFICIALS (Detection, Origin, Destination States)

Detection State Official (receiving radiation detection info) Name:

(4) Organization: **Minnesota Department of Health** Ph.: Fax.: **(651) 643-2152**

Origin State Official (prior to detection) Name:

(5) Organization: Ph.: Fax.:

Destination State Official (after detection) Name:

(6) Organization: Ph.: Fax.:

DESTINATION FOR RADIOACTIVE MATERIAL IDENTIFICATION AND/OR DISPOSITION
If carrier and shipper to this location are different than (2) and (3), show info in REMARKS

Company Name: Location:

(7) Contact person: Ph.: Fax.:

APPROVAL OF SHIPMENT AND SPECIAL CONDITIONS

CONDITIONS:

(8) Signature: Ph.: Fax.: **(651) 643-2152**

Title: Organization: **Minnesota Department of Health** Date:

IDENTIFICATION OF RADIOACTIVE MATERIAL AND DISPOSITION INFORMATION AT DESTINATION

(9) Name: Title: Date:

Organization: Ph.: Fax.:

RECORD OF TRANSMITTALS (Shipment Approvals and Identification/Disposition)
Circumstances may influence distribution)

Shipment Approvals -- (Sent by (4) or (8)) to (Show date sent)

(1) (2) (3) (5) (6)

(7) OED CRCPD OTHER

Record of Identification and Disposition -- (Sent by (7), (9), or) to

(3) (5) (6) (4) or (8) OED CRCPD

OTHER

REMARKS, OTHER INFORMATION:

In case of an emergency, notify the National Response Center (800) 424-8802 and the (9) authorizing official. Give the Exemption Number and Approval Number.

ATTACHMENT 3:
DOT EXEMPTION FORM FOR
LANDFILL WASTE

Annex A

DOT-E 11406 SHIPMENT APPROVAL FORM

Approval Number: **MN - - 03 -** (Refer to E 11406, para. 8a)

This shipment of waste or recycle materials contains unidentified radioactive material causing low level radiation outside the vehicle. Shipment is under Exemption DOT-E 11406 without a determination of materials meeting or not meeting the regulatory definition of radioactive material. The shipment is a minor radiological concern based on considerations of the U.S. Dept. of Transportation and the state official signing this shipment approval document.

DETAILS OF DETECTION SITE, MATERIALS, AND ORIGIN

FACILITY: Name: Type:

Address:

(1) Contact Person: Ph. : Fax.:

☐ Highway or ☐ Rail Vehicle type: ID. No.:

Company:

(2) Contact Person: Ph. : Fax.:

Description of waste and release risk factors:

Radiation Measurement: Date/Time Performed:

mrem/hr (max): Location on vehicle:

Inst. Mfgr./Type/Model: Background mR/hr:

Shipment OriginCompany: Address:

Waste Origin:

(3) Contact person: Ph.: Fax.:

RADIATION CONTROL OFFICIALS (Detection, Origin, Destination States)

Detection State Official (receiving radiation detection info) Name:

(4) Organization: **Minnesota Department of Health** Ph.: Fax.: **(651) 643-2152**

Origin State Official (prior to detection) Name:

(5) Organization: Ph.: Fax.:

Destination State Official (after detection) Name:

(6) Organization: Ph.: Fax.:

DESTINATION FOR RADIOACTIVE MATERIAL IDENTIFICATION AND/OR DISPOSITION
If carrier and shipper to this location are different than (2) and (3), show info in REMARKS

Company Name: Location:

(7) Contact person: Ph. Fax.

APPROVAL OF SHIPMENT AND SPECIAL CONDITIONS

CONDITIONS:

(8) Signature: Ph.: Fax.: **(651) 643-2152**

Title: Organization: **Minnesota Department of Health** Date:

IDENTIFICATION OF RADIOACTIVE MATERIAL AND DISPOSITION INFORMATION AT DESTINATION

(9) Name: Title: Date:

Organization: Ph.: Fax.:

RECORD OF TRANSMITTALS (Shipment Approvals and Identification/Disposition)
Circumstances may influence distribution)

Shipment Approvals -- (Sent by to (4) or (8)) to (Show date sent)

OED CRCPD (1) (2) (3)

(5) (6) (7) OTHER

Record of Identification and Disposition -- (Sent by (7), (9), or OTHER) to

OED CRCPD (3) (5) (6)

(4) or (8) OTHER

REMARKS, OTHER INFORMATION:

In case of an emergency, notify the National Response Center (800) 424-8802 and the (8) authorizing official. Give the Exemption No. E 11406 and Approval No.

SECTION II
FIELD OPERATIONS

PERSONAL PROTECTION

Dosimetry

Ensure that each member of the team has an OSD and an electronic dosimeter. If self-reading pocket dosimeters (SRPD) are used, they must be re-zeroed and the initial readings recorded along with the serial numbers for each member of the team.

SRPD Precautions:

- Read dosimetry initially and every half-hour thereafter. Re-zero your 0-200 mR dosimeter if the reading reaches 3/4 scale, i.e., 150 mR.
- Handle dosimeters (SRPDs) with care.
- If dropped or significantly shocked, read the dosimeter to see if indicator is off scale or if it reads radically different from other team member's dosimeters. If there is a problem, exit the area.

Radiation Exposure Control and Limits

To be consistent with power plant exposure limits, the Turnaround Dose Limit is established as 1.0 Roentgen (R). Listed in the table below are the federal limits for power plant response that can be used as guidelines in responding to emergencies.

Federal Dose Limits for Emergency Workers

Dose Limit (rem)	Activity	Condition
5	All	
10	Protecting Valuable property	Lower Dose not Practicable
25	Life saving or protection of large populations	Lower Dose not Practicable
>25	Life saving or protection of large populations	Only on voluntary basis to persons fully aware of risks

Dose Rate Limits

Personnel should consider withdrawal if survey readings indicate a general radiation field of 100 mR/hr gamma or greater.

Contamination Limits

Anti-Cs should be changed when they are greater or close to 1,000 ccpm plus background.

Protective Clothing and Contamination Control

Anti-contamination clothing is provided for personal protection. It is important that the responders are constantly aware of the presence of contamination and take all precautions necessary to minimize its spread and ingestion. Higher levels of contamination have a higher potential for spreading.

Contamination Control Guidelines/Precautions

- Do not eat, drink or smoke in the field.
- Conduct periodic personnel monitoring, particularly after taking samples in high grass or bushes.
- When working in the plume it is a higher priority to leave the plume area as soon as possible than it is to take time-consuming steps in contamination control. Monitoring, decontamination, and anti-contamination clothing change-out should be done outside the plume.
- Monitor hands and change gloves frequently to reduce the chance of becoming contaminated.
- Monitor feet before coming back into the vehicle, when practical.
- Replace anti-contamination clothing if levels reach 1,000 cpm or greater above background.
- When possible, place equipment upon equipment tarps or other uncontaminated areas.
- Take the necessary steps to minimize contamination of the inside of the vehicle, monitor equipment used in the field before placing it back in the vehicle, decontaminate if necessary.
- Bag instrument probes.

Sequence for Putting on Protective Clothing

1. Put on the coveralls and tape the zipper. **NOTE: Always leave a tab on the tape for easy removal.**
2. Put on the outer boots and tape the coveralls to the boots. The coverall legs should be over the boots.
3. If the hood is separate from the coveralls, put on the hood and tape the bottom edge to the coveralls.
4. Put on a hardhat and reflective vest.
5. After recording initial readings, place dosimetry in a bag.
6. Put on a pair of inner gloves. Ensure that they are underneath the wristband of the coveralls. Tape the wristband.
7. Put on outer gloves.

Sequence for Removing Protective Clothing

1. Remove the outer gloves, turning them inside out over a bag that is designated a disposal bag.
2. Remove the dosimetry and hand to station personnel.
3. Remove the hardhat and vest. Place in a bag that is **not** designated for disposal. These items can be decontaminated and reused later.
4. If the hood is not part of the coverall, remove the tape from the hood and bending backwards

over the bag designated for disposal (disposal bag.), peel the hood off backwards and place in the disposal bag.

5. Remove the tape from the coveralls and boots and remove the coveralls, turning them inside out. Put them in the bag designated for disposal.

6. Remove the first boot and step onto the step off pad with your clean foot while keeping your hands and the remaining booted foot inside the contaminated area. Remove the remaining boot and place that clean foot onto the step off pad still keeping your gloved hands over the contaminated area or the disposal bag.

7. Remove the final (inner) layer of gloves by turning them inside out as you peel them off over the disposal bag. Put them in the disposal bag.

Sequence for Changing Protective Clothing in the Field

1. Remove the outer gloves, turning them inside out over a garbage bag.

2. Remove the dosimetry and place on clean equipment tarp. Monitor and decontamination if necessary by brushing and/or shaking the bag in an area away from equipment.

3. Remove the hardhat and vest. Decontaminate if necessary.

4. If the hood is not part of the coverall remove the tape from the hood and bending backwards over a garbage bag, peel the hood off backwards and place in a bag for disposal later.

5. Remove the tape from the coveralls and boots and remove the coveralls, turning them inside out as they are removed. Put them in the disposal bag.

6. Remove the outer boots one at a time and step onto the clean tarp with your clean feet. Put them in the disposal bag.

7. Remove the final (inner) gloves by turning them inside out as you peel them off over the disposal bag. Put them in the disposal bag.

8. Don new protective clothing using the Sequence for Putting on Protective Clothing.

INSTRUMENT OPERATION

Monitoring and Sampling teams perform certain steps prior to being dispatched from the FRMAC. If a team is dispatched directly to the field in relief of another team, these steps should be performed as soon as is reasonably convenient, such as during shift change.

Preoperational Quality Control Check

1. Check instrument for
    - Unusual or unexpected response or behavior
    - Physical damage
2. Check batteries.
3. Set instrument to lowest range that provides an on-scale reading.

Quality Control Check

1. Ensure the calibration certificate has not expired.
2. Check the battery.
3. Look for normal background response.
4. Check each instrument at the beginning and end of each shift.
5. Perform instrument source checks if sources are available. Ensure reading is within the acceptable range.

Operational Check
Operational checks of radiation survey instruments should be performed periodically and after doing any minor maintenance such as changing batteries or fixing a loose cable. In addition to the above, complete the following when check sources are available:

1. Use appropriate check source.
2. Perform check in predetermined geometry to give defined exposure or count rate.
3. Perform preceding step on each scale calibrated for use.

Alpha-emitting Radioactive Material
Alpha-emitting radioactive materials include plutonium, americium, and other actinides.

CAUTION
Never "wrap" an alpha probe with plastic. Alpha radiation cannot be measured through plastic.

Alpha Contamination Meter
Alpha radiation has very short range. A zinc sulfide scintillator or proportional counter is used as the measuring device.

1. Choose a surface that is relatively flat. A cloth or paper large-area wipe can be surveyed with a portable instrument to test for contamination on irregular surfaces.

2. Take measurements as close as possible to the surface using caution not to puncture the probe.

Note: Any dew or snow overburden on the contamination may reduce or block the alpha radiation. Because of geometry and environmental factors, alpha contamination survey meters are useful for identifying but are not optimal for quantifying alpha contamination.

- Avoid damage or contamination of instrument window or probe area covering material.
- Since alpha particles have a short range in air, standoff attachments can be used to keep the probe about 0.64 cm (0.25 inches) from the monitored surface.
- Hold the probe with gloved fingertips extending below bottom edge of the probe.
- Do not use masking tape to pick up particles from the window. Residual adhesive on the window covering may cause additional contaminating particles and foreign material to adhere.

- Alpha surveys of large areas are qualitative because only representative locations can be checked. Usual survey techniques involve making several surface measurements at regular distances over the area. The number of measurements depends on size of area and monitoring time available.

- The holes in the probe window can be repaired with small pieces of opaque tape or paint; sensitive area will be decreased and some measurement error will be introduced. When temporary repairs have been made, instruments should be returned for repair and calibration as soon as practical.

SURFACE CONTAMINATION SURVEYS

Direct Scan

1. Make sequential measurements over the entire surface, as appropriate, with the stationary detector or by slowly sweeping the detector over the surface. If the detector passes over an isolated, small-diameter source, the number of pulses produced by the source in the detector will be inversely proportional to the scanning speed.

CAUTION
Nominal scanning velocity should not exceed 5 cm (2 inches) per second.

2. Hold the probe stationary no more than 0.64 cm (0.25 inches) from the probe window to the monitored surface.

3. Hold sensitive window or probe area over each part of the surface monitored long enough to observe the average value of the meter needle fluctuation.

4. Speaker- or headphone-equipped instruments are desirable for low-level monitoring.

5. Record all measurements.

Indirect (Smear or Wipe) Method

1. Select a representative sampling surface that:
   - Is flat, smooth, and stationary, if possible.
   - Smear can be rubbed on and smear will not roll up or fall apart.

2. Mark off known area such as:
   - 100 cm^2 or 10 × 10 cm (4 × 4 in) or approximately the size of a dollar bill.
   - 30 × 30 cm (1 ft^2 or 1 × 1 ft)

3. Label the envelope or plastic bag with the appropriate information (sample location, date, time, and collector's initials).

4. With two gloved fingers, carefully rub the smear over the pre-marked area. Apply moderate pressure; be consistent if performing multiple smears.

5. Take care not to shake off collected material.

6. Determine the amount of radioactive material on the smear with the appropriate instrument of known efficiency (including geometry). A GM pancake probe is usually used for beta/gamma and an appropriate alpha instrument for alpha contamination.

7. Place the smear in an envelope.

8. Record readings.

9. Package and label in accordance with *Packaging and Labeling* section.

NOTE: If several smears are taken from one location, make an area drawing that identifies smears by number and location.

GENERAL AIR SAMPLE MONITORING INSTRUCTIONS

Particulate Filter Counting

- Complete a separate sample label for the filter and cartridge. Place the labels and the bagged filter and cartridge.
- Sample counting should be done in a low background area if possible (i.e., <100 CPM).
- Never place the air sampler on the ground.
- Count the CPM on the inlet side of the particulate filter using a survey meter by placing the detector 1/8" from the bagged filter. Subtract the background CPM to find the ccpm (Corrected Counts Per Minute or "Net CPM").
- If required, decontaminate the filter head after use by spraying with water and wiping dry with paper towels, changing gloves often.
- Record the results on the Sample Control Form.

Air Sampling Records

Each air sample label should include:

- sample time
- date
- location
- contact radiation levels
- sampling duration
- average flow rate
- sampler correction factor

PACKAGING AND LABELING

Precautions

- Avoid cross-contamination.
- Wear disposable gloves.
- Change gloves frequently if contamination is suspected.
- Segregate above background samples (5 times background unless otherwise directed).

- In transit, store above background samples (5 times background unless otherwise directed) in a shielded area of the vehicle or as far away from passenger area as possible and separated from all dosimeters.
- Ensure samples are secure.
- When exiting/entering vehicle, ensure samples are not dislodged from storage area.

Procedure
After performing the sample collection and preparation procedures given in the specific procedure for the type of sample collected, complete the following to prepare the collected sample for transport.

1. Perform surface gamma radiation exposure rate survey of sample container.
2. Record results on the shipping tag.
3. Seal the bag, taking care not to contaminate outer surface of the bag.
4. Place the bagged item in another plastic bag.
5. Load samples in vehicle for transport to Sample Control.
6. When leaving vehicle, ensure that all samples are secure and vehicle is locked.

SECTION III
NUCLEAR MATERIAL EVENT REPORTING - NMED

SA-300 Reporting Material Events
Appendix (Rev. 1)

Handbook on Nuclear Material Event Reporting in the Agreement States

Final Report

April 24, 2001

(Excerpted and Abridged by the Minnesota Department of Health)

Abstract

The review and analysis of operational event information increases the effectiveness of the U.S. Nuclear Regulatory Commission (NRC) and Agreement State regulatory programs by identifying safety-significant events and concerns, and their causes. The information from reports of medical misadministrations, overexposures, equipment failures, and other events that have occurred involving the use of nuclear materials licensed by either the NRC or the Agreement States is invaluable in assessing trends or patterns and identifying possible inadequacies or unreliability of specific equipment or procedures. The reported information will significantly aid in understanding why the events occurred and identifying any actions necessary to improve the effectiveness of NRC and Agreement States regulatory programs. The information is also used in preparation of NRC's performance report to Congress. This handbook, which supercedes the previous February 20, 1998-version, has been developed to provide information to the staff of the Agreement and non-Agreement States that are responsible for the preparation of event reports for incidents and events involving the use of nuclear materials that have occurred in their State. Reporting of Agreement State material events to NRC is mandatory for purposes of compatibility. The handbook describes the procedure to be followed in reporting material events to NRC. Guidance is provided on what information should be reported, the level of detail, and where to report. Information is also provided on obtaining Federal assistance for radiological emergencies. Procedures for identifying and reporting Abnormal Occurrences (AOs) are also included. The objective of the handbook is to:

- Improve technical information
- Standardize format
- Ensure consistency
- Facilitate information retrieval

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List of Tables

1. Introduction

This handbook contains guidance for Agreement States on reporting material event information to the Nuclear Regulatory Commission (NRC) for events that have occurred in their State. It also provides guidance for use by non-Agreement States when reporting events involving lost, stolen or found sources of naturally occurring and accelerator-produced radioactive materials. The reported information aids in understanding why the events occurred and in identifying actions to help ensure safety and improve the overall effectiveness of the NRC and Agreement State regulatory programs. Guidance is provided on (1) reporting significant events to the NRC Operations Center; (2) providing 30-60 day notification and follow-up event information; (3) schedule for event reporting; (4) reporting formats (i.e., electronic reporting to the Nuclear Materials Events Database (NMED) or written reports (mail, Fax, or email) to the Director, Office of State and Tribal Programs (STP); and (5) reporting event information for events meeting the abnormal occurrence (AO) criteria. An appendix to the Handbook contains (1) a glossary of terms, and (2) a listing of reference materials. NOTE: This procedure does not contain guidance on NMED data entry (coding). For guidance on data entry, an electronic copy of the NMED users guide has been included under the *Help* support icon in the upgraded Microsoft Access 97/2000 version of the NMED software program.

1.1 Why do we collect event information?

Operating experience is an essential element in the regulatory process for insuring that licensed activities are conducted safely. Reporting operating incidents and events helps to identify deficiencies in the safe use of AEA radioactive material and to ensure that corrective actions are taken to prevent recurrence. The *Government Performance Results Act of 1994 (GPRA)*, required the Agency to establish measurable outcome oriented performance goals linked to Agency programs and activities in a strategic plan. An annual performance report to Congress is prepared that evaluates the materials program against the metric performance goals. The metric goals are based on current and historical event reporting data. A 1993 General Accounting Office (GAO) report identified the compilation and presentation of national materials data as an area for improvement and recommended that NRC take appropriate action to ensure that the information on radiation events is reported completely and accurately. Further, reliable information should be available to NRC, the Congress, and the States to identify patterns and trends and determine appropriate changes for the programs.[1] NRC conducts reviews of all operating experience reports, from both NRC licensees and Agreement States, to identify safety concerns early, and to further evaluate individual safety concerns for any *generic safety issues* (GSIs) that could apply to a broader class of licensees. Prompt reporting of event information, including 30 day report information, helps the staff identify or detect possible safety concerns as early as possible. An event or condition could, by itself appear insignificant, but when compared with national information, could become a generic concern. In-depth analysis of event report

[1] Nuclear Regulation: Better Criteria and Data Would Help Ensure Safety of Nuclear Materials, GAO/RCED-93-90.

data may result in the identification of actions that could lead to improvements in the effectiveness of NRC and Agreement State regulatory programs. Event analysis may also result in the issuance of information notices warning of possible safety concerns and assessment of the need for regulatory changes or revisions. Feedback is provided to Agreement State regulators, the industry, and the public.

NRC publishes a quarterly report that presents information on the results of statistical analysis of event data and any significant or generic issues or concerns. The *Nuclear Materials Events (NMED) Database Quarterly Report* is available in electronic form at the NMED Internet Website: http://nmed.inel.gov. A nuclear material newsletter is also published quarterly by NRC's Office of Nuclear Material Safety and Safeguards (NMSS) that includes information on safety concerns identified during that quarter.

1.2 What is the governing regulatory authority?

- Under Section 274 of the AEA, Agreement States have assumed regulatory authority over byproduct source and certain quantities of special nuclear materials. The AEA directs NRC to cooperate with the States in the formulation of standards to protect employees or the general public against hazards of radiation and to assure that State and Commission programs will be coordinated and compatible. Article VI of the Agreement Between the State and the US NRC states that "the State and the Commission agree to keep each other informed of events, accidents, and licensee performance that may have generic implications or otherwise be of regulatory interest."

- Under the AEA and the Energy Reorganization Act of 1974 (ERA), as amended, the NRC evaluates material event reports for both and Agreement State licensees, and AOs that have occurred in licensed facilities. In addition, the ERA requires NRC to provide to Congress on an annual basis, information on significant events that meet the AO criteria.

- Due to the importance of operating experience as an essential element in the regulatory process for ensuring that licensed activities are conducted safely, the Commission directed the staff to make Agreement State reporting of events to NRC's NMED database an item of compatibility (See Reference section, June 30, 1997, SECY-97-054). The implementing procedures are contained in STP Procedure SA-200 (See Reference section).

- The guidance contained in this handbook is to assist NRC and Agreement State staff in the joint sharing and analysis of event information. It does not address evaluation of Agreement State programs. The AEA directs the Commission to periodically review actions taken by the States under the Agreements to insure adequacy and compatibility with the provisions of the Act. NRC conducts periodic evaluations of Agreement State programs under the *Integrated Materials Performance Evaluation Program (IMPEP)*, which includes an evaluation of event response, reporting, follow-up, and close-out. (See Reference for STP Procedure SA-100 (IMPEP))

1.3 How do you determine if an event is reportable?

Agreement States should report to NRC all events reported to their State by State licensees under State regulations equivalent to NRC's reporting requirements. Section 4 of this guide contains a listing of the *U.S. Code of Federal Regulations (10 CFR)* regulatory reporting requirements for material event information. The 10 CFR reporting requirements form the basis for equivalent reporting requirements in Agreement State regulations. The listing references the specific 10 CFR reporting requirements, followed by a brief description of the types of events that fall under the reporting requirement, and the periodicity for reporting. This list begins on page 11 of the "Handbook."

New Please note the new reference in All Agreement State Letter SP-98-038, dated May 5, 1998, regarding expansion of the Federal Bureau of Investigation (FBI) criminal investigative jurisdiction to include byproduct material. A revision to the U.S. Code assigns lead responsibility for material events involving ***theft or terrorist activities*** to the FBI.

The States are encouraged to voluntarily report an occurrence that actually happened (event) or something that may happen (condition) that does not meet the regulatory reporting criteria that the State believes might be of safety significance or of generic interest or concern, or involves media interest.

1.4 What is the Nuclear Materials Events Database (NMED)?

The NMED database contains a historical collection of information on the occurrence, description, and resolution of events involving the use of radioactive material in the United States (source, byproduct, special nuclear material, naturally occurring, and accelerator-produced radioactive material). NMED accommodates the sharing of material event data submitted by Agreement and non-Agreement States and the NRC. The data includes information on material events from January 1990 through the present. The database is maintained by NMSS through a contractor, Idaho National Engineering and Environmental Laboratory (INEEL).

1.5 Reporting Lost, Stolen and Abandoned Sources

New The NMED database has been expanded to include additional information on ***lost, stolen, and abandoned sources*** in coordination with a national effort led by the *Conference of Radiation Control Program Directors, Inc., (CRCPD)* to track lost and found radioactive material (including non-AEA and unlicensed material) found in both Agreement and non-Agreement States. The data will be collected from all States, and in some cases non-licensee organizations and members of the public. Non-Agreement States should follow

the guidance provided in Section 2 . "Reporting Material Events," to report any lost, stolen and abandoned non-AEA and unlicensed material. (See All Agreement State Letter SP-98-018, March 17, 1998).

NOTE: FBI notification should be considered if the event involves the possibility of theft or terrorist activities. Based on health and safety significance the issuance of a press release should also be considered.

2. Reporting Material Events

In accordance with the provisions of compatible Agreement State regulations, Agreement State licensees are required to report the occurrence of material incidents and events to the Agreement State regulatory agency. As an item of compatibility, the Agreement States provide reports of incidents and events involving the use of nuclear materials by Agreement State licensees to NRC. Non-Agreement States have been requested by CRCPD to voluntarily report any lost, stolen and abandoned non-AEA and unlicensed material. This section presents information on reporting (1) significant events to the NRC Operations Center, (2) 30-60 day reportable events, and (3) follow-up event information.

2.1 Reporting Significant Events (Reportable within 24 hrs. by Agreement State licensee)

Agreement States should report significant events to the NRC Operations Center within 24 hours of notification by an Agreement State licensee. Significant events are those requiring prompt notification as determined under applicable Agreement State regulations. Information should be reported to the NRC Operations Center via voice at (301) 816-5100 or (301) 951-0550 or by FAX at (301) 816-5151. A Sample FAX page has been included at the end of Section 2, see Table 1. (For reference, NRC reporting requirements for significant events are presented in Section 4.)

2.2 Initial NMED Record for Significant Events

A copy of the initial event notification information received from an Agreement State on significant events is used by INEEL to establish an initial record in the national NMED database. INEEL will use the *Event Report Identification No.*, consisting of the State ID, year, and a sequential ID No., e.g., (TN-00-001) when entering the initial event record into NMED. The State should use that Event Report Identification number when providing updates to the initial NMED event record using the State's local Microsoft Access, NMED database. (See Section 2.5, of this Handbook for guidance on reporting follow-up event information to NMED.)

2.3 *Radiological Emergency Response Assistance Available to the States for Significant Material Events*

States may request Federal assistance through the NRC Operations Center staff. The Federal government, upon request, has the capability to provide assistance to States in responding to radiological emergencies. Under the Federal Radiological Emergency Response Plan (FRERP), NRC is the lead Federal agency (LFA) for radiological emergencies involving AEA material where the material can be traced back to an individual NRC or Agreement State licensee. As the LFA, NRC is responsible for coordination of the Federal response, including providing assistance from NRC and arranging for assistance from other agencies, e.g., FEMA, DOE, etc., as requested by the States. Federal assistance is available to provide ground and aerial radiological monitoring (e.g., missing source), medical advice on radiation effects and treatment, consequence projection, and protective action assessment.

FAX TO: NRC OPERATIONS CENTER	
Agreement State Agency:	[State] Dept. of Health, Division of Radiation Protection
Event Report ID No.:	State ID, YR, No., e.g. WA-00-002
License No.:	CL-Z00X-1
Licensee:	County Inspection Inc.
Event date and time:	April 6, 2001, between 4:00 and 5:00 am
Event location:	City, State
Event type:	Stolen Radiography Device
Notifications:	[State] Dept. of Health has notified local police, and the FBI due to possibility of unlawful criminal activity. Press release has not been issued at this time.
Event description:	[State] Dept. of Health was notified on **[date]**, by a representative from **[licensee]**, of the theft of a radiography camera from a locked equipment trailer on Thursday morning, April 6, 2001. The locked camera and the keys to the camera were stolen. The radiography camera is identified as XYZ Company, Model 160B, serial No. B-3333, containing **[isotope]** **[activity, when known]** 88.3 curies of Iridium-192. The device cables were not stolen. The State has an inspector on site and will continue to keep NRC informed of the status of our investigation.
Transport vehicle description:	N/A
Media attention:	[State] Dept. of Health has received inquiries from the media
Point of contact:	Bob Brown, 301-415-0001

Table 1. Sample FAX Sheet to NRC Operations Center

2.4 30 - 60 Day Event Notification

Agreement States should report events requiring greater than 24 hours notification by Agreement States licensees, as determined under applicable Agreement State regulations, to NRC on a monthly basis. (For reference, NRC reporting requirements for events are presented in Section 4.) Reports may be made either electronically or in written form. NRC staff encourages Agreement States to electronically report all events using the NMED database software and entry screens.

The following paragraphs provide additional information on reporting events and NMED. For guidance on data entry (coding), an electronic copy of the NMED users guide has been included under the *Help* support icon in the upgraded Microsoft Access 97/2000 version of the NMED software program. The upgrade NMED software program also contains downloadable sample NMED data entry screen (previously included in this Handbook).

a. ***Assign Event Report Identification No.***

This number should appear on all reports, including preliminary, initial notification reports, and any follow-up reports. The Event Report Notification No. should consist of the State or State agency ID, year, and a sequentially assigned ID number, e.g., **(NYDOL-99-001), (NYC-99-001), (TX-00-001), (GA-00-001), (NE-00-001), (CA-00-001)** for each agency in your State. NOTE: The Agreement State ID number field in NMED can accommodate up to four characters for the State or agency identifier. The "Agreement State ID No." should be specified by the State for all telephone, electronic or written notification involving each specific event.

b. ***Basic Event Information***

Section 3 provides a listing of the minimum event information that should be provided. When submitting an initial event report, please provide as much information as is known at the time the report is prepared regarding the items indicated in Section 3. Updated information should be subsequently provided in follow-up reports (see Section 2.5).

c. ***Electronic Reporting to NMED***

Provide an electronic NMED report via E-mail or PC diskette to the NMED contractor, based on the information provided by the Agreement State licensee in the 5, 15, 30 or 60 day report. If you need additional help, you may contact the INEEL NMED Project Manager, Dante Huntsman, electronically via Internet email at: dhun@inel.gov, or by telephone at 208-526-2741, or the NRC NMED Project Manager, Sam Pettijohn, via e-mail SLP@nrc.gov or telephone: 301-415-6822.

d. *Internet Access to NMED*

An Internet (query only) version of NMED with several drop-down point-and-click menus is available. The Internet version of the NMED program eliminates the need for INEEL to provide users with periodic diskette updates of the national NMED data. Users may download the latest NMED national database information via Internet file transfer. Internet access to the NMED is currently controlled either by a user -ID and password, or a user -ID and Internet Protocol (IP) Addresses. If passwords are required contact Dante Huntsman, INEEL by e-mail message at: dhun@inel.gov or by telephone at 208-526-2741. Future plans include upgrading the Internet version of NMED to provide open public access to material event information. *NOTE: Agreement States should continue to use the Microsoft Access data entry program for maintaining a local events database and for submitting NMED event reports to INEEL.*

e. *Written Event Reports*

Written event reports, including e-mail or fax, should be sent to the Director, STP. Written report information should be comparable to the minimum basic information identified in Section 3. Reports should be provided in an optical character recognition (OCR) scannable format. Please include an ***Event Report Cover Page*** for all written form event information provided to NRC. Use of the Event Report Cover Page helps ensure our Document Control staff can readily identify, classify and appropriately record the document. A sample cover page is provided on page 10 of this Handbook.

2.5 Reporting Follow-up Event Information

Follow-up material event reports--providing the results of investigations into what, where, when and how the event or conditions occurred--through resolution and close out, should be provided for all events, both significant (24 hr. reportable) and 30-60 day reportable events.

a. Follow-up reports through a closeout of the event should be provided electronically or in writing to NRC on a monthly basis. Enter any new or supplemental information to the initial NMED record. A complete event report should include all investigative and medical information through closeout. (See minimum basic event information in Section 3.)

b. The initial event report identification number (**State\Yr.\No.**) should be included whenever additional follow-up event information is provided. Indicate that it is a follow-up report.

c. Additionally, when providing follow-up NMED event information, provide clear reference to documents on file that the State used to generate the NMED event report, e.g., a licensee inspection report dated mm/dd/yr., if applicable and appropriate.

d. Any follow-up information that revises earlier information or provides additional information on a given event should be provided to ensure a complete historical NMED record.

3. Minimum Basic Event Information for a Complete Report

The following listing identifies the minimum basic information that should be provided for all events.

A. What happened, and when?	
1. Agreement State, Event Report ID No.	7. Sealed source, device, etc, (make, model #, serial #)
2. Licensee (Name, address), License No.	8. Leak test information, when applicable
3. Event date and time of occurrence	9. Equipment (make, model #, serial #), and clear description of any equipment problems.
4. Date notified of event by licensee or non-licensee	10. Persons involved, consequences
5. Radionuclide, activity	11. Transportation, identify shipper, package type and ID No.
6. Any exposures (indicate short and long-term effects.)	12. Abnormal occurrence (Y/N)
B. Why did it happen?	
13. Cause, and contributing factors	
C. What actions did the licensee take to prevent recurrence?	
14. Notifications: patient, physician	15. Licensee corrective actions
D. Events involving lost, stolen or abandoned material	
16. Provide status through resolution (update record when found)	
E. What actions did the State take?	
17. Notifications: local police, FBI, and other States; as needed	18. Enforcement actions
F. Describe any generic implications	
19. Identify any possible generic safety concerns	20. Potential for others to experience the same event

EVENT REPORT COVER PAGE

AGREEMENT STATE

EVENT REPORT ID NO.: MN - __ - ___
(State\Yr.\No.)

DATE:

TO: _____
Director
Office of State and Tribal Programs

SUBJECT:

STATE:

Signature and Title: _____

_____

_____

_____

Public Availability of Event Information: Any event information that is considered preliminary pre-decisional information by the State should be clearly identified on the cover page as follows: "Preliminary, Not for Public Disclosure." For event information in NRCs possession, the final determination on whether to withhold from public disclosure will be made by NRC on a case-by-case basis in accordance with the requirements of 10 CFR Part 9.

Table 2. Event Report Cover Page

Regulatory Reporting Requirements

NRC reporting requirements are contained in multiple Parts of Title 10 of the Code of Federal Regulations (10 CFR). The following provides a complete listing of the cur CFR material reporting requirements for which Agreement States should have compatible regulations.

10 CFR Part	Reporting Category		Reporting Requirement	Notification
	Significant	30-60 Day		
20, Standards for Protection Against Radiation	20.1906(d)(1)		reports of removable contamination on package >limits in 10 CFR 71.87.	Immediate
	20.1906(d)(2)		radiation levels on package > limits in 10 CFR 71.47	Immediate
	20.2201(a)(1)(i)		reports of theft or loss of licensed material > 1000 X App C value	Immediate
		20.2201(a)(1)(ii)	reports of theft or loss of licensed material > 10 X App. C value	30 days
	20.2202(a)(1)		exposure (real or threatened) ≥ TEDE of 25 rem (.25 Sv), or eye or lens dose equiv. of 75 rem (.75 Sv) or shallow dose equiv. (skin\extremities) of 250 rads (2.5 Gy).	Immediate
	20.2202(b)(1)		exposure (real or threatened) ≥ TEDE of 5 rem (.05 Sv), or eye or lens dose equiv. of 15 rem (.15 Sv), or shallow dose equiv. (skin\extremities) of 50 rads (.5 Gy).	24 hours
	20.2202(a)(2)		release where individual could have intake > 5 X ALI over 24 hours.	Immediate
	20.2202(b)(2)		release where individual could have intake > 1 X ALI over 24 hours	24 hours
		3(a), (b)	radiation exposures, releases or concentrations of radioactive material that exceed the limits.	30 days
21, Reporting of Defects & Noncompliance		)(1-2)	ıg of defect in basic component, structure or system.[2]	60 days
30, Rules of General Applicability to Domestic Licensing of Byproduct Material	30.50(a)		events involving prevention of immediate protective action, involving exposures or releases that could exceed regulatory limits	4 hours

[2] Not a compatibility requirement for Agreement States, but States voluntarily provide information on equipment failure and defects.

Regulatory Reporting Requirements

NRC reporting requirements are contained in multiple Parts of Title 10 of the Code of Federal Regulations (10 CFR). The following provides a complete listing of the cur CFR material reporting requirements for which Agreement States should have compatible regulations.

10 CFR Part	Reporting Category		Reporting Requirement	Notification
	Significant	30-60 Day		
	30.50(b)(1)		event involving unplanned contamination restricting access >24 hours (no isotopes with half-lives <24 hrs)	24 hours
	30.50(b)(2)		event involving equipment failure or disability to function as designed when equipment is required to be available and operable and no redundant equipment is available and operable	24 hours
	30.50(b)(3)		event involving unplanned medical treatment of contaminated person	24 hours
	30.50(b)(4)		nvolving fire, explosion affecting integrity of material, device or container, and material exceeds 5Xs ALI	24 hours
31, General Domestic Licenses for Byproduct Material		31.5(c)(5)	failure or damage to shielding, on-off mechanism or indicator, or ≥ 0.005 microcuries (185 Bq) removable radioactive material for generally licensed device	30 days
34, Licenses for Radiography & Radiation Safety Requirements for Radiographic Operations	34.27(d)		ng of leaking sources, leak test results ≥ 0.005 microcurie (185 Bq)	5 days
		34.101(a)	radiography source disconnect, inability to retract source, or component failure (critical to safe operation of device)	30 days
35, Medical Use of Byproduct Material	35.33(a)		notifications and reports of misadministrations[3]	Next day (24 hours)
	35.59(e)(2)		leak testing sealed sources and brachytherapy sources	5 days
36, Licenses & Radiation Safety Requirements for	36.83		irradiator events, release of material, defective components, systems or structures; (if not reported under other 10 CFR reporting requirements)	24 hours

[3] Misadministration events require 15 day licensee event report and 24 hour notification to referring physician and patient.

Regulatory Reporting Requirements

NRC reporting requirements are contained in multiple Parts of Title 10 of the Code of Federal Regulations (10 CFR). The following provides a complete listing of the cur CFR material reporting requirements for which Agreement States should have compatible regulations.

10 CFR Part	Reporting Category		Reporting Requirement	Notification
	Significant	30-60 Day		
Irradiators				
39, Licenses & Radiation Safety Requirements for Well-Logging	39.35		leaking sealed sources found during periodic leak testing requirement	5 days
	39.77 (a)		well logging source rupture	Immediate
		39.77(b)	theft or loss, exposures, excessive concentration of rad material	30 days
		39.77(c) and (d)	when apparent recovery impossible, irretrievable source, abandonment	60 days
40, Domestic Licensing of Source Material	40.26(c)(2)		tailings or waste retention system failure that results in a release of material into unrestricted areas, or unusual conditions	Immediate
	40.60(a) (b)(1)-(b)(4) (c)(1)-(c)(2)		requirements for domestic licensing of source material to receive, possess, use, transfer, or deliver source and byproduct material (NOTE: Same as 30.50 above)	
70, Domestic Licensing of Special Nuclear Material	70.50(a)	70.50 (b) (c)	events involving special nuclear material (SNM)	(a) 24 hours (b) 30 days (c) 60 days

Table 3. EXAMPLES OF REPORTABLE EVENTS

This Table provides examples of reportable material events or occurrences that are required to be reported by both NRC and Agreement State material licensees. The Table addresses specific reporting requirements for either immediate notification (within 24 hours or less) or 30 day written reports.

Immediately reportable under 10 CFR 20.2201	**Stolen Portable Moisture Density Gauge** Licensee reported that a [Manufacturer] [Model #] [serial #] portable gauge containing 10 millicuries of Cesium-137 and 50 millicuries of Americium-241:Beryllium was stolen from the licensee's vehicle parked at the licensee's facility. The gauge was padlocked in its original carrying case. The State is following the incident and working with local authorities to develop a press release. Local law enforcement and the FBI have been notified. Follow-up information will be provided to NRC on the recovery of the stolen gauge and entered into NMED.
Reportable within 24 hours under 10 CFR 30.50(b) (2) and 20.2201	**Possible Loss of Control and Damage to Portable Gauge** Licensee reported that a [Manufacturer] [Model #] [serial #] moisture density gauge had been damaged on March 28, 2001. The gauge contained 7.9 millicuries of Cesium-137 and 40 millicuries of Americium-241. A technician left the gauge unattended for a brief time and upon returning found that a construction vehicle had run over the gauge. The source rod was broken but the source was undamaged and remained in the shielded position. Wipe tests and instrument survey verified no leakage. The gauge was returned to the manufacturer for repair. The licensee was cited for not keeping licensed material under constant surveillance in an unrestricted area. Report has been entered in NMED.
Reportable within 30 days under 20.1906	**Shipment of Brachytherapy Sources Received with Radiation Levels Exceeding Regulatory Limits** A medical licensee reported receiving a shipment of two packages containing cesium-137 brachytherapy sources. Radiation surveys of the packages with an ion chamber detector found radiation levels of 250 millirem per hour on one package, which exceeds the State and Federal limit at the external surface of a package of 200 millirem per hour. The third and final package was received two days later with radiation levels of 400 millirem per hour at the surface of the package. The shipper has retained a consultant to determine the cause of the elevated radiation levels. The State will keep NRC informed of the results of the consultant's review of the event, and the information will be entered into NMED.
Reportable within 24 hours under 10 CFR 20.1301, 20.2203	**Exposure to Non-radiation Worker at a Licensed Facility** A licensee reported to the State that a non-radiation worker had received an exposure as a result of picking up a 5 curie Americium-241:Beryllium neutron source used for well logging and placing it in his pocket. The worker, a temporary contractor employee, was cleaning a well logging tool at the licensee facility. (The licensee was under the assumption that all of the source material had been removed from the equipment.) While cleaning the tool, the source fell out, and the worker picked it up and placed it his pocket. The worker was not a radiation worker and had no knowledge of what the object was. Preliminary calculations performed by [identify Consultant/Contractor] indicate that the individual may have received a dose of 4-6 Rem. The licensee's RSO is investigating the incident. The State plans to keep NRC informed of the ongoing results of the investigation, and the information will be entered into NMED.

Reportable within 24 hours under 10 CFR Part 35 and 30.50(b)(2)	**Possible Misadministration involving a Teletherapy Unit Malfunction** A patient undergoing a Cobalt-60 Teletherapy treatment with a [Manufacturer][Model Number] received an unintended exposure. The RSO estimated that the patient received an exposure of 138 centiGray (Rads) to a depth of 0.5 centimeters to the wrong treatment site, based on a possible total treatment time of 1.5 minutes. The exposure occurred as a result of two power disruptions during a thunderstorm. The loss of electrical power caused the unit table to move which resulted in treatment to the wrong site. The patient received 0.35 minutes of the intended fractionated treatment time of 1.5 minutes. The patient was prescribed a total dose of 5040cGy to be given in 28 fractions of 180 cGy per day at the rate of 5 fractions per week. The prescribing physician elected not to make up the missed dose. The prescribing physician indicated that the patient is not expected to have any adverse effects from the misadministration. The patient and referring physician were notified of the event. The licensee was able to recreate the event to demonstrate how the event occurred. The licensee has contacted the manufacturer. The State will keep NRC informed of the results of the review for any generic implications.
Reportable within 24 hours under 10 CFR 36.83(a)(9)	**Possible Loss of Water or Leakage from Source Water Pool at Irradiator Facility** Licensee notified the State that the controls at a Co-60 irradiator facility were indicating that the water level was low, circulating pump off, and fill valves were open. The pool water level gauge indicated a pool water level of 93 inches, well below the normal level of 137 inches. Previous incidents indicated that a loss of compressed air pressure to the water level gauge could result in an erroneously low water level gauge reading, causing the automatic pool fill valves to open, and the pool water circulating pump to turn off. The compressed air system pressure was found to be in the normal range, but the operator found water and congealed oil in the air line supplying the pool water level gauge, and the air line supplying the elevator control valve. Further investigation found that the compressed air line water traps were full of water. A past similar incident resulted in a failure to raise the elevator. The operator then verified that the pool water level was in fact normal. The licensee requested the building maintenance personnel to diagnose and repair the compressed air supply immediately, to prevent the conductivity in the pool water from reaching abnormal levels as a result of the resin filter circulating pump being automatically turned off by the false low pool water level meter reading. Maintenance personnel responded and replaced a failed compressed air dryer, and monitored the open air lines to clear the lines of water. A float activated automatic water drain was installed in the air line to prevent a possible recurrence by allowing any water to automatically drain from the air line.

5. NRC Publication and Distribution of Event Notifications

5.1 Event Notifications (ENs) are Available on Internet

All events reported to the NRC Operations Center are currently entered into the NRC Event Notification (EN) database. ENs are publicly available through Internet on NRC's external home page at (http://www.nrc.gov/opa) under *Event Reports*, within one workday of notification. As a result of public access to this information, Agreement and non-Agreement States may receive contacts from the public or media regarding events and requesting additional information.

5.2 Preliminary Notifications (PNs) are Used to Distribute Event Information

Preliminary Notifications (PNs) are brief summary reports of significant events issued by the NRC staff to notify the Commission of the occurrence of a significant event. PNs are based on information provided by State radiation control program staff. PNs are usually issued within approximately two hours of notification of the occurrence of a significant event. The PN will be publicly available through Internet on NRC's external home page under PN Reports at (http//www.nrc.gov/opa). Updates to PNs occur when significant additional information about an event is provided to NRC. When preparing PNs, NRC staff may contact the State for additional information on the event.

6. NRC Safety Reviews of Material Event Reports

6.1 NRC Review of Material Events for Safety Significance and Generic Issues

A. A *Generic Assessment Panel (GAP)* has been established within NRC to review all material event information. A weekly review of all new NRC or Agreement State licensee event information that has been entered into NMED is conducted by NRC staff. The objective of the review is to identify any events that may be safety significant or may involve GSIs, i.e., equipment malfunction or failure, significant exposures, etc. GSIs are defined as a safety concern that may affect the design, construction, operation, or decommissioning of all, several, or a class of regulated operations, and may have the potential to require licensees or certificate holders to make safety improvements and/or require new or revised requirements or guidance.

B. ***Requests for additional information***: Based on the results of the GAP review, Agreement State staff may be contacted by the Regional State Agreements Officer (RSAO) by voice or email to discuss the event. Additional information may be requested to help determine the safety significance and any possible generic implications (e.g., equipment malfunction or failure, significant exposures). Specific issues identified as a result of the review are tracked through close-out of the event. To provide the States reasonable time for review and investigation of reported events, any requests for additional information to States will be conducted within the following schedule.

1. Schedule for requesting additional information:

   If necessary, NRC staff may contact Agreement States for additional information on ***significant events*** that pose or could pose public health and safety risks. Such requests would occur on an as needed basis, possibly within hours to a few days of notification of the occurrence of the event, based on the safety significance.

   For events that have not been identified as safety significant, when necessary, the RSAO, or a designee, may contact Agreement States for additional information within 30 days for a (15 day event notification)) and within 60 days for a (30 day event notification) after NRC's receipt of the initial notification from the State. A request for follow-up information may also be sent routinely via email by the NMED contractor, (e.g., when the NMED record is incomplete after 60 days from receipt of the initial record).

6.2 Quarterly Operational Events Briefing Review of "Significant" Events

A. Events identified as having a "significant" potential risk to public health and safety may receive additional NRC management review at the quarterly NRC Operational Events Briefing. The quarterly briefing, attended by managers and staff from the offices of NMSS, STP, Incident Response Operations (IRO), Nuclear Regulatory Research (RES), and the Regions is convened to review and assess health and safety-related issues, e.g., cause, effects, generic implications, mitigating actions, etc. NRC headquarters and region staff continue to follow-up and review material events discussed at the *operational events briefing* through closure of the event, which includes checking to see that the final report information has been entered into NMED. Based on potential safety risks identified as a result of event review and analyses, NRC may take actions to reduce potential health and safety risks to the public by issuing safety-related notifications to licensees, concerning software problems, equipment modifications, etc. Further research and analysis may result in regulatory or programmatic changes.

B. Agreement State staff may be requested to participate in the briefings by telephone to discuss specific events, the status, results of licensee or State investigation activities and licensee corrective actions, and the potential generic significance of the event. Agreement State participation helps in the exchange of event information and in follow-up actions if generic implications are identified.

7. Abnormal Occurrence Guidelines and Criteria

7.1 Introduction

This section presents the guidelines and criteria to be followed when assessing the significance of an event or occurrence to see if it meets the criteria established to identify an abnormal occurrence (AO). Section 208 of the Energy Reorganization Act of 1974 (ERA) (Public Law 93-438, 42 USC 5848) identifies an abnormal occurrence as an unscheduled incident or event that the Commission determines to be significant from the standpoint of public health or safety. Section 208 of the Act also requires that the Commission inform Congress of any abnormal occurrences. The Agreement States support the NRC in their effort to keep Congress apprised of any significant events that may directly affect public health or safety by providing information on proposed AOs that have occurred in their State.

7.2 AO Policy Information

The Commission submits a report to Congress identifying any AOs. The Federal Reports Elimination and Sunset Act of 1995 requires that AOs be reported to Congress on an annual basis (see "Report to Congress on Abnormal Occurrences, Fiscal Year 1996," NUREG-0090, Vol. 19). Section 208 of the ERA indicates that each report shall contain:

(1) The date and place of each occurrence;

(2) The nature and probable consequence of each occurrence;

(3) The cause or causes of each; and

(4) Any action taken to prevent recurrence.

As specified in Section 208, within 15 days of receiving information of each AO, the Commission shall provide as wide dissemination to the public as reasonably possible as soon as such information becomes available.

A final AO policy statement containing criteria for determining an AO was published in the *Federal Register* on December 19, 1996, (61 FR 67072). Revised AO criteria were published in the *Federal Register* on April 17, 1997 (62 FR 18820) to incorporate minor changes and to revise criterion III covering Fuel Cycle Licensees.

An incident or event will be considered an AO if it involves a major reduction in the degree of protection of the public health or safety. This type of incident or event would have a moderate or severe impact on the public health or safety and could include, but need not be limited to the following:

(1) Moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the Commission;

(2) Major degradation of essential safety-related equipment; or

(3) Major deficiencies in design, construction, use of, or management controls for facilities or radioactive material licensed by or otherwise regulated by the Commission.

7.3 *AO Criteria*

Agreement State staff should routinely screen events against the AO criteria as part of their routine program. Any events identified as potential AOs should be reported to NRC. Additionally, Agreement States are requested to prepare a special written report for potential AOs. Agreement State staff should follow the guidelines for preparing AO write-ups contained in Section 7.4 of this Handbook. When questions arise on a given event, it may sometimes be necessary for NRC to directly contact an Agreement State representative and request additional information.

The criteria for determining an AO and the guidelines for "Other Events of Interest" were stated in an NRC Policy Statement. The following AO criteria was published in the *Federal Register* on December 19, 1996, (61 FR 76072). The policy statement was revised to include criteria for gaseous diffusion plants and published in the *Federal Register* on April 17, 1997, (62 FR 18820).

The guidelines were revised for Appendix C "Other Events of Interest" by the Commission in a Staff Requirements Memorandum, SECY-98-175, dated September 4, 1998.

AO Criteria

As published in the Federal Register on December 19, 1996 (61 FR 67072) and as revised and published on April 17, 1997 (62 FR 18820) to incorporate gaseous diffusion plants.

Criteria by types of events used to determine which incidents or events will be considered for reporting as AOs are as follows:

I. For All Licensees.

A. Human Exposure to Radiation from Licensed Material.

1. Any unintended radiation exposure[4] to an adult (any individual 18 years of age or older) resulting in an annual total effective dose equivalent (TEDE) of 250 millisievert (mSv) (25 rem) or more; or an annual sum of the deep dose equivalent (external dose) and committed dose equivalent (intake of radioactive material) to any individual organ or tissue other than the lens of the eye, bone marrow and the gonads, of 2500 mSv (250 rem) or more; or an annual dose equivalent to the lens of the eye, of 1 Sv (100 rem) or more; or an annual sum of the deep dose equivalent and committed dose equivalent to the bone marrow, and the gonads, of 1 Sv (100 rem) or more; or an annual shallow-dose equivalent to the skin or extremities of 2500 mSv (250 rem) or more.

2. Any unintended radiation exposure to any minor (an individual less than 18 years of age) resulting in an annual TEDE of 50 mSv (5 rem) or more, or to an embryo/fetus resulting in a dose equivalent of 50 mSv (5 rem) or more.

3. Any radiation exposure that has resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician.

B. Discharge or Dispersal of Radioactive Material from its Intended Place of Confinement.

1. The release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceed 5000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20, unless the licensee

[4] An "unintended radiation exposure" includes any occupational exposure, exposure to the general public, or exposure as a result of a medical misadministration (as defined in §35.2) involving the wrong individual that exceeds the reporting values established in the regulations.

All other reported medical misadministrations will be considered for reporting as an AO under the criteria for medical licensees. In addition, unintended radiation exposures include any exposure to a nursing child, fetus, or embryo as a result of an exposure (other than an occupational exposure to an undeclared pregnant woman) to a nursing mother or pregnant woman above specified values.

has demonstrated compliance with §20.1301 using §20.1302(b)(1) or 20.1302(b)(2)(ii).

2 Radiation levels in excess of the design values for a package, or the loss of confinement of radioactive material resulting in one or more of the following: (a) a radiation dose rate of 10 mSv (1 rem) per hour or more at 1 meter (3.28 feet) from the accessible external surface of a package containing radioactive material; (b) a radiation dose rate of 50 mSv (5 rem) per hour or more on the accessible external surface of a package containing radioactive material and that meet the requirements for "exclusive use" as defined in 10 CFR 71.47; or (c) release of radioactive material from a package in amounts greater than the regulatory limits in 10 CFR 71.51(a)(2).

C. Theft, Diversion, or Loss of Licensed Material, or Sabotage or Security Breach.[5]

1. Any lost, stolen, or abandoned sources that exceed 0.01 times the A_1 values, as listed in 10 CFR Part 71, Appendix A, Table A-1, for special form (sealed/non-dispersible) sources, or the smaller of the A_2 or 0.01 times the A_1 values, as listed in Table A-1, for normal form (unsealed/dispersible) sources or for sources for which the form is not known. Excluded from reporting under this criterion are those events involving sources that are lost, stolen, or abandoned under the following conditions: sources abandoned in accordance with the requirements of 10 CFR 39.77(c); sealed sources contained in labeled, rugged source housings; recovered sources with sufficient indication that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 did not occur during the time the source was missing; and unrecoverable sources lost under such conditions that doses in excess of the reporting thresholds specified in AO criteria I.A.1 and I.A.2 were not known to have occurred.

2. A substantiated case of actual or attempted theft or diversion of licensed material or sabotage of a facility.

3. Any substantiated loss of special nuclear material or any substantiated inventory discrepancy that is judged to be significant relative to normally expected performance, and that is judged to be caused by theft or diversion or by substantial breakdown of the accountability system.

4. Any substantial breakdown of physical security or material control (i.e., access control containment or accountability systems) that significantly weakened the protection against theft, diversion, or sabotage.

[5] Information pertaining to certain incidents may be either classified or under consideration for classification because of national security implications. Classified information will be withheld when formally reporting these incidents in accordance with Section 208 of the Energy Reorganization Act of 1974, as amended. Any classified details regarding these incidents would be available to the Congress, upon request, under appropriate security arrangements.

D. Other Events (i.e., those concerning design, analysis, construction, testing, operation, use, or disposal of licensed facilities or regulated materials).

1. An accidental criticality [10 CFR 70.52(a)].

2. A major deficiency in design, construction, control, or operation having significant safety implications requiring immediate remedial action.

3. A serious deficiency in management or procedural controls in major areas.

4. Series of events (where individual events are not of major importance), recurring incidents, and incidents with implications for similar facilities (generic incidents) that create a major safety concern.

II. For Commercial Nuclear Power Plant Licensees.

A. Malfunction of Facility, Structures, or Equipment.

1. Exceeding a safety limit of license technical specification (TS) ['50.36(c)].

2. Serious degradation of fuel integrity, primary coolant pressure boundary, or primary containment boundary.

3. Loss of plant capability to perform essential safety functions so that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, General Design Criterion (GDC) 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

B. Design or Safety Analysis Deficiency, Personnel Error, or Procedural or Administrative Inadequacy.

1. Discovery of a major condition not specifically considered in the safety analysis report (SAR) or TS that requires immediate remedial action.

2. Personnel error or procedural deficiencies that result in loss of plant capability to perform essential safety functions so that a release of radioactive materials, which could result in exceeding the dose limits of 10 CFR Part 100 or 5 times the dose limits of 10 CFR Part 50, Appendix A, GDC 19, could occur from a postulated transient or accident (e.g., loss of emergency core cooling system, loss of control rod system).

III. For Fuel Cycle Facilities.

1. A shutdown of the plant or portion of the plant resulting from a significant event and/or violation of a law, regulation, or a license/certificate condition.

2. A major condition or significant event not considered in the license/certificate that requires immediate remedial action.

3. A major condition or significant event that seriously compromises the ability of a safety system to perform its designated function that requires immediate remedial action to prevent a criticality, radiological or chemical process hazard.

IV. For Medical Licensees.

A medical misadministration that:

(a) Results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rad) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 Gy (1000 rad) to any other organ; and

(b) Represents either (1) a dose or dosage that is at least 50 percent greater than that prescribed in a written directive or (2) a prescribed dose or dosage that (i) is the wrong radiopharmaceutical,[6] or (ii) is delivered by the wrong route of administration, or (iii) is delivered to the wrong treatment site, or (iv) is delivered by the wrong treatment mode, or (v) is from a leaking source(s).

V. Guidelines for "Other Events of Interest"

The Commission may determine that events other than AOs may be of interest to Congress and the public and should be included in an Appendix to the AO report as Other Events of Interest. Guidelines for events to be included in the AO report for this purpose may include, but not necessarily be limited to, events that do not meet the AO criteria but that have been perceived by Congress or the public to be of high health and safety significance, have received significant media coverage, or have caused the NRC to increase its attention to or oversight of a program area, or a group of similar events that have resulted in licensed materials entering the public domain in an uncontrolled manner.[7]

[6] The wrong radiopharmaceutical as used in the AO criterion for medical misadministrations refers to any radiopharmaceutical other than the one listed in the written directive or in the clinical procedures manual.

[7] Staff Requirements Memorandum, SECY-98-175, dated September 4, 1998.

Glossary

DPC The Document Processing Center (DPC) is an internal NRC automated document search and retrieval system, indexed by a unique identification (Accession) No. for use by the staff of the NRC.

EN The Event Notification (EN) system is an internal NRC automated event tracking system used by the NRC Operations Center to track information on incoming notifications of the occurrence of significant material events that have or may affect public health and safety. Significant material events are reported to the NRC Operations Center by NRC licensees, staff of the Agreement States, other Federal agencies, and the public. The EN's are published each workday through the Internet.

Gray Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule/kilogram (100 rads).

Metric System The metric system is now included in all Federal documents. All event reports should include the dual system of Units (SI) in the following order. First, use the International System of Units (SI) with the English System unit equivalent following in parentheses. Spell out the first time it appears; continue with an abbreviation, (see examples below). 1000 centiGray (cGy) (1000 rad) the first time, and continue with 1000 cGy (1000 rad). 50 millisieverts (mSv) (5 rem) 730 megabecquerel (MBQ) (20.4 mCi)

NMED The Nuclear Materials Events Database (NMED), maintained by NRC, is a historical collection of incidents and events that have occurred throughout the United States involving the use of radioactive material covered under the Atomic Energy Act. This excludes events occurring at nuclear power plants.

NRC Ops Center The NRC Operations Center in Rockville, Maryland, serves as the focal coordination point for communicating with NRC licensees, State agencies, and other Federal agencies about operating events in both the nuclear reactor and nuclear material industry. The Operations Center is staffed 24 hours a day by an NRC Headquarters Operations Officer (HOO), who is trained to receive, evaluate, and respond to events reported to the Operations Center.

PN Preliminary Notifications (PN) are brief summary reports of significant events issued by the NRC staff to notify the Commission of the occurrence of a significant event that appears to have health and safety significance or major public or media interest. PNs are based on information provided by State radiation control program staff. These reports are publicly available through Internet on NRC's external home page under PN Reports at (http//www.nrc.gov/opa).

RSAO The Regional State Agreements Officer (RSAO) is a designated staff member, in an NRC regional office, who serves as the point of contact for the region and the Office of State and Tribal Programs regarding Agreement State radiation control programs, and who participates in technical reviews of Agreement State radiation control programs.

Rad Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/grams or 0.01 joule/kilogram (0.01 gray)

Rem Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem. is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert).

Sievert Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rem.).

Radiation Measurements				
	Radioactivity	Absorbed Dose	Dose Equivalent	Exposure
Common Units	Curie (Ci)	Rad	rem	Roentgen (R)
SI Units	Becquerel (Bq)	Gray (Gy)	Sievert (Sv)	Coulomb/kilogram

Conversion Equivalence		
1 Curie = 3.7×10^{10} disintegrations per sec.		1 becquerel = 1 disintegration per sec.
1 millicurie (mCi)	equals	37 Megabecquerels (MBq)
1 rad	equals	0.01 gray
1 rem	equals	0.01 Seivert (Sv)
1 roentgen (R)	equals	0.000258 coulomb/kilogram
1 megabecquerel (MBq)	equals	0.027 millicuries (mCi)
1 gray (Gy)	equals	100 rad
1 sievert (Sv)	equals	100 rem
1 coulomb/kilogram (C/kg)	equals	3876 roentgens (R)

Conversion Factors		
To Convert From	**To**	**Multiply By**
Curies (Ci)	becquerels (Bq)	3.7×10^{10}
millicuries (mCi)	megabecquerels (MBq)	37
microcuries (µCi)	megabecquerels (MBq)	0.037
millirads (mrads)	milligrays (mGy)	0.01
millirems (mrems)	microsieverts (µSv)	10
milliroentgens (mR)	microcoulombs/kilogram (µC/kg)	0.258
becquerels (Bq)	Curies (Ci)	2.7×10^{-11}
megabecquerels (MBq)	millicuries (mCi)	0.027
megabecquerels (MBq)	microcuries (µCi)	27
milligrays (mGy)	millirads (mrads)	100
microsieverts (µSv)	millirems (mrems)	0.01
microcoulombs/kilogram (µC/kg)	milliroentgens (mR)	3.88

E

MINNESOTA DEPARTMENT OF HEALTH

INSTRUCTION CONCERNING PRENATAL RADIATION EXPOSURE

Radiation Control Unit

Asbestos, Lead, Indoor Air & Radiation Section

Division of Environmental Health

Minnesota Department of Health

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INSTRUCTION CONCERNING PRENATAL RADIATION EXPOSURE

A. INTRODUCTION

The Minnesota Department of Health (MDH) requires instruction for all individuals who, in the course of their employment, are likely to receive an occupational exposure in excess of 100 millirem (1 mSv) in a year. The instructions should include the health protection problems associated with exposure to radiation and/or radioactive material; precautions or procedures to minimize exposure; and the purposes and functions of protective devices employed. The instructions must be commensurate with potential radiological health protection problems present in the work place.

The MDH rules on radiation protection are specified in Chapter 4731.2000, "Standards for Protection Against Radiation". Licensees are required to "ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 500 millirem (5 mSv)". MDH rules also require licensees to "make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman." A declared pregnant woman is defined as a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

This regulatory guide is intended to provide information to pregnant women and other personnel to help them make decisions regarding radiation exposure during pregnancy. This Regulatory Guide supplements "Instruction Concerning Risks from Occupational Radiation Exposure", which contains a broad discussion of the risks from exposure to ionizing radiation.

Other sections of MDH rules also specify requirements for monitoring external and internal occupational dose to a declared pregnant woman. Licensees are required to monitor the occupational dose to a declared pregnant woman using an individual monitoring device if it is likely that the declared pregnant woman will receive, from external sources, a deep dose equivalent in excess of 100 millirem (1 mSv). The licensee must maintain records of dose to an embryo/fetus if monitoring was required, and the records of dose to the embryo/ fetus must be kept with the records of dose to the declared pregnant woman. The declaration of pregnancy must be kept on file, but may be maintained separately from the dose records. The licensee must retain the required form or record until MDH terminates each pertinent license requiring the record.

B. DISCUSSION

Exposure to any level of radiation is assumed to carry with it a certain amount of risk. In the absence of scientific certainty regarding the relationship between low dose exposure and health effects, the scientific community generally assumes that any exposure to ionizing radiation may cause undesirable biological effects. In addition, the assumption is that the likelihood of these effects increases as the dose increases. For radiation protection purposes, these assumptions represent a conservative approach. At the occupational dose limit for the whole body of 5 rem (50 mSv) per year, the risk is believed to be very low.

The magnitude of risk of childhood cancer following in utero exposure is uncertain: both negative and positive studies have been reported. The data from these studies "are consistent with a lifetime cancer risk resulting from exposure during gestation which is two to three times that for the adult" (NCRP Report No. 116, Ref. 2). The available scientific literature indicates that the 500 millirem (5 mSv) limit provides an adequate margin of protection for the embryo/fetus. This dose limit reflects the desire to limit the total lifetime risk of leukemia and other cancers associated with radiation exposure during pregnancy.

In order for a pregnant worker to take advantage of the lower exposure limit and dose monitoring provisions, the woman must declare her pregnancy in writing to the licensee. A form letter for declaring

pregnancy is provided in this guide. The licensee may use its own form letter for declaring pregnancy. A separate written declaration should be submitted for each pregnancy.

C. REGULATORY POSITON

1. Who Should Receive Instruction

Female workers who require training under 4731.1000 should be provided with the information contained in this guide. In addition to the information contained in "Instruction Concerning Risks from Occupational Radiation Exposure," this information may be included as part of the training provided to employees.

2. Providing Instruction

The occupational worker may be given a copy of this guide with its Appendix, an explanation of the contents of the guide, and an opportunity to ask questions and request additional information. The information in this guide and its Appendix should also be provided to any worker or supervisor who may be affected by a declaration of pregnancy or who may have to act in response to such a declaration.

Classroom instruction may supplement the written information. If the licensee provides classroom instruction, the instructor should have some knowledge of the biological effects of radiation to be able to answer questions that may go beyond the information provided in this guide. Videotaped presentations may be used for classroom instruction. Regardless of whether the licensee provides classroom training, the licensee should give workers the opportunity to ask questions about the information. The licensee may take credit for instruction that the worker has received within the past year at other licensed facilities or in other courses or training.

3. Licensee's Policy on Declared Pregnant Women

The instruction provided should describe the licensee's specific policy on declared pregnant women, including how those policies may affect a woman's work situation. In particular, the instruction should include a description of the licensee's policies, if any, which may affect the declared pregnant woman's work situation after she has filed a written declaration of pregnancy.

The instruction should also identify the person to contact for additional information and identify who should receive the written declaration of pregnancy. Name (e.g., John Smith), position (e.g., immediate supervisor, the radiation safety officer) or department (e.g., the personnel department) may identify the recipient of the woman's declaration.

4. Duration of Lower Dose Limits for the Embryo/ Fetus

The lower dose limit for the embryo/fetus should remain in effect until the woman withdraws the declaration in writing or the woman is no longer pregnant. If a declaration of pregnancy were withdrawn, the dose limit for the embryo/fetus would apply only to the time from the estimated date of conception until the time that the declaration is withdrawn. If the declaration is not withdrawn, the written declaration may be considered expired one year after submission.

5. Substantial Variations Above a Uniform Monthly Dose Rate

The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman to satisfy the 500 millirem (5 mSv) limit to the embryo/fetus. The National Council on Radiation Protection and Measurements (NCRP) recommends a **monthly** dose limit of 50 millirem (0.5 mSv) to the embryo/ fetus once the pregnancy is known (Ref. 2). In view of the NCRP recommendation, any monthly dose of less than 100 millirem (1 mSv) may be considered as not a substantial variation above a uniform monthly dose rate and as such will not require licensee justification. However, the licensee should justify a monthly dose greater than 100 millirem (1 mSv).

D. IMPLEMENTATION

The purpose of this section is to provide information to licensees and applicants regarding MDH's plans for using this regulatory guide.

Unless a licensee or an applicant proposes an acceptable alternative for complying with the specified regulations, MDH will use the methods described in this guide to evaluate instructions to workers on the radiation exposure of pregnant women.

REFERENCES

1. MDH Regulatory Guide, "Instruction Concerning Risks from Occupational Radiation Exposure."

2. National Council on Radiation Protection and Measurements (1993). *Limitation of Exposure to Ionizing Radiation.* NCRP Report No. 116, Bethesda, MD.

APPENDIX
QUESTIONS AND ANSWERS CONCERNING PRENATAL RADIATION EXPOSURE

1. Why am I receiving this information?

Chapter 4731.1000, "Instructions to Workers," requires that licensees instruct individuals in radiation protection as appropriate for the situation if in the course of employment they are likely to receive in a year an occupational dose in excess of 100 millirem (1 mSv). The instruction below describes information that occupational workers and their supervisors should know about the radiation exposure of the embryo/fetus of pregnant women.

The regulations allow a pregnant woman to decide whether or not she wants formally to declare her pregnancy to take advantage of lower dose limits for the embryo/fetus. This instruction provides information to help women make an informed decision whether to declare a pregnancy.

2. If I become pregnant, am I required to declare my pregnancy?

No. The choice of whether or not to declare your pregnancy is voluntary. If you choose to declare your pregnancy, you must do so in writing. A lower radiation dose limit will then apply to your embryo/fetus. If you choose not to declare your pregnancy, you and your embryo/fetus will continue to be subject to the same radiation dose limits that apply to other occupational workers.

3. If I declare my pregnancy in writing, what happens?

If you choose to declare your pregnancy in writing, the licensee must take measures to limit the dose to your embryo/fetus to 500 millirem (5 millisievert) during the entire pregnancy. This is one-tenth of the dose that an occupational worker may receive in a year. If you have already received a dose exceeding 500 millirem (5 mSv) in the period between conception and the declaration of your pregnancy, an additional dose of 50 millirem (0.5 mSv) is allowed during the remainder of the pregnancy. In addition, licensees are required to make efforts to avoid substantial variation above a uniform monthly dose rate. All the 500 millirem (5 mSv) allowed dose should not occur in a short period during the pregnancy.

This may mean that, if you declare your pregnancy, the licensee may not permit you to do some of your normal job functions if those functions would have allowed you to receive more than 500 millirem. You also may not be able to have some emergency response responsibilities.

4. Why do the regulations have a lower dose limit for the embryo/fetus of a declared pregnant woman than for a pregnant worker who has not declared?

A lower dose limit for the embryo/fetus of a declared pregnant woman is based on a consideration of greater sensitivity to radiation of the embryo/fetus and the involuntary nature of the exposure. Several scientific advisory groups have recommended that the dose to the embryo/fetus be limited to a fraction of the occupational dose limit. The lower dose limit is not required to be implemented unless the worker declares her pregnancy.

5. What are the potentially harmful effects of radiation exposure to my embryo/fetus?

The occurrence and severity of health effects caused by ionizing radiation are dependent upon the type and total dose of radiation received, as well as the time over which the exposure was received. See Regulatory Guide "Instruction Concerning Risks from Occupational Exposure" for more information. The main concern is embryo/fetal susceptibility to the harmful long-term effects of radiation, such as cancer.

6. Are there any risks of genetic defects?

Although radiation injury has been induced experimentally in rodents and insects, and in the experiments was transmitted and became manifest as hereditary disorders in their offspring, radiation has not been identified as a cause of such effect in humans. Therefore, the risk of genetic effects attributable to radiation exposure is speculative. For example, no genetic effects have been documented in any of the Japanese atomic bomb survivors, their children, or their grandchildren.

7. What if I decide that I do not want any radiation exposure at all during my pregnancy?

You may ask your employer for a job that does not involve any exposure at all to occupational radiation dose, but your employer is not obligated to provide you with a job involving no radiation exposure. Even if you receive no occupational exposure at all, your embryo/fetus will receive some radiation dose (on average 75 millirem (0.75 mSv)) during your pregnancy from natural background radiation.

MDH, other Agreement States, and the NRC have reviewed the available scientific literature and concluded that the 500 millirem (5 mSv) limit provides an adequate margin of protection for the embryo/fetus. This dose limit reflects the desire to limit the total lifetime risk of leukemia and other cancers. If this dose limit is exceeded, the total lifetime risk of cancer to the embryo/fetus may increase incrementally. However, you must decide what level of risk to accept. More detailed information on potential risk to the embryo/fetus from radiation exposure can be found in the References.

8. What effect will formally declaring my pregnancy have on my job status?

Only the licensee can tell you what effect a written declaration of pregnancy will have on your job status. As part of your radiation safety training, the licensee should tell you the company's policies with respect to the job status of declared pregnant woman. In addition, before you declare your pregnancy, you may want to talk to your supervisor or your radiation safety officer. You may want to ask how a declaration of pregnancy would effect you and your job status.

In many cases you can continue in your present job with no change and still meet the dose limit for the embryo/fetus. For example, most workers at commercial power reactors (approximately 93%) receive occupational radiation doses that are less than 500 millirem (5 mSv) in 12 months (Ref. 11). The licensee may also consider the likelihood of increased radiation exposures from accidents and abnormal events before making a decision to allow you to continue in your present job.

If your current work might cause the dose to your embryo/fetus to exceed 500 millirem (5 mSv), the licensee has various options. It is possible that the licensee can and will make a reasonable

accommodation that will allow you to continue performing your current job. For example, your employer may have another qualified employee do a small part of the job that accounts for some of your radiation exposure.

9. What information must I provide in my written declaration of pregnancy?

You should provide, in writing, your name, a declaration that you are pregnant, the estimated date of conception (only the month and year need be given), and the date that you give the letter to the licensee. A form letter that you can use is included at the end of these questions and answers. You may use that letter, use a form letter the licensee has provided to you, or write your own letter.

10. To declare my pregnancy, do I have to have documented medical proof that I am pregnant?

MDH regulations do not require that you provide medical proof of your pregnancy. However, regulations do not preclude the licensee from requesting medical documentation of your pregnancy, especially if a change in your duties is necessary in order to comply with the 500 millirem (5 mSv) dose limit.

11. Can I tell the licensee orally rather than in writing that I am pregnant?

No. The regulations require that the declaration must be in writing.

12. If I have not declared my pregnancy in writing, but the licensee suspects that I am pregnant, do the lower dose limits apply?

No. The lower dose limits for pregnant women apply only if you have declared your pregnancy in writing. The United States Supreme Court has ruled "Decisions about the welfare of future children must be left to the parents who conceive, bear, support, and raise them rather than to the employers who hire those parents." (Reference 7). The Supreme Court has also ruled that your employer might not restrict you from a specific job "because of concerns about the next generation." Thus, the lower limits apply only if you choose to declare your pregnancy in writing.

13. If I am planning to become pregnant but am not yet pregnant and I inform the licensee of that in writing, do the lower dose limits apply?

No. The requirement for lower limits applies only if you declare in writing that you are already pregnant.

14. What if I have a miscarriage or find out that I am not pregnant?

If you have declared your pregnancy in writing, you should promptly inform the licensee in writing that you are no longer pregnant. However, if you have not formally declared your pregnancy in writing, you need not inform the licensee of your non-pregnant status.

15. How long is the lower dose limit in effect?

The dose to the embryo/fetus must be limited until you withdraw your declaration in writing or you inform the licensee in writing that you are no longer pregnant. If the declaration is not withdrawn, the written declaration may be considered expired one year after submission.

16. If I have declared my pregnancy in writing, can I revoke my declaration of pregnancy even if I am still pregnant?

Yes, you may. The choice is entirely yours. If you revoke your declaration of pregnancy, the lower dose limit for the embryo/fetus no longer applies.

17. What if I work at a licensed facility under a contract?

The regulations state that you should formally declare your pregnancy to the licensee in writing. The licensee has the responsibility to limit the dose to the embryo/fetus.

18. Where can I get additional information?

The references to this Appendix contain helpful information, especially the MDH Regulatory Guide, "Instruction Concerning Risks from Occupational Radiation Exposure," for general information on radiation risks. The licensee should be able to provide you with a copy of this document.

For information on legal aspects, see "The Rock and the Hard Place: Employer Liability to Fertile or Pregnant Employees and Their Unborn Children - What Can the Employer Do?" which is an article in the journal *Radiation Protection Management.*

REFERENCES FOR APPENDIX

National Council on Radiation Protection and Measurements (1993). Limitation of Exposure to Ionizing Radiation. NCRP Report No. 116, Bethesda, MD.

International Commission on Radiological Protection (1991). Recommendations of the International Commission on Radiological Protection. ICRP Publication 60, Ann. ICRP 21: No. 1-3, Pergamon Press, Oxford, UK.

Minnesota Department of Health "Instruction Concerning Risks from Occupational Radiation Exposure," (Electronically available at www.health.state.mn.us/divs/eh/radiation/ram).

Committee on the Biological Effects of Ionizing Radiations, National Research Council, (1990). Health Effects of Exposure to Low Levels of Ionizing Radiation (BEIR V), National Academy Press, Washington, DC.

United Nations Scientific Committee on the Effects of Atomic Radiation (1997). Sources and Effects of Ionizing Radiation, United Nations, New York.

Doll, R. & Wakeford, R. (1997) "Risk of Childhood Cancer from Fetal Irradiation," The British Journal of Radiology, 70, 130-139.

Wiedis, D., Jose, D.E., and Phoebe, T.O. (Jan./Feb.1994). "The Rock and the Hard Place: Employer Liability to Fertile or Pregnant Employees and Their Unborn Children-What Can the Employer Do?" Radiation Protection Management, 11, 41-49.

National Council on Radiation Protection and Measurements, (1994). Considerations Regarding the Unintended Radiation Exposure of the Embryo, Fetus, or Nursing Child. NCRP Commentary No. 9, Bethesda, MD.

National Council on Radiation Protection and Measurements (1993). Risk Estimates for Radiation Protection, NCRP Report No. 115, Bethesda, MD.

National Radiological Protection Board, (1998). Advice on Exposure to Ionizing Radiation During Pregnancy. Chilton, Didcot, UK.

Thomas, M.L. & Hagemeyer, D. (1998). Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1996. Twenty- Ninth Annual Report, NUREG-0713, Vol. 18, USNRC.[1]

[1] Copies are available at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202) 512-1800) or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW, Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington. DC 20555: telephone (202) 634-3273; fax (202) 634-3343.

FORM LETTER FOR DECLARING PREGNANCY

This form letter is provided for your convenience. To make your written declaration of pregnancy, you may fill in the blanks in this form letter, you may use a form letter the licensee has provided to you, or you may write your own letter.

DECLARATION OF PREGNANCY

To: _____

In accordance with the MDH rules, I am declaring that I am pregnant.

I understand the radiation dose to my embryo/fetus during my entire pregnancy will not be allowed to exceed 500 millirem (5 millisievert) (unless that dose has already been exceeded between the time of conception and submitting this letter). I also understand that meeting the lower dose limit may require a change in job or job responsibilities during my pregnancy.

_____

(Your signature)

_____

(Your name printed)

_____

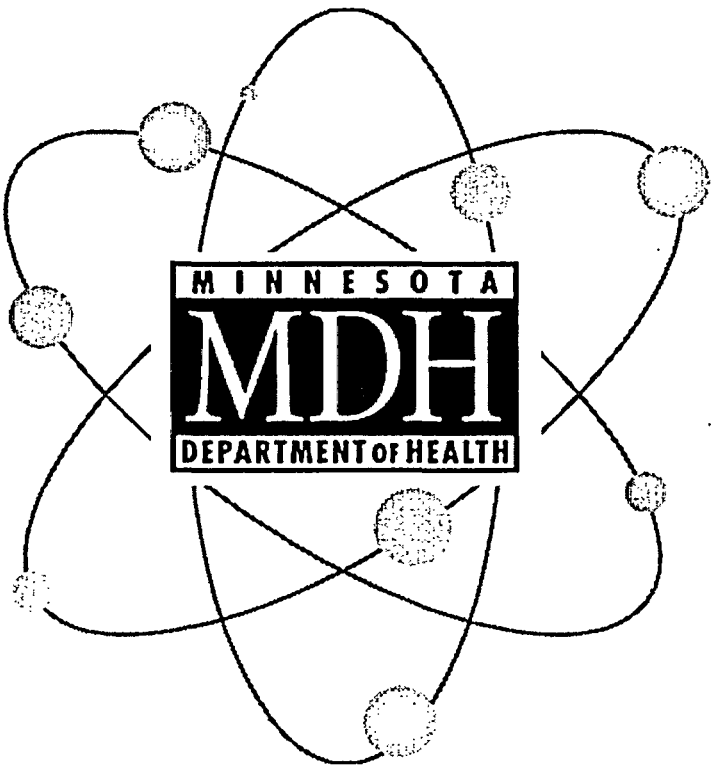
(Date)

SUMMARY OF REVISIONS

REVISION	SECTION	DESCRIPTION

F

MINNESOTA DEPARTMENT OF HEALTH



INSTRUCTION CONCERNING RISKS FROM OCCUPATIONAL RADIATION EXPOSURE

Radiation Control Unit

Asbestos, Lead, Indoor Air & Radiation Section

Division of Environmental Health

Minnesota Department of Health

January 2005

INSTRUCTION CONCERNING RISKS FROM OCCUPATIONAL RADIATION EXPOSURE

INTRODUCTION

4731.1000, "Instructions to Workers," requires that all individuals who, in the course of their employment, are likely to receive an annual occupational dose in excess of 100 mrem (1 mSv) are instructed in the health protection issues associated with exposure to radioactive materials or radiation. Before a planned special exposure, the individuals involved must be informed of the estimated doses and associated risks.

This revision conforms to the requirements of MDH rules, which:

- Establish dose limits based on the effective dose equivalent (EDE);
- Require the summing of internal and external dose;
- Establish a requirement that licensees use procedures and engineering controls to the extent practicable to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA);
- Provide for planned special exposures; and
- Establish a dose limit for the embryo/fetus of an occupationally exposed declared pregnant woman.

DISCUSSION

It is important to qualify the material presented in this guide with the following considerations.

The coefficient used in this guide for occupational radiation risk estimates, 4×10^{-4} health effects per rem, is based on data obtained at much higher doses and dose rates than those encountered by workers. (Thus, if each member in a group of 10,000 people were to receive one additional rem per year, statistically there would be four additional instances of cancer in that group.) The risk coefficient obtained at high doses and dose rates was reduced to account for the reduced effectiveness of lower doses and dose rates in producing the stochastic effects observed in studies of exposed humans.

The assumption of a linear extrapolation from the lowest doses at which effects are observable down to the occupational range has considerable uncertainty. The report from the Committee on the Biological Effects of Ionizing Radiation (Ref. 1) states that

> "...departure from linearity cannot be excluded at low doses below the range of observation. Such departures could be in the direction of either an increased or decreased risk. Moreover, epidemiologic data cannot rigorously exclude the existence of a threshold in the 100 mrem dose range. Thus, the possibility that there may be no risk from exposures comparable to external natural background radiation cannot be ruled out. At such low doses and dose rates, it must be acknowledged that the lower limit of the range of uncertainty in the risk estimates extends to zero."

The issue of beneficial effects from low doses, or hormesis, in cellular systems is addressed by the United Nations Scientific Committee on the Effects of Atomic Radiation (Ref. 2). UNSCEAR states that "... it would be premature to conclude that cellular adaptive responses could convey possible beneficial effects to the organism that would outweigh the detrimental effects of exposures to low doses of low-LET radiation.

Without scientific certainty regarding the relationship between low doses and health effects, and as a conservative assumption for radiation protection purposes, the scientific community generally assumes that any exposure to ionizing radiation can cause biological effects. It is assumed that the effects may be

harmful to the exposed person and that the magnitude or probability of these effects is directly proportional to the dose. These effects may be classified into three categories:

Somatic Effects: Physical effects occurring in the exposed person. These effects may be observable after a large or acute dose. Effects may include cancer that may occur years after exposure to radiation.

Genetic Effects: Abnormalities that may occur in the future children of exposed individuals and in subsequent generations (genetic effects exceeding normal incidence have not been observed in any of the studies of human populations).

Teratogenic Effects: Effects such as cancer or congenital malformation that may be observed in children who were exposed during the fetal and embryonic stages of development. (These effects have been observed from high, i.e., above 20 rems (0.2 Sv), acute exposures.)

The normal incidence of effects from natural and manmade causes is significant. For example, approximately 20% of people die from various forms of cancer whether or not they ever receive occupational exposure to radiation. To avoid increasing the incidence of such biological effects, regulatory controls are imposed on occupational doses to adults and minors and on doses to the embryo/fetus from occupational exposures of declared pregnant women.

Radiation protection training for workers who are occupationally exposed to ionizing radiation is an essential component of any program designed to ensure compliance with MDH regulations. A clear understanding of what is presently known about the biological risks associated with exposure to radiation will result in more effective radiation protection training. It should also generate more worker interest in complying with radiation protection standards. In addition, pregnant women and other occupationally exposed workers should have relevant information on radiation risks. This information will enable them to make informed decisions regarding the acceptance of these risks. It is intended that workers who receive this instruction will develop respect for the risks involved, rather than excessive fear or indifference.

REGULATORY POSITION

Instruction to workers should be given before occupational exposure and periodically thereafter. The frequency of retraining might range from annually for licensees with complex operations to every three years for licensees who possess, for example, only low-activity sealed sources. If a worker is to participate in a planned special exposure, the worker should be informed of the associated risks.

In providing instruction concerning health protection problems associated with exposure to radiation, all occupationally exposed workers and their supervisors should be given specific instruction on the risk of biological effects resulting from exposure to radiation. The extent of these instructions should be commensurate with the radiological risks present in the workplace.

The instruction should be presented to workers and supervisors orally, in printed form, or in any other effective communication media. This guide provides information for demonstrating compliance with the training requirements in Chapter 4731.1020. Individuals should be given an opportunity to discuss the information and to ask questions. Testing is recommended, and each trainee should be asked to acknowledge in writing that the instruction has been received and understood. A copy of the acknowledgement should be placed in the employee's permanent record.

IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the MDH staff's plans for using this regulatory guide.

Except in those cases in which an applicant or licensee proposes acceptable alternative methods for complying with specified portions of the MDH's regulations, the guidance and instructional materials in this guide will be used in the evaluation of applications for new licenses, license renewals, and license amendments and for evaluating compliance with Chapter 4731.

REFERENCES

1. National Research Council, *Health Effects of Exposure to Low Levels of Ionizing Radiation,* Report of the Committee on the Biological Effects of Ionizing Radiation (BEIR V), National Academy Press, Washington, DC, 1990.

2. United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), *Sources and Effects of Ionizing Radiation,* United Nations, New York, 1993.

INSTRUCTION CONCERNING RISKS FROM OCCUPATIONAL RADIATION EXPOSURE

This instructional material is intended to provide the user with the best available information about the health risks from occupational exposure to ionizing radiation. Ionizing radiation consists of energy or small particles, such as gamma rays and beta and alpha particles, emitted from radioactive materials, which can cause chemical or physical damage when they deposit energy in living tissue. A question and answer format is used. Many of the questions or subjects were developed in consultation with personnel experienced in radiation protection training (i.e., workers, union representatives, and licensee representatives).

This Regulatory Guide contains updated material on biological effects and risks and on typical occupational exposure. Additionally, it conforms to the revised Chapter 4731.2000, "Standards for Protection Against Radiation." The information is intended to help develop respect by workers for the risks associated with radiation, rather than unjustified fear or lack of concern. Additional guidance concerning other topics in radiation protection training is provided in other regulatory guides.

1. What is meant by health risk?

A health risk is generally thought of as something that may endanger health. Scientists consider health risk to be the statistical probability or mathematical chance that personal injury, illness, or death may result from some action. Most people do not think about health risks in terms of mathematics. Instead, most of us consider the health risk of a particular action in terms of whether we believe that particular action will or will not cause us some harm. The intent of this Regulatory Guide is to provide estimates of, and explain the bases for, the risk of injury, illness, or death from occupational radiation exposure. Risk can be quantified in terms of the probability of a health effect per unit of dose received.

When X-rays, gamma rays, and ionizing particles interact with living materials, such as our bodies, they may deposit enough energy to cause biological damage. Radiation can cause several different types of events, such as the very small physical displacement of molecules, changing a molecule to a different form, or ionization. Ionization is the removal of electrons from atoms and molecules. When the quantity of radiation energy deposited in living tissue is high enough, biological damage can occur as a result of chemical bonds being broken and cells being damaged or killed. These effects can result in observable clinical symptoms.

The basic unit for measuring absorbed radiation is the rad. One rad (0.01 gray in the International System of units) equals the absorption of 100 ergs (a small but measurable amount of energy) in a gram of material such as tissue exposed to radiation. To reflect biological risk, rads must be converted to rems. The new international unit is the sievert (1 rem = .01 Sv). This conversion accounts for the differences in damage by different types of radiation. The rem is used to estimate biological risk. For beta and gamma radiation, a rem is considered equal to a rad.

2. What are the possible health effects of exposure to radiation?

Health effects from exposure to radiation range from no effect at all to death, including diseases such as leukemia or bone, breast, and lung cancer. Very high (hundreds of rads), short-term doses of radiation have been known to cause prompt (or early) effects, such as vomiting and diarrhea[1], skin burns, cataracts, and even death. It is suspected that radiation exposure may be linked to the potential for

[1] These symptoms are early indicators of what is referred to as the acute radiation syndrome, caused by high doses delivered over a short time period, which includes damage to the blood forming organs such as bone marrow, damage to the gastrointestinal system, and, at very high doses, can include damage to the central nervous system.

genetic effects in the children of exposed parents. Also, children who were exposed to high doses (20 or more rads) of radiation before birth (as an embryo/fetus) have shown an increased risk of mental retardation and other congenital malformations. These effects (with the exception of genetic effects) have been observed in various studies of medical radiologists, uranium miners, radium workers, radiotherapy patients, and the people exposed to radiation from atomic bombs dropped on Japan. In addition, radiation effects studies with laboratory animals, in which the animals were given relatively high doses, have provided extensive data on radiation-induced health effects, including genetic effects. It is important to note that these kinds of health effects result from high doses, compared to occupational levels, delivered over a relatively short period of time.

Although studies have not shown a consistent cause-and-effect relationship between current levels of occupational radiation exposure and biological effects, it is prudent from a worker protection perspective to assume that some effects may occur.

3. What is meant by early effects and delayed or late effects?

EARLY EFFECTS

Early effects, which are also called immediate or prompt effects, are those that occur shortly after a large exposure that is delivered within hours to a few days. They are observable after receiving a very large dose in a short period of time, for example, 300 rads (3 Gy) received within a few minutes to a few days. Early effects are not caused at the levels of radiation exposure allowed under the MDH's occupational limits.

Early effects occur when the radiation dose is large enough to cause extensive biological damage to cells so that large numbers of cells are killed. For early effects to occur, this radiation dose must be received within a short time period. This type of dose is called an acute dose or acute exposure. The same dose received over a long time period would not cause the same effect. Our body's natural biological processes are constantly repairing damaged cells and replacing dead cells. If the cell damage is spread over time, our body is capable of repairing or replacing some of the damaged cells, reducing the observable adverse conditions.

For example, a dose to the whole body of about 300-500 rads (3-5 Gy), more than 60 times the annual occupational dose limit, if received within a short time period (e.g., a few hours) will cause vomiting and diarrhea within a few hours; loss of hair, fever, and weight loss within a few weeks; and about a 50 percent chance of death if medical treatment is not provided. These effects would not occur if the same dose were accumulated gradually over many weeks or months (Refs. 1 and 2). Thus, one of the justifications for establishing annual dose limits is to ensure that occupational dose is spread out over time.

It is important to distinguish between whole body and partial body exposure. A localized dose to a small volume of the body would not produce the same effect as a whole body dose of the same magnitude. For example, if only the hand were exposed, the effect would mainly be limited to the skin and underlying tissue of the hand. An acute dose of 400 to 600 rads (4-6 Gy) to the hand would cause skin reddening. Recovery would occur over the following months and no long-term damage would be expected. An acute dose of this magnitude to the whole body could cause death within a short time without medical treatment. Medical treatment would lessen the magnitude of the effects and the chance of death. However, medical treatment would not totally eliminate the effects or the chance of death.

DELAYED EFFECTS

Delayed effects may occur years after exposure. These effects are caused indirectly when the radiation changes parts of the cells in the body, which causes the normal function of the cell to change. For example, normal healthy cells turn into cancer cells. The potential for these delayed health effects is one of the main concerns addressed when setting limits on occupational doses.

A delayed effect of special interest is genetic effects. Genetic effects may occur if there is radiation damage to the cells of the gonads (sperm or eggs). These effects may show up as genetic defects in the children of the exposed individual and succeeding generations. However, if any genetic effects (i.e., effects in addition to the normal expected number) have been caused by radiation, the numbers are too small to have been observed in human populations exposed to radiation. For example, the atomic bomb survivors (from Hiroshima and Nagasaki) have not shown any significant radiation-related increases in genetic defects (Ref. 3). Effects have been observed in animal studies conducted at very high levels of exposure and it is known that radiation can cause changes in the genes in cells of the human body. However, it is believed that by maintaining worker exposures below the MDH limits and consistent with ALARA, a margin of safety is provided such that the risk of genetic effects is almost eliminated.

4. What is the difference between acute and chronic radiation dose?

Acute radiation dose usually refers to a large dose of radiation received in a short period of time. Chronic dose refers to the sum of small doses received repeatedly over long time periods, for example, 20 mrem (or millirem, which is 1-thousandth of a rem) (0.2 mSv) per week every week for several years. It is assumed for radiation protection purposes that any radiation dose, either acute or chronic, may cause delayed effects. However, only large acute doses cause early effects; chronic doses within the occupational dose limits do not cause early effects. Since the MDH limits do not permit large acute doses, concern with occupational radiation risk is primarily focused on controlling chronic exposure for which possible delayed effects, such as cancer, are of concern.

Using exposure to the sun's rays as an example can show the difference between acute and chronic radiation exposure. An intense exposure to the sun can result in painful burning, peeling, and growing of new skin. However, repeated short exposures provide time for the skin to be repaired between exposures. Whether exposure to the sun's rays is long term or spread over short periods, some of the injury may not be repaired and may eventually result in skin cancer.

Cataracts are an interesting case because they can be caused by both acute and chronic radiation. A certain threshold level of dose to the lens of the eye is required before there is any observable visual impairment, and the impairment remains after the exposure is stopped. The threshold for cataract development from acute exposure is an acute dose on the order of 100 rads (1 Gy). Further, a cumulative dose of 800 rads (8 Gy) from protracted exposures over many years to the lens of the eye has been linked to some level of visual impairment (Refs. 1 and 4). These doses exceed the amount that may be accumulated by the lens from normal occupational exposure under the current regulations.

5. What is meant by external and internal exposure?

A worker's occupational dose may be caused by exposure to radiation that originates outside the body. This type of dose is called external exposure. Exposure to radiation from radioactive material that has been taken into the body is called internal exposure. Most MDH licensed activities involve little, if any, internal exposure. It is the current scientific consensus that a rem of radiation dose has the same biological risk regardless of whether it is from an external or an internal source. The MDH requires that dose from external exposure and dose from internal exposure be added together, if each exceeds ten percent of the annual limit, and that the total be within occupational limits. The sum of external and internal dose is called the total effective dose equivalent (TEDE) and is expressed in units of rems (Sv).

Although unlikely, radioactive materials may enter the body through breathing, eating, drinking, or open wounds. They may also be absorbed through the skin. The intake of radioactive materials by workers is generally due to breathing contaminated air. Radioactive materials may be present as fine dust or gases in the workplace atmosphere. The surfaces of equipment and workbenches may be contaminated, and these materials can be re-suspended in air during work activities.

If any radioactive material enters the body, the material goes to various organs or is excreted, depending on the biochemistry of the material. Most radioisotopes are excreted from the body in a few days. However, a fraction of any uranium taken into the body will deposit in the bones, where it remains for a longer time. Uranium is slowly eliminated from the body, mostly by way of the kidneys. Most workers are not exposed to uranium. Radioactive iodine is preferentially deposited in the thyroid gland, which is located in the neck.

To limit risk to specific organs and the total body, an annual limit on intake (ALI) has been established for each radionuclide. When more than one radionuclide is involved, the intake amount of each radionuclide is reduced proportionally. MDH regulations specify the concentrations of radioactive material in the air to which a worker may be exposed. These concentrations are termed the derived air concentrations (DACs). These limits are the total amounts allowed if no external radiation is received. The resulting dose from the internal radiation sources (from breathing air at 1 DAC) is the maximum allowed to an organ or to the worker's whole body.

6. How does radiation cause cancer?

The mechanisms of radiation-induced cancer are not completely understood. When radiation interacts with the cells of our bodies, a number of events can occur. The damaged cells can repair themselves and permanent damage is not caused. The cells can die, much like the large numbers of cells that die every day in our bodies, and be replaced through the normal biological processes. Radiation may cause a change to occur in the cell's reproductive structure. The effected cells can mutate and subsequently be repaired without effect, or they can form pre-cancerous cells, which may become cancerous. Radiation is only one of many agents with the potential for causing cancer, and cancer caused by radiation cannot be distinguished from cancer attributable to any other cause.

Radiobiologists have studied the relationship between large doses of radiation and cancer (Refs. 5 and 6). These studies indicate that damage or change to genes in the cell nucleus is the main cause of radiation-induced cancer. This damage may occur directly through the interaction of the ionizing radiation in the cell or indirectly through the actions of chemical products produced by radiation interactions within cells. Cells are able to repair most damage within hours; however, some cells may not be repaired properly. Such incorrectly repaired damage is thought to be the origin of cancer, but incorrect repair does not always cause cancer. Some cell changes are benign or cause the cell to die; these changes do not lead to cancer.

Many factors such as age, general health, inherited traits, sex, as well as exposure to other cancer causing agents such as cigarette smoke can affect susceptibility to the cancer-causing effects of radiation. Many diseases are caused by the interaction of several factors, and these interactions appear to increase the susceptibility to cancer.

7. Who developed radiation risk estimates?

Radiation risk estimates were developed by several national and international scientific organizations over the last 40 years. These organizations include the National Academy of Sciences (which has issued several reports from the Committee on the Biological Effects of Ionizing Radiations, BEIR), the National

Council on Radiation Protection and Measurements (NCRP), the International Commission on Radiological Protection (ICRP), and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). Each of these organizations continues to review new research findings on radiation health risks.

Several reports from these organizations present new findings on radiation risks based upon revised estimates of radiation dose to survivors of the atomic bombing at Hiroshima and Nagasaki. For example, UNSCEAR published risk estimates in 1988 and 1993 (Refs. 5 and 6). The NCRP also published a report in 1988, "New Dosimetry at Hiroshima and Nagasaki and Its Implications for Risk Estimates' (Ref. 7). In January 1990, the National Academy of Sciences released the fifth report of the BEIR Committee, "Health Effects of Exposure to Low Levels of Ionizing Radiation" (Ref. 4). Each of these publications also provides extensive bibliographies on other published studies concerning radiation health effects for those who may wish to read further on this subject.

8. What are the estimates of the risk of fatal cancer from radiation exposure?

We do not know exactly what the chances are of getting cancer from a low-level radiation dose, primarily because the few effects that may occur cannot be distinguished from normally occurring cancers. However, we can make estimates based on extrapolation from extensive knowledge from scientific research on high dose effects. Estimates of radiation effects at high doses are better known than are those of most chemical carcinogens (Ref. 8).

From currently available data, the risk value for an occupational dose of 1 rem (0.01 Sv) Total Effective Dose Equivalent (TEDE) is 4 in 10,000 of developing a fatal cancer, or approximately 1 chance in 2,500 of fatal cancer per rem of TEDE received. The uncertainty associated with this risk estimate does not rule out the possibility of higher risk, or the possibility that the risk may even be zero at low occupational doses and dose rates.

The radiation risk incurred by a worker depends on the amount of dose received. Under the linear model explained above, a worker who receives 5 rems (0.05 Sv) in a year incurs ten times as much risk as another worker who receives only 0.5 rem (0.005 Sv). Very few workers receive doses near 5 rems (0.05 Sv) per year (Ref. 9).

According to the BEIR V report (Ref. 4), approximately one in five adults normally will die from cancer from all possible causes such as smoking, food, alcohol, drugs, air pollutants, natural background radiation, and inherited traits. Thus, in any group of 10,000 workers, we can estimate that about 2,000 (20%) will die from cancer without any occupational radiation exposure.

To explain the significance of these estimates, we will use as an example a group of 10,000 people, each exposed to 1 rem (0.01 Sv) of ionizing radiation. Using the risk factor of 4 effects per 10,000 rem of dose, we estimate that 4 of the 10,000 people might die from delayed cancer because of that one rem dose. The actual number could be more or less than 4. However, in addition to the 2,000 normal cancer fatalities expected to occur in that group from all other causes, it is estimated that 4 more might die from delayed cancer. This means that a one rem (0.01 Sv) dose may increase an individual worker's chances of dying from cancer from 20 percent to 20.04 percent. If one's lifetime occupational dose is 10 rems, we could raise the estimate to 20.4 percent. A lifetime dose of 100 rems may increase chances of dying from cancer from 20 to 24 percent. The average measurable dose for radiation workers was 0.31 rem (0.0031 Sv) for 1993 (Ref. 9). Today, very few workers ever accumulate 100 rems (1 Sv) in a working lifetime. The average career dose of workers at licensed facilities is 1.5 rems (0.015 Sv), which represents an estimated increase from 20 to about 20.06 percent in the risk of dying from cancer.

It is important to understand the probability factors here. A similar question would be, "If you select one card from a full deck of cards, will you get the ace of spades?" This question cannot be answered with a

simple yes or no. The best answer is that your chance is 1 in 52. However, if 1000 people each select one card from full decks, we can predict that about 20 of them will get an ace of spades. Each person will have I chance in 52 of drawing the ace of spades, but there is no way we can predict which persons will get that card. The issue is further complicated by the fact that in a drawing by 1000 people, we might get only 15 successes, and in another, perhaps 25 correct cards in 1000 draws. We can say that if you receive a radiation dose, you will have increased your chances of eventually developing cancer. It is assumed that the more radiation exposure you get, the more you increase your chances of cancer.

The normal chance of dying from cancer is about one in five for persons who have not received any occupational radiation dose. The additional chance of developing fatal cancer from an occupational exposure of 1 rem (0.01 Sv) is about the same as the chance of drawing any ace from a full deck of cards three times in a row. The additional chance of dying from cancer from an occupational exposure of 10 rem (0.1 Sv) is about equal to your chance of drawing two aces successively on the first two draws from a full deck of cards.

It is important to realize that these risk numbers are only estimates based on data for people and research animals exposed to high levels of radiation in short periods of time. There is still uncertainty with regard to estimates of radiation risk from low levels of exposure. Many difficulties are involved in designing research studies that can accurately measure the projected small increases in cancer cases that might be caused by low exposures to radiation as compared to the normal rate of cancer.

These estimates are considered by the MDH staff to be the best available for the worker to use to make an informed decision concerning acceptance of the risks associated with exposure to radiation. A worker who decides to accept this risk should try to keep exposure to radiation as low as is reasonably achievable (ALARA) to avoid unnecessary risk.

9. If I receive a radiation dose that is within occupational limits, will it cause me to get cancer?

Probably not. Based on the risk estimates previously discussed, the risk of cancer from doses below the occupational limits is believed to be small. Assessments of the cancer risks that may be associated with low doses of radiation are projected from data available at doses larger than 10 rems (0.1 Sv) (Ref. 3). Only in studies involving radiation doses significantly above occupational limits are there dependable determinations of the risk of cancer. Below the limits, the effect is small compared to differences in the normal cancer incidence. The ICRP, NCRP, and other standards-setting organizations assume for radiation protection purposes that there is some risk, no matter how small the dose. Some scientists believe that the risk drops off to zero at some low dose. This is called the threshold effect. However, the ICRP and NCRP endorse a straight-line model as a conservative means of assuring safety.

For regulatory purposes, the number of effects is assumed to decrease in a straight line as the dose decreases. Because the scientific evidence does not conclusively demonstrate whether there is or is not an effect at low doses, even small doses are assumed to have some chance of causing cancer. Thus, a principle of radiation protection is to do more than merely meet the allowed regulatory limits; doses should be kept as low as is reasonably achievable (ALARA). This is as true for natural carcinogens such as sunlight and natural radiation as it is for those that are manmade, such as cigarette smoke, smog, and X-rays.

10. How can we compare the risk of cancer from radiation to other kinds of health risks?

One way to make these comparisons is to compare the average number of days of life expectancy lost because of the effects associated with each particular health risk. Estimates are calculated by looking at a large number of persons, recording the age when death occurs from specific causes, and estimating the

average number of days of life lost as a result of these early deaths. The total number of days of life lost is then averaged over the total observed group.

Several studies have compared the average days of life lost from exposure to radiation with the number of days lost as a result of being exposed to other health risks. The word "average" is important because an individual who gets cancer loses about 15 years of life expectancy, while his or her coworkers do not suffer any loss.

Some representative numbers are presented in Table 1. For regulated industries with larger doses, the average measurable occupational dose in 1993 was 0.31 rem (0.0031 Sv). A simple calculation based on the article by Cohen and Lee (Ref. 10) shows that 0.3 rem (0.003 Sv) per year from age 18 to 65 results in an average loss of 15 days. These estimates indicate that the health risks from occupational radiation exposure are smaller than the risks associated with many other events or activities we meet and accept in normal day-to-day activities.

Table 1- Estimated Loss of Life Expectancy From Health Risks

Health risk	Estimate of Life Expectancy Lost (Average)
Smoking 20 cigarettes a day Overweight (by 15%) Alcohol Consumption (US Average)	6 years 2 years 1 year
Motor Vehicle Accidents Home Accidents Drowning All Accidents Combined	207 days 74 days 24 days 1 year
All Natural Hazards (earthquake, lightning, flood, etc.)	7 days
Medical Radiation	6 days
Occupational Exposure 0.3 rem/year from age 18-65 1 rem/year from age 18-65	 15 days 51 days

[a]Adapted from Reference 10.

It is also useful to compare the estimated average number of days of life lost from occupational exposure to radiation with the number of days lost as a result of working in several types of industries. Table 2 shows average days of life expectancy lost as a result of fatal work-related accidents. Table 2 does not include non-accident types of occupational risks such as occupational disease and stress because the data are not available.

These comparisons are not ideal because we are comparing the possible effects of chronic radiation exposure to different kinds of risk such as accidental death, in which death is inevitable if the event

occurs. This is the best we can do because good data are not available on chronic exposure to other workplace carcinogens. Also, the estimates of loss of life expectancy for workers from radiation-induced cancer do not take into consideration the competing effect on the life expectancy of the workers from industrial accidents.

Table 2 – Estimated Loss of Life Expectancy From Industrial Accidents

Industry Type	Estimated Days of Life Expectancy Lost (Average)
All industries	60
Agriculture	320
Construction	227
Mining and Quarrying	167
Transportation and Public Utilities	160
Government	60
Manufacturing	40
Trade	27
Services	27

[a]Adapted from Reference 10.

11. What are the health risks from radiation exposure to the embryo/fetus?

During certain stages of development, the embryo/fetus is believed to be more sensitive to radiation damage than adults. Studies of atomic bomb survivors exposed to acute radiation doses exceeding 20 rads (0.2 Gy) during pregnancy show that children born after receiving these doses have a higher risk of mental retardation. Other studies suggest that an association exists between exposure to diagnostic X-rays before birth and carcinogenic effects in childhood and in adult life. Scientists are uncertain about the magnitude of the risk. Some studies show the embryo/fetus to be more sensitive to radiation-induced cancer than adults, but other studies do not. In recognition of the possibility of increased radiation sensitivity, and because dose to the embryo/fetus is involuntary on the part of the embryo/ fetus, a more restrictive dose limit has been established for the embryo/fetus of a declared pregnant radiation worker. See Regulatory Guide entitled, "Instruction Concerning Prenatal Radiation Exposure."

If an occupationally exposed woman declares her pregnancy in writing, she is subject to the more restrictive dose limits for the embryo/fetus during the remainder of the pregnancy. The dose limit of 500 mrems (5 mSv) for the total gestation period applies to the embryo/fetus and is controlled by restricting the exposure to the declared pregnant woman. Restricting the woman's occupational exposure, if she declares her pregnancy, raises questions about individual privacy rights, equal employment opportunities, and the possible loss of income. Because of these concerns, the declaration of pregnancy by a female radiation worker is voluntary. Also, the declaration of pregnancy can be withdrawn for any reason, for example, if the woman believes that her benefits from receiving the occupational exposure would outweigh the risk to her embryo/fetus from the radiation exposure.

12. Can a worker become sterile or impotent from normal occupational radiation exposure?

No. Temporary or permanent sterility cannot be caused by radiation at the levels allowed under MDH's occupational limits. There is a threshold below which these effects do not occur. Acute doses on the

order of 10 rems (0.1 Sv) to the testes can result in a measurable but temporary reduction in sperm count. Temporary sterility (suppression of ovulation) has been observed in women who have received acute doses of 150 rads (1.5 Gy). The estimated threshold (acute) radiation dose for induction of permanent sterility is about 200 rads (2 Gy) for men and about 350 rads (3.5 Gy) for women (Refs. 1 and 4). These doses are far greater than the MDH's occupational dose limits for workers.

Although acute doses can affect fertility by reducing sperm count or suppressing ovulation, they do not have any direct effect on one's ability to function sexually. No evidence exists to suggest that exposures within the MDH's occupational limits have any effect on the ability to function sexually.

13. What are the MDH occupational dose limits?

For adults, an annual limit that does not exceed:

- 5 rems (0.05 Sv) for the total effective dose equivalent (TEDE), which is the sum of the external exposure to the whole body and the dose from intakes of radioactive material.

- 50 rems (0.5 Sv) for the total organ dose equivalent (TODE), which is the sum of the external exposure to the whole body and the dose to any individual organ or tissue, other than the lens of the eye.

- 15 rems (0.15 Sv) for the lens dose equivalent (LDE), which is the external dose to the lens of the eye.

- 50 rems (0.5 Sv) for the shallow dose equivalent (SDE), which is the external dose to the skin or to any extremity.

For minor workers, the annual occupational dose limits are 10 percent of the dose limits for adult workers. (A "minor worker" is an individual less than 18 years of age.)

For protection of the embryo/fetus of a declared pregnant woman, the dose limit is 0.5 rem (5 mSv) during the entire pregnancy. If the declared pregnant woman has already received a dose exceeding 500 millirem (5 mSv) in the period between conception and the declaration of pregnancy, an additional dose of 50 millirem (0.5 mSv) is allowed during the remainder of the pregnancy.

The occupational dose limit for adult workers of 5 rems (0.05 Sv) TEDE is based on consideration of the potential for delayed biological effects. The 5-rem (0.05 Sv) limit, together with application of the concept of keeping occupational doses ALARA, provides a level of risk of delayed effects considered acceptable by the MDH. The limits for individual organs are below the dose levels at which early biological effects are observed in the individual organs.

The dose limit for the embryo/fetus of a declared pregnant woman is based on a consideration of the possibility of greater sensitivity to radiation of the embryo/fetus and the involuntary nature of the exposure.

14. What is meant by ALARA?

ALARA means "as low as reasonably achievable." Aside from providing an upper limit on an individual's permissible radiation dose, MDH requires that its licensees establish radiation protection programs and use procedures and engineering controls to achieve occupational doses, and doses to the public, as far below the limits as is reasonably achievable. "Reasonably achievable" also means "to the extent practical." What is practical depends on the purpose of the job, the state of technology, the costs for averting doses, and the benefits. Although implementation of the ALARA principle is a required integral

part of each licensee's radiation protection program, it does not mean that each radiation exposure must be kept to an absolute minimum. It does, however, mean that "reasonable" efforts must be made to avert dose. In practice, ALARA includes planning tasks involving radiation exposure so as to reduce dose to individual workers and the work group.

There are several ways to control radiation doses, e.g., limiting the time in radiation areas, maintaining distance from sources of radiation, and providing shielding of radiation sources to reduce dose. The use of engineering controls, from the design of facilities and equipment to the actual set-up and conduct of work activities, is also an important element of the ALARA concept.

An ALARA analysis should be used in determining whether the use of respiratory protection is advisable. In evaluating whether or not to use respirators, the goal should be to achieve the optimal sum of external and internal doses. For example, the use of respirators can lead to increased work time within radiation areas, which increases external dose. The advantage of using respirators to reduce internal exposure must be evaluated against the increased external exposure and related stresses caused by respirators. Heat stress, reduced visibility, and reduced communication associated with the use of respirators could expose a worker to far greater risks than are associated with the internal dose avoided by use of the respirator. To the extent practical, engineering controls, such as containments and ventilation systems, should be used to reduce workplace airborne radioactive materials.

15. What are background radiation exposures?

The average person is constantly exposed to ionizing radiation from several sources. Our environment and even the human body contain naturally occurring radioactive materials (e.g., Potassium-40) that contribute to the radiation dose that we receive. The largest source of natural background radiation exposure is radon, a colorless, odorless, chemically inert gas, which causes about 55 percent of our average, non-occupational exposure. Cosmic radiation originating in space contributes additional exposure. The use of X-rays and radioactive materials in medicine and dentistry adds to our population exposure. As shown below in Table 3, the average person receives an annual radiation dose of about 0.36 rem (3.6 mSv). By age 20, the average person will accumulate over 7 rems (70 mSv) of dose. By age 50, the total dose is up to 18 rems (180 mSv). After 70 years of exposure this dose is up to 25 rems (250 mSv).

16. What are the typical radiation doses received by workers?

For 1993, almost half of the quarter of a million people who were monitored for occupational exposure to radiation had no measurable doses. The other half had an average dose of about 310 mrem (3.1 mSv) for the year. Of these, 93 percent received an annual dose of less than 1 rem (10 mSv); 98.7 percent received less than 2 rems (20 mSv); and the highest reported dose was for two individuals who each received between 5 and 6 rems (50 and 60 mSv).

Table 4 lists average occupational doses for workers (persons who had measurable doses) in various occupations based on 1993 data. It is important to note that beginning in 1994, licensees have been required to sum external and internal doses and certain licensees are required to submit annual reports. Certain types of licensees, such as nuclear fuel fabricators, may report a significant increase in worker doses because of the exposure to long-lived airborne radionuclides and the requirement to add the resultant internal dose to the calculation of occupational doses.

Table 3 – Average Annual Effective Dose Equivalent to Individuals in the U.S.

Source	Effective Dose Equivalent (mrems)	
Natural		
Radon	200	
Other than Radon	100	
Total		300
Nuclear Fuel Cycle		0.05
Consumer Products [b]		9
Medical		
Diagnostic X-rays	39	
Nuclear Medicine	14	
Total		53
	Total: about 360 mrems/year	

[a] Adapted from Table 8.1, NCRP 93 (Ref. 11).
[b] Includes building material, television receivers, luminous watches, smoke detectors, etc. (from Table 5.1, NCRP 93, Ref. 11).

Table 4 – Reported Occupational Doses for 1993 [A]

Occupational Subgroup	Average Measurable Dose per Worker (millirems)
Industrial Radiography	540
Commercial Nuclear Power Reactors	310
Manufacturing and Distribution of Radioactive Materials	300
Low-Level Radioactive Waste Disposal	270
Independent Spent Nuclear Fuel Storage	260
Nuclear Fuel Fabrication	130

[A] From Table 3.1 in NUREG-0713 (Ref. 9).

17. How do I know how much my occupational dose (exposure) is?

If you are likely to receive more than ten percent of the annual dose limits, MDH requires your employer to do the following:

- Monitor your dose
- Maintain records of your dose
- Inform you of your dose at least annually

The purpose of this monitoring is so that the MDH can be sure that licensees are complying with the occupational dose limits and the ALARA principle.

External exposures are monitored by using individual monitoring devices. These devices are required to be used if it appears likely that external exposure will exceed ten percent of the allowed annual dose, i.e., 0.5 rem (5 mSv). The most commonly used monitoring devices are film badges, thermoluminescence dosimeters (TLDs), optically stimulated dosimeters (OSDs), electronic dosimeters, and direct reading pocket dosimeters.

With respect to internal exposure, your employer is required to monitor your occupational intake of radioactive material. The employer must assess the resulting dose if it appears likely that you will receive greater than ten percent of the annual limit on intake (ALI). Internal exposure can be estimated by measuring the radiation emitted from the body (for example, with a "whole body counter") or by measuring the radioactive materials contained in biological samples such as urine or feces. Dose estimates can also be made if one knows how much radioactive material was in the air and the length of time during which the air was breathed.

18. What happens if a worker exceeds the annual dose limit?

If a worker receives a dose that exceeds any of the annual dose limits, the regulations prohibit any occupational exposure during the remainder of the year in which the limit is exceeded. The licensee is also required to file an overexposure report with the MDH and provide a copy to the individual who received the dose. The licensee may be subject to MDH enforcement action such as a fine (civil penalty), just as individuals are subject to a traffic fine for exceeding a speed limit. The fines and, in some serious or repetitive cases, suspension of a license are intended to encourage licensees to comply with the regulations.

Radiation protection limits do not define safe or unsafe levels of radiation exposure. Exceeding a limit does not mean that you will get cancer. For radiation protection purposes, it is assumed that risks are related to the size of the radiation dose. Therefore, when your dose is higher your risk is also considered to be higher. These limits are similar to highway speed limits. If you drive at 70 mph, your risk is higher than at 55 mph, even though you may not have an accident. Those who set speed limits have determined that the risks of driving more than the speed limit are not acceptable. In the same way, Chapter 4731 establishes a limit for normal occupational exposure of 5 rems (0.05 Sv) a year. Although you will not necessarily get cancer or some other radiation effect at doses above the limit, it does mean that the licensee's safety program has failed in some way. Investigation is warranted to determine the cause and correct the conditions leading to the doses exceeding the limit.

19. What is meant by a "planned special exposure"?

A "planned special exposure" (PSE) is an infrequent exposure to radiation, separate from and in addition to the radiation received under the annual occupational limits. The licensee can authorize additional dose in any one year that is equal to the annual occupational dose limit as long as the individual's total dose from PSEs does not exceed five times the annual dose limit during the individual's lifetime. For example,

licensees may authorize PSEs for an adult radiation worker to receive doses up to an additional 5 rems (0.05 Sv) in a year above the 5-rem (0.05-Sv) annual TEDE occupational dose limit. Each worker is limited to no more than 25 rems (0.25 Sv) from planned special exposures in his or her lifetime. Such exposures are only allowed in exceptional situations when alternatives for avoiding the additional exposure are not available or are impractical.

Before the licensee authorizes a PSE, the licensee must ensure that the worker is informed of the purpose and circumstances of the planned operation, the estimated doses expected, and the procedures to keep the doses ALARA while considering other risks that may be present.

20. Why do some facilities establish administrative control levels that are below the MDH limits?

There are two reasons. First, MDH regulations state that licensees must take steps to keep exposures to radiation ALARA. Specific approval from the licensee for workers to receive doses more than administrative limits usually results in more critical risk-benefit analyses as each additional increment of dose is approved for a worker. Second, an administrative control level that is set lower than the MDH limit provides a safety margin designed to help the licensee avoid doses to workers more than the limit.

21. Why aren't medical exposures considered as part of a worker's allowed dose?

MDH rules exempt medical exposure, but equal doses of medical and occupational radiation have equal risks. Medical exposure to radiation is justified for reasons that are quite different from the reasons for occupational exposure. A physician prescribing an X-ray, for example, makes a medical judgment that the benefit to the patient from the resulting medical information justifies the risk associated with the radiation. This judgment may or may not be accepted by the patient. Similarly, each worker must weigh the benefits and acceptability of occupational radiation risk, just as each worker must decide on the acceptability of any other occupational hazard.

Consider a worker who receives a dose of 3 rems (0.03 Sv) from a series of X-rays in connection with an injury or illness. This dose and any associated risk must be justified on medical grounds. If the worker had also received 2 rems (0.02 Sv) on the job, the combined dose of 5 rems (0.05 Sv) would in no way incapacitate the worker. Restricting the worker from additional job exposure during the remainder of the year would not have any effect on the risk from the 3 rems (0.03 Sv) already received from the medical exposure. If the individual worker accepts the risks associated with the X-rays on the basis of the medical benefits and accepts the risks associated with job-related exposure on the basis of employment benefits, it would be unreasonable to restrict the worker from employment involving exposure to radiation for the rest of the year.

22. How should radiation risks be considered in an emergency?

Emergencies are unplanned events in which actions to save lives or property may warrant additional doses for which no particular limit applies. Rare situations may occur in which a dose in excess of occupational limits would be unavoidable in order to carry out a lifesaving operation or to avoid a large dose to large populations. However, persons called upon to undertake any emergency operation should do so only on a voluntary basis and with full awareness of the risks involved.

For perspective, the Environmental Protection Agency (EPA) has published emergency dose guidelines (Ref. 2). These guidelines state that doses to all workers during emergencies should, to the extent practical, be limited to 5 rems (0.05 Sv). The EPA further states that there are some emergencies for which higher limits may be justified. The dose resulting from such emergency exposures should be limited to 10 rems (0.1 Sv) for protecting valuable property, and to 25 rems (0.25 Sv) for lifesaving

activities and the protection of large populations. In the context of this guidance, the dose to workers that is incurred for the protection of large populations might be considered justified for situations in which the collective dose to others that is avoided as a result of the emergency operation is significantly larger than that incurred by the workers involved.

Table 5 presents the estimates of the fatal cancer risk for a group of 1,000 workers of various ages, assuming that each worker received an acute dose of 25 rems (0.25 Sv) in the course of assisting in an emergency. The estimates show that a 25-rem emergency dose might increase an individual's chances of developing fatal cancer from about 20% to about 21%.

Table 5 – Risk of Premature Death From Exposure to 25 Rems Acute Dose

Age at Exposure (years)	Estimated Risk of Premature Death (Deaths per 1000 persons exposed)
20-30	9.1
30-40	7.2
40-50	5.3
50-60	3.5

Source: EPA-400-R-92-001 (Ref. 2).

23. How were radiation dose limits established?

The radiation dose limits in Chapter 4731.2020 were established based on the recommendations of the ICRP and NCRP as endorsed in Federal radiation protection guidance developed by the EPA (Ref. 12). The limits were recommended by the ICRP and NCRP with the objective of ensuring that working in a radiation-related industry was as safe as working in other comparable industries. The dose limits and the principle of ALARA should ensure that risks to workers are maintained indistinguishable from risks from background radiation.

24. What are the options if a worker decides that the risks associated with occupational radiation exposure are too high?

If the risks from exposure to occupational radiation are unacceptable to a worker, he or she can request a transfer to a job that does not involve exposure to radiation. However, the risks associated with the exposure to radiation that workers, on the average, actually receive are comparable to risks in other industries and are considered acceptable by the scientific groups that have studied them. An employer is not obligated to guarantee a transfer if a worker decides not to accept an assignment that requires exposure to radiation.

Any worker has the option of seeking other employment in a non-radiation occupation. However, the studies that have compared occupational risks in the nuclear industry to those in other job areas indicate that nuclear work is relatively safe. Thus, a worker may find different kinds of risk but will not necessarily find significantly lower risks in another job.

REFERENCES

1. B. R. Scott et al., "Health Effects Model for Nuclear Power Plant Accident Consequence Analysis," Part I: *Introduction, Integration, and* Summary, US Nuclear Regulatory Commission, NUREG/CR-4214, Revision 2, Part I, October 1993.

2. US Environmental Protection Agency, *Manual of Protective Action Guides and Protective Actions for Nuclear Incidents,* EPA-400-R-92001, May 1992.

3. International MDH on Radiological Protection, *Annals of the ICRP, Risks Associated with Ionizing Radiation,* Volume 22, No. 1, Pergamon Press, Oxford, UK, 199 1.

4. National Research Council, *Health Effects of Exposure to Low Levels of Ionizing Radiation, Re*port of the Committee on the Biological Effects of Ionizing Radiation (BEIR V), National Academy Press, Washington, DC, 1990.

5. United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), *Sources, Effects and Risks of Ionizing Radiation,* Report E.88.IX.7, United Nations, New York, 1988.

6. United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), *Sources and Effects of Ionizing Radiation,* United Nations, New York, 1993.

7. National Council on Radiation Protection and Measurements, *New Dosimetry at Hiroshima and Nagasaki and Its Implications for Risk Estimates,* Proceedings of the Twenty-third Annual Meeting of the National Council on Radiation Protection and Measurements Held on April 89, 1987 (1988).

8. National Council on Radiation Protection and Measurements, *Comparative Carcinogenicity of Ionizing Radiation and Chemicals,* NCRP Report No. 96, March 1989.

9. C. T. Raddatz and D. Hagemeyer, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1993," US Nuclear Regulatory Commission, NUREG-0713, Volume 15, January 1995.'

10. B. L. Cohen and I. S. Lee, "Catalog of Risks Extended and Updated, *"Health Physics,"* Vol. 61, September 1991.

11. National Council on Radiation Protection and Measurements, *Ionizing Radiation Exposure of the Population of the United States,* NCRP Report No. 93, September 1987.

12. US Environmental Protection Agency, "Radiation Protection Guidance to Federal Agencies for Occupational Exposure," *Federal Register,* Vol. 52, No. 17, January 27, 1987.

13. International MDH on Radiological Protection, *1990 Recommendations of the International Commission on Radiological Protection,* ICRP Publication 60, Pergamon Press, Oxford, UK, 199 1.

14. National Council on Radiation Protection and Measurements, *Limitation of Exposure to Ionizing Radiation,* NCRP Report No. 116, March 1993.

BIBLIOGRAPHY

Abrahamson, *S., et al.,* "Health Effects Models for Nuclear Power Plant Accident Consequence Analysis," Part II: *Scientific Bases for Health Effects Models,* US Nuclear Regulatory Commission, NUREG/ CR-4214, Rev. 1, Part II, May 1989.

Abrahamson, S., *et al.,* "Health Effects Models for Nuclear Power Plant Accident Consequence Analysis, Modifications of Models Resulting From Recent Reports on Health Effects of Ionizing Radiation, Low LET Radiation," Part *11: Scientific Basis for Health Effects Models,* US Nuclear Regulatory Commission, NUREG/CR-4214, Rev. 1, Part II, Addendum 1, August 1991.

Abrahamson, S., *et al.,* "Health Effects Models for Nuclear Power Plant Accident Consequence Analysis, Modifications of Models Resulting From Addition of Effects of Exposure to Alpha-Emitting Radionuclides," Part II: *Scientific Bases for Health Effects Models,* US Nuclear Regulatory Commission, NUREG/CR-4214, Rev. 1, Part II, Addendum 2, May 1993.

International Commission on Radiological Protection, *Radiation Protection,* Recommendations of the International Commission on Radiological Protection, ICRP Publication 26, Pergamon Press, Oxford, UK, January 1977.

National Council on Radiation Protection and Measurements, *Public Radiation Exposure From Nuclear Power Generation in the United States,* NCRP Report No. 92, December 1987.

National Council on Radiation Protection and Measurements, *Exposure of the Population in the United States and Canada from Natural Background Radiation,* NCRP Report No. 94, December 1987.

National Council on Radiation Protection and Measurements, *Exposure of the US Population From Occupational Radiation,* NCRP Report No. 101, June 1989.

National Council on Radiation Protection and Measurements, *Risk Estimates for Radiation Protection,* NCRP Report No. 115, December 1993.

National Council on Radiation Protection and Measurements, *Limitation of Exposure to Ionizing Radiation,* NCRP Report No. 116, March 1993.

National Safety Council, *Accident Facts,* 1993 Edition, Itasca, Illinois, 1993.

US Environmental Protection Agency, "Radiation Protection Guidance to Federal Agencies for Occupational Exposure," *Federal Register,* Vol. 52, No. 17, January 27, 1987.

US Nuclear Regulatory Commission, "Instruction Concerning Prenatal Radiation Exposure," Regulatory Guide 8.13, Revision 2, December 1987.

US Nuclear Regulatory Commission, "Monitoring Criteria and Methods To Calculate Occupational Radiation Doses," Regulatory Guide 8.34, July 1992.

US Nuclear Regulatory Commission, "Planned Special Exposures," Regulatory Guide 8.35, June 1992.

US Nuclear Regulatory Commission, "Radiation Dose to the Embryo/Fetus," Regulatory Guide 8.36, July 1992.

SUMMARY OF REVISIONS

REVISION	SECTION	DESCRIPTION

I. INSPECTION OBJECTIVES

To determine if licensed decommissioning activities are being conducted in a manner that will protect the health and safety of workers and the general public.

To determine if licensed decommissioning programs are being conducted according to MDH requirements.

II. INSPECTION REQUIREMENTS

A review of the licensed activities will be commensurate with the scope of and the risks associated with the licensee's program. An evaluation of safety and compliance with MDH requirements will be based on direct observation of work activities, interviews with workers, and demonstrations by workers performing tasks regulated by MDH. In addition, independent measurements of radiation conditions at the facility and a review of licensee records should be completed.

In reviewing records and discussing issues with the licensee, cover the period back to the last inspection. Older records or issues preceding the last inspection should be reviewed if warranted by circumstances, such as a history of incidents, non-compliance, or high radiation exposures.

The inspection program should be tailored to each specific licensee. Most materials licensees will not require submittal of a formal decommissioning plan for MDH review and approval. Some materials licensees, such as medical teletherapy, well loggers, and industrial radiographers, may only require a final status survey report, etc., to effect license termination, and will not require any actual decontamination or dismantling of facilities. Clean-up efforts for most materials licensees will not be a major effort. Some licensees, however, such as manufacturers of radioactive chemicals and certain academic and research institutions, may require significant decommissioning efforts by the licensees and significant inspection activities by the MDH staff.

Inspectors should review NUREG/CR-5849, "Manual for Conducting Radiological Surveys in Support of License Termination." Portions of the US Department of Energy (DOE) "Decommissioning Handbook" (published by the Office of Environmental Restoration in March 1994) may be beneficial also.

The field notes in Appendices A and B should be used by the inspector for each inspection.

A. **Inspection Requirements Applicable from Operations** -- 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.

B. **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

III. 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 are 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.

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
- ☐ Routine
- ☐ Initial Decommissioning
- ☐ Unannounced
- ☐ Special
- ☐ 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:		

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:		

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

Observations and Remarks:

SUMMARY OF REVISIONS

REVISION	SECTION	DESCRIPTION

H

MINNESOTA DEPARTMENT OF HEALTH

REGULATORY GUIDE FOR THE RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIALS

Radiation Control Unit

Asbestos, Lead, Indoor Air & Radiation Section

Division of Environmental Health

Minnesota Department of Health

January 2005

REGULATORY GUIDE
FOR RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIALS

A. INTRODUCTION

In Minnesota rules 4731.4427, "Release of Individuals Containing Radiopharmaceuticals or Permanent Implants," a licensee is permitted to release any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent (TEDE) to any other person coming into contact with the released individual is not likely to exceed 0.5 rem (5 mSv [mSv]). Further, 4731.4427 requires that the licensee provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 0.1 rem (1 mSv). If the dose to a breast-feeding child could exceed 0.1 rem (1 mSv) assuming there were no interruption of breast-feeding, the instructions shall also include

(1) guidance on the interruption or discontinuation of breast-feeding; and
(2) information on the consequences of failure to follow the guidance.

The licensee should maintain a record of the basis for authorizing the release of an individual for three years after the date of release if the total effective dose equivalent is calculated by

(1) using the retained activity rather than the activity administered;
(2) using an occupancy factor less than 0.25 at 1 meter;
(3) using the biological or effective half-life; or
(4) considering the shielding by tissue.

The licensee should maintain a record that instructions were provided to a breast-feeding woman if the radiation dose to the child from continued breast-feeding could result in a total effective dose equivalent exceeding 0.5 rem (5 mSv). The record should be retained for three years after the date of release.

In this guide, the individual administered the radioactive material is referred to as the Patient.

This document provides guidance to the licensee on determining:

(1) When the licensee may authorize the release of a patient who has been administered radiopharmaceuticals or permanent implants containing radioactive material;
(2) When instructions to the patient are required; and
(3) When records are generated and maintained.

The guide lists the activities of commonly used radionuclides and their corresponding dose rates that a patient may contain and be released in compliance with the dose limits in 4731.4427.

B. DISCUSSION

The activities at which patients could be released are calculated by using the method discussed in the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides" (Ref. 1).

NCRP Report No. 37 uses the following equation to calculate the exposure until time t at a distance r from the patient:

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

Where:

D(t) = Accumulated exposure at time t (in roentgens)

34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44)

Γ = Specific gamma ray constant for a point source, R/mCi-hr at 1 cm

Q_o = Initial activity of the point source in millicuries, at the time of the release

T_p = Physical half-life in days

r = Distance from the point source to the point of interest in centimeters

t = Exposure time in days

This guide uses the NCRP equation (Equation 1) in the following manner to calculate the activities at which patients may be released.

- The dose to an individual likely to receive the highest dose from exposure to the patient is taken to be the dose to total decay. Therefore, $(1 - e^{-0.693t/T_p})$ is set equal to 1.
- It is assumed that 1 roentgen is equal to 10 mSv (1 rem).
- The exposure rate constants and physical half-lives for radionuclides typically used in nuclear medicine and brachytherapy procedures are given in Appendix A to this guide.
- Default activities at which patients may be released are calculated using the physical half-lives of the radionuclides and do not account for the biological half-lives of the radionuclides.
- When release is based on biological elimination (i.e., the effective half-life) rather than just the physical half-life of the radionuclide, Equation 1 is modified to account for the up-take and retention of the radionuclide by the patient as discussed in Appendix B.
- For radionuclides with a physical half-life greater than 1 day and no consideration of biological elimination, it is assumed that the individual likely to receive the highest dose from exposure to the patient would receive a dose of 25 percent of the dose to total decay (0.25 in Equation 2) at a distance of 1 meter. Selection of 25 percent of the dose to total decay at 1 meter for estimating the dose is based on measurements discussed in the supporting regulatory analysis (Ref. 2). The analysis indicates the dose calculated using an occupancy factor, E, of 25 percent at 1 meter is conservative in most normal situations.
- For radionuclides with a physical half-life less than or equal to 1 day, it is difficult to justify an occupancy factor of 0.25 because relatively long-term averaging of behavior cannot be assumed. Under this situation, occupancy factors from 0.75 to 1.0 may be more appropriate.

Thus, for radionuclides with a physical half-life greater than 1 day:

$$D(\infty) = \frac{34.6\ \Gamma\ Q_0\ T_p\ (0.25)}{100\ cm^2} \qquad \text{(Equation 2)}$$

For radionuclides with a physical half-life less than or equal to 1 day and if an occupancy factor of 1.0 is used:

$$D(\infty) = \frac{34.6\ \Gamma\ Q_0\ T_p\ (1)}{100\ cm^2} \qquad \text{(Equation 3)}$$

Equations 2 and 3 calculate the dose from external exposure to gamma radiation. These equations do not include the dose from internal intake by household members and members of the public because the dose from intake by other individuals is expected to be small for most radiopharmaceuticals (less than a few percent) relative to the external gamma dose (see Section B.3, "Internal Dose," of Appendix B).

Further, the equations above do not apply to the dose to breast-feeding infants or children who continue to breast-feed. Patients who are breast-feeding must be considered separately.

C. REGULATORY POSITION

1. RELEASE CRITERIA

Licensees should use one of the following options to release a patient who has been administered radiopharmaceuticals or permanent implants containing radioactive material in accordance with regulatory requirements.

1.1 Release of Patients Based on Administered Activity

In compliance with the dose limit in 4731.4427, licensees may release patients from licensee control if the activity administered is no greater than the activity in Column 1 of Table 1. The activities in Table 1 are based on a total effective dose equivalent of 0.5 rem (5 mSv) to an individual using conservative assumptions of

(1) administered activity,

(2) physical half-life,

(3) occupancy factor of 0.25 at 1 meter for physical half-lives greater than 1 day, and, for conservatism, an occupancy factor of 1 at 1 meter for physical half-lives less than or equal to 1 day, and

(4) no shielding by tissue.

The total effective dose equivalent is approximately equal to external dose because the internal dose is a small fraction of the external dose (see Section B.3, "Internal Dose," of Appendix B). In this case, no record of the release of the patient is required unless the patient is breast-feeding.

If the activity administered exceeds the activity in Column 1 of Table 1, the licensee may release the patient when the activity has decayed to the activity in Column 1 of Table 1. In this case, a record is required because the patient's release is based on the retained activity rather than the administered activity. The activities in Column 1 of Table 1 were calculated using either Equation 2 or 3, depending on the physical half-life of the radionuclide.

If a radionuclide not listed in Table 1 is administered, the licensee can demonstrate compliance with the regulation by maintaining, for MDH inspection, a calculation of the release activity that corresponds to the dose limit of 0.5 rem (5 mSv). Equation 2 or 3 may be used, as appropriate, to calculate the activity Q corresponding 0.5 rem (5 mSv).

The release activities in Column 1 of Table 1 do not include consideration of the dose to a breast-feeding child from ingestion of radiopharmaceuticals contained in a patient's breast milk. When the patient is breast-feeding, the activities in Column 1 of Table 1 are not applicable to the child. In this case, it may be necessary to give specific instructions as a condition for release. If failure to interrupt or discontinue could result in a dose to the breast-feeding child more than 0.5 rem (5 mSv), a record that instructions were provided is required.

1.2 Release of Patients Based on Measured Dose Rate

Licensees may release patients who are administered radionuclides in amounts greater than the activities listed in Column 1 of Table 1 provided that the measured dose rate at 1 meter (from the surface of the patient) is no greater than the value in Column 2 of Table 1 for that radionuclide. In this case, however, a record is required because the release considers shielding by tissue.

If a radionuclide not listed in Table 1 is administered and the licensee chooses to release a patient based

on the measured dose rate, the licensee should first calculate a dose rate that corresponds to the 0.5 rem (5 mSv) dose limit. If the measured dose rate at 1 meter is no greater than the calculated dose rate, the patient may be released. A record of the release is required. The dose rate at 1 meter may be calculated from Equation 2 or 3, as appropriate, because the dose rate at 1 meter is equal to Γ Q/10,000 cm^2.

1.3 Release of Patients Based on Patient - Specific Dose Calculations

Licensees may release patients based on dose calculations using patient-specific parameters. With this method, the licensee must calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis. If the calculated maximum likely dose to an individual is no greater than 0.5 rem (5 mSv), the patient may be released. Using this method, licensees may be able to release patients with activities greater than those listed in Column 1 of Table 1 by taking into account the effective half-life of the radioactive material and other factors that may be relevant to the particular case. If the dose calculation included consideration of retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis for the release is required.

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

2. INSTRUCTIONS

2.1 Activities and Dose Rates Requiring Instructions

For some administrations, the released patients must be given instructions, including written instructions, on how to maintain doses to other individuals as low as is reasonably achievable after the patients are released.[1] Licensees may use Column 1 of Table 2 to determine the activity above which instructions must be given to patients. Column 2 provides corresponding dose rates at 1 meter, based on the activities in Column 1. If the patient is breast-feeding, additional instructions may be necessary.

The activities or dose rates in Table 2 may be used for determining when instructions must be given. When patient-specific calculations (as described in Appendix B) are used, instructions must be provided if the calculation indicates a dose that is greater than 0.1 rem (1 millisievert).

If a radionuclide not listed in Table 2 is administered, the licensee may calculate the activity or dose rate that corresponds to 0.1 rem (1 millisievert). Equation 2 or 3, as appropriate, may be used.

2.2 Additional Instructions for Release of Patients Who Could be Breast-Feeding After Release

Licensees must provide instructions on the discontinuation or the interruption period of breast-feeding, and the consequences of failing to follow the recommendation. This presumes that the licensee will inquire, as appropriate, regarding the breast-feeding status of the patient. The purpose of the instructions (e.g., on interruption or discontinuation) is to permit licensees to release a patient who could be breast-feeding when the dose to the child could exceed 0.5 rem (5 mSv) if there is no interruption of breast-feeding.

Instructions on discontinuation interruption of breast-feeding and the consequences of failing to follow the recommendation must be provided if the patient could be breast-feeding a child after release. Instructions must also be provided if the patient was administered a radiopharmaceutical with an activity above the value stated in Column 1 of Table 3. The patient should also be informed if there would be no consequences to breast-feeding. Table 3 also provides recommendations for interrupting or discontinuing breast-feeding to minimize the dose to below 0.1 rem (1 millisievert) if the patient has received certain radiopharmaceutical doses. The radiopharmaceuticals listed in Table 3 are commonly used in medical diagnosis and treatment.

If a radiopharmaceutical not listed in Table 3 is administered to a patient who could be breast-feeding, the licensee should evaluate whether instructions, records, (or both) are required. If information on the excretion of the radiopharmaceutical is not available, an acceptable method is to assume that 50 percent

[1] MDH does not intend to enforce patient compliance with instructions nor is it the licensee's responsibility to do so.

of the administered activity is excreted in the breast milk (Ref. 2). The dose to the child can be calculated by using the dose conversion factors given for a newborn infant by Stabin (Ref. 3).

2.3 Content of Instructions

The instructions should be specific to the type of treatment given, such as permanent implants or radioiodine for hyperthyroidism or thyroid carcinoma, and they may include additional information for individual situations. However, the instructions should not interfere with or contradict the best medical judgment of physicians. The instructions may include the name of a knowledgeable person to contact and that person's telephone number in case the patient has any questions. Additional instructions appropriate for each modality, as shown in examples below, may be provided.

Table 1 – Activities and Dose Rates for Authorizing Patient Release

Radionuclide	Activity at or below which patients may be released		Dose rate at 1 meter, at or below which patients may be released	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	19	520	0.08	8
Au-198	3.5	93	0.21	21
Cr-51	4.8	130	0.02	2
Cu-64	8.4	230	0.27	27
Cu-67	14	390	0.22	22
Ga-67	8.7	240	0.18	18
I-123	6.0	160	0.26	26
I-125	0.25	7	0.01	1
I-125 implant	0.33	9	0.01	1
I-131	1.2	33	0.07	7
In-111	2.4	64	0.2	20
Ir-192	0.074	2	0.008	0.8
P-32	**	**	**	**
Pd-103 implant	1.5	40	0.03	3
Re-186	28	770	0.15	15
Re-188	29	790	0.20	20
Sc-47	11	310	0.17	17
Se-75	0.089	2	0.005	0.5
Sm-153	26	700	0.3	30
$Sn\text{-}117^{m}$	1.1	29	0.04	4
Sr-89	**	**	**	**
$Tc\text{-}99^{m}$	28	760	0.58	58
Tl-201	16	430	0.19	19
Y-90	**	**	**	**
Yb-169	0.37	10	0.02	2

* If the release is based on the dose rate at 1 meter in Column 2, the licensee must maintain a record because the measurement includes shielding by tissue.

** Activity and dose rate limits are not applicable in this case because of the minimal exposure to members of he public resulting from activities normally administered for diagnostic or therapeutic purposes.

NOTES: The millicurie values were calculated using Equations 2 or 3 and the physical half-life. The gigabecquerel values were calculated based on the millicurie values and the conversion factor from millicuries to Gigabecquerels. The dose rate values are calculated based on the millicurie values and the exposure rate constants.

In general, the values are rounded to two significant figures. However, less than 10 millicuries (0.37 Gigabecquerel) or 10 millirems (0.1 millisievert) per hour are rounded to one significant figure.

2.3.1 Instructions Regarding Radiopharmaceutical Administrations

For procedures involving radiopharmaceuticals, additional instructions may include the following:

- Maintaining distance from other persons, including separate sleeping arrangements.
- Minimizing time in public places (e.g., public transportation, grocery stores, shopping centers, theaters, restaurants, sporting events).
- Precautions to reduce the spread of radioactive contamination.

The length of time each of the precautions should be in effect.

The Society of Nuclear Medicine published a pamphlet in 1987 that provides information for patients receiving treatment with radioiodine (Ref. 4). This pamphlet was prepared jointly by the Society of Nuclear Medicine and the US Nuclear Regulatory Commission. The pamphlet contains spaces for the physician to fill in the length of time that each instruction should be followed. While this pamphlet was written for the release of patients to whom less than 30 millicuries (1,110 Megabecquerels) of Iodine-131 had been administered, MDH still considers the instructions in this pamphlet to be an acceptable method for meeting the requirements of 4731.4442 provided the times filled in the blanks are appropriate for the activity and the medical condition.

If additional instructions are required because the patient is breast-feeding, the instructions should include appropriate recommendations on whether to interrupt breast-feeding, the length of time to interrupt breast-feeding, or, if necessary, the discontinuation of breast-feeding. The instructions should include information on the consequences of failure to follow the recommendation to interrupt or discontinue breast-feeding. The consequences should be explained so that the patient will understand that, in some cases, breast-feeding after an administration of certain radionuclides should be avoided. For example, if breast-feeding is continued after procedures involving Iodine-131, the child's thyroid could be harmed. Most diagnostic procedures involve radionuclides other than radioiodine and there would be no consequences; guidance should simply address avoiding any unnecessary radiation exposure to the child from breast-feeding. If the Society of Nuclear Medicine's pamphlet is given at release to a patient who is breast-feeding a child, the pamphlet should be supplemented with guidance on the interruption or discontinuation of breast-feeding and information on consequences of failure to follow the guidance.

The requirement for written instructions to patients who could be breast-feeding does not in any way interfere with the discretion and judgment of the physician in specifying the detailed instructions and recommendations.

2.3.2 Instructions Regarding Permanent Implants

For patients who have received permanent implants, additional instructions may include the following:

> A small radioactive source has been placed (implanted) inside your body. The source is actually many small metallic pellets or seeds, which are each about 1/3 to 1/4 of an inch long, similar in size and shape to a grain of rice. To minimize exposure to radiation to others from the source inside your body, you should do the following for _____days.
>
> - Stay at a distance of _____ feet from _____.
> - Maintain separate sleeping arrangements.
> - Minimize time with children and pregnant women.
> - Do not hold or cuddle children.
> - Avoid public transportation.
> - Examine any bandages or linens that come into contact with the implant site for any pellets or seeds that may have come out of the implant site.
> - If you find a seed or pellet that falls out:
>   - Do not handle it with your fingers.
>   - Use something like a spoon or tweezers to place it in another container that you can close

with a lid.
- Place the container with the seed or pellet in a location away from people.
- Notify one of the persons listed in this instruction.

3. RECORDS

3.1 Records of Release

There is no requirement for record keeping on the release of patients who were released in accordance with Column 1 of Table 1. However, if the release of the patient is based on a dose calculation that considered one of the following, a record of the basis for the release is required.

- retained activity
- an occupancy factor less than 0.25 at 1 meter
- effective half-life
- shielding by tissue

This record should include the patient identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radioactive material administered, the administered activity, and the date of the administration. In addition, depending on the basis for release, records should include the following information.

(1) **For Immediate Release of a Patient Based on a Patient-Specific Calculation:** The equation used, including the patient-specific factors and their bases that were used in calculating the dose to the person exposed to the patient, and the calculated dose. The patient-specific factors (see Appendix B of this guide) include the effective half-life and uptake fraction for each component of the bio-kinetic model, the time that the physical half-life was assumed to apply to retention, and the occupancy factor. The basis for selecting each of these values should be included in the record.

(2) **For Immediate Release of a Patient Based on Measured Dose Rate:** The results of the measurement, the specific survey instrument used, and the name of the individual performing the survey.

(3) **For Delayed Release of a Patient Based on Radioactive Decay Calculation:** The time of the administration, date and time of release, and the results of the decay calculation.

(4) **For Delayed Release of a Patient Based on Measured Dose Rate:** The results of the survey meter measurement, the specific survey instrument used, and the name of the individual performing the survey.

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

Radionuclide	Activity above which instructions are required		Dose rate at 1 meter above which instructions are required	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	3.8	100	0.02	2
Au-198	0.69	19	0.04	4
Cr-51	0.96	26	0.004	0.4
Cu-64	1.7	45	0.05	5
Cu-67	2.9	77	0.04	4
Ga-67	1.7	47	0.04	4
I-123	1.2	33	0.05	5
I-125	0.05	1	0.002	0.2
I-125 implant	0.074	2	0.002	0.2
I-131	0.24	7	0.02	2
In-111	0.47	13	0.04	4
Ir-192	0.011	0.3	0.002	0.2
P-32	**	**	**	**
Pd-103 implant	0.3	8	0.007	0.7
Re-186	5.7	150	0.03	3
Re-188	5.8	160	0.04	4
Sc-47	2.3	62	0.03	3
Se-75	0.018	0.5	0.001	0.1
Sm-153	5.2	140	0.06	6
Sn-117^{m}	0.21	6	0.009	0.9
Sr-89	**	**	**	**
Tc-99^{m}	5.6	150	0.12	12
Tl-201	3.1	85	0.04	4
Y-90	**	**	**	**
Yb-169	0.073	2	0.004	0.4

* The activity values were computed based on 0.1 rem (1 millisievert) total effective dose equivalent.

** Activity and dose rate limits are not applicable in this case because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic purposes.

NOTES: The millicurie values were calculated using Equations 2 or 3 and the physical half-life. The gigabecquerel values were calculated based on millicurie values and the conversion factor from millicuries to gigabecquerels. The dose rate values were calculated based on millicurie values and exposure rate constants.

In general, values are rounded to two significant figures. However, values less than 10 millicuries (0.37 gigabecquerel) or 10 millirems (0.1 millisievert) per hour are rounded to one significant figure. Details of the calculations are provided in NUREG-1492 (Ref.2).

Table 3 – Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breast-Feeding

Radiopharmaceutical	Activity Above Which Instructions Are Required		Activity Above Which a Record Is Required		Examples of Recommended Duration of Interruption of Breast-Feeding*
	(MBq)	(mCi)	(MBq)	(mCi)	
I-131 NaI	0.01	0.0004	0.07	0.002	Complete cessation (for this child)
I-123 NaI	20	0.5	100	3	
I-123 OIH	100	4	700	20	
I-123 mIBG	70	2	400	10	24 hr for 10 mCi (370 MBq) 12 hr for 4mCi (150 MBq)
I-125 OIH	3	0.08	10	0.4	
I-131 OIH	10	0.30	60	1.5	
Tc-99^m DTPA	1,000	30	6,000	150	
Tc-99^m Pertechnetate	50	1.3	200	6.5	12.6 hr for 30 mCi (150 MBq)
Tc-99^m Pertechnetate	100	3	600	15	24 hr for 30 mCi (1,100 MBq) 12 hr for 12mCi (440 MBq)
Tc-99^m DISIDA	1,000	30	6,000	150	
Tc-99^m Glucoheptonate	1,000	30	6,000	170	
Tc-99^m HAM	400	10	2,000	50	
Tc-99^m MIBI	1,000	30	6,000	150	
Tc-99^m MDP	1,000	30	6,000	150	
Tc-99^m PYP	900	25	4,000	120	
Tc-99^m Red Blood Cell in Vitro Labeling	400	10	2,000	50	6 hr for 20 mCi (740 MBq)
Tc-99^m Red Blood Cell in Vitro Labeling	1,000	30	6,000	150	
Tc-99^m Sulfur Colloid	300	7	1,000	35	6 hr for 12mCi (440 MBq)
Tc-99^m DTPA Aerosol	1,000	30	6,000	150	
Tc-99 MAG3	1,000	30	6,000	150	
Tc-99^m White Blood Cells	100	4	600	15	24 hr for 5mCi (1,100 MBq) 12 hr for 2mCi (440 MBq)

Table 3 (continued)

Radiopharmaceutical	Activity Above Which Instructions Are Required		Activity Above Which a Record Is Required		Examples of Recommended Duration of Interruption of Breast-Feeding*
	(MBq)	(mCi)	(MBq)	(mCi)	
Ga-67 Citrate	1	0.04	7	0.2	1 month for 4mCi (150 MBq) 2 weeks for 1.3 mCi (50 MBq) 1 week for 0.2 mCi (7 MBq)
Cr-51 EDTA	60	1.6	300	8	
In-111 White Blood Cells	10	0.2	40	1	1 week for 0.5 mCi (20 MBq)
Tl-201 Chloride	40	1	200	5	2 weeks for 3 mCi (110 MBq)

* The duration of interruption of breast-feeding is selected to reduce the maximum dose to a newborn infant to less than 0.1 rem (1 millisievert), although the regulatory limit is 0.5 rem (5 mSv). The actual doses that would be received by most infants would be far below 0.1 rem (1 millisievert). Of course, the physician may use discretion in the recommendation, increasing or decreasing the duration of interruption.

NOTES: Activities are rounded to one significant figure, except when it was considered appropriate to use two significant figures. Details of the calculations are shown in NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (Ref. 2).

If there is no recommendation in Column 3 of this table, the maximum activity normally administered is below the activities that require instructions on interpretation or disconnection of breast-feeding.

In some situations, a calculation may be case specific for a class of patients who all have the same patient-specific factors. In this case, the record for a particular patient's release may reference the calculation for the class of patients.

Records should be kept in a manner that ensures the patient's confidentiality, that is, the records should not contain the patient's name or any other information that could lead to identification of the patient. These record-keeping requirements may also be used to verify that licensees have proper procedures in place for assessing potential third-party exposure associated with and arising from exposure to patients administered radioactive material.

3.2 Records of Instructions for Breast-Feeding Patients

If failure to interrupt or discontinue breast-feeding could result in a dose to the child more than 0.5 rem (5 mSv), records that instructions were provided is required. Column 2 of Table 3 states, for the radiopharmaceuticals commonly used in medical diagnosis and treatment, the activities that would require such records when administered to patients who are breast-feeding.

The record should include the patient's identifier (in a way that ensures that confidential patient information is not traceable or attributable to a specific patient), the radiopharmaceutical administered, the administered activity, the date of the administration, and whether instructions were provided to the patient who could be breast-feeding.

4. Summary Table

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

D. IMPLEMENTATION

The purpose of this section is to provide information to licensees and applicants regarding the MDH's plans for using this regulatory guide. Except in those cases in which a licensee proposes an acceptable alternative method for complying with 4731.4427, the methods described in this guide will be used in the evaluation of a licensee's compliance.

Table 4 – Summary of Released Criteria, Required Instructions to Patients, and Records to be Maintained

PATIENT GROUP	BASIS FOR RELEASE	CRITERIA FOR RELEASE	INSTRUCTIONS NEEDED?	RELEASE RECORDS REQUIRED?
All patients, including patients who are breast-feeding	Administered activity	Administered activity ≤ Column 1 of Table 1	Yes - Administered activity > Column 1 of Table 2	No
	Retained activity	Retained activity ≤ Column 1 of Table 1	Yes - if retained activity > Column 1 of Table 2	Yes
	Measured dose rate	Measured dose rate ≤ Column 2 of Table 1	Yes - if dose rate > Column 2 of Table 2	Yes
	Patient-specific calculations	Calculated dose ≤ 5 mSv (0.5 rem)	Yes - if calculated dose > 1 mSv (0.1 rem)	Yes
Patients who are breast feeding	All the above bases for release		Additional instructions required if: Administered activity > Column 1 of Table 3 or Licensee calculated dose from breast-feeding > 1 mSv (0.1 rem) to the child	Records that instructions were provided are required if: Administered activity > Column 2 of Table 3 or Licensee calculated dose from continued breast-feeding > 5 mSv (0.5 rem) to the child

REFERENCES

National Council on Radiation Protection and Measurements (NCRP), (1970). Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides. NCRP Report No. 37, October 1, 1970. Available for sale from the NCRP, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814-3095.

Nuclear Regulatory Commission (February 1997). Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material. (NUREG 1492 [Final Report]).

Society of Nuclear Medicine. (1987). Guidelines for Patients Receiving Radioiodine Treatment. [Brochure]. New York, NY. This pamphlet may be obtained from the Society of Nuclear Medicine, 136 Madison Avenue, New York, NY 10016-6760.

Stabin, M. (1995). Internal Dosimetry in Pediatric Nuclear Medicine. In Treves, S. (Ed.), Pediatric Nuclear Medicine. New York: Springer Verlag.

APPENDIX A

Table A-1 – Half-lives and Exposure Rate Constants of Radionuclides Used in Medicine

Radionuclides[1]	Half-life (Days)[2]	Exposure Rate Constant[3] (R/mCi-h at 1 cm)	Radionuclide[1]	Half-life (Days)[2]	Exposure Rate Constant[3] (R/mCi-h at I cm)
Ag-111	7.45	0.150	Pd-103 implant	16.96	0.86[5]
Au-198	2.696	2.3	Re-186	3.777	0.2
Cr-51	27.704	0.16	Re-188	0.708	0.26
Cu-64	0.529	1.2	Sc-47	3.351	0.56
Cu-67	2.578	0.58	Se-75	119.8	2.0
Ga-67	3.261	0.753	Sm-153	1.946	0.425
I-123	0.55	1.61	Sn-117^m	13.61	1.48
I-125	60.14	1.42	Sr-89	50.5	NA[6]
I-125 implant	60.14	1.11[4]	Tc-99^m	0.251	0.756
I-131	8.04	2.2	Tl-201	3.044	0.447
In-111	2.83	3.21	Y-90	2.67	NA[6]
Ir-192 implant	74.02	4.59[4]	Yb-I69	32.01	1.83
P-32	14.29	NA[6]			

1 Although non-by-product materials are not regulated by MDH, information on non-byproduct material is included in this regulatory guide for the convenience of the licensee.

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

3 Values for the exposure rate constant for Au-198, Cr-51, Cu-64, I-131, Sc-47, and Se-75 were taken from the Radiological Health Handbook, U.S. Department of Health, Education and Welfare, pg. 135, 1970. For Cu-67, I-123, In-111, Re-186, and Re-188, the values for the exposure rate constant were taken from D.E. Barber, J.W. Baum, and C.B. Meinhold, "Radiation Safety Issues Related to Radio-labeled Antibodies," NUREG/CR-4444, USNRC, Washington, DC, 1991. For Ag-111, Ga-67, I-125, Sm-153, Sn-117m, Tc-99m, Tl-201, and Yb-169, the exposure rate constants were calculated because the published values for these radionuclides were an approximation, presented as a range, or varied from one reference to another. Details of the calculations of the exposure rate constants are shown in Table A.2 of Appendix A of NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," USNRC, February 1997.

4 R. Nath, A.S. Meigooni, and A.J. Meli, "Dosimetry on Traverse Axis of ^{125}I and ^{192}Ir Interstitial Brachytherapy Sources," Medical Physics, Volume 17, Number 6, November/December 1990. The exposure rate constant given is a measured value averaged for several source models and takes into account the attenuation of gamma rays within the implant capsule itself.

5 A.S. Meigonni, S. Sabnis, R. Nath, "Dosimetry of Palladium-103 Brachytherapy Sources for Permanent Implants," Endocurietherapy Hyperthemia Oncology, Volume 6, April 1990. The exposure rate constant given is the apparent value (i.e., with respect to the apparent source activity) and takes into account the attenuation of the gamma rays within the implant capsule itself.

6 Not applicable (NA) because the release activity is not based on beta emissions.

APPENDIX B
PROCEDURES FOR CALCULATING DOSES BASED ON PATIENT-SPECIFIC FACTORS

A licensee may release a patient who has been administered an activity higher than the values listed in Column 1 of table 1 of this regulatory guide if dose calculations using patient-specific parameters, which are less conservative than the conservative assumptions, show that the potential total effective dose equivalent to any individual would be no greater than 0.5 rem (5 mSv).

If the release of a patient is based on a patient specific calculation that considered retained activity, an occupancy factor less than 0.25 at 1 meter, effective half-life, or shielding by tissue, a record of the basis of the release is required.

The following equation can be used to calculate doses:

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

Where:

D(t) = Accumulated exposure at time t (in roentgens)

34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44)

Γ = Specific gamma ray constant for a point source, R/mCi-hr at 1 cm

Q_o = Initial activity of the point source in millicuries, at the time of the release

T_p = Physical half-life in days

r = Distance from the point source to the point of interest in centimeters

t = Exposure time in days

B.1 OCCUPANCY FACTOR

B.1.1 Rationale for Occupancy Factors Used To Derive Table 1

In Table 1 of this regulatory guide, the activities at which patients could be released were calculated using the physical half-life of the radionuclide and an occupancy factor at 1 meter of either 0.25 (if the radionuclide has a half-life longer than 1 day) or 1.0 (if the radionuclide has a half-life less than or equal to 1 day). The basis for the occupancy factor of 0.25 at 1 meter is that measurements of doses to family members as well as considerations of normal human behavior (as discussed in the supporting regulatory analysis (Ref. B-1)) suggest that an occupancy factor of 0.25 at 1 meter, when used in combination with the physical half-life, will produce a generally conservative estimate of the dose to family members when instructions on minimizing doses to others are given.

An occupancy factor of 0.25 at 1 meter is not considered appropriate when the physical half-life is less than or equal to 1 day, and hence, the dose is delivered over a short time. Specifically, the assumptions regarding patient behavior that led to an occupancy factor of 0.25 at 1 meter include the assumption that the patient will not be in close proximity to other individuals for several days. However, when the dose is from a short lived radionuclide, the time that individuals spend in close proximity to the patient immediately following release will be most significant because the dose to other individuals could be a large fraction of the total dose from the short-lived radionuclide. Thus, to be conservative when providing generally applicable release quantities that may be used with little consideration of the specific details of a particular patient's release, the values calculated in Table 1 were based on an occupancy factor of 1 at 1 meter when the half-life is less than or equal to 1 day.

B.1.2 Occupancy Factors To Consider for Patient Specific Calculations

The selection of an occupancy factor for patient specific calculations will depend on whether the physical or effective half-life of the radionuclide is used and whether instructions are provided to the patient before release. The following occupancy factors, E, at I meter, may be used for patient-specific calculations.

- E = 0.75 when a physical half-life, an effective half-life, or a specific time period under consideration (e.g., bladder holding time) is less than or equal to 1 day.
- E = 0.25 when an effective half-life is greater than 1 day if the patient has been given instructions, such as
  - Maintain a prudent distance from others for at least the first 2 days.
  - Sleep alone in a room for at least the first night.
  - Do not travel by airplane or mass transportation for at least the first day.
  - Do not travel on a prolonged automobile trip with others for at least the first 2 days.
  - Have sole use of a bathroom for at least the first 2 days.
  - Drink plenty of fluids for at least the first 2 days.
- E = 0.125 when an effective half-life is greater than one day if the patient has been given instructions, such as
  - Follow the instructions for E = 0.25 above.
  - Live alone for at least the first two days.
  - Have few visits by family or friends for at least the first two days.
- In a two-component model (e.g., uptake of Iodine-131 using thyroidal and extra-thyroidal components), if the effective half-life associated with one component is less than or equal to one day but is greater than one day for the other component, it is more justifiable to use the occupancy factor associated with the dominant component for both components.

Example 1: Calculate the maximum likely dose to an individual exposed to a patient who has received 60 millicuries (2,220 Megabecquerels) of Iodine-131 The patient has been provided with instructions to maintain a prudent distance from others for at least 2 days, lives alone, drives home alone, and stays at home for several days without visitors.

Solution: The dose to total decay (t = 8) is calculated based on the physical half-life using Equation B-1. (This calculation illustrates the use of physical half-life. To account for biological elimination, calculations described in the next section should be used.)

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

Since the patient has been provided with instructions for reducing exposure as recommended for an occupancy factor of E = 0.125, the occupancy factor of 0.125, at 1 meter may be used.

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

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

Since the dose is less than 0.5 rem (5 mSv), the patient may be released, instructions must be given to the patient on maintaining doses to others as low as is reasonably achievable. A record of the calculation must be maintained because an occupancy factor less than 0.25 at 1meter was used.

B.2 EFFECTIVE HALF-LIFE

A licensee may take into account the effective half-life of the radioactive material to demonstrate compliance with the dose limits for individuals exposed to the patient that are stated in 4731.4427. The effective half-life is defined as:

$$T_{eff} = \frac{T_b \times T_p}{T_b + T_p} \qquad \text{(Equation B-2)}$$

Where

T_b = biological half-life of the radionuclide

T_p = physical half-life of the radionuclide.

The behavior of Iodine-131 can be modeled using two components: extra-thyroidal iodide (i.e., existing outside of the thyroid) and thyroidal iodide following uptake by the thyroid. The effective half-lives for the extra-thyroidal and thyroidal fractions (i.e., F_1 and F_2, respectively) can be calculated with the following equations.

$$T_{1eff} = \frac{T_{b1} \times T_p}{T_{b1} + T_p} \qquad \text{(Equation B-3)}$$

$$T_{2eff} = \frac{T_{b2} \times T_p}{T_{b2} + T_p} \qquad \text{(Equation B-4)}$$

Where:

T_{bl} = biological half-life for extra-thyroidal iodide

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

T_p = physical half-life of Iodine-131.

However, simple exponential excretion models do not account for (a) the time for the Iodine-131 to be absorbed from the stomach to the blood and (b) the holdup of iodine in the urine while in the bladder. Failure to account for these factors could result in an underestimate of the dose to another individual. Therefore, this guide makes a conservative approximation to account for these factors by assuming that, during the first 8 hours after the administration, about 80 percent of the Iodine-131 administered is removed from the body at a rate determined only by the physical half-life of Iodine-131.

Thus, an equation to calculate the dose from a patient administered Iodine-131 may have three components. The first component is the dose for the first 8 hours (0.33-days) after administration. This component comes directly from Equation B-1 using the physical half-life and a factor of 80 percent. The second component is the dose from the extra-thyroidal component from 8 hours to total decay. In this component, the first exponential factor represents the activity at t = 8 hours based on the physical half-life of Iodine-131. The second exponential factor represents the activity from t = 8 hours to total decay based on the effective half-life of the extra-thyroidal component. The third component, the dose from the thyroidal component for 8 hours to total decay, is calculated in the same manner as the second component. The full equation is shown as Equation B-5.

$$D(\infty) = \frac{34.6\,\Gamma\,Q_0}{(100\text{ cm})^2} \{E_1\ T_p\ (O.8)\ (1 - e^{-0.693.(0.33)/Tp})$$

(Equation B-5)

$$+e^{-0.693(0.33)/Tp} E_2 F_1 T_{1eff} + e^{-0.693(0.33)/Tp} E_2 F_2 T_{2eff}\}$$

F_1 = Extra-thyroidal uptake fraction

F_2 = Thyroidal uptake fraction

E_1 = Occupancy factor from 8 hours

E_2 = Occupancy factor from 8 hours to total decay

All the other parameters are as defined in Equations B-1, B-3, and B-4. Acceptable values for F_1, T_{1eff}, F_2, and T_{2eff} are shown in Table B-1 for thyroid ablation and treatment of thyroid remnants after surgical removal of the thyroid for thyroid cancer. If these values have been measured for a specific individual, the measured values may be used.

The record of the patient's release is described in Regulatory Position 3.1 of this guide.

Example 2: Thyroid Cancer: Calculate the maximum likely dose to an individual exposed to a patient who has been administered 200 millicuries (7,400 Megabecquerels) of Iodine-131 for the treatment of thyroid remnants and metastases.

Solution: In this example, we will calculate the dose by using Equation B-5 to account for the elimination of Iodine-131 from the body, based on the effective half-lives appropriate for thyroid cancer. The physical half-life and the exposure rate constant are from Table A-1. The uptake fractions and effective half-lives are from Table B-1. An occupancy factor, E, of 0.75 at 1 meter will be used for the first component because the time period under consideration is less than 1 day. However, for the second and third components, an occupancy factor of 0.25 will be used because (1) the effective half-life associated with the dominant component is greater than I day and (2) patient-specific questions were provided to the patient to justify the occupancy factor (see Section B.1.2, "Occupancy Factors To Consider for Patient-Specific Calculations," of this Appendix B).

Substituting the appropriate values into Equation B-5, the dose to total decay is

$$D(\infty) = \frac{34.6(2.2)(200)}{(100cm)^2}\{(0.75)(8.04)(0.8)(1-e^{-0.693(0.33)/8.04})$$

$$+e^{-0.693(0.33)/8.04}(0.25)(0.95)(0.32)$$

$$+e^{-0.693(0.33)/8.04}(0.25)(0.05)(7.3)\}$$

$D(\infty)$ = 0.453 rem (4.53 mSv)

Therefore, thyroid cancer patients administered 200 millicuries (7,400 megabecquerels) of Iodine-131 or less would not have to remain under licensee control and could be released under 4731.4427, assuming that the foregoing assumptions can be justified for the individual patient's case and that the patient is given instructions. Patients administered somewhat larger activities could also be released immediately if the dose is not greater than 0.5 rem (5 mSv).

In the example above, the thyroidal fraction, $F_2 = 0.05$, is a conservative assumption for persons who have had surgery to remove thyroidal tissue. If F_2 has been measured for a specific patient, the measured value may be used.

Example 3: Hyperthyroidism: Calculate the maximum likely dose to an individual exposed to a patient who has been administered 55 millicuries (2,035 Megabecquerels) of Iodine-131 for the treatment of hyperthyroidism (i.e., thyroid ablation).

Solution: In this example, we will again calculate the dose using Equation B-5, Table A-1, and Table B-1 to account for the elimination of Iodine-131 from the body by using the effective half-lives appropriate for hyperthyroidism. An occupancy factor, E, of 0.25 at 1 meter will be used for the second and third components of the equation because patient-specific instructions were provided to justify the occupancy factor (see Section B.1.2, "Occupancy Factors To Consider for Patient-Specific Calculations").

Substituting the appropriate values into Equation B-5, the dose to total decay is

$$D(\infty) = \frac{34.6(2.2)(55)}{(100\text{cm})^2}\{(0.75)(8.04)(0.8)(1-e^{-0.693(0.33)/8.04}\}$$

$$+e^{-0.693(0.33)/8.04}(0.25)(0.20)(0.32)$$

$$+e^{-0.693(0.33)/8.04}(0.25)(0.80)(5.2)\}$$

$$D(\infty) = 0.486 \text{ rem (4.86 mSv)}$$

Therefore, hyperthyroid patients administered 55 millicuries (2,035 Megabecquerels) of Iodine-131 would not have to remain under licensee control and could be released when the occupancy factor of 0.25 in the second and third components of the equation is justified.

In the example above, the thyroidal fraction, $F_2 = 0.8$, is a conservative assumption for persons who have this treatment for hyperthyroidism. If F_2 has been measured for a specific patient, the measured value may be used.

Table B-1 – Uptake Fractions and Effective Half-Lives for Iodine-131 Treatments

Medical Condition	Extra-thyroidal Component		Thyroidal Component	
	Uptake Fraction F_1	Effective Half-Life T_{1eff} (day)	Uptake Fraction F_2	Effective half-life T_{2eff} (day)
Hyperthyroidism	0.20[1]	0.32[2]	0.80[1]	5.2[1]
Post Thyroidectomy for Thyroid Cancer	0.95[3]	0.32[2]	0.05[3]	7.3[2]

[1] M.G. Stabin et al., "Radiation.. Dosimetry for the Adult Female and Fetus from Iodine-131 Administration in Hyperthyroidism," Journal of Nuclear Medicine, Volume 32, Number 5, May 1991. The thyroid uptake fraction of 0.90 was selected as one that is seldom exceeded by the data shown in Figure 1 in this reference document. The effective half-life of 5.2 days for the thyroid component was derived from a biological half-life of 15 days, which was obtained from a straight-line fit that accounts for about 75 percent of the data points shown in Figure 1 of this Journal of Nuclear Medicine document.

[2] International Commission on Radiological Protection (ICRP), "Radiation Dose to Patients from Radiopharmaceuticals," ICRP Publication No. 53, March 1987. (Available for sale from Pergamon Press, Inc., Elmsford, NY 10523.) The data in this ICRP document suggest that the extra-thyroidal component effective half-life in normal subjects is about 0.32 days. Lacking other data, this value is applied to hyperthyroid cancer patients. For thyroid cancer, the thyroidal component effective half-life of 7.3 days is based on a biological half-life of 80 days (adult thyroid) as suggested in this ICRP document.

[3] The thyroidal uptake fraction of 0.05 was recommended by Dr. M. Pollycove, MD, NRC medical visiting fellow, as an upper limit post Thyroidectomy for thyroid cancer.

B.3 INTERNAL DOSE

For some radionuclides, such as Iodine-131, there may be concerns that the internal dose of an individual from exposure to a released patient could be significant. A rough estimate of the maximum likely committed effective dose equivalent from internal exposure can be calculated from Equation B-6.

$$D_i = Q\,(10^{-5})(DCF) \qquad \text{(Equation B-6)}$$

Where:

D_i = Maximum likely internal committed effective dose equivalent to the individual exposed to the patient in rems

Q = Activity administered to the patient in millicuries

10^{-5} = Assumed fractional intake

DCF = Dose conversion factor to convert an intake in millicuries to an internal committed effective dose equivalent (such as tabulated in Reference B-2).

Equation B-6 uses a value of 10^{-5} as the fraction of the activity administered to the patient that would be taken in by the individual exposed to the patient. A common rule of thumb is to assume that no more than one millionth of the activity being handled will become an intake to an individual working with the material. This guideline was developed in Reference B-3 for cases of worker intakes during normal workplace

operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases from a facility, but it does not specifically apply for cases of intake by an individual exposed to a patient. However, two studies (Refs. B-4 and B-5) regarding the intakes of individuals exposed to patients administered Iodine-131 indicated that intakes were generally of the order of 1 millionth of the activity administered to the patient and that internal doses were far below external doses. To account for the most highly exposed individual and to add a degree of conservatism to the calculations, a fractional transfer of 10^{-5} has been assumed.

Example 4, Internal Dose: Using the ingestion pathway, calculate the maximum internal dose to a person exposed to a patient who has been administered 33 millicuries (1,110 Megabecquerels) of Iodine-131. The ingestion pathway was selected since it is likely that most of the intake would be through the mouth or through the skin, which is most closely approximated by the ingestion pathway.

Solution: This is an example of the use of Equation B-6. The dose conversion factor DCF for the ingestion pathway is 53 rems/millicurie from Table 2.2 of Reference B-2.

Substituting the appropriate values into Equation B-6, the maximum internal dose to the person is

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

$$D_i = 0.017 \text{ rem } (0.17 \text{ mSv})$$

In this case, the external dose to the other person would be no greater than 0.5 rem (5 mSv), while the internal dose would be about 0.017 rem (0.17 millisievert). Thus, the internal dose is about 3 percent of the external gamma dose. Internal doses may be ignored in the calculations if they are likely to be less than 10 percent of the external dose since the internal dose would be significantly less than the uncertainty in the external dose.

The conclusion that internal contamination is relatively unimportant in the case of patient release was also reached by the NCRP. The NCRP addressed the risk of intake of radionuclides from patients' secretions and excreta in NCRP Commentary No. 11, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients" (Ref. B-6). The NCRP concluded, "Thus, a contamination incident that could lead to a significant intake of radioactive material is very unlikely." For additional discussion on the subject, see Reference B-1.

REFERENCES FOR APPENDIX B

Brodsky, A. (1980). Resuspension Factors and Probabilities of Intake of Material in Process (or 'Is 10^{-6} a Magic Number in Health Physics?'). Health Physics, 39, 6.

Buchanan, R.C.T. & Brindle, J.M. (1970) Radioiodine Therapy to Out-patients-The Contamination Hazard. British Journal of Radiology, 43.

Eckerman, K.F., Wolbarst, A.B., & Richardson, A.C.B. (1988). Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion. Federal Guidance Report No. 11. Washington, D.C.: U.S. Environmental Protection Agency.

Jacobson, A.P., Plato, P.A., & Toeroek, D. (1978) Contamination of the Home Environment by Patients Treated with Iodine-131. American Journal of Public Health, 68, 3.

National Council on Radiation Protection and Measurements (February 28, 1995). Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients, Commentary No. 11.

Nuclear Regulatory Commission (February 1997). Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material. (NUREG 1492 [Final Report]).

APPENDIX C
BIOASSAY REQUIREMENTS FOR MEDICAL PERSONNEL WHO ADMINISTER RADIOIODINE TO PATIENTS

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. Because the bioassay requirement for medical personnel is only applicable in the case of administration to hospitalized patients, it may be possible for medical personnel to prepare or administer substantial doses of radiopharmaceuticals without coming under the bioassay requirements in 4731.4442.

Licensees should note that although they may no longer be tied to a bioassay program because of the new patient release criteria, they are still 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 1 year, an intake in excess of the applicable ALI in Table I, Columns 1 and 2, of 4731.2750.

Licensees are required to review the potential exposures of their employees and to monitor them if there is a likelihood that the intake may exceed 10 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.

SUMMARY OF REVISIONS

REVISION	SECTION	DESCRIPTION

MINNESOTA DEPARTMENT OF HEALTH
RADIOACTIVE MATERIALS UNIT

Inspector Fieldwork Evaluation

DATE:

INSPECTOR: MDH EVALUATOR:

LICENSEE: LICENSE NO.:

LOCATION: ☐ ANNOUNCED ☐ UNANNOUNCED

DATE OF INSPECTION: INSPECTION TYPE:

I. PRELIMINARY DISCUSSION WITH INSPECTOR	Done
A. Explain the extent of the reviewer's participation in the inspection.	☐
B. Discuss the procedure for introducing the reviewer to the licensee and explaining his presence during the inspection.	☐
C. Explain the method that will be used for evaluating the inspector's performance.	☐

II. SUMMARY OF EVALUATION

A. Inspector's performance rating:
☐ Meets the Guidelines
☐ Needs Improvement

B. Comments:

C. The inspector would benefit from additional training in:

D. The evaluation was discussed with me.

_____ _____
Inspector's Signature Date

_____ _____
Qualified Inspector Date

III. INSPECTOR'S PREPARATION

A.	Has the inspector reviewed the license and prior compliance history?	☐ NA	☐ Yes	☐ No
B.	Has the inspector planned the inspection?	☐ NA	☐ Yes	☐ No
C.	Does the inspector have the appropriate instruments?	☐ NA	☐ Yes	☐ No
D.	Are the instruments in calibration?	☐ NA	☐ Yes	☐ No
E.	Does the inspector have the necessary supplemental materials? (Regulations, inspection forms, personal dosimetry, ID, wipe materials, smoke tubes & bombs, thermal anemometer, dose calibrator sources, instrument check sources, etc.)	☐ NA	☐ Yes	☐ No

Comments:

IV. OPENING

A.	Was opening interview conducted with management?	☐ NA	☐ Yes	☐ No
B.	Were incidents or overexposures discussed?	☐ NA	☐ Yes	☐ No
C.	Did the licensee understand the purpose, scope and techniques?	☐ NA	☐ Yes	☐ No

Comments:

V. INSPECTION

A.	Did the inspector use appropriate form or checklist?	☐ NA	☐ Yes	☐ No
B.	Did inspector perform "walk through" at beginning of inspection?	☐ NA	☐ Yes	☐ No
C.	Were licensee operations and use and handling of material observed?	☐ NA	☐ Yes	☐ No
D.	Were the facilities checked for proper posting?	☐ NA	☐ Yes	☐ No
E.	Was security verified?	☐ NA	☐ Yes	☐ No
F.	Were workers checked for personal dosimetry?	☐ NA	☐ Yes	☐ No
G.	Were workers interviewed to verify their understanding of safety procedures?	☐ NA	☐ Yes	☐ No
H.	Were ancillary workers also interviewed?	☐ NA	☐ Yes	☐ No
I.	Were adequate wipes, surveys, measurements taken?	☐ NA	☐ Yes	☐ No
J.	Did inspector check for adherence to ALARA?	☐ NA	☐ Yes	☐ No
K.	Were records verified against oral statements for:			
	(1) procurement and inventory?	☐ NA	☐ Yes	☐ No
	(2) receipt and transfer of material?	☐ NA	☐ Yes	☐ No
	(3) internal audits?	☐ NA	☐ Yes	☐ No
	(4) qualification and training of users?	☐ NA	☐ Yes	☐ No
	(5) emergency plan/procedures?	☐ NA	☐ Yes	☐ No
	(6) committee meetings, minutes?	☐ NA	☐ Yes	☐ No
	(7) authorized users?	☐ NA	☐ Yes	☐ No
	(8) instrument calibration?	☐ NA	☐ Yes	☐ No
	(9) dose calibrator tests?	☐ NA	☐ Yes	☐ No
	(10) surveys and monitoring?	☐ NA	☐ Yes	☐ No
	(11) personnel dosimetry, bioassay?	☐ NA	☐ Yes	☐ No
	(12) leak tests?	☐ NA	☐ Yes	☐ No
	(13) generator-assay, moly breakthrough, logs?	☐ NA	☐ Yes	☐ No
	(14) release of effluents, sewer & air?	☐ NA	☐ Yes	☐ No
	(15) management, disposal?	☐ NA	☐ Yes	☐ No

Comments:

L.. Did the inspector safely handle radioactive material? ☐ NA ☐ Yes ☐ No

M. Did the inspector address all necessary elements of the licensee's program? ☐ NA ☐ Yes ☐ No
If not, explain:

N. Were hazards or potential problems discovered and followed up? ☐ NA ☐ Yes ☐ No
If not, explain:

Comments:

VI. CLOSING

A. Was there careful assembly of supporting information prior to exit interview? ☐ NA ☐ Yes ☐ No

B. Did the inspector close with appropriate level of management, or make every effort to do so? ☐ NA ☐ Yes ☐ No

C. Were recommendations clearly distinguished from items of noncompliance? ☐ NA ☐ Yes ☐ No

D. Were items of noncompliance fully explained, with regulation or license condition cited? ☐ NA ☐ Yes ☐ No

E. Did the inspector explain what follow-up actions would occur (enforcement letter, etc.)? ☐ NA ☐ Yes ☐ No

F. Was the licensee advised of any requirements? ☐ NA ☐ Yes ☐ No

G. Did the inspector properly decide if certain practices or operations should cease immediately? ☐ NA ☐ Yes ☐ No

H. Were previous items of noncompliance discussed? ☐ NA ☐ Yes ☐ No

Comments:

VII. PROFESSIONALISM

A. Did the inspector use proper judgment in evaluating radiation safety? ☐ NA ☐ Yes ☐ No

B. Did the inspector demonstrate an adequate knowledge of health physics and regulations? ☐ NA ☐ Yes ☐ No

C. Was the inspector's appearance appropriate or the type of licensee? ☐ NA ☐ Yes ☐ No

D. Was rapport with management and workers sufficient for free exchange of information? ☐ NA ☐ Yes ☐ No

E. Were the inspector's questions phrased appropriately? ☐ NA ☐ Yes ☐ No

Comments

VIII. INSPECTION REPORT

A. Did the inspector document all items in the Inspection report? ☐ NA ☐ Yes ☐ No

B. Were all deficiencies addressed? ☐ NA ☐ Yes ☐ No

C. Was the inspection report generated in a timely manner? ☐ NA ☐ Yes ☐ No

Comments

REVIEWED:

Radiation Control Unit Supervisor	Date
Section Manager	Date

MINNESOTA DEPARTMENT OF HEALTH

GAMMA KNIFE INSPECTION REPORT

Date of this inspection:

License No.:

Licensee (Name and Address):

Address letter to:

cc:

Licensee Contact:

Telephone No.:

Last Amendment No.:

Date of Amendment:

Priority: ☐ 2

Category: ☐ 2310

Date of last inspection:

Type of inspection:

☐ Announced ☐ Unannounced

☐ Routine ☐ Special

☐ Initial ☐ Reactive

Summary of findings and action:

☐ No Violation, letter issued
☐ Violation(s), letter issued
☐ Action on previous Violation(s)

Inspector:

☐ Timothy Donakowski
☐ John Goepferd
☐ George F. Johns, Jr.
☐ Sue McClanahan
☐ Craig Verke
☐ Katherine Johnson
☐ Other:

Next inspection date:

Frequency: ☐ Routine ☐ Accelerated

Inspector Signature:	Date:
Approval Signature:	Date:

Revised 6/23/04

INDIVIDUALS INTERVIEWED DURING INSPECTION

	NAME	TITLE
☐		
☐		
☐		
☐		
☐		
☐		
☐		

* Indicates which individuals were at the exit briefing

1. INSPECTION HISTORY: ☐N/A Initial Inspection

A. Last inspection conducted on:

B. Violations were identified. ☐ N/A ☐ Yes ☐ No

C. Response letter dated:

D. Violations identified during previous inspection:

REQUIREMENT	VIOLATION	CORRECTED	STATUS

E. If any violation(s) identified during the last inspection were not corrected, explain.

2. LICENSE CONDITIONS:

A. All license conditions reviewed. ☐ Yes ☐ No

B. Licensed activities were conducted in accordance with License Conditions except as noted elsewhere in this report. ☐ Yes ☐ No

3. ORGANIZATION:

A. Briefly describe the Organization

B. Radiation Safety Officer (RSO)

(1) Appointed. [4731.4405, subp. 1, B] ☐ N/A ☐ Yes ☐ No

(2) Fulfills duties of RSO. [4731.4405, subp. 1, F] ☐ N/A ☐ Yes ☐ No

(3) Has sufficient authority. [4731.4405, subp. 1, G] ☐ N/A ☐ Yes ☐ No

C. Radiation Safety Committee (RSC)

(1) RSC approved use and reviews use at RSC meetings [4731.4405, subp. 1, F] ☐ N/A ☐ Yes ☐ No

(2) Committee reviews use in annual program audit [4731.2010, subp. 3] ☐ N/A ☐ Yes ☐ No

(3) RSC has implemented corrective actions. ☐ N/A ☐ Yes ☐ No

D. Authorized Users - Device used under supervision of an authorized user **(LC)** ☐ N/A ☐ Yes ☐ No

REMARKS:

4. SCOPE OF PROGRAM:

A. Briefly describe scope of program, including types of equipment, uses involving licensed material, frequency of use, etc.

B. Radiation safety program changes. [4731.4405, subp. 2] ☐ N/A ☐ Yes ☐ No

REMARKS:

5. OPERATING AND EMERGENCY PROCEDURES:

A. Procedures are posted. [4731.4466, C & D] ☐ N/A ☐ Yes ☐ No

B. Procedures are as submitted with license. ☐ N/A ☐ Yes ☐ No

C. Device used in accordance with the manufacturer's radiation safety and operating instructions. [4731.4463, A] ☐ N/A ☐ Yes ☐ No

D. At least one individual trained in safe use and emergency procedures is physically present while device in use ☐ N/A ☐ Yes ☐ No

E. Authorized user and either medical physicist or RSO is physically present while device in use **(LC)** ☐ N/A ☐ Yes ☐ No

F. Only patient is in treatment room during device use. [4731.4466. B (2)] ☐ N/A ☐ Yes ☐ No

G. Emergency Actions:

(1) Procedures are located at the console unit [4731.4466, C] ☐ N/A ☐ Yes ☐ No

(2) Procedures contain names and telephone numbers of authorized users and the RSO. [4731.4466, B, 4 c] ☐ N/A ☐ Yes ☐ No

(3) Licensee has responded to emergencies ☐ N/A ☐ Yes ☐ No

If yes, were authorized user and medical physicist or RSO notified ☐ N/A ☐ Yes ☐ No

If yes, was MDH notified [4731.2610] ☐ N/A ☐ Yes ☐ No

(4) Emergency response equipment available [4731.4467, H] ☐ N/A ☐ Yes ☐ No

REMARKS:

6. TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS:

A. Instructions to workers. [4731.1020, subp. 1] ☐ N/A ☐ Yes ☐ No

B. Periodic retraining (interval <12 months) is provided to device operators. [4731.4466, E] ☐ N/A ☐ Yes ☐ No

C. Operator training on proper use of device. [4731.4466, E] ☐ N/A ☐ Yes ☐ No

D. Operators, physicians, and medical physicists have been given emergency training including dry run [4731.4466, F] ☐ N/A ☐ Yes ☐ No

E. Records maintained. [4731.4466, G] ☐ N/A ☐ Yes ☐ No

REMARKS:

7. RADIOLOGICAL PROTECTION PROCEDURES:

A. Radiation Levels in unrestricted areas are within limits [4731.2100, subp. 2] ☐ N/A ☐ Yes ☐ No

B. Radiation levels in unrestricted areas are monitored after source installation or replacement. [4731.4469 or 4731.4471] ☐ N/A ☐ Yes ☐ No

Date of initial source installation or last source exchange:

Date of radiation survey:

C. Personnel monitoring is provided to appropriate individuals [4731.2020, 4731.2070 and 4731.2080] ☐ N/A ☐ Yes ☐ No

REMARKS:

8. PERSONNEL RADIATION MONITORING – EXTERNAL:

A. Film or TLD supplier: Frequency:

B. Supplier NVLAP approved. [4731.2200, subp. 3] ☐ N/A ☐ Yes ☐ No

C. Processor's reports reviewed by:

D. Licensee uses MDH forms or equivalent. [4731.2520, subp. 4] ☐ N/A ☐ Yes ☐ No

E. MDH inspector reviewed personnel monitoring records for period

through

F. Maximum annual whole body dose:

G. Dose(s) exceeded regulatory limits. [4731.2020] ☐ N/A ☐ Yes ☐ No

H. Licensee has implemented an ALARA program. [4731.2010] ☐ N/A ☐ Yes ☐ No

(1) Annual review by radiation safety committee. [4731.4405, subp. 1, F] ☐ N/A ☐ Yes ☐ No

(2) Written description of ALARA program available. [4731.4405] ☐ N/A ☐ Yes ☐ No

REMARKS:

9. NOTIFICATION AND REPORTS:

A. Licensee provides notifications and reports to individuals. [4731.1030] ☐ N/A ☐ Yes ☐ No

B. Licensee in compliance regarding reporting theft or loss. [4731.2600] ☐ N/A ☐ Yes ☐ No

C. Licensee in compliance regarding Overexposures and notification of incidents. [4731.2610] ☐ N/A ☐ Yes ☐ No

D. Licensee in compliance regarding reporting of excessive levels and concentrations. [4731.2620] ☐ N/A ☐ Yes ☐ No

E. Radiation exposure reports furnished at termination, if requested by workers. [4731.1030, subp. 4] ☐ N/A ☐ Yes ☐ No

REMARKS:

10. POSTING AND LABELING:

A. Radiation Areas posted. [4731.2310, subp 1] ☐ N/A ☐ Yes ☐ No

B. High Radiation Areas posted. [4731.2310, subp. 2] ☐ N/A ☐ Yes ☐ No

C. Use or storage areas posted "Caution Radioactive Material." [4731.2310, subp. 5] ☐ N/A ☐ Yes ☐ No

D. Notice to Workers posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

E. Notice to Employees posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

F. Device(s) are properly labeled ☐ N/A ☐ Yes ☐ No

REMARKS:

11. FACILITIES, MATERIALS, AND EQUIPMENT:

A. Facilities described in license application. ☐ N/A ☐ Yes ☐ No

B. Facilities are as described. ☐ N/A ☐ Yes ☐ No

C. Storage and use of radioactive material.

(1) Licensee secures stored radioactive material to prevent unauthorized removal or access. [4731.2290, subp. 1 & 2] ☐ N/A ☐ Yes ☐ No

(2) Licensee controls and maintains surveillance of radioactive material in use to prevent unauthorized removal or access. [4731.2290, subp. 1 & 2] ☐ N/A ☐ Yes ☐ No

12. GENERAL REQUIREMENTS FOR GAMMA STEREOTACTIC RADIOSURGERY UNITS.

A. Dedicated treatment rooms are equipped with continuous viewing and intercom systems. [4731.4467, E] ☐ N/A ☐ Yes ☐ No

B. Electrical interlock systems are installed at each entry. [4731.4467, C] ☐ N/A ☐ Yes ☐ No

C. Once activated, door interlock must be reset. [4731.4467, C, 3] ☐ N/A ☐ Yes ☐ No

D. Back-up system is available to observe patient's during treatment **(LC)** ☐ N/A ☐ Yes ☐ No

If no, are treatments suspended ☐ N/A ☐ Yes ☐ No

E. Has separate backup power supply separate from power supply [4731.4474, subp. 3, A (1)] ☐ N/A ☐ Yes ☐ No

F. Allows only persons approved to be present during treatments [4731.4466, B, (2)] ☐ N/A ☐ Yes ☐ No

G. Prevent more than one radiation producing device in treatment room [4731.4466, B (3)] ☐ N/A ☐ Yes ☐ No

H. Radiation monitor to ensure radiation levels at ambient levels [4731.4467, D] ☐ N/A ☐ Yes ☐ No

I. Emergency response equipment available near treatment room [4731.4467, H] ☐ N/A ☐ Yes ☐ No

J. Calibrated dosimetry system in place [4731.4468, subp. 1] ☐ N/A ☐ Yes ☐ No

K. Locks off console if any safety checks fail [4731.4472, subp. 5] ☐ N/A ☐ Yes ☐ No

L. Written procedures for spot checks established by authorized medical physicist [4731.4472, subp.2] ☐ N/A ☐ Yes ☐ No

M. Spot check results reviewed by authorized medical physicist [4731.4472, subp. 3] ☐ N/A ☐ Yes ☐ No

N. Records maintained [4731.4472, subp. 6] ☐ N/A ☐ Yes ☐ No

REMARKS:

13. DAILY CHECKS PRIOR TO USE FOR GAMMA KNIFE RADIOSURGERY UNITS [4731.4474, SUBP. 1 C]

A. Viewing and intercom systems are checked at the beginning of each day of use [4731.4474, subp. 4, C] ☐ N/A ☐ Yes ☐ No

B. Interlock operation tested daily [4731.4474, subp. 4, A] ☐ N/A ☐ Yes ☐ No

C. Records of interlock operation are maintained for 3 years ☐ N/A ☐ Yes ☐ No

D. Monitor operation is checked

daily before use. [4731.4474, subp. 1] ☐ N/A ☐ Yes ☐ No

E. Records of monitor checks are maintained for 3 years ☐ N/A ☐ Yes ☐ No

REMARKS:

14. PERIODIC SPOT CHECKS COMPLETED MONTHLY. ☐ N/A ☐ Yes ☐ No

A. Output measured with dosimetry system [4731.4474, subp. 3, B, (2)] ☐ N/A ☐ Yes ☐ No

B. Difference between the measurement made and anticipated output [4731.4474, subp. 3, B, 2)] ☐ N/A ☐ Yes ☐ No

C. "On-off" error. [4731.4474, subp. 3, B, (5)] ☐ N/A ☐ Yes ☐ No

D. Treatment table retraction mechanism operation [4731.4474, subp. 3, A, (1)] ☐ N/A ☐ Yes ☐ No

E. Operation of helmet microswitches [4731.4474, subp. 3, A (2)] ☐ N/A ☐ Yes ☐ No

F. Emergency timing circuits [4731.4474, subo.3, A, (3)] ☐ N/A ☐ Yes ☐ No

H. Stereotactic frames and localizing devices (trunnions) [4741.4474, subp. 3, A, (4)] ☐ N/A ☐ Yes ☐ No

I. Source output against computer calculations [4731.4474, subp. 3, B, (3)] ☐ N/A ☐ Yes ☐ No

J. Timer accuracy, constancy and linearity. [4731.4474, subp. 3, B, (4)] ☐ N/A ☐ Yes ☐ No

K. Trunnion centricity [4731.4474, subp. 3, B, (6) ☐ N/A ☐ Yes ☐ No

15. PERIODIC SPOT CHECKS:

A. Electrical interlocks at room entrance [4731.4474,subp.4, A] ☐ N/A ☐ Yes ☐ No

B. Source exposure indicator lights [4731.4474, sub.4, B] ☐ N/A ☐ Yes ☐ No

C. Viewing and interocm systems [4731.4474, subp. 4, C] ☐ N/A ☐ Yes ☐ No

D. Timer termination [4731.4474, subp. 4, D] ☐ N/A ☐ Yes ☐ No

E. Radiation monitors to indicate room exposures [4731.4474, subp. 4, E] ☐ N/A ☐ Yes ☐ No

F. Emergency off buttons [4731.4474, subp. 4, F] ☐ N/A ☐ Yes ☐ No

16. FULL CALIBRATION FOR GAMMA STEREOTACTIC RADIOSURGERY UNITS:

A. Before first medical use of unit [4731.4471, subp. 1, A] ☐ N/A ☐ Yes ☐ No

B. Before medical use when spot checks measurements indicate output difference of 5% [4731.4471, subp. 1, B(1)] ☐ N/A ☐ Yes ☐ No

C. Following replacement of sources or reinstallation in new location [4731.4471, subp. 1, B, (2)] ☐ N/A ☐ Yes ☐ No

D. Following any repair that includes removal of sources or major components [4731.4471, subp 1, B, (3)] ☐ N/A ☐ Yes ☐ No

E. At intervals not exceeding one year [4731.4471, subp. 1, C] ☐ N/A ☐ Yes ☐ No

17. FIVE YEAR CALIBRATION FOR GAMMA STEREOTACTIC RADIOSURGERY UNITS:

A. Fully inspected and serviced in 5 years [4731.4477, subp. 1] ☐ N/A ☐ Yes ☐ No

B. Inspections and service performed by licensed individuals [4731.4477, subp. 2] ☐ N/A ☐ Yes ☐ No

C. Records are maintained [4731.4477, subp. 3] ☐ N/A ☐ Yes ☐ No

18. RADIATION DETECTION EQUIPMENT:

A. Permanent radiation monitor is installed in dedicated treatment room. [4731.4474, subp 4, E] ☐ N/A ☐ Yes ☐ No

MAKE	MODEL

B. Visible notice when source is exposed or partially exposed. [4731.4474, subp. 4, C] ☐ N/A ☐ Yes ☐ No

C. Visible to someone entering room. [4731.4474, subp. 4, C] ☐ N/A ☐ Yes ☐ No

19. PORTABLE SURVEY INSTRUMENTS:

A. Survey meters required by 4731.2220, subp. 1. ☐ N/A ☐ Yes ☐ No

B. Survey meters are calibrated before first use, annually and following repair [4731.4421] ☐ N/A ☐ Yes ☐ No

C. Meter checked with dedicated check source daily before use [not required] ☐ N/A ☐ Yes ☐ No

MAKE	MODEL	S/N	CALIBRATION DATE

20. MAINTENANCE:

A. Only authorized individuals perform maintenance, repair and inspection. [4731.4465, A] ☐ N/A ☐ Yes ☐ No

Name of organization/individual:

B. Manufacturer's schedule for service is followed **(LC)** ☐ N/A ☐ Yes ☐ No

Date of last service:

21. RADIOACTIVE SOURCES:

A. Approved source(s) are used/possessed ☐ N/A ☐ Yes ☐ No

B. Leak tests are performed semi-annually. [4731.2200, subp. 1] ☐ N/A ☐ Yes ☐ No

Date of last test(s):

C. Source installation and replacement by authorized individuals only [4731.4465, A] ☐ N/A ☐ Yes ☐ No

21. CALIBRATION/DOSIMETRY SYSTEM:

Dosimetry system calibrated by NIST or AAPM lab every two years. [4731.4468, subp. 1] ☐ N/A ☐ Yes ☐ No

Name of calibration lab:

Last date of calibration:

REMARKS

22. INTERNAL AUDITS OR INSPECTIONS:

A.	Audits required. [4731.2010, subp. 3]	☐ N/A ☐ Yes ☐ No
B.	Audits or inspections conducted.	☐ N/A ☐ Yes ☐ No
	(1) Audits conducted by:	
	(2) Frequency:	
	(3) Scope of audit:	
C.	Records maintained. [4731.2500]	☐ N/A ☐ Yes ☐ No
D.	Records reviewed. [4731.2010, subp.3]	☐ N/A ☐ Yes ☐ No

23. MEDICAL EVENTS:

A.	Medical events have occurred.	☐ N/A ☐ Yes ☐ No
B.	Licensee in compliance with reporting requirements for medical events. [4731.4525, subp. 1 or subp. 3]	☐ N/A ☐ Yes ☐ No
C.	Appropriate action taken to prevent recurrence.	☐ N/A ☐ Yes ☐ No
D.	Records maintained. [4731.4525, and 4731.0200]	☐ N/A ☐ Yes ☐ No

24. WASTE DISPOSAL:

	Sources transferred to authorized individuals [4731.2400]	☐ N/A ☐ Yes ☐ No

25. BULLETINS AND INFORMATION NOTICES:

A.	Bulletins and Information Notices are received by the licensee.	☐ N/A ☐ Yes ☐ No
B.	Licensee took action in response to Bulletins and Information Notices.	☐ N/A ☐ Yes ☐ No

26. **INDEPENDENT MEASUREMENTS:**

A. Independent measurements made by inspector. ☐ N/A ☐ Yes ☐ No

B. Survey instrument: **Victoreen 190 Serial Number 856**

C. Last date of calibration:

D. Describe measurements and compare with Licensee's readings.

26 **SUMMARY OF VIOLATIONS:**

MINNESOTA DEPARTMENT OF HEALTH

GAUGE INSPECTION REPORT

Date of this inspection:

License No.:

Licensee (Name and Address):

Address letter to:

cc:

Licensee Contact:

Telephone No.:

Last Amendment No.:

Date of Amendment:

Priority: ☐ 5 ☐ T

Category: ☐ 3120 ☐ 3122 ☐ 3123 ☐ 3124

Date of last inspection:

Type of inspection:

☐ Announced ☐ Unannounced

☐ Routine ☐ Special

☐ Initial ☐ Reactive

Summary of findings and action:

☐ No Violation, letter issued
☐ Violation(s), letter issued
☐ Action on previous Violation(s)

Inspector:

☐ Timothy Donakowski
☐ John Goepferd
☐ George F. Johns, Jr.
☐ Sue McClanahan
☐ Craig Verke
☐ Katherine Johnson
☐ Other:

Next inspection date:

Frequency: ☐ Routine ☐ Accelerated

Inspector Signature:	Date:
Approval Signature:	Date:

Revised 6/23/04

INDIVIDUALS INTERVIEWED DURING INSPECTION

*	NAME	TITLE
☐		
☐		
☐		
☐		

☒ Indicates which individuals were at the exit briefing

1. INSPECTION HISTORY: ☐ N/A Initial Inspection

A. Last inspection conducted on:

B. Violations were identified. ☐ Yes ☐ No

C. Response letter dated:

D. Violations identified during previous inspection:

REQUIREMENT	VIOLATION	CORRECTED	STATUS

E. If any violation(s) identified during the last inspection were not corrected, explain.

2. LICENSE CONDITIONS:

A. All license conditions reviewed. ☐ N/A ☐ Yes ☐ No

B. Licensed activities were conducted in accordance with License Conditions except as noted elsewhere in this report. ☐ N/A ☐ Yes ☐ No

3. ORGANIZATION:

A. Briefly describe the organizational structure.

B. Structure meets license requirements. ☐ Yes ☐ No

REMARKS:

4. SCOPE OF PROGRAM:

A. Multiple authorized locations of use. ☐ Yes ☐ No

B. List locations inspected.

C. Briefly describe scope of program, including types of equipment, uses involving licensed material, frequency of use, etc.

REMARKS:

5. **TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS:**

A. Instructions to workers. [4731.1030, subp. 1] ☐ Yes ☐ No

B. Training program required. ☐ N/A ☐ Yes ☐ No

(1) If required, briefly describe program

(2) Training program implemented. ☐ N/A ☐ Yes ☐ No

(3) Retraining program required. ☐ N/A ☐ Yes ☐ No

(4) Retraining program implemented. ☐ N/A ☐ Yes ☐ No

(5) Records maintained. ☐ N/A ☐ Yes ☐ No

REMARKS:

6. **RADIOLOGICAL PROTECTION PROCEDURES:**

A. Radioactive material used in accordance with approved procedures. ☐ N/A ☐ Yes ☐ No

B. Individual's understanding of procedures appeared adequate:

(1) In general rules for safe use of RAM. ☐ N/A ☐ Yes ☐ No

(2) In emergency procedures. ☐ N/A ☐ Yes ☐ No

C. Changes in procedures since last inspection. ☐ N/A ☐ Yes ☐ No

(1) Changes authorized. ☐ N/A ☐ Yes ☐ No

REMARKS:

7. **PERSONNEL RADIATION MONITORING – EXTERNAL:** ☐ N/A

A. Film or TLD supplier: Frequency:

B. Supplier NVLAP approved. [4731.2200, subp. 3, A] ☐ N/A ☐ Yes ☐ No

C. Processor's reports reviewed by:

D. Licensee uses MDH forms or equivalent. [4731.2520] ☐ N/A ☐ Yes ☐ No

E. MDH inspector reviewed personnel monitoring records for period

through

F. Maximum annual whole body dose:

G. Dose(s) exceeded regulatory limits. [4731.2020] ☐ N/A ☐ Yes ☐ No

REMARKS:

8. **NOTIFICATION AND REPORTS:**

A. Licensee provides notifications and reports to individuals. [4731.1030] ☐ N/A ☐ Yes ☐ No

B. Licensee in compliance regarding reporting. of theft or loss. [4731.2600] ☐ N/A ☐ Yes ☐ No

C. Licensee in compliance regarding notification of incidents. [4731.2610] ☐ N/A ☐ Yes ☐ No

D. Licensee in compliance regarding reporting of overexposures and excessive levels and concentrations. [4731.2620] ☐ N/A ☐ Yes ☐ No

E. Termination reports furnished, if requested by workers. [4731.1030, subp. 4] ☐ N/A ☐ Yes ☐ No

REMARKS:

9. **POSTING AND LABELING:**

A. Radiation Areas posted. [4731.2310, subp. 1] ☐ N/A ☐ Yes ☐ No

B. Use or storage areas posted "Caution Radioactive Material." [4731.2310, subp. 5] ☐ N/A ☐ Yes ☐ No

C. Containers or devices labeled. [4731.2330] ☐ N/A ☐ Yes ☐ No

D. Notice to Workers posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

E. Notice to Employees posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

REMARKS:

10. **FACILITIES, MATERIALS, AND EQUIPMENT:**

A. Facilities described in license application. ☐ N/A ☐ Yes ☐ No

B. Facilities are as described. ☐ N/A ☐ Yes ☐ No

C. Gauges and sources as licensed. ☐ N/A ☐ Yes ☐ No

GAUGE MANUFACTURER	MODEL	S/N	SOURCE(S)	ACTIVITY

D. Storage and use of radioactive material.

(1) Adequate method to prevent unauthorized individuals from entering restricted area. ☐ N/A ☐ Yes ☐ No

(2) Sources stored in unrestricted areas secured from unauthorized removal. [4731.2290, subp 1 & 2] ☐ N/A ☐ Yes ☐ No

(3) Material not in storage and in unrestricted area secured against unauthorized removal. [4731.2290, subp. 1 & 2] ☐ N/A ☐ Yes ☐ No

(4) Physical inventories conducted at intervals not to exceed six (6) months. [L/C] ☐ N/A ☐ Yes ☐ No

(5) Records retained for five (5) years. [L/C] ☐ N/A ☐ Yes ☐ No

E. Survey instrument(s) ☐ N/A

INSTRUMENT MANUFACTURER	MODEL NO.	SERIAL NO.	CALIBRATION DATE(S)

REMARKS:

11. INTERNAL AUDITS OR INSPECTIONS:

A. Audits required. [4731.2010, subp. 3] ☐ Yes ☐ No

B. Audits or inspections conducted. ☐ Yes ☐ No

(1) Audits conducted by:

(2) Frequency:

(3) Scope of audit:

C. Records maintained. ☐ Yes ☐ No

D. Records reviewed. ☐ Yes ☐ No

REMARKS:

12. TRANSPORTATION (4731.0402) AND 49 CFR 171-178:

A. Licensee makes shipments of RAM. ☐ N/A ☐ Yes ☐ No

B. Shipments are:

☐ Delivered to common carriers.

☐ Transported in licensee's own private vehicles.

☐ No shipment since last inspection.

NOTE: Complete only if shipment made since last inspection

C. Shipments:

(1) Authorized packages used. ☐ N/A ☐ Yes ☐ No

(2) Package type used:

(3) DOT-7A performance test records on file [173.415(a)] ☐ N/A ☐ Yes ☐ No

(4) Type B packages are approved [173.416] ☐ N/A ☐ Yes ☐ No

(5) Licensee has COCs on file with Agency. [4731.0406, subp. 3] ☐ N/A ☐ Yes ☐ No

(6) For special form sources, performance test records on file. [173.476(a)] ☐ N/A ☐ Yes ☐ No

(7) Packages properly labeled. [172.403(b)] ☐ N/A ☐ Yes ☐ No

(8) Packages properly marked. [172.301(a)] ☐ N/A ☐ Yes ☐ No

(9) Proper shipping papers prepared. [172.200] ☐ N/A ☐ Yes ☐ No

(10) Shipping paper contains emergency response telephone number that is maintained while hazardous materials is being transported. [172.201(d)] ☐ N/A ☐ Yes ☐ No

(11) Shipping papers readily accessible during transport. [177.817(e)] ☐ N/A ☐ Yes ☐ No

(12) Shipping papers retained for 375 days or a record of shipments maintained [177.817(f)] ☐ N/A ☐ Yes ☐ No

(a) The record includes shipping name, identification number, quantity transported, and date of shipment.. ☐ N/A ☐ Yes ☐ No

(13) Vehicles placarded, as required. [172.504(a)] ☐ N/A ☐ Yes ☐ No

(14) Cargo blocked and braced. [177.842(d)] ☐ N/A ☐ Yes ☐ No

(15) Incidents reported to DOT. [171.15] ☐ N/A ☐ Yes ☐ No

REMARKS:

13. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL:

A. Describe receipt of packages of radioactive material. ☐ N/A

B. Transfers performed as required. [4731.0815] ☐ N/A ☐ Yes ☐ No

C. Records of receipt, transfer, & disposal of radioactive material. [4731.0210] ☐ N/A ☐ Yes ☐ No

REMARKS:

14. LEAK TESTS:

A. Leak tests required. ☐ N/A ☐ Yes ☐ No

B. Leak tests performed. ☐ N/A ☐ Yes ☐ No

REMARKS:

15. **WASTE DISPOSAL:**

A. Describe waste disposal methods.

B. Radioactive material disposed of as authorized. [4731.2400] ☐ N/A ☐ Yes ☐ No

REMARKS:

16. **BULLETINS AND INFORMATION NOTICES:**

A. Bulletins and Information Notices are received by the licensee. ☐ N/A ☐ Yes ☐ No

B. Licensee took action in response to Bulletins and Information Notices. ☐ N/A ☐ Yes ☐ No

REMARKS:

17. **ENVIRONMENTAL MONITORING PROGRAM:**

A. An environmental monitoring program is required. ☐ N/A ☐ Yes ☐ No

B. Environmental monitoring program has been implemented. ☐ N/A ☐ Yes ☐ No

REMARKS:

18. **INDEPENDENT MEASUREMENTS:**

A. Independent measurements made by inspector. ☐ N/A ☐ Yes ☐ No

B. Survey instrument: **Victoreen 190 Serial Number 856**

C. Last date of calibration:

D. Describe measurements.

REMARKS:

19. **SUMMARY - LIST OF VIOLATIONS:**

MINNESOTA DEPARTMENT OF HEALTH

GENERAL LICENSED MATERIALS INSPECTION REPORT

(Only for gauging devices)

Date of this inspection:
Inspection Report No.:

License No.:

Licensee (Name and Address):

Address letter to:

cc:

Licensee Contact:

Telephone No.:

Priority: ☐ 5 ☐ T

Category: ☐ 3120 ☐ 3122 ☐ 3123 ☐ Other

Date of last inspection:

Type of inspection:
☐ Announced ☐ Unannounced
☐ Routine ☐ Special
☐ Initial ☐ Reactive

Summary of findings and action:

☐ No Violation, letter issued
☐ Violation(s), letter issued
☐ Action on previous Violation(s)

Inspector:

☐ Timothy Donakowski
☐ John Goepferd
☐ George F. Johns, Jr.
☐ Sue McClanahan
☐ Craig Verke
☐ Katherine Johnson
☐ Other:

Next inspection date:

Frequency: ☐ Routine ☐ Accelerated

Inspector Signature:	Date:
Approval Signature:	Date:

Revised 6/23/04

INDIVIDUALS INTERVIEWED DURING INSPECTION

*	NAME	TITLE
☐		
☐		
☐		
☐		
☐		

☒ Indicates which individuals were at the exit briefing

1. **INSPECTION HISTORY:** ☐ N/A Initial Inspection

A. Last inspection conducted on:

B. Violations were identified. ☐ Yes ☐ No

C. Response letter dated:

D. Violations identified during previous inspection:

REQUIREMENT	VIOLATION	CORRECTED	STATUS

E. If any violation(s) identified during the last inspection were not corrected, explain.

2. **ORGANIZATION:**

Briefly describe the organizational structure.

REMARKS:

3. **SCOPE OF PROGRAM:**

A. Multiple authorized locations of use. ☐ Yes ☐ No

B. List locations inspected.

C. Briefly describe scope of program, including types of equipment, uses involving licensed material, frequency of use, etc.

REMARKS:

4. OPERATIONAL CHECKS: [4731.3215, subp. 3,B]

A. Proper operation of the "on-off" mechanism checked at at intervals not to exceed 6 months or at intervals specified in the Sealed Source and Device Catalog. ☐ Yes ☐ No

B. Were there any failures of the "on-off mechanism ☐ Yes ☐ No

If so, explain:

C. Operation of the device suspended ☐ N/A ☐ Yes ☐ No

D. MDH notified ☐ N/A ☐ Yes ☐ No

REMARKS:

5. TRAINING PROGRAM:

A. Briefly describe program

B. Training program implemented. ☐ Yes ☐ No

C. Records maintained. ☐ Yes ☐ No

REMARKS:

6. RADIOLOGICAL PROTECTION PROCEDURES:

A. Radioactive material used in accordance with approved procedures. ☐ Yes ☐ No

B. Individual's understanding of procedures appeared adequate:

(1) In general rules for safe use of RAM. ☐ Yes ☐ No

(2) In emergency procedures. ☐ Yes ☐ No

REMARKS:

7. POSTING AND LABELING:

A. Containers or devices labeled. [4731.2330 & 4731.3200, subp. 3, A] ☐ Yes ☐ No

B. Notice to Workers posted. [4731.1010] ☐ Yes ☐ No

C. Notice to Employees posted. [4731.1010] ☐ Yes ☐ No

REMARKS:

8. FACILITIES, MATERIALS, AND EQUIPMENT:

A. Gauges and sources as registered. ☐ Yes ☐ No

	MANUFACTURER	MODEL	S/N
Device			
Source			
Device			
Source			
Device			
Source			
Device			
Source			
Device			
Source			
Device			
Source			

B. Storage and use of radioactive material.

(1) Adequate method to prevent unauthorized individuals from entering restricted area. ☐ Yes ☐ No

(2) Sources stored in unrestricted areas secured from unauthorized removal. [4731.2290, subp. 1 & 2] ☐ N/A ☐ Yes ☐ No

(3) Material not in storage and in unrestricted area secured against unauthorized removal. [4731.2290, subp. 1 & 2] ☐ N/A ☐ Yes ☐ No

REMARKS:

9. AUDITS:

A. Audits or inspections conducted. ☐ Yes ☐ No

B. Audits conducted by:

C. Frequency:

D. Scope of audit:

REMARKS:

10. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL:

A. Describe receipt of packages of radioactive material. ☐ N/A

B. Were any devices transferred to another recipient other than the manufacturer ☐ N/A ☐ Yes ☐ No

If yes, was the transferee provided with: [4731.3215, subp. 3, J]

(1) A copy of Chapter 4731.3215, subp. 3, B ☐ N/A ☐ Yes ☐ No

(2) A copy of the manufacturer requirements ☐ N/A ☐ Yes ☐ No

C. Was the MDH notified in writing within 30 days of transfer ☐ N/A ☐ Yes ☐ No

D. Records of receipt, transfer, & disposal of radioactive material. [4731.0210] ☐ N/A ☐ Yes ☐ No

REMARKS:

11. LEAK TESTS [4731.3200, subp. 3,B]

ISOTOPE	ACTIVITY	SERIAL #	LEAK TEST DATE(S)

A. Leak tests performed as required by manufacturer label. ☐ N/A ☐ Yes ☐ No

B. Leak test results are less than .005 microcuries ☐ Yes ☐ No

C. Records maintained ☐ Yes ☐ No

REMARKS:

12. WASTE DISPOSAL:

A. Describe waste disposal methods.

B. Radioactive material disposed of as authorized. ☐ N/A ☐ Yes ☐ No

REMARKS:

13. INDEPENDENT MEASUREMENTS:

A. Independent measurements made by inspector. ☐ Yes ☐ No

B. Survey instrument: **Victoreen 190 Serial Number 856**

C. Last date of calibration:

D. Describe measurements.

REMARKS:

14. SUMMARY OF VIOLATIONS:

MINNESOTA DEPARTMENT OF HEALTH

HIGH DOSE AFTERLOADER INSPECTION REPORT

Date of this inspection:

License No.:

Licensee (Name and Address):

Address letter to:

cc:

Licensee Contact:

Telephone No.:

Last Amendment No.:

Date of Amendment:

Priority: ☐ 2

Category: ☐ 2230 ☐ 2231

Date of last inspection:

Type of inspection:
☐ Announced ☐ Unannounced
☐ Routine ☐ Special
☐ Initial ☐ Reactive

Summary of findings and action:

☐ No Violation, letter issued
☐ Violation(s), letter issued
☐ Action on previous Violation(s)

Inspector:

☐ Timothy Donakowski
☐ John Goepferd
☐ George F. Johns, Jr.
☐ Sue McClanahan
☐ Craig Verke
☐ Katherine Johnson
☐ Other:

Next inspection date:

Frequency: ☐ Routine ☐ Accelerated

Inspector Signature:	Date:
Approval Signature:	Date:

Revised 6/23/04

INDIVIDUALS INTERVIEWED DURING INSPECTION

*	NAME	TITLE
☐		
☐		
☐		
☐		
☐		
☐		
☐		
☐		
☐		

* Indicates which individuals were at the exit briefing

1. INSPECTION HISTORY ☐ N/A Initial Inspection

A. Last inspection conducted on:

B. Violations were identified. ☐ N/A ☐ Yes ☐ No

C. Response letter dated:

D. Violations identified during previous inspection:

REQUIREMENT	VIOLATION	CORRECTED	STATUS

E. If any violation(s) identified during the last inspection were not corrected, explain.

2. LICENSE CONDITIONS:

A. All license conditions reviewed ☐ Yes ☐ No

B. Licensed activities were conducted in accordance with License Conditions except as noted elsewhere in this report. ☐ Yes ☐ No

3. ORGANIZATION:

A. Briefly describe the organizational structure.

B. Structure meets license requirements. ☐ Yes ☐ No

C. Radiation Safety Officer (RSO)

(1) Authorized on license. [4731.4405, subp. 1, B] ☐ N/A ☐ Yes ☐ No

(2) Fulfills duties of RSO. [4731.4405, subp. 1, F] ☐ N/A ☐ Yes ☐ No

(3) Has sufficient authority. [4731.4405, subp. 1, G] ☐ N/A ☐ Yes ☐ No

D. Radiation Safety Committee (RSC)

(1) RSC approved use of afterloader and reviews use at RSC meetings [4731.4405, subp. 1, F] ☐ N/A ☐ Yes ☐ No

(2) RSC reviews use of afterloaders in annual program audit [4731.2010, subp. 3] ☐ N/A ☐ Yes ☐ No

(3) RSC has implemented corrective actions **(LC)** ☐ N/A ☐ Yes ☐ No

E. Authorized Users
Device used under supervision of an authorized user **(LC)** ☐ N/A ☐ Yes ☐ No

REMARKS:

4. **SCOPE OF PROGRAM:**

A. Describe scope of the program (staff size, type of equipment, uses involving licensed material, frequency of use, etc) ☐ N/A ☐ Yes ☐ No

B. Multiple places of use ☐ N/A ☐ Yes ☐ No

C. Are all locations listed on license? **(LC)** ☐ N/A ☐ Yes ☐ No

D. Were on-site inspections performed at each location?
If no, explain ☐ N/A ☐ Yes ☐ No

REMARKS:

5. **OPERATING AND EMERGENCY PROCEDURES:**

A. Procedures are posted [4731.4466, C] ☐ N/A ☐ Yes ☐ No

B. Procedures are identical or more restrictive than those submitted with license **(LC)** ☐ N/A ☐ Yes ☐ No

C. Procedures are approved by RSC [4731.4405, subp. 1,F] ☐ N/A ☐ Yes ☐ No

D. Radiation survey of device and patient is performed to ensure source is returned to shielded position [4731.4427] ☐ N/A ☐ Yes ☐ No

E. Records of radiation surveys maintained for three years [4731.4427] ☐ N/A ☐ Yes ☐ No

F. At least one individual trained in safe use and emergency procedures is physically present while device in use [4731.4467, G, (2)(b)] ☐ N/A ☐ Yes ☐ No

G. Authorized user and either medical physicist or RSO is physically present while device in use [4731.4467, G, (2), (a)] ☐ N/A ☐ Yes ☐ No

H. Only patient is in treatment room during device use [4731.4466, B, (1)] ☐ N/A ☐ Yes ☐ No

REMARKS

6. EMERGENCY PROCEDURES:

A. Procedures are located at the console [4731.4466, C] ☐ N/A ☐ Yes ☐ No

B. Procedures contain names and telephone numbers of authorized users and the RSO [4731.4466,B, 4, (c)] ☐ N/A ☐ Yes ☐ No

C. Licensee has responded to emergencies ☐ N/A ☐ Yes ☐ No

If yes, were authorized user and medical physicist or RSO notified ☐ N/A ☐ Yes ☐ No

If yes, was MDH notified [4731.2610] ☐ N/A ☐ Yes ☐ No

D. Emergency response equipment available [4731.4467, H] ☐ N/A ☐ Yes ☐ No

REMARKS

7. TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS:

A. Facility individuals received initial and periodic training

(1) Instructions to workers [4731.1020] ☐ N/A ☐ Yes ☐ No

(2) Proper use of device [4731.4466, E] ☐ N/A ☐ Yes ☐ No

B. Individual(s) providing training are listed in license application (LC) ☐ N/A ☐ Yes ☐ No

C. Periodic retraining (interval <12 months) is provided to device operators. [4731.4466, E] ☐ N/A ☐ Yes ☐ No

C. Operators, physicians, and medical physicists have been given emergency training including dry run. [4731.4466, F] ☐ N/A ☐ Yes ☐ No

E. Briefly describe training/retraining program

8. RADIOLOGICAL PROTECTION PROCEDURES:

A. Radiation Levels in unrestricted areas are within limits. [4731.2100, subp. 2] ☐ N/A ☐ Yes ☐ No

B. Radiation levels in unrestricted areas are monitored after source exchange/replacement or unit relocation. [4731.4470, subp. 1, B 91)] ☐ N/A ☐ Yes ☐ No

Date of last source exchange:
Date of radiation survey:

C. Personnel monitoring is provided to appropriate individuals. [4731.2020; 4731.2070; 4731.2080] ☐ N/A ☐ Yes ☐ No

REMARKS

9. PERSONNEL RADIATION MONITORING – EXTERNAL: ☐ N/A

A. Film or TLD supplier: Frequency:

B. Supplier NVLAP approved. [4731.2200, subp. 3, A] ☐ N/A ☐ Yes ☐ No

C. Processor's reports reviewed by:

D. Licensee uses MDH forms or equivalent. [4731.2520] ☐ N/A ☐ Yes ☐ No

E. MDH inspector reviewed personnel monitoring records for period

through

F. Maximum annual whole body dose: mrem

G. Maximum annual extremity dose: mrem

H. Dose(s) exceeded regulatory limits. [4731.2020] ☐ N/A ☐ Yes ☐ No

10. PERSONNEL RADIATION MONITORING – INTERNAL: ☐ N/A

A. Potential for exposure of individual to airborne RAM exists. ☐ N/A ☐ Yes ☐ No

B. Monitoring for airborne radioactivity conducted to show compliance. [4731.2010, subp. 4] ☐ N/A ☐ Yes ☐ No

C. Records maintained. [4731.2510] ☐ N/A ☐ Yes ☐ No

D. Briefly describe licensee's program fore monitoring airborne radioactivity.

E. Bioassay program required. ☐ N/A ☐ Yes ☐ No

F. Bioassay program implemented as described in license application. ☐ N/A ☐ Yes ☐ No

G. Ventilation checks completed annually. ☐ N/A ☐ Yes ☐ No

11. NOTIFICATION AND REPORTS:

A. Any medical events? ☐ N/A ☐ Yes ☐ No

B. If yes, were they reported [4731.4525] ☐ N/A ☐ Yes ☐ No

C. Any failures/problems of device ☐ N/A ☐ Yes ☐ No

D. If yes, were they reported under 4731.2610. ☐ N/A ☐ Yes ☐ No

E. Licensee provides notifications and reports to individuals [4731.1030] ☐ N/A ☐ Yes ☐ No

F. License in compliance regarding reporting theft or loss. [4731.2600] ☐ N/A ☐ Yes ☐ No

G. Licensee in compliance regarding overexposures and notification of incidents [4731.2610] ☐ N/A ☐ Yes ☐ No

H. Licensee in compliance regarding reporting of excessive levels and concentrations [4731.2610] ☐ N/A ☐ Yes ☐ No

I. Radiation exposure report furnished at termination, if requested by workers [4731.1030, subp. 4] ☐ N/A ☐ Yes ☐ No

REMARKS

12. POSTING AND LABELING:

A. Radiation Areas posted. [4731.2310, subp. 4] ☐ N/A ☐ Yes ☐ No

B. High Radiation Areas posted [4731.2110, subp. 2] ☐ N/A ☐ Yes ☐ No

C. Use or storage areas posted "Caution Radioactive Material." [4731.2310, subp. 5] ☐ N/A ☐ Yes ☐ No

D. Containers or devices labeled. [4731.2330] ☐ N/A ☐ Yes ☐ No

E. Notice to Workers posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

F. Notice to Employees posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

13. FACILITIES, MATERIALS AND EQUIPMENT:

A. Facilities described in license application. ☐ N/A ☐ Yes ☐ No

B. Facilities are as described. ☐ N/A ☐ Yes ☐ No

C. Devices used in authorized locations ☐ N/A ☐ Yes ☐ No

D. Use is limited to locations approved in License **(LC)** ☐ N/A ☐ Yes ☐ No

14. GENERAL REQUIREMENTS FOR HIGH DOSE AFTERLOADERS:

A. Only one radiation device can be placed in operation at a time within one treatment room [4731.4466, B, (3)] ☐ N/A ☐ Yes ☐ No

B. Dedicated treatment rooms are equipped with continuous viewing and intercom systems [4731.4467, E] ☐ N/A ☐ Yes ☐ No

C. Back-up system is available to observe patient's during treatment **(LC)** ☐ N/A ☐ Yes ☐ No

If no, are treatments suspended ☐ N/A ☐ Yes ☐ No

D.	Electrical interlock systems are installed at each entry [4731.4467, C]	☐ N/A	☐ Yes	☐ No
E.	Once activated, door interlock must be reset **(LC)**	☐ N/A	☐ Yes	☐ No
F.	Allows only persons approved to be present during treatments. [4731.4466, B, 2]	☐ N/A	☐ Yes	☐ No
G.	Licensee prevents more than one radiation producing device in treatment room . [4731.4466, B (3)]	☐ N/A	☐ Yes	☐ No
H.	Radiation monitor to ensure radiation levels at ambient levels [4731.4467, D]	☐ N/A	☐ Yes	☐ No
I.	Emergency response equipment near treatment room [4731.4467, H]	☐ N/A	☐ Yes	☐ No
J.	Calibrated dosimetry system in place [4731.4468, subp. 1]	☐ N/A	☐ Yes	☐ No
K.	Written procedures for spot checks established by authorized medical physicist [4731.4473, subp. 2]	☐ N/A	☐ Yes	☐ No
L.	Spot check results reviewed by authorized medical physicist [4731.4472, subp. 6]	☐ N/A	☐ Yes	☐ No
M.	Afterloader and storage devices are properly labeled [4731.2330]	☐ N/A	☐ Yes	☐ No
N.	Records maintained [4731.4472, subp. 6]	☐ N/A	☐ Yes	☐ No

REMARKS:

15. PERIODIC SPOT CHECKS:

A.	Required before first medical use on a given day [4731.4473, subp. 1,A]	☐ N/A	☐ Yes	☐ No
B.	Required after each source installation [4731.4473, subp. 1, C]	☐ N/A	☐ Yes	☐ No
C.	Electrical interlocks at each afterloader unit room entrances [4731.4473, subp. 4, A]	☐ N/A	☐ Yes	☐ No
D.	Source exposure indicator lights [4731.4473, subp. 4, B]	☐ N/A	☐ Yes	☐ No
E.	Viewing and intercom systems [4731.4473, subp. 4, C]	☐ N/A	☐ Yes	☐ No
F.	Emergency response equipment [4731.4473, subp. 4, D]	☐ N/A	☐ Yes	☐ No

G. Radiation monitors used to indicate source position [4731.4473, subp. 4, E] ☐ N/A ☐ Yes ☐ No

H. Timer accuracy [4731.4473, subp. 4, F] ☐ N/A ☐ Yes ☐ No

I. Date and time in unit's computer [4731.4473, subp. 4, G] ☐ N/A ☐ Yes ☐ No

J. Decayed source activity in computer [4731.4473, subp. 4, H] ☐ N/A ☐ Yes ☐ No

K. Licensee locks out control if any system fails [4731.4473, Subp. 5] ☐ N/A ☐ Yes ☐ No

L. Records are maintained [4731.4473, subp. 6] ☐ N/A ☐ Yes ☐ No

REMARKS:

16. FULL CALIBRATION FOR HIGH DOSE AFTERLOADERS:

A. Required before the first medical use of unit [4731.4470, subp. 1, A] ☐ N/A ☐ Yes ☐ No

B. Required before medical use following:
(1) Replacement of source [4731.4470, subp. 1, B, (1)] ☐ N/A ☐ Yes ☐ No

(2) Repair including removal of source or major repair of components [4731.4470, subp. 1, B, (1)] ☐ N/A ☐ Yes ☐ No

Date of last source replacement:
Date of last monthly calibration:

C. Intervals not exceeding one quarter with sources whose half-life exceeds 75 days [4731.4470, subp 1, C] ☐ N/A ☐ Yes ☐ No

D. Required determinations: [4731.4470]
(1) Output within +/- 5% [4731.4470, subp.2, A] ☐ N/A ☐ Yes ☐ No

(2) Source positioning accuracy +/-1 mm [4731.4470, subp. 2, B] ☐ N/A ☐ Yes ☐ No

(3) Source retraction with backup battery [4731.4470, subp. 2, C] ☐ N/A ☐ Yes ☐ No

(4) Length of source transfer tubes [4731.4470, subp. 2, D] ☐ N/A ☐ Yes ☐ No

(5) Timer accuracy and linearity [4731.4470, subp. E] ☐ N/A ☐ Yes ☐ No

(6) Length of applicators [4731.4470, subp.2, F] ☐ N/A ☐ Yes ☐ No

(7) Function of source transfer tubes, etc.

[4731.4470, subp. 2 G] ☐ N/A ☐ Yes ☐ No

E. Calibrations made according to published protocols. [4731.4470, subp. 4] ☐ N/A ☐ Yes ☐ No

F. Corrections made within 1 % of physical decay [4731.4470, subp. 7] ☐ N/A ☐ Yes ☐ No

G. Calibrations and corrections performed by authorized medical physicist [4731.4470, subp. 8] ☐ N/A ☐ Yes ☐ No

H. Records are maintained [4732.4470, subp. 9] ☐ N/A ☐ Yes ☐ No

REMARKS:

17. RADIATION DETECTION EQUIPMENT:

A. Permanent radiation monitor is installed in dedicated treatment room [4731.4467, D] ☐ N/A ☐ Yes ☐ No

MAKE	MODEL

B. Visible notice when source is exposed or partially exposed ☐ N/A ☐ Yes ☐ No

C. Visible to someone entering room ☐ N/A ☐ Yes ☐ No

D. Has separate backup power supply separate from power supply to afterloader ☐ N/A ☐ Yes ☐ No

18. PORTABLE SURVEY INSTRUMENTS:

A. Meters required by 4731.2200, subp. 1 & 2 and 4731.4464, A. ☐ N/A ☐ Yes ☐ No

B. Meter range is adequate **(LC)** ☐ N/A ☐ Yes ☐ No

C. List meter model and range

MAKE	MODEL	S/N	CALIBRATION DATE	RANGE

19. **MAINTENANCE:**

A. Only authorized individuals perform maintenance, repair and inspection [4731.4465, A and B] ☐ N/A ☐ Yes ☐ No

Name of organization/individual

B. Records of maintenance, inspection and Service maintained for duration of device use. [4731.4465, D] ☐ N/A ☐ Yes ☐ No

C. Afterloaders inspected at required intervals [4731.4470, subp. 1, D] ☐ N/A ☐ Yes ☐ No

Manufacturer's schedule for service is followed (LC) ☐ N/A ☐ Yes ☐ No

Frequency:
Date of last service:

REMARKS

20. **CALIBRATION/DOSIMETRY SYSTEM:**

Dosimetry system calibrated by NIST or AAPM lab every two years **(LC)** ☐ N/A ☐ Yes ☐ No

Name of calibration lab:
Last date of calibration:

REMARKS

21. **RADIOACTIVE MATERIALS:**

Approved sources are used/possessed [4731.4463] ☐ N/A ☐ Yes ☐ No

REMARKS

22. **INTERNAL AUDITS OR INSPECTIONS:**

A. Audits required. [4731.2010] ☐ Yes ☐ No

B. Audits or inspections conducted. ☐ Yes ☐ No

(1) Audits conducted by:

(2) Frequency:

(3) Scope of audit:

C. Records maintained. [4731.4525; 4731.2500] ☐ N/A ☐ Yes ☐ No

D. Records reviewed. [4731.4405] ☐ N/A ☐ Yes ☐ No

23. MEDICAL EVENTS:

A. Medical events have occurred. ☐ N/A ☐ Yes ☐ No

B. Licensee in compliance with reporting requirements For medical events [4731.4525, subp. 1 or subp.3] ☐ N/A ☐ Yes ☐ No

C. Appropriate action taken to prevent recurrence ☐ N/A ☐ Yes ☐ No

D. Records maintained [4731.4525 and 4731.0200] ☐ N/A ☐ Yes ☐ No

REMARKS:

24. WASTE DISPOSAL:

Sources transferred to authorized individuals [4731.2400] ☐ N/A ☐ Yes ☐ No

Name of organization:

REMARKS

25. BULLENTINS AND INFORMATION NOTICES:

A. Bulletins and information notices are received by licensee. ☐ N/A ☐ Yes ☐ No

B. Licensee took action in response to the

bulletins and information notices. ☐ N/A ☐ Yes ☐ No

26. **INDEPENDENT MEASUREMENTS:**

MAKE	MODEL	S/N	CALIBRATION DATE

A. Detail location and results of confirmatory measurements

B. Independent measurements made by inspector ☐ N/A ☐ Yes ☐ No

C. Survey instrument: **Victoreen 190 Serial Number 856**

D. Last date of calibration:

E. Describe measurements and compare with Licensee's readings.

27. SUMMARY OF VIOLATIONS

MINNESOTA DEPARTMENT OF HEALTH

INDUSTRIAL/ACADEMIC INSPECTION REPORT

Date of this inspection:

License No.:

Licensee (Name and Address):

Address letter to:

cc:

Licensee Contact:

Telephone No.:

Last Amendment No.:

Date of Amendment:

Priority: ☐ 5 ☐

Category: ☐ 99200 ☐ Other

Date of last inspection:

Type of inspection:

☐ Announced
☐ Unannounced

☐ Routine
☐ Special

☐ Initial
☐ Reactive

Summary of findings and action:

☐ No Violation, letter issued
☐ Violation(s), letter issued
☐ Action on previous Violation(s)

Inspector:

☐ Timothy Donakowski
☐ John Goepferd
☐ George F. Johns, Jr.
☐ Sue McClanahan
☐ Craig Verke
☐ Katherine Johnson
☐ Other:

Next inspection date:

Frequency: ☐ Routine ☐ Accelerated

Inspector Signature:	Date:
Approval Signature:	Date:

Revised 6/23/04

INDIVIDUALS INTERVIEWED DURING INSPECTION

*	NAME	TITLE
☐		
☐		
☐		
☐		

☒ Indicates which individuals were at the exit briefing

1. INSPECTION HISTORY: ☐ N/A Initial Inspection

A. Last inspection conducted on:

B. Violations were identified. ☐ N/A ☐ Yes ☐ No

C. Response letter dated:

D. Violations identified during previous inspection:

REQUIREMENT	VIOLATION	CORRECTED	STATUS

E. If any violation(s) identified during the last inspection were not corrected, explain.

2. LICENSE CONDITIONS:

A. All license conditions reviewed. ☐ Yes ☐ No

B. Licensed activities were conducted in accordance with License Conditions except as noted elsewhere in this report. ☐ Yes ☐ No

3. ORGANIZATION:

A. Briefly describe the organizational structure.

B. Structure meets license requirements. ☐ Yes ☐ No

C. Licensee required to have a Radiation Safety Committee (RSC) ☐ Yes ☐ No

(1) If Yes, RSC fulfills requirements. ☐ N/A ☐ Yes ☐ No

(2) Records of RSC activities maintained. ☐ N/A ☐ Yes ☐ No

D. Radiation Safety Officer (RSO)

(1) Authorized on license. ☐ N/A ☐ Yes ☐ No

(2) Fulfills duties of RSO. ☐ N/A ☐ Yes ☐ No

REMARKS:

4. SCOPE OF PROGRAM:

A. Multiple authorized locations of use. ☐ Yes ☐ No

B. List locations inspected.

C. Briefly describe scope of program, including types of equipment, uses involving licensed material, frequency of use, etc.

REMARKS:

5. TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS:

A. Instructions to workers. [4731.1020] ☐ N/A ☐ Yes ☐ No

B. Training program required. ☐ N/A ☐ Yes ☐ No

(1) If required, briefly describe program

(2) Training program implemented. ☐ N/A ☐ Yes ☐ No

(3) Retraining program required. ☐ N/A ☐ Yes ☐ No

(4) Retraining program implemented. ☐ N/A ☐ Yes ☐ No

(5) Records maintained. ☐ N/A ☐ Yes ☐ No

REMARKS:

6. **RADIOLOGICAL PROTECTION PROCEDURES:**

A. Radioactive material used in accordance with approved procedures. ☐ N/A ☐ Yes ☐ No

B. Individual's understanding of procedures appeared adequate:

(1) In general rules for safe use of RAM. ☐ N/A ☐ Yes ☐ No

(2) In emergency procedures. ☐ N/A ☐ Yes ☐ No

C. Changes in procedures since last inspection. ☐ N/A ☐ Yes ☐ No

(1) Changes authorized. ☐ N/A ☐ Yes ☐ No

REMARKS:

7. **PERSONNEL RADIATION MONITORING – EXTERNAL:** ☐ N/A

A. Film or TLD supplier: Frequency:

B. Supplier NVLAP approved. [4731.2200, subp. 3, A] ☐ N/A ☐ Yes ☐ No

C. Processor's reports reviewed by:

D. Licensee uses MDH forms or equivalent. [4731.2520] ☐ N/A ☐ Yes ☐ No

E. MDH inspector reviewed personnel monitoring records for period

through

F. Maximum annual whole body dose: mrem

G. Maximum annual extremity dose: mrem

H. Dose(s) exceeded regulatory limits. [4731.2200] ☐ N/A ☐ Yes ☐ No

I. Pocket dosimeters used. ☐ N/A

(1) Type used:

(2) Frequency of recharging:

(3) Readings comparable with film badge/TLD. ☐ N/A ☐ Yes ☐ No

REMARKS:

8. PERSONNEL RADIATION MONITORING – INTERNAL: ☐ N/A

A. Potential for exposure of individuals to airborne RAM exists. ☐ N/A ☐ Yes ☐ No

B. Monitoring for airborne radioactivity conducted to show compliance. [4731.2010, subp. 4] ☐ N/A ☐ Yes ☐ No

C. Records maintained. [4731.2510, subp. 2, C] ☐ N/A ☐ Yes ☐ No

D. Briefly describe licensee's program for monitoring airborne radioactivity.

E. Bioassay program required. ☐ N/A ☐ Yes ☐ No

F. Bioassay program implemented as described in license application. ☐ N/A ☐ Yes ☐ No

G. Ventilation checks completed annually ☐ N/A ☐ Yes ☐ No

REMARKS:

9. NOTIFICATION AND REPORTS:

A. Licensee provides notifications and reports to individuals. [4731.1030] ☐ N/A ☐ Yes ☐ No

B. Licensee in compliance regarding reporting of theft or loss. [4731.2600] ☐ N/A ☐ Yes ☐ No

C. Licensee in compliance regarding notification of incidents.

[4731.2610] ☐ N/A ☐ Yes ☐ No

D. Licensee in compliance regarding reporting of overexposures and excessive levels and concentrations. [4731.2620] ☐ N/A ☐ Yes ☐ No

E. Termination reports furnished, if requested by workers. [4731.1030, subp. 4] ☐ N/A ☐ Yes ☐ No

REMARKS:

10. POSTING AND LABELING:

A. Radiation Areas posted. [4731.2310, subp. 1] ☐ N/A ☐ Yes ☐ No

B. High Radiation Areas posted. [4731.2310, subp. 2] ☐ N/A ☐ Yes ☐ No

C. Use or storage areas posted "Caution Radioactive Material." [4731.2310, subp. 5] ☐ N/A ☐ Yes ☐ No

D. Containers or devices labeled. [4731.2330] ☐ N/A ☐ Yes ☐ No

E. Notice to Workers posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

F. Notice to Employees posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

REMARKS:

11. FACILITIES, MATERIALS, AND EQUIPMENT:

A. Facilities described in license application. ☐ N/A ☐ Yes ☐ No

B. Facilities are as described. ☐ N/A ☐ Yes ☐ No

C. Storage and use of radioactive material.

(1) Adequate method to prevent unauthorized individuals from entering restricted area. ☐ N/A ☐ Yes ☐ No

(2) Sources stored in unrestricted areas secured from unauthorized removal. [4731.2290, subp. 1 & 2] ☐ N/A ☐ Yes ☐ No

(3) Material not in storage and in unrestricted area secured against unauthorized removal. [4731.2290, supb. 1 &2] ☐ N/A ☐ Yes ☐ No

(4) Physical inventories conducted at intervals not to exceed six (6) months. **[LC]** ☐ N/A ☐ Yes ☐ No

(5) Records retained for five (5) years. **[LC]** ☐ N/A ☐ Yes ☐ No

D. Survey instrument(s)

(1) Possession and use of operable survey instruments required. ☐ Yes ☐ No

INSTRUMENT MANUFACTURER	MODEL NO.	SERIAL NO.	CALIBRATION DATE

(2) Capability of radiation survey instruments adequate for program. ☐ N/A ☐ Yes ☐ No

(3) Calibration performed, as required. [4731.2202, subp. 2] ☐ N/A ☐ Yes ☐ No

(4) Records maintained. ☐ N/A ☐ Yes ☐ No

REMARKS:

12. INTERNAL AUDITS OR INSPECTIONS

A. Audits required. [4731.2010, subp. 3] ☐ Yes ☐ No

B. Audits or inspections conducted. ☐ Yes ☐ No

(1) Audits conducted by:

(2) Frequency:

(3) Scope of audit:

C. Records maintained. ☐ N/A ☐ Yes ☐ No

D. Records reviewed. ☐ N/A ☐ Yes ☐ No

REMARKS:

13. TRANSPORTATION (4731.0402) AND 49 CFR 171-178:

A. Licensee makes shipments of RAM. ☐ Yes ☐ No

B. Shipments are:

☐ Delivered to common carriers.

☐ Transported in licensee's own private vehicles.

☐ No shipment since last inspection.

NOTE: Complete only if shipment made since last inspection

C. Shipments:

(1) Authorized packages used. ☐ N/A ☐ Yes ☐ No

(2) Package type used:

(3) DOT-7A performance test records on file. [173.415(a)] ☐ N/A ☐ Yes ☐ No

(4) Type B packages are approved [173.416] ☐ N/A ☐ Yes ☐ No

(5)	Licensee has COCs on file with Agency. [4731.0406, subp. 3]	☐ N/A ☐ Yes ☐ No
(6)	Licensee has QA program approved by Agency. [4731.0406, subp. 2]	☐ N/A ☐ Yes ☐ No
(7)	For special form sources, performance test records on file. [173.476(a)]	☐ N/A ☐ Yes ☐ No
(8)	Packages properly labeled. [172.403(b)]	☐ N/A ☐ Yes ☐ No
(9)	Packages properly marked. [172.301(a)]	☐ N/A ☐ Yes ☐ No
(10)	Proper shipping papers prepared. [172.200]	☐ N/A ☐ Yes ☐ No
11)	Shipping paper contains emergency response telephone number that is maintained while hazardous materials is being transported. [172.201(d)]	☐ N/A ☐ Yes ☐ No
(12)	Shipping papers readily accessible during transport. [177.817(e)]	☐ N/A ☐ Yes ☐ No
(13)	Vehicles placarded, as required. [172.504(a)]	☐ N/A ☐ Yes ☐ No
(14)	Cargo blocked and braced. [177.842(d)]	☐ N/A ☐ Yes ☐ No
(15)	Incidents reported to DOT. [171.15]	☐ N/A ☐ Yes ☐ No

REMARKS:

14. **RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL:**

A. Describe receipt of packages of radioactive material. ☐ N/A

B. Procedure for opening packages. [40.65(5)] ☐ N/A ☐ Yes ☐ No

C. Incoming packages monitored for radioactive contamination. [4731.2350, subp. 1 and 4731.2350, subp. 5] ☐ N/A ☐ Yes ☐ No

D. Incoming packages monitored for radiation levels. [4731.2350, subp. 2, A or C and 4731.2350, subp. 3] ☐ N/A ☐ Yes ☐ No

E. Transfers performed as required. [4731.0815] ☐ N/A ☐ Yes ☐ No

F. Records of receipt surveys. [4731.210, subp. 1] ☐ N/A ☐ Yes ☐ No

G. Records of receipt, transfer, & disposal of radioactive material. [4731.0210] ☐ N/A ☐ Yes ☐ No

REMARKS:

15. **WASTE DISPOSAL:**

A. Describe waste disposal methods - Liquid and Solids.

B. Radioactive material disposed of as authorized. [4731.2400] ☐ N/A ☐ Yes ☐ No

C. Disposal to sanitary sewerage system within limits. [4731.2400] ☐ N/A ☐ Yes ☐ No

D. Disposal by incineration, as specified in 4731.2430 or 4731.2410; 4731.2240 ☐ N/A ☐ Yes ☐ No

E. Waste disposal by decay in storage. [4731.4429] ☐ N/A ☐ Yes ☐ No

F. Record of disposal by decay in storage. [4731.4508] ☐ N/A ☐ Yes ☐ No

G. Transfer of low-level waste for disposal [4731.2450] ☐ N/A ☐ Yes ☐ No

H. Survey of waste before disposal. [4731.2200] ☐ N/A ☐ Yes ☐ No

I. Records of waste surveys. [4731.2510] ☐ N/A ☐ Yes ☐ No

J. If LLW is stored because access to a burial site has been denied, answer (1), (2), and (3) below. ☐ N/A

(1) Adequate control of waste in storage. ☐ Yes ☐ No

(2) Packages labeled and integrity maintained. ☐ Yes ☐ No

(3) Records of surveys and material accountability are maintained. ☐ Yes ☐ No

REMARKS:

16. SURVEYS:

A. Briefly describe survey requirements (both direct reading and surveys for removable contamination).

B. Records of surveys. [4731.2510, subp. 1] ☐ N/A ☐ Yes ☐ No

C. Leak tests required. ☐ N/A ☐ Yes ☐ No

D. Leak tests performed. ☐ N/A ☐ Yes ☐ No

REMARKS:

17. **BULLETINS AND INFORMATION NOTICES:**

A. Bulletins and Information Notices are received by the licensee. ☐ N/A ☐ Yes ☐ No

B. Licensee took action in response to Bulletins and Information Notices. ☐ N/A ☐ Yes ☐ No

REMARKS:

18. **ENVIRONMENTAL MONITORING PROGRAM:**

A. An environmental monitoring program is required. ☐ N/A ☐ Yes ☐ No

B. Environmental monitoring program has been implemented. ☐ N/A ☐ Yes ☐ No

REMARKS:

19. **FINANCIAL ASSURANCE AND RECORD KEEPING FOR DECOMMISSIONING:**

A. Decommissioning funding plan required. ☐ N/A ☐ Yes ☐ No

B. Plan submitted. [4731.0580] ☐ N/A ☐ Yes ☐ No

REMARKS:

20. **INDEPENDENT MEASUREMENTS:**

A. Independent measurements made by inspector. ☐ Yes ☐ No

B. Survey instrument: **Victoreen 190 Serial Number 856**

C. Last date of calibration:

D. Describe measurements and compare with Licensee's readings.

REMARKS:

21. **SUMMARY - LIST OF VIOLATIONS:**

MINNESOTA DEPARTMENT OF HEALTH

MEDICAL FACILITY INSPECTION REPORT

Date of this inspection:

License No.:

Licensee (Name and Address):

Address letter to:

cc:

Licensee Contact:

Telephone No.:

Last Amendment No.:

Date of Amendment:

Priority: ☐ 3 ☐ 5

Category: ☐ 2120 ☐ 2121 ☐ 2200 ☐ 2201

Date of last inspection:

Type of inspection:

☐ Announced ☐ Unannounced

☐ Routine ☐ Special

☐ Initial ☐ Reactive

Summary of findings and action:

☐ No Violation, letter issued
☐ Violation(s), letter issued
☐ Action on previous Violation(s)

Inspector:

☐ Timothy Donakowski
☐ John Goepferd
☐ George F. Johns, Jr.
☐ Sue McClanahan
☐ Craig Verke
☐ Katherine Johnson
☐ Other:

Next inspection date:

Frequency: ☐ Routine ☐ Accelerated

Inspector Signature:	Date:
Approval Signature:	Date:

Revised 6/23/04

INDIVIDUALS INTERVIEWED DURING INSPECTION

*	NAME	TITLE
☐		
☐		
☐		
☐		
☐		
☐		
☐		
☐		
☐		

☒ Indicates which individuals were at the exit briefing

1. INSPECTION HISTORY: ☐ N/A Initial Inspection

A. Last inspection conducted on:

B. Violations were identified. ☐ N/A ☐ Yes ☐ No

C. Response letter dated:

D. Violations identified during previous inspection:

REQUIREMENT	VIOLATION	CORRECTED	STATUS

E. If any violation(s) identified during the last inspection were not corrected, explain.

2. LICENSE CONDITIONS:

A. All license conditions reviewed. ☐ Yes ☐ No

B. Licensed activities were conducted in accordance with License Conditions except as noted elsewhere in this report. ☐ Yes ☐ No

3. ORGANIZATION:

A. Briefly describe the organizational structure.

B. Structure meets license requirements. ☐ Yes ☐ No

C. Radiation Safety Officer (RSO)

(1) Appointed. [4731.4405, subp.1 B] ☐ N/A ☐ Yes ☐ No

(2) Fulfills duties of RSO. [4741.4405, subp. 1, F] ☐ N/A ☐ Yes ☐ No

(3) Has sufficient authority. [4731.4405, subp. 1, G] ☐ N/A ☐ Yes ☐ No

D. Radiation Safety Committee (RSC) ☐ N/A ☐ Yes ☐ No

(1) Membership as specified. [4731.4405, subp. 1, F] ☐ N/A ☐ Yes ☐ No

(2) Meetings held quarterly. **[LC]** ☐ N/A ☐ Yes ☐ No

(3) Quorums established. **[LC]** ☐ N/A ☐ Yes ☐ No

(4) Has sufficient authority. **[LC]** ☐ N/A ☐ Yes ☐ No

(5) Committee reviews program annually. **[LC]** ☐ N/A ☐ Yes ☐ No

(6) Record of Committee meetings. **LC]** ☐ N/A ☐ Yes ☐ No

E. Visiting Authorized User ☐ N/A

(1) Has written permission. [4731.4405, subp. 1, A, (2)] ☐ Yes ☐ No

(2) Visitor's license on file. [4731.4403, subp. 3, B, (4)] ☐ N/A ☐ Yes ☐ No

(3) Performs only those procedures authorized on visitor's license. [4731.4407, A, (2)] ☐ N/A ☐ Yes ☐ No

(4) Uses materials under licensee's license or 60 days per year or less. [4731.4405, subp. 1, C] ☐ N/A ☐ Yes ☐ No

(5) Records maintained 5 years after visitor's last visit. [4731.500, subp. 1 & 2] ☐ N/A ☐ Yes ☐ No

F. Mobile Nuclear Medicine Service. ☐ N/A

(1) Licensee uses mobile nuclear medicine service. ☐ N/A ☐ Yes ☐ No

(2) Licensee operates mobile nuclear medicine service. [4731.4428, A, B, & C] ☐ N/A ☐ Yes ☐ No

(3) Mobile nuclear medicine service meets technical requirements. [4731.4428, A, (2), (3),(4) ☐ N/A ☐ Yes ☐ No

REMARKS:

4. SCOPE OF PROGRAM:

A. Multiple authorized locations of use. ☐ N/A ☐ Yes ☐ No

B. List locations inspected.

C. Briefly describe scope of program, including types of equipment, uses involving licensed material, frequency of use, etc.

D. Radiation safety program changes. [4731.4405, subp. 2] ☐ N/A ☐ Yes ☐ No

REMARKS:

5. TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS:

A. Instructions to workers. [4731.1020, subp. 1] ☐ N/A ☐ Yes ☐ No

B. Training program required. ☐ N/A ☐ Yes ☐ No

(1) If required, briefly describe program

(2) Training program implemented. ☐ N/A ☐ Yes ☐ No

(3) Retraining program required. ☐ N/A ☐ Yes ☐ No

(4) Retraining program implemented. ☐ N/A ☐ Yes ☐ No

(5) Records maintained. ☐ N/A ☐ Yes ☐ No

REMARKS:

6. **RADIOLOGICAL PROTECTION PROCEDURES:**

A. Radioactive material used in accordance with approved procedures. **[LC]** ☐ N/A ☐ Yes ☐ No

B. Individual's understanding of procedures appeared adequate:

(1) In general rules for safe use of RAM. ☐ N/A ☐ Yes ☐ No

(2) In emergency procedures. ☐ N/A ☐ Yes ☐ No

7. **PERSONNEL RADIATION MONITORING – EXTERNAL:** ☐ N/A

A. Film or TLD supplier: Frequency:

B. Supplier NVLAP approved. [4731.2200, subp. 3, A] ☐ N/A ☐ Yes ☐ No

C. Processor's reports reviewed by:

D. Licensee uses MDH forms or equivalent. [4731.2520] ☐ N/A ☐ Yes ☐ No

E. MDH inspector reviewed personnel monitoring records for period

through

F. Maximum annual whole body dose: **mrem**

G. Maximum annual extremity dose: **mrem**

H. Dose(s) exceeded regulatory limits. [4731.2020] ☐ N/A ☐ Yes ☐ No

I. Licensee has implemented an ALARA program. [4731.2010, subp. 2] ☐ N/A ☐ Yes ☐ No

(1) Annual review by radiation safety committee. [4731.2010, subp. 3] ☐ N/A ☐ Yes ☐ No

(2) Written description of ALARA program available. [4731.2010, subp. 2] ☐ N/A ☐ Yes ☐ No

REMARKS:

8. **PERSONNEL RADIATION MONITORING – INTERNAL:** ☐ N/A

A. Potential for exposure of individuals to airborne RAM exists. ☐ N/A ☐ Yes ☐ No

B. Monitoring for airborne radioactivity conducted to show compliance. [4731.2010, subp.4] ☐ N/A ☐ Yes ☐ No

C. Records maintained [4731.2510, subp. 2, C] ☐ N/A ☐ Yes ☐ No

D. Bioassay program implemented as described in correspondence with Agency. ☐ N/A ☐ Yes ☐ No

E. Radioactive gases. ☐ N/A

Licensee can demonstrate compliance with requirements for airborne dose limits? ☐ N/A ☐ Yes ☐ No

(1) Clearance time and safety procedures are posted. [not required] ☐ N/A ☐ Yes ☐ No

(2) Reusable collection system checked monthly. [not required] ☐ N/A ☐ Yes ☐ No

(3) Ventilation rates checked each six months for negative pressure. [not required] ☐ N/A ☐ Yes ☐ No

(4) Other ☐ N/A ☐ Yes ☐ No

REMARKS:

9. **NOTIFICATION AND REPORTS:**

A. Licensee provides notifications and reports to individuals. [4731.1030] ☐ N/A ☐ Yes ☐ No

B. Licensee in compliance regarding reporting theft or loss. [4731.2600] ☐ N/A ☐ Yes ☐ No

C. Licensee in compliance regarding overexposures notification of incidents. [4731.2610] ☐ N/A ☐ Yes ☐ No

D. Licensee in compliance regarding reporting of and excessive levels and concentrations. [4731.2620] ☐ N/A ☐ Yes ☐ No

E. Termination reports furnished, if requested by workers. [4731.1030, subp. 4] ☐ N/A ☐ Yes ☐ No

REMARKS:

10. POSTING AND LABELING:

A. Radiation Areas posted. [4731.2310, subp. 1 or 3] ☐ N/A ☐ Yes ☐ No

B. High Radiation Areas posted. [4731.2310, subp. 2] ☐ N/A ☐ Yes ☐ No

C. Use or storage areas posted "Caution Radioactive Material." [431.2310, subp. 5] ☐ N/A ☐ Yes ☐ No

C. Containers or devices labeled. [4731.2330] ☐ N/A ☐ Yes ☐ No

E. Notice to Workers posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

F. Notice to Employees posted. [40.110(3)] ☐ N/A ☐ Yes ☐ No

G. Permits to Practice posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

REMARKS:

11. FACILITIES, MATERIALS, AND EQUIPMENT:

A. Facilities described in license application. ☐ N/A ☐ Yes ☐ No

B. Facilities are as described. ☐ N/A ☐ Yes ☐ No

C. Storage and use of radioactive material.

(1) Licensee secures stored radioactive material to prevent unauthorized removal or access. [4731.2290, subp. 1 & 2] ☐ N/A ☐ Yes ☐ No

(2) Licensee controls and maintains surveillance of radioactive material in use to prevent unauthorized removal or access. ☐ N/A ☐ Yes ☐ No

D. Dose Calibrator.

(1) Licensee possesses a dose calibrator. [4731.4420 or 4731.4422] ☐ N/A ☐ Yes ☐ No

MANUFACTURER	MODEL NO.	SERIAL NO.

(2) Licensee calibrates in accordance with manufacturer's instructions [4731.4420, B] ☐ N/A ☐ Yes ☐ No

(a) Constancy checked. [not required] ☐ N/A ☐ Yes ☐ No

(b) Linearity tested. [not required] ☐ N/A ☐ Yes ☐ No

(c) Accuracy tested. [not required] ☐ N/A ☐ Yes ☐ No

(d) Geometry dependence test. [not required] ☐ N/A ☐ Yes ☐ No

(3) Records maintained. ☐ N/A ☐ Yes ☐ No

[4731.4420, C and 4731.4501, subp. 1]

(4) RSO signs linearity, accuracy, and geometry dependence tests. [4731.4501, subp. 1 & 2] ☐ N/A ☐ Yes ☐ No

E. Survey instruments.

INSTRUMENT MANUFACTURER	MODEL NO.	SERIAL NO.	CALIBRATION DATE(S)

(1) Appropriate operable survey instruments [4731.4420 & 4731.4422] ☐ N/A ☐ Yes ☐ No

(2) Calibration, as required. [4731.4421, A, B, & C] ☐ N/A ☐ Yes ☐ No

(3) Records maintained. [4731.4502, subp. 2] ☐ N/A ☐ Yes ☐ No

F. Syringes containing RAM properly labeled and shielded, unless contraindicated. [4731.4425] ☐ N/A ☐ Yes ☐ No

G. Syringes properly labeled. [4731.4425] ☐ N/A ☐ Yes ☐ No

H. Vials containing RAM properly shielded. [4731.4425] ☐ N/A ☐ Yes ☐ No

I. Vials properly labeled. [4731.4425] ☐ N/A ☐ Yes ☐ No

REMARKS:

12. MATERIALS:

A. Licensee uses unit doses. ☐ N/A ☐ Yes ☐ No

B. Licensee uses generator. ☐ N/A ☐ Yes ☐ No

C. Licensee possesses sealed sources or

brachytherapy sources. ☐ N/A ☐ Yes ☐ No

D. Isotope, chemical form, quantity and use, as authorized. [4731.4403] ☐ N/A ☐ Yes ☐ No

E. Molybdenum-99 breakthrough. ☐ N/A

(1) Tests performed. [4731.4435, B] ☐ N/A ☐ Yes ☐ No

(2) Records of tests maintained. [4731.4509] ☐ N/A ☐ Yes ☐ No

F. Leak tests.

(1) Leak tests performed on sealed sources and brachytherapy sources. [4731.4424, B] ☐ N/A ☐ Yes ☐ No

ISOTOPE	SOURCE SERIAL NO.	LEAK TEST DATE(S)

(2) Leak test records in units of microcuries. [4731.0210, subp. 3] ☐ N/A ☐ Yes ☐ No

(3) Leak test records signed by RSO. [4731.4504, subp. 1] ☐ N/A ☐ Yes ☐ No

(4) Records of leak tests kept for 3 years. [4731.4504, subp. 1] ☐ N/A ☐ Yes ☐ No

G. Inventories.

(1) Semi-annual inventory of sealed sources. [4731.4424. G] ☐ N/A ☐ Yes ☐ No

(2) Inventory records signed by RSO. [4731.4504, subp. 2, D] ☐ N/A ☐ Yes ☐ No

(3) Records of leak tests and inventories kept for 3 years. [4731.4504, subp. 2] ☐ N/A ☐ Yes ☐ No

REMARKS:

13. RADIOPHARMACEUTICAL THERAPY: ☐ N/A

A. Iodine radiopharmaceutical therapy 30 millicuries or greater? ☐ N/A ☐ Yes ☐ No

B. Licensee gives oral and written safety instructions for personnel caring for patients. [4731.4441] ☐ N/A ☐ Yes ☐ No

C. Record of training. [4731.4510] ☐ N/A ☐ Yes ☐ No

D. Patient room surveys. [4731.4442] ☐ N/A ☐ Yes ☐ No

E. Record of room survey. [4731.4511] ☐ N/A ☐ Yes ☐ No

F. Release of patients containing radiopharmaceuticals meets [4731.4527]. ☐ N/A ☐ Yes ☐ No

G. Thyroid burden measurements on all individuals involved in dose administration. [not required] ☐ N/A ☐ Yes ☐ No

H. Record of thyroid measurements. [4731.2500] ☐ N/A ☐ Yes ☐ No

REMARKS:

14. BRACHYTHERAPY: ☐ N/A

A. Licensee gives oral and written safety instructions to personnel caring for patients. [4731.4453] ☐ N/A ☐ Yes ☐ No

B. Record of training maintained. [4731.4510] ☐ N/A ☐ Yes ☐ No

C. Patient area surveyed. [4731.4451] ☐ N/A ☐ Yes ☐ No

D. Release of patients containing permanent implants or radiopharmaceuticals. [4731.4506. subp. 1] ☐ N/A ☐ Yes ☐ No

E. Surveys performed before releasing patients being treated with temporary implants. [4731.4451] ☐ N/A ☐ Yes ☐ No

F. Record of patient survey. [4731.4511] ☐ N/A ☐ Yes ☐ No

G. Brachytherapy sources inventoried each time sources are returned to storage after use. [4731.4452] ☐ N/A ☐ Yes ☐ No

H. Record of brachytherapy source utilization. [4731.4512] ☐ N/A ☐ Yes ☐ No

I. Brachytherapy sources inventoried each quarter. [4731.4452] ☐ N/A ☐ Yes ☐ No

J. Record of inventory. [4731.4512] ☐ N/A ☐ Yes ☐ No

K. Brachytherapy source storage area surveyed. [4731.4451 & 4731.4452] ☐ N/A ☐ Yes ☐ No

L. Record of survey of storage area. [4731.4512] ☐ N/A ☐ Yes ☐ No

REMARKS:

15. MEDICAL EVENTS:

A. Medical events have occurred. ☐ N/A ☐ Yes ☐ No

B. Licensee in compliance with reporting requirements

for any medical events. [4731.4525, subp 1 or subp 3] ☐ N/A ☐ Yes ☐ No

C. Appropriate action taken to prevent recurrence. ☐ N/A ☐ Yes ☐ No

D. Records maintained. [4731.4525] ☐ N/A ☐ Yes ☐ No

REMARKS:

16. INTERNAL AUDITS OR INSPECTIONS:

A. Audits required. [4731.2010, subp. 3] ☐ N/A ☐ Yes ☐ No

B. Audits or inspections conducted. ☐ N/A ☐ Yes ☐ No

(1) Audits conducted by:

(2) Frequency:

(3) Scope of audit:

C. Records maintained. [4731.2500, A, (2)] ☐ N/A ☐ Yes ☐ No

D. Records reviewed. ☐ N/A ☐ Yes ☐ No

REMARKS:

17. TRANSPORTATION (4731.0402) AND 49 CFR 171-178:

A. Licensee makes shipments of RAM. ☐ N/A ☐ Yes ☐ No

B. Shipments are:

☐ Delivered to common carriers.

☐ Transported in licensee's own private vehicles.

☐ No shipment since last inspection.

NOTE: Complete only if shipment made since last inspection

C. Shipments:

(1) Authorized packages used. ☐ N/A ☐ Yes ☐ No

(2) Package type used:

(3) DOT-7A performance test records on file. [173.415(a)] ☐ N/A ☐ Yes ☐ No

(4) For special form sources, performance test records on file. [173.476(a)] ☐ N/A ☐ Yes ☐ No

(5) Packages properly labeled. [172.403(b)] ☐ N/A ☐ Yes ☐ No

(6) Packages properly marked. [172.301(a)] ☐ N/A ☐ Yes ☐ No

(7) Proper shipping papers prepared. [172.200] ☐ N/A ☐ Yes ☐ No

(8) Shipping paper contains emergency response telephone number that is maintained while hazardous materials is being transported. [172.201(d)] ☐ N/A ☐ Yes ☐ No

(9) Licensee makes return shipments of pharmacy doses. ☐ N/A ☐ Yes ☐ No

(1) If yes, licensee assumes all responsibility for shipping. ☐ N/A ☐ Yes ☐ No

(2) If no, describe arrangements between licensee and pharmacy regarding shipping requirements.

REMARKS:

18. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL:

A. Describe how packages are received and by whom. ☐ N/A

B. Procedure for opening packages. [4731.2350, subp. 1] ☐ N/A ☐ Yes ☐ No

C. Incoming packages monitored for radioactive contamination. ☐ N/A ☐ Yes ☐ No

[4731.2350, subp 2, A or C & 4731.2350, subp. 3]

D. Incoming packages monitored for external radiation levels. [4731.2350,subp. 2, B or C] ☐ N/A ☐ Yes ☐ No

E. Transfers performed, as required. [4731.0815] ☐ N/A ☐ Yes ☐ No

F. Records of receipt surveys. [4731.2510, subp. 1] ☐ N/A ☐ Yes ☐ No

G. Records of receipt, transfer, & disposal of radioactive material. [4731.0210] ☐ N/A ☐ Yes ☐ No

REMARKS:

19. WASTE DISPOSAL:

A. Describe waste disposal methods - Liquid and Solids.

B. Radioactive material disposed of as authorized. [4731.2400] ☐ N/A ☐ Yes ☐ No

C. Disposal to sanitary sewerage system within limits. [4731.2420] ☐ N/A ☐ Yes ☐ No

D. Disposal by incineration, as specified in [4731.1430 or 4731.2410; 4731.2440] ☐ N/A ☐ Yes ☐ No

E. Waste disposal by decay in storage. [4731.4429] ☐ N/A ☐ Yes ☐ No

F. Record of disposal by decay in storage. [4731.4508] ☐ N/A ☐ Yes ☐ No

G. Transfer of low-level waste for disposal [4731.2450] ☐ N/A ☐ Yes ☐ No

H. Survey of waste before disposal. [4731.2200] ☐ N/A ☐ Yes ☐ No

I. Records of waste surveys. [4731.2510] ☐ N/A ☐ Yes ☐ No

J. If LLW is stored because access to a burial site has been denied, answer (1), (2), and (3) below. ☐ N/A

(1) Adequate control of waste in storage. ☐ N/A ☐ Yes ☐ No

(2) Packages labeled and integrity maintained. ☐ N/A ☐ Yes ☐ No

(3) Records of surveys and material accountability are maintained. ☐ N/A ☐ Yes ☐ No

REMARKS:

20. AREA SURVEYS

A. Ambient dose rate surveys. [4731.4426, A] ☐ N/A ☐ Yes ☐ No

B. Contamination surveys conducted. [4731.2200, subp. 1] ☐ N/A ☐ Yes ☐ No

C. Action levels established. [not required] ☐ N/A ☐ Yes ☐ No

D. Dose rate survey records in mR/hr. [4731.4505] ☐ N/A ☐ Yes ☐ No

E. Contamination survey records maintained in dpm/100 cm^2. [4731.4505, not in DPM/100 cm^2] ☐ N/A ☐ Yes ☐ No

REMARKS:

21. **BULLETINS AND INFORMATION NOTICES:**

A. Bulletins and Information Notices are received by the licensee. ☐ N/A ☐ Yes ☐ No

B. Licensee took action in response to Bulletins and Information Notices. ☐ N/A ☐ Yes ☐ No

REMARKS:

22. **FINANCIAL ASSURANCE AND RECORD KEEPING FOR DECOMMISSIONING:**

A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination. [4731.0580, subp 6, A] ☐ N/A ☐ Yes ☐ No

B. Records include all required information. [4731.0580, subp. 3] ☐ N/A ☐ Yes ☐ No

REMARKS:

23. **INDEPENDENT MEASUREMENTS:**

A. Independent measurements made by inspector. ☐ N/A ☐ Yes ☐ No

B. Survey instrument: **Victoreen 190 Serial Number 856**

C. Last date of calibration:

D. Describe measurements and compare with Licensee's readings.

REMARKS:

24. SUMMARY OF VIOLATIONS:

MINNESOTA DEPARTMENT OF HEALTH

NUCLEAR VAN INSPECTION REPORT

Date of this inspection:

License No.:

Licensee (Name and Address):

Address letter to:

cc:

Licensee Contact:

Telephone No.:

Last Amendment No.:

Date of Amendment:

Priority: ☐ 3

Category: ☐ 2220

Date of last inspection:

Type of inspection:

☐ Announced
☐ Unannounced

☐ Routine
☐ Special

☐ Initial
☐ Reactive

Summary of findings and action:

☐ No Violation, letter issued
☐ Violation(s), letter issued
☐ Action on previous Violation(s)

Inspector:

☐ Timothy Donakowski
☐ John Goepferd
☐ George F. Johns, Jr.
☐ Sue McClanahan
☐ Craig Verke
☐ Katherine Johnson
☐ Other:

Next inspection date:

Frequency: ☐ Routine ☐ Accelerated

Inspector Signature:	Date:
Approval Signature:	Date:

Revised 6/23/04

INDIVIDUALS INTERVIEWED DURING INSPECTION

*	NAME	TITLE
☐		
☐		
☐		
☐		
☐		
☐		
☐		
☐		

☒ Indicates which individuals were at the exit briefing

1. **INSPECTION HISTORY:** ☐ N/A Initial Inspection

   A. Last inspection conducted on:

   B. Violations were identified. ☐ N/A ☐ Yes ☐ No

   C. Response letter dated:

   D. Violations identified during previous inspection:

REQUIREMENT	VIOLATION	CORRECTED	STATUS

   E. If any violation(s) identified during the last inspection were not corrected, explain.

2. **LICENSE CONDITIONS:** ☐ N/A ☐ Yes ☐ No

   A. All license conditions reviewed. ☐ N/A ☐ Yes ☐ No

   B. Licensed activities were conducted in accordance with License Conditions except as noted elsewhere in this report. ☐ N/A ☐ Yes ☐ No

3. **ORGANIZATION:**

   A. Briefly describe the organizational structure.

   B. Structure meets license requirements. ☐ Yes ☐ No

C. Radiation Safety Officer (RSO)

(1) Appointed. [4731.4405, subp. 1, B] ☐ N/A ☐ Yes ☐ No

(2) Fulfills duties of RSO. [4731.4405, subp. 1, F] ☐ N/A ☐ Yes ☐ No

(3) Has sufficient authority. [4731.4405, subp. 1, G] ☐ N/A ☐ Yes ☐ No

D. Visiting Authorized User ☐ N/A

(1) Has written permission. [4731.4405, subp. 1, A] ☐ N/A ☐ Yes ☐ No

(2) Visitor's license on file. [4731.4405, subp. 3, B,4] ☐ N/A ☐ Yes ☐ No

(3) Performs only those procedures authorized on visitor's license. [4731.4407, A, 2] ☐ N/A ☐ Yes ☐ No

(4) Uses materials under licensee's license or 60 days per year or less. [4731.4405, subp. 1, C] ☐ N/A ☐ Yes ☐ No

(5) Records maintained 5 years after visitor's last visit. [4731.4500, subp. 1 & 2] ☐ N/A ☐ Yes ☐ No

E. Mobile nuclear medicine service meets technical requirements. [4731.4428, A, 2,3,&4] ☐ N/A ☐ Yes ☐ No

REMARKS:

4. SCOPE OF PROGRAM:

A. List locations inspected.

B. Briefly describe scope of program, including types of equipment, uses involving licensed material, frequency of use, etc.

C. Radiation safety program changes. [4731.4405, subp. 2] ☐ N/A ☐ Yes ☐ No

REMARKS:

5. **TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS:**

A. Instructions to workers. [4731.1020, subp. 1] ☐ N/A ☐ Yes ☐ No

B. Training program required. ☐ N/A ☐ Yes ☐ No

(1) If required, briefly describe program

(2) Training program implemented. ☐ N/A ☐ Yes ☐ No

(3) Retraining program required. ☐ N/A ☐ Yes ☐ No

(4) Retraining program implemented. ☐ N/A ☐ Yes ☐ No

(5) Records maintained. ☐ N/A ☐ Yes ☐ No

6. **RADIOLOGICAL PROTECTION PROCEDURES:**

A. Radioactive material used in accordance with approved procedures. **[LC]** ☐ N/A ☐ Yes ☐ No

B. Individual's understanding of procedures appeared adequate:

(1) In general rules for safe use of RAM. ☐ N/A ☐ Yes ☐ No

(2) In emergency procedures. ☐ N/A ☐ Yes ☐ No

REMARKS:

7. **PERSONNEL RADIATION MONITORING – EXTERNAL:** ☐ N/A

A. Film or TLD supplier: Frequency:

B. Supplier NVLAP approved. [4731.2200, subp. 3, A] ☐ N/A ☐ Yes ☐ No

C. Processor's reports reviewed by:

D. Licensee uses MDH forms or equivalent. [4731.2520] ☐ N/A ☐ Yes ☐ No

E. MDH inspector reviewed personnel monitoring records for period

through

F. Maximum annual whole body dose: **mrem**

G. Maximum annual extremity dose: **mrem**

H. Dose(s) exceeded regulatory limits. [4731.2020] ☐ N/A ☐ Yes ☐ No

I. Licensee has implemented an ALARA program. [4731.2010, subp.2] ☐ N/A ☐ Yes ☐ No

J. Written description of ALARA program available. [4731.2010, subp.2] ☐ N/A ☐ Yes ☐ No

REMARKS:

8. **PERSONNEL RADIATION MONITORING – INTERNAL:** ☐ N/A

A. Potential for exposure of individuals to airborne RAM exists. ☐ N/A ☐ Yes ☐ No

B. Monitoring for airborne radioactivity conducted to show compliance. [4731.2010, subp. 4] ☐ N/A ☐ Yes ☐ No

C. Records maintained [4731.2510, subp.2, C] ☐ N/A ☐ Yes ☐ No

D. Bioassay program implemented as described in correspondence with Agency. ☐ N/A ☐ Yes ☐ No

E. Radioactive gases. ☐ N/A

(1) Clearance time and safety procedures are posted. [4731.2240 & 4731.2050] ☐ N/A ☐ Yes ☐ No

(2) Reusable collection system checked monthly. [not required] ☐ N/A ☐ Yes ☐ No

(3) Ventilation rates checked each six months for negative pressure. [not required] ☐ N/A ☐ Yes ☐ No

REMARKS:

9. NOTIFICATION AND REPORTS:

A. Licensee provides notifications and reports to individuals. [4731.1030] ☐ N/A ☐ Yes ☐ No

B. Licensee in compliance regarding reporting theft or loss. [4731.2600] ☐ N/A ☐ Yes ☐ No

C. Licensee in compliance regarding overexposures notification of incidents. [4731.2610] ☐ N/A ☐ Yes ☐ No

D. Licensee in compliance regarding reporting of and excessive levels and concentrations. [4731.2620] ☐ N/A ☐ Yes ☐ No

E. Termination reports furnished, if requested by workers. [4731.1030, subp. 4] ☐ N/A ☐ Yes ☐ No

REMARKS:

10. POSTING AND LABELING:

A. Radiation Areas posted. [4731.2310, subp. 1] ☐ N/A ☐ Yes ☐ No

B. Use or storage areas posted "Caution Radioactive Material." [4731.2310, subp.5] ☐ N/A ☐ Yes ☐ No

C. Containers or devices labeled. [4731.2330] ☐ N/A ☐ Yes ☐ No

D. Notice to Workers posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

E. Notice to Employees posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

REMARKS:

11. FACILITIES, MATERIALS, AND EQUIPMENT:

A. Facilities described in license application. ☐ N/A ☐ Yes ☐ No

B. Facilities are as described. ☐ N/A ☐ Yes ☐ No

C. Storage and use of radioactive material.

(1) Adequate method to prevent unauthorized individuals from entering restricted area. ☐ N/A ☐ Yes ☐ No

(2) Licensee secures radioactive material to prevent unauthorized removal or access. [4731.2290, subp. 1 & 2] ☐ N/A ☐ Yes ☐ No

D. Dose Calibrator.

(1) Licensee possesses and uses a dose calibrator. [4731.4420 and 4731.4422] ☐ N/A ☐ Yes ☐ No

MANUFACTURER	MODEL NO.	SERIAL NO.

(the following items (2-6) are not listed separately in 4731, but should be checked in accordance with manufacturer's specifications)

(2) Constancy checked ☐ N/A ☐ Yes ☐ No

(3) Linearity tested. ☐ N/A ☐ Yes ☐ No

(4) Accuracy tested ☐ N/A ☐ Yes ☐ No

(5) Geometry dependence test ☐ N/A ☐ Yes ☐ No

(6) Readings mathematically corrected if linearity error is greater than 10%. ☐ N/A ☐ Yes ☐ No

(7) Records maintained. [4731.4420, C & 4731.4502, subp.1] ☐ N/A ☐ Yes ☐ No

(8) RSO signs linearity, accuracy, and geometry dependence tests. [4731.4507, subp. 1 & 2] (Radiation safety program in 4731. 4500, subp. 1, B) ☐ N/A ☐ Yes ☐ No

E. Survey instruments.

INSTRUMENT MANUFACTURER	MODEL NO.	SERIAL NO.	CALIBRATION DATE(S)

(1) Appropriate operable survey instruments [4731.4420 & 4731.4422] ☐ N/A ☐ Yes ☐ No

(2) Calibration, as required. [4731.4421, A, B & C] ☐ N/A ☐ Yes ☐ No

(3) Records maintained. [4731.4405] ☐ N/A ☐ Yes ☐ No

F. Syringes containing RAM properly labeled and shielded, unless contraindicated. [4731.4502, subp. 2] ☐ N/A ☐ Yes ☐ No

G. Syringes properly labeled. [4731.4425] ☐ N/A ☐ Yes ☐ No

H. Vials containing RAM properly shielded. [4731.4425] ☐ N/A ☐ Yes ☐ No

I. Vials properly labeled. [4731.4425] ☐ N/A ☐ Yes ☐ No

REMARKS:

12. MATERIALS:

A. Licensee uses unit doses. ☐ N/A ☐ Yes ☐ No

B. Licensee uses generator. ☐ N/A ☐ Yes ☐ No

C. Licensee possesses sealed sources. ☐ N/A ☐ Yes ☐ No

D. Isotope, chemical form, quantity and use, as authorized. [4731.4403] ☐ N/A ☐ Yes ☐ No

E. Molybdenum-99 breakthrough. ☐ N/A

(1) Tests performed. [4731.4435, B] ☐ N/A ☐ Yes ☐ No

(2) Records of tests maintained. [4731.4427] ☐ N/A ☐ Yes ☐ No

F. Leak tests.

(1) Leak tests performed on sealed sources and brachytherapy sources. [4731.4424, B] ☐ N/A ☐ Yes ☐ No

ISOTOPE	SOURCE SERIAL NO.	LEAK TEST DATE(S)

(2) Leak test records in units of microcuries. [4731.0210, subp. 3] ☐ N/A ☐ Yes ☐ No

(3) Leak test records signed by RSO. [4731.4504, subp. 1] ☐ N/A ☐ Yes ☐ No

(4) Records of leak tests kept for 3 years. [4731.4504, subp. 1] ☐ N/A ☐ Yes ☐ No

G. Inventories.

(1) Semi-annual inventory of sealed sources. [4731.4424,G] ☐ N/A ☐ Yes ☐ No

(2) Inventory records signed by RSO. [4731.4504, subp. 2,D] ☐ N/A ☐ Yes ☐ No

(3) Records of leak tests and inventories kept for 3 years. [4731.4504, subp. 2] ☐ N/A ☐ Yes ☐ No

REMARKS:

13. RADIOPHARMACEUTICAL THERAPY: ☐ N/A

A. Release of patients containing radiopharmaceuticals meets 4731.4427. ☐ N/A ☐ Yes ☐ No

B. Thyroid burden measurements on all individuals involved in dose administration. [4731.2050] ☐ N/A ☐ Yes ☐ No

C. Record of thyroid measurements. [4731.2500] ☐ N/A ☐ Yes ☐ No

REMARKS:

14. MEDICAL EVENTS:

A. Medical events have occurred. ☐ N/A ☐ Yes ☐ No

B. Licensee in compliance with reporting requirements for medical events. [4731.4525, subp. 1 or 3] ☐ N/A ☐ Yes ☐ No

C. Appropriate action taken to prevent recurrence. ☐ N/A ☐ Yes ☐ No

D. Records maintained. [4731.4525 and 4731.0200] ☐ N/A ☐ Yes ☐ No

15. INTERNAL AUDITS OR INSPECTIONS:

A. Audits required. [4731.2010, subp. 3] ☐ N/A ☐ Yes ☐ No

B. Audits or inspections conducted. ☐ N/A ☐ Yes ☐ No

(1) Audits conducted by:

(2) Frequency:

(3) Scope of audit:

C. Records maintained. [4731.4524 and 4731.2500, A] ☐ N/A ☐ Yes ☐ No

D. Records reviewed. [4731.4405] ☐ N/A ☐ Yes ☐ No

REMARKS:

16. TRANSPORTATION (4731.0402) AND 49 CFR 171-178:

A. Licensee makes shipments of RAM. ☐ N/A ☐ Yes ☐ No

B. Shipments are:

☐ Delivered to common carriers.

☐ Transported in licensee's own private vehicles.

C. Shipments:

(1) Authorized packages used. ☐ N/A ☐ Yes ☐ No

(2) Package type used:

(3) DOT-7A performance test records on file. [173.415(a)] ☐ N/A ☐ Yes ☐ No

(4) For special form sources, performance test records on file. [173.476(a)] ☐ N/A ☐ Yes ☐ No

(5) Packages properly labeled. [172.403(b)] ☐ N/A ☐ Yes ☐ No

(6) Packages properly marked. [172.301(a)] ☐ N/A ☐ Yes ☐ No

(7) Proper shipping papers prepared. [172.200] ☐ N/A ☐ Yes ☐ No

(8) Shipping paper contains emergency response telephone number that is maintained while hazardous materials is being transported. [172.201(d)] ☐ N/A ☐ Yes ☐ No

(9) Licensee makes return shipments of pharmacy doses. ☐ N/A ☐ Yes ☐ No

(1) If yes, licensee assumes all responsibility for shipping. ☐ N/A ☐ Yes ☐ No

(2) If no, describe arrangements between licensee and pharmacy regarding shipping requirements.

REMARKS:

17. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL:

A. Describe how packages are received and by whom. ☐ N/A

B. Procedure for opening packages. [4731.2350, subp. 1 & 5] ☐ N/A ☐ Yes ☐ No

C. Incoming packages monitored for radioactive contamination. [4731.2350, subp. 2, A or C; and 4731.2350, subp. 3] ☐ N/A ☐ Yes ☐ No

D. Incoming packages monitored for external radiation levels. **[LC]** ☐ N/A ☐ Yes ☐ No

E. Transfers performed, as required. [4731.0815] ☐ N/A ☐ Yes ☐ No

F. Records of receipt surveys. [4731.2510, subp. 1] ☐ N/A ☐ Yes ☐ No

G. Records of receipt, transfer, & disposal of radioactive material. [4731.0210] ☐ N/A ☐ Yes ☐ No

REMARKS:

18. WASTE DISPOSAL:

A. Describe waste disposal methods - Liquid and Solids.

B. Radioactive material disposed of as authorized. [4731.2400] ☐ N/A ☐ Yes ☐ No

C. Waste disposal by decay in storage. [4731.4429] ☐ N/A ☐ Yes ☐ No

D. Record of disposal by decay in storage. [4731.4508] ☐ N/A ☐ Yes ☐ No

E. Transfer of low-level waste for disposal [4731.2450] ☐ N/A ☐ Yes ☐ No

F. Survey of waste before disposal. [4731.2200] ☐ N/A ☐ Yes ☐ No

G. Records of waste surveys. [4731.2510] ☐ N/A ☐ Yes ☐ No

H. If LLW is stored because access to a burial site has been denied, answer (1), (2), and (3) below. ☐ N/A

(1) Adequate control of waste in storage. ☐ N/A ☐ Yes ☐ No

(2) Packages labeled and integrity maintained. ☐ N/A ☐ Yes ☐ No

(3) Records of surveys and material accountability are maintained. ☐ N/A ☐ Yes ☐ No

REMARKS:

19. **AREA SURVEYS:**

A. Ambient dose rate surveys. [4731.4426, A] ☐ N/A ☐ Yes ☐ No

B. Contamination surveys conducted. [4731.2200, subp. 1] ☐ N/A ☐ Yes ☐ No

C. Action levels established. [not required] ☐ N/A ☐ Yes ☐ No

D. Dose rate survey records in mR/hr. [4731.4505] ☐ N/A ☐ Yes ☐ No

E. Contamination survey records maintained in dpm/100 cm^2. [4731.4505 (not in dpm] ☐ N/A ☐ Yes ☐ No

REMARKS:

20. **BULLETINS AND INFORMATION NOTICES:**

A. Bulletins and Information Notices are received by the licensee. ☐ N/A ☐ Yes ☐ No

B. Licensee took action in response to Bulletins and Information Notices. ☐ N/A ☐ Yes ☐ No

REMARKS:

21. **FINANCIAL ASSURANCE AND RECORD KEEPING FOR DECOMMISSIONING:**

A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination. [4731.0580, subp. 6, A] ☐ N/A ☐ Yes ☐ No

B. Records include all required information. [4731.0580, subp.3] ☐ N/A ☐ Yes ☐ No

REMARKS:

22. **INDEPENDENT MEASUREMENTS:**

A. Independent measurements made by inspector. ☐ N/A ☐ Yes ☐ No

B. Survey instrument: **Victoreen 190 Serial Number 856**

C. Last date of calibration:

D. Describe measurements and compare with Licensee's readings.

REMARKS:

22. **SUMMARY - LIST OF VIOLATIONS:**

MINNESOTA DEPARTMENT OF HEALTH

PHARMACY INSPECTION REPORT

Date of this inspection:

License No.:

Licensee (Name and Address):

Address letter to:

cc:

Licensee Contact:

Telephone No.:

Last Amendment No.:

Date of Amendment:

Priority: ☐ 2

Category: ☐ 2500

Date of last inspection:

Type of inspection:

☐ Announced
☐ Unannounced

☐ Routine
☐ Special

☐ Initial
☐ Reactive

Summary of findings and action:

☐ No Violation, letter issued
☐ Violation(s), letter issued
☐ Action on previous Violation(s)

Inspector:

☐ Timothy Donakowski
☐ John Goepferd
☐ George F. Johns, Jr.
☐ Sue McClanahan
☐ Craig Verke
☐ Katherine Johnson
☐ Other:

Next inspection date:

Frequency: ☐ Routine ☐ Accelerated

Inspector Signature:	Date:
Approval Signature:	Date:

Revised 6/23/04

INDIVIDUALS INTERVIEWED DURING INSPECTION

*	NAME	TITLE
☐		
☐		
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☐		

☒ Indicates which individuals were at the exit briefing

1. **INSPECTION HISTORY:** ☐ N/A Initial Inspection

A. Last inspection conducted on:

B. Violations were identified. ☐ Yes ☐ No

C. Response letter dated:

D. Violations identified during previous inspection:

REQUIREMENT	VIOLATION	CORRECTED	STATUS

E. If any violation(s) identified during the last inspection were not corrected, explain.

2. **LICENSE CONDITIONS:**

A. All license conditions reviewed. ☐ N/A ☐ Yes ☐ No

B. Licensed activities ere conducted in accordance with License Conditions except as noted elsewhere in this report. ☐ N/A ☐ Yes ☐ No

3. **ORGANIZATION:**

A. Briefly describe the organizational structure.

B. Structure meets license requirements. ☐ Yes ☐ No

C. Radiation Safety Officer (RSO)

(1) Appointed. [4731.4405, subp. 1, B] ☐ Yes ☐ No

(2) Fulfills duties of RSO. [4731.4405, subp. 1, F] ☐ Yes ☐ No

(3) Has sufficient authority. [4731.4405, subp. 1, G] ☐ Yes ☐ No

D. Visiting Authorized Nuclear Pharmacist ☐ N/A

(1) Has written permission. [4731.4405, subp. 1, A] ☐ Yes ☐ No

(2) Visitor's license on file. [4731.4405, subp. 3, B, 4] ☐ Yes ☐ No

(3) Performs only those procedures authorized on visitor's license. [4731.4407, A, 2] ☐ Yes ☐ No

(4) Uses materials under licensee's license or 60 days per year or less. [4731.4405, subp. 1, C] ☐ Yes ☐ No

(5) Records maintained 3 years after visitor's last visit. [4731.4500, subp. 1 & 2] ☐ Yes ☐ No

REMARKS:

4. SCOPE OF PROGRAM:

A. Multiple authorized locations of use. ☐ Yes ☐ No

B. List locations inspected.

C. Briefly describe scope of program, including types of equipment, uses involving licensed material, frequency of use, etc.

D. Radiation safety program changes. [4731.4428, A, 2,3,& 4] ☐ Yes ☐ No

REMARKS:

5. **TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS:**

A. Instructions to workers. [4731.1020, subp. 1] ☐ Yes ☐ No

B. Training program required. ☐ Yes ☐ No

(1) If required, briefly describe program

(2) Training program implemented. ☐ N/A ☐ Yes ☐ No

(3) Retraining program required. ☐ N/A ☐ Yes ☐ No

(4) Retraining program implemented. ☐ N/A ☐ Yes ☐ No

(5) Records maintained. ☐ N/A ☐ Yes ☐ No

REMARKS:

6. **RADIOLOGICAL PROTECTION PROCEDURES:**

A. Radioactive material used in accordance with approved procedures. **[LC]** ☐ N/A ☐ Yes ☐ No

B. Individual's understanding of procedures appeared adequate:

(1) In general rules for safe use of RAM. ☐ N/A ☐ Yes ☐ No

(2) In emergency procedures. ☐ N/A ☐ Yes ☐ No

REMARKS:

7. **PERSONNEL RADIATION MONITORING – EXTERNAL:**

A. Film or TLD supplier: Frequency:

B. Supplier NVLAP approved. [4731.2200, subp. 3, A] ☐ N/A ☐ Yes ☐ No

C. Processor's reports reviewed by:

D. Licensee uses MDH forms or equivalent. [4731.2520] ☐ N/A ☐ Yes ☐ No

E. MDH inspector reviewed personnel monitoring records for period

through

F. Maximum annual whole body dose:

G. Maximum annual extremity dose:

H. Dose(s) exceeded regulatory limits. [4731.2020] ☐ N/A ☐ Yes ☐ No

I. Licensee has implemented an ALARA program. [4731.2010, subp. 2] ☐ N/A ☐ Yes ☐ No

J. Written description of ALARA program available [4731.2010, subp. 2] ☐ N/A ☐ Yes ☐ No

REMARKS:

8. **PERSONNEL RADIATION MONITORING – INTERNAL:** ☐ N/A

A. Potential for exposure of individuals to airborne RAM exists. ☐ N/A ☐ Yes ☐ No

B. Monitoring for airborne radioactivity conducted to show compliance. [4731.2010, subp. 4] ☐ N/A ☐ Yes ☐ No

C. Records maintained [4731.2510, subp. 2, C] ☐ N/A ☐ Yes ☐ No

D. Bioassay program implemented as described in correspondence with Agency. ☐ N/A ☐ Yes ☐ No

E. Radioactive gases. ☐ N/A

(1) Reusable collection system checked monthly. [not required] ☐ Yes ☐ No

(2) Ventilation rates checked each six months for negative pressure. [not required] ☐ N/A ☐ Yes ☐ No

REMARKS:

9. NOTIFICATION AND REPORTS:

A. Licensee provides notifications and reports to individuals. [4731.1030] ☐ N/A ☐ Yes ☐ No

B. Licensee in compliance regarding reporting theft or loss. [4731.2600] ☐ N/A ☐ Yes ☐ No

C. Licensee in compliance regarding overexposures notification of incidents. [4731.2610] ☐ N/A ☐ Yes ☐ No

D. Licensee in compliance regarding reporting of and excessive levels and concentrations. [4731.2620] ☐ N/A ☐ Yes ☐ No

E. Termination reports furnished, if requested by workers. [4731.1030, subp. 4] ☐ N/A ☐ Yes ☐ No

REMARKS:

10. POSTING AND LABELING:

A. Radiation Areas posted. [4731.2310, subp. 1] ☐ N/A ☐ Yes ☐ No

B. High Radiation Areas posted. [4731.2310, subp. 2] ☐ N/A ☐ Yes ☐ No

C. Use or storage areas posted "Caution Radioactive Material." [4731.2310, subp. 5] ☐ N/A ☐ Yes ☐ No

D. Containers or devices labeled. [4731.2330] ☐ N/A ☐ Yes ☐ No

E. Notice to Workers posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

F. Notice to Employees posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

REMARKS:

11. FACILITIES, MATERIALS, AND EQUIPMENT:

A. Facilities described in license application. ☐ N/A ☐ Yes ☐ No

B. Facilities are as described. ☐ N/A ☐ Yes ☐ No

C. Storage and use of radioactive material.

(1) Adequate method to prevent unauthorized individuals from entering restricted area. ☐ N/A ☐ Yes ☐ No

(2) Licensee secures radioactive material to prevent unauthorized removal or access. [4731.2290, subp.1 & 2] ☐ N/A ☐ Yes ☐ No

D. Dose Calibrator.

(1) Licensee possesses and uses a dose calibrator. [4731.4420 and 4731.4422] ☐ Yes ☐ No

MANUFACTURER	MODEL NO.	SERIAL NO.

(the following items (2-6) are not listed separately in 4731, but should be checked in accordance with manufacturer's specifications)

(2) Constancy checked. ☐ N/A ☐ Yes ☐ No

(3) Linearity tested. ☐ N/A ☐ Yes ☐ No

(4) Accuracy tested. ☐ N/A ☐ Yes ☐ No

(5) Geometry dependence test. ☐ N/A ☐ Yes ☐ No

(6) Readings mathematically corrected if linearity error is greater than 10%. ☐ N/A ☐ Yes ☐ No

(7) Records maintained. ☐ N/A ☐ Yes ☐ No
{4731.4420, C & 4731.4502, subp. 1]

(8) RSO signs linearity, accuracy, and geometry dependence tests. ☐ N/A ☐ Yes ☐ No
[4731.4507, sub. 1 & 2]
[Radiation safety program in 4731.4500, subp. 1, B]

E. Survey instruments.

INSTRUMENT MANUFACTURER	MODEL NO.	SERIAL NO.	CALIBRATION DATE(S)

(1) Appropriate operable survey instruments [4731.4420 & 4731.442 ☐ N/A ☐ Yes ☐ No

(2) Calibration, as required. [4731.4421, A, B & C] ☐ N/A ☐ Yes ☐ No

(3) Records maintained. [4731.4405] ☐ N/A ☐ Yes ☐ No

F Syringes properly labeled. [4731.4425] ☐ N/A ☐ Yes ☐ No

G. Vials containing RAM properly shielded. [4731.4425] ☐ N/A ☐ Yes ☐ No

H. Vials properly labeled. [4731.4425] ☐ N/A ☐ Yes ☐ No

REMARKS:

12. MATERIALS:

A. Licensee uses generator. ☐ N/A ☐ Yes ☐ No

B. Licensee possesses sealed sources ☐ N/A ☐ Yes ☐ No

C. Isotope, chemical form, quantity and use, as authorized. [4731.4403] ☐ N/A ☐ Yes ☐ No

D. Molybdenum-99 breakthrough. ☐ N/A

(1) Tests performed. [4731.4435, B] ☐ N/A ☐ Yes ☐ No

(2) Records of tests maintained. [4731.4427] ☐ N/A ☐ Yes ☐ No

E. Leak tests.

(1) Leak tests performed on sealed sources [4731.4424, B] ☐ N/A ☐ Yes ☐ No

ISOTOPE	SOURCE SERIAL NO.	LEAK TEST DATE(S)

(2) Leak test records in units of microcuries. [4731.0210, subp. 3] ☐ N/A ☐ Yes ☐ No

(3) Leak test records signed by RSO. [4731.4504, subp. 1] ☐ N/A ☐ Yes ☐ No

(4) Records of leak tests kept for 3years. [4731.4504, subp. 1] ☐ N/A ☐ Yes ☐ No

G. Inventories.

(1) Semi-annual inventory of sealed sources. [4731.4424, G] ☐ N/A ☐ Yes ☐ No

(2) Inventory records signed by RSO. [4731.4504, subp. 2] ☐ N/A ☐ Yes ☐ No

(3) Records of leak tests and inventories kept for 3 years. [4731.4505, subp. 2] ☐ N/A ☐ Yes ☐ No

REMARKS:

13. INTERNAL AUDITS OR INSPECTIONS:

A. Audits required. [4731.2010, subp. 3] ☐ Yes ☐ No

B. Audits or inspections conducted. ☐ Yes ☐ No

(1) Audits conducted by:

(2) Frequency:

(3) Scope of audit:

C. Records maintained. ☐ Yes ☐ No

D. Records reviewed. ☐ Yes ☐ No

REMARKS:

14. TRANSPORTATION (4731.0402) AND 49 CFR 171-178:

A. Licensee makes shipments of RAM. ☐ N/A ☐ Yes ☐ No

B. Shipments are:

☐ Delivered to common carriers.

☐ Transported in licensee's own private vehicles.

☐ No shipment since last inspection.

NOTE: Complete only if shipment made since last inspection

C. Shipments:

(1) Authorized packages used. ☐ N/A ☐ Yes ☐ No

(2) Package type used:

(3) DOT-7A performance test records on file. [173.415(a)] ☐ N/A ☐ Yes ☐ No

(4) For special form sources, performance test records on file. [173.476(a)] ☐ N/A ☐ Yes ☐ No

(5) Packages properly labeled. [172.403(b)] ☐ N/A ☐ Yes ☐ No

(6) Packages properly marked. [172.301(a)] ☐ N/A ☐ Yes ☐ No

(7) Proper shipping papers prepared. [172.200] ☐ N/A ☐ Yes ☐ No

(8) Shipping paper contains emergency response telephone number that is maintained while hazardous materials is being transported. [172.201(d)] ☐ N/A ☐ Yes ☐ No

REMARKS:

15. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL:

A. Describe how packages are received and by whom.

B. Procedure for opening packages. [4731.2350, subp. 1 & 5] ☐ N/A ☐ Yes ☐ No

C. Incoming packages monitored for radioactive contamination. [4731.2350, subp. 2, A or C and 4731.2350, subp. 3] ☐ N/A ☐ Yes ☐ No

D. Incoming packages monitored for external radiation levels. **[LC]** ☐ N/A ☐ Yes ☐ No

E. Transfers performed, as required. [4731.0815] ☐ N/A ☐ Yes ☐ No

F. Records of receipt surveys. [4731.2510, subp. 1] ☐ N/A ☐ Yes ☐ No

G. Records of receipt, transfer, & disposal of radioactive material. [4731.0210] ☐ N/A ☐ Yes ☐ No

REMARKS:

16. WASTE DISPOSAL:

A. Describe waste disposal methods - Liquid and Solids.

B. Radioactive material disposed of as authorized. [4731.2400] ☐ N/A ☐ Yes ☐ No

C. Disposal to sanitary sewerage system within limits. [4731.2420] ☐ N/A ☐ Yes ☐ No

D. Disposal by incineration, as specified in 4731.2430. ☐ N/A ☐ Yes ☐ No

E. Waste disposal by decay in storage. [4731.4429] ☐ N/A ☐ Yes ☐ No

F. Record of disposal by decay in storage. [4731.4508] ☐ N/A ☐ Yes ☐ No

G. Transfer of low-level waste for disposal [4731.2450] ☐ N/A ☐ Yes ☐ No

H. Survey of waste before disposal. [4731.2200] ☐ N/A ☐ Yes ☐ No

I. Records of waste surveys. [4731.2510] ☐ N/A ☐ Yes ☐ No

J. If LLW is stored because access to a burial site has been denied, answer (1), (2), and (3) below. ☐ N/A

(1) Adequate control of waste in storage. ☐ N/A ☐ Yes ☐ No

(2) Packages labeled and integrity maintained. ☐ N/A ☐ Yes ☐ No

(3) Records of surveys and material accountability are maintained. ☐ N/A ☐ Yes ☐ No

REMARKS:

17. AREA SURVEYS:

A. Ambient dose rate surveys. [4731.4426, A] ☐ N/A ☐ Yes ☐ No

B. Contamination surveys conducted. [4731.2200, subp. 1] ☐ N/A ☐ Yes ☐ No

C. Action levels established. [Not required] ☐ N/A ☐ Yes ☐ No

D. Dose rate survey records in mR/hr. [4731.4505] ☐ N/A ☐ Yes ☐ No

E. Contamination survey records maintained in dpm/100 cm^2. [4731.4505 (not in dpm)] ☐ N/A ☐ Yes ☐ No

F. Exclusive use vehicles surveyed with radiation detection instrument after each use. 49 CFR 173.443(c) ☐ N/A ☐ Yes ☐ No

REMARKS:

18. **BULLETINS AND INFORMATION NOTICES:**

A. Bulletins and Information Notices are received by the licensee. ☐ N/A ☐ Yes ☐ No

B. Licensee took action in response to Bulletins and Information Notices. ☐ N/A ☐ Yes ☐ No

REMARKS:

19. **FINANCIAL ASSURANCE AND RECORD KEEPING FOR DECOMMISSIONING:**

A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination. [4731.0580, subp. 6, A] ☐ N/A ☐ Yes ☐ No

B. Records include all required information. [4731.0580,subp. 3] ☐ N/A ☐ Yes ☐ No

REMARKS:

20. **INDEPENDENT MEASUREMENTS:**

A. Independent measurements made by inspector. ☐ N/A ☐ Yes ☐ No

B. Survey instrument: **Victoreen 190 Serial Number 856**

C. Last date of calibration:

D. Describe measurements and compare with Licensee's readings.

REMARKS:

21. SUMMARY OF VIOLATIONS:

MINNESOTA DEPARTMENT OF HEALTH

INDUSTRIAL RADIOGRAPHY FIELD INSPECTION REPORT

Date of this inspection:

License No.:

Licensee (Name and Address):

Address letter to:

cc:

Licensee Contact:

Telephone No.:

Last Amendment No.:

Date of Amendment:

Priority: ☐ 1

Category: ☐ 3320

Date of last inspection:

Location of Field Site:

Type of inspection: ☐ Announced ☐ Unannounced ☐ Routine ☐ Special ☐ Initial ☐ Reactive

Summary of findings and action:

☐ No Violation, letter issued
☐ Violation(s), letter issued
☐ Action on previous Violation(s)

Inspector:

☐ Timothy Donakowski
☐ John Goepferd
☐ George F. Johns, Jr.
☐ Sue McClanahan
☐ Craig Verke
☐ Katherine Johnson
☐ Other:

Next inspection date:

Frequency: ☐ Routine ☐ Accelerated

Inspector Signature:	Date:
Approval Signature:	Date:

Revised 6/23/04

KEY: A = Acceptable V = Violation U = Unresolved NI = Not Inspected

INDIVIDUALS INTERVIEWED DURING INSPECTION

X	NAME	TITLE
☐		
☐		
☐		
☐		

☒ Indicates which individuals were at the exit briefing

1. SECURITY OF RADIOACTIVE MATERIAL:

A. Device(s) are kept locked except when under direct surveillance. [4731.4050, subp. 1, B] ☐A ☐V ☐U ☐NI

B. When locked and not under direct surveillance, exposure device(s) and storage container(s) are secured to prevent tampering and removal. [4731.4050, subp. 2] ☐A ☐V ☐U ☐NI

Comments:

REMARKS:

2. SECURITY AND POSTING OF RADIATION AREAS:

A. Direct surveillance of the operation to protect against unauthorized entry. [4731.4190] ☐A ☐V ☐U ☐NI

B. Posting of Radiation and High Radiation Areas, as required. [4731.2310, subp. 1 & 2] ☐A ☐V ☐U ☐NI

Comments:

REMARKS:

3. PERSONNEL MONITORING:

A. Film badge(s) or TLD(s) worn. ☐A ☐V ☐U ☐NI

B. Direct reading dosimeter(s) worn. ☐A ☐V ☐U ☐NI

DOSIMETER MANUFACTURER	MODEL NO.	SERIAL NO.	CALIBRATION DATE

KEY: A = Acceptable V = Violation U = Unresolved NI = Not Inspected

C. Range of pocket dosimeter(s) is at least 0-200 mR. [4731.4170, subp. 1, C] ☐A ☐V ☐U ☐NI

D. Pocket dosimeter(s) recharged at start of each work shift. [4731.4170, subp. 1, C] ☐A ☐V ☐U ☐NI

Comments:

E. Alarm ratemeter(s) are worn. [4731.4170, subp. 1, A] ☐A ☐V ☐U ☐NI

RATEMETER MANUFACTURER	MODEL NO.	SERIAL NO.	CALIBRATION DATE

Comments:

REMARKS:

4. RADIATION SURVEYS AND INSTRUMENTS:

A. Survey instrument(s) being used at site [4731.4180, subp. 1,A] ☐A ☐V ☐U ☐NI

INSTRUMENT MANUFACTURER	MODEL NO.	SERIAL NO.	CALIBRATION DATE

B. Operable and calibrated within past six months. [4731.4060, subp. 2] ☐A ☐V ☐U ☐NI

C. Capable of measuring 2 mR/hr through 1 R/hr. [4731.4060, subp. 1] ☐A ☐V ☐U ☐NI

D. Physical radiation survey after each radiographic exposure to ensure source has returned to a shielded condition. [4731.4180, subp. 1, B] ☐A ☐V ☐U ☐NI

E. Physical radiation survey prior to securing radiography device or storage container. [4731.4180, subp.1, C] ☐A ☐V ☐U ☐NI

F. Survey competed to verify boundaries ☐A ☐V ☐U ☐NI

Comments:

REMARKS:

KEY: A = Acceptable V = Violation U = Unresolved NI = Not Inspected

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5. EXPOSURE DEVICE AND SOURCE:

EXPOSURE DEVICE MANUFACTURER	MODEL NO.	SERIAL NO.

A. Conforms to requirements of 4731.4030. ☐A ☐V ☐U ☐NI

B. Labeled with Licensee's name, address and telephone number. [4731.4030, subp. 2] ☐A ☐V ☐U ☐NI

C. Labeled with chemical symbol and mass number of the radionuclide in the device. [4731.subp. 2] ☐A ☐V ☐U ☐NI

SOURCE ISOTOPE	ACTIVITY	DATE DETERMINED	SOURCE MODEL	SERIAL NUMBER

Comments:

REMARKS:

6. TRANSPORTATION (4731.0402) AND 49 CFR 171-178:

A. Package properly marked. ☐A ☐V ☐U ☐NI

B. Proper shipping papers prepared. ☐A ☐V ☐U ☐NI

C. Shipping paper contains emergency response telephone number that is maintained while hazardous materials is being transported. [172.201(d)] ☐A ☐V ☐U ☐NI

D. Shipping papers readily accessible. ☐A ☐V ☐U ☐NI

E. Cargo blocked and braced. ☐A ☐V ☐U ☐NI

Comments:

REMARKS:

KEY: A = Acceptable V = Violation U = Unresolved NI = Not Inspected

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7. TRAINING:

The radiographer(s) and radiographer assistant(s) were trained in subjects outlined in 4731.4360. ☐A ☐V ☐U ☐NI

RADIOGRAPHER'S NAME	ISSUING AGENCY	ID CARD NO.	EXPIRATION DATE

During the inspection demonstrated understanding of 4731.4140, subp. 6.

A. Characteristics of gamma radiation. ☐A ☐V ☐U ☐NI

B. Units of radiation dose. ☐A ☐V ☐U ☐NI

C. Hazards of exposure to radiation. ☐A ☐V ☐U ☐NI

D. Levels of radiation from licensed material. ☐A ☐V ☐U ☐NI

E. Methods of controlling radiation dose. ☐A ☐V ☐U ☐NI

F. Use of radiation survey instruments. ☐A ☐V ☐U ☐NI

G. Survey techniques ☐A ☐V ☐U ☐NI

H. Use of personnel monitoring equipment. ☐A ☐V ☐U ☐NI

I. Remote handling equipment. ☐A ☐V ☐U ☐NI

J. Radiographic exposure devices. ☐A ☐V ☐U ☐NI

K. Storage containers. ☐A ☐V ☐U ☐NI

Comments:

REMARKS:

KEY: A = Acceptable V = Violation U = Unresolved NI = Not Inspected

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8. OPERATING AND EMERGENCY PROCEDURES:

The radiographer(s) and assistant(s) had copies of operating & emergency procedures. ☐A ☐V ☐U ☐NI

Demonstrated understanding of: 4731.4140, subp. 1]

A. Handling and use of licensed sealed sources and radiographic devices to prevent exposure to radiation doses in excess of limits. ☐A ☐V ☐U ☐NI

B. Methods and occasions for conducting radiation surveys. ☐A ☐V ☐U ☐NI

C. Methods for controlling access to radiographic areas. ☐A ☐V ☐U ☐NI

D. Methods and occasions for locking & securing radiographic exposure devices, storage containers, and sealed sources. ☐A ☐V ☐U ☐NI

E. Personnel monitoring and the use of personnel monitoring equipment. ☐A ☐V ☐U ☐NI

F. Transporting sealed sources to field locations, including the packaging and storage of exposure devices and containers in vehicles and control of the sealed sources during transport. ☐A ☐V ☐U ☐NI

G. Minimizing exposure of persons in the event of an accident. ☐A ☐V ☐U ☐NI

H. Procedure for notifying proper person in the event of an accident. ☐A ☐V ☐U ☐NI

I.	Maintenance of records.	☐A	☐V	☐U	☐NI
J.	Inspection and maintenance of radiographic exposure devices and storage containers.	☐A	☐V	☐U	☐NI

KEY: A = Acceptable V = Violation U = Unresolved NI = Not Inspected

K.	Steps that must be taken by radiography personnel if a pocket dosimeter is found to be off-scale.	☐A	☐V	☐U	☐NI
l.	The procedure for reporting defects and noncompliance as required by 4731.4150, subp. 1, l.	☐A	☐V	☐U	☐NI

Comments:

REMARKS:

9. RECORDS:

A	Survey records. [4731.4180, subp. 2]	☐A	☐V	☐U	☐NI
B.	Utilization logs. [4731.4260, subp. 2]	☐A	☐V	☐U	☐NI
C.	Leak tests. [4731.4240]	☐A	☐V	☐U	☐NI

Comments:

REMARKS:

10. CONFIRMATORY MEASUREMENTS:

A. Independent Survey Performed by Inspector ☐ Yes ☐ No

B. Survey instrument: **Victoreen 190 Serial Number 856**

C. Last date of calibration:

D. Reference source reading at calibration:

E. Reference source reading at inspection:

F. Survey at perimeter of restricted area:

Range mR/hr to mR/hr

G. Side-by-side measurement of surface radiation level of exposure device with source locked in secured position.

Licensee's measurement: mR/hr

MDH measurement: mR/hr

11. ITEMS NOT INSPECTED (NI) – JUSTIFICATION:

12. SUMMARY OF VIOLATIONS:

MINNESOTA DEPARTMENT OF HEALTH

INDUSTRIAL RADIOGRAPHY INSPECTION REPORT

Date of this inspection:

License No.:

Licensee (Name and Address):

Address letter to:

cc:

Licensee Contact:

Telephone No.:

Last Amendment No.:

Date of Amendment:

Priority: ☐ 2 ☐ 1

Category: ☐ 3310 ☐ 3320

Date of last inspection:

Type of inspection:

☐ Announced ☐ Unannounced

☐ Routine ☐ Special

☐ Initial ☐ Reactive

Summary of findings and action:

☐ No Violation, letter issued
☐ Violation(s), letter issued
☐ Action on previous Violation(s)

Inspector:

☐ Timothy Donakowski
☐ John Goepferd
☐ George F. Johns, Jr.
☐ Sue McClanahan
☐ Craig Verke
☐ Katherine Johnson
☐ Other:

Next inspection date:

Frequency: ☐ Routine ☐ Accelerated

Inspector Signature:	Date:
Approval Signature:	Date:

Revised 6/23/04

INDIVIDUALS INTERVIEWED DURING INSPECTION

*	NAME	TITLE
☐		
☐		
☐		
☐		
☐		
☐		
☐		
☐		
☐		

☒ Indicates which individuals were at the exit briefing

1. **INSPECTION HISTORY:** ☐ N/A Initial Inspection

   A. Last inspection conducted on:

   B. Violations were identified. ☐ Yes ☐ No

   C. Response letter dated:

   D. Violations identified during previous inspection.

REQUIREMENT	VIOLATION	CORRECTED	STATUS

   E. If any violation(s) identified during the last inspection were not corrected, explain.

2. **LICENSE CONDITIONS:**

   A. All license conditions reviewed. ☐ N/A ☐ Yes ☐ No

   B. Licensed activities were conducted in accordance with License Conditions except as noted elsewhere in this report. ☐ N/A ☐ Yes ☐ No

3. **FIELD LOCATION:**

   A. Field work authorized. ☐ N/A ☐ Yes ☐ No

   B. Field inspection conducted. ☐ N/A ☐ Yes ☐ No

LOCATION	DATES

REMARKS:

4. ORGANIZATION:

A. Briefly describe the organizational structure.

B. Structure meets license requirements. ☐ Yes ☐ No

C. Radiation Safety Officer (RSO)

(1) Authorized on license. ☐ Yes ☐ No

(2) Fulfills duties of RSO. ☐ Yes ☐ No

REMARKS:

5. SCOPE OF PROGRAM:

A. Multiple authorized locations of use. ☐ Yes ☐ No

B. List locations inspected.

C. Briefly describe scope of program, including types of equipment, uses involving licensed material, frequency of use, etc.

REMARKS:

6. OPERATING AND EMERGENCY PROCEDURES:

The radiographer(s) and assistant(s)
had copies of operating & emergency

procedures. Demonstrated understanding of:
4731.4140, subp. 1 ☐N/A ☐Yes ☐No

A. Handling and use of licensed sealed sources and radiographic devices to prevent exposure to radiation doses in excess of limits. ☐N/A ☐Yes ☐No

B. Methods and occasions for conducting radiation surveys. ☐N/A ☐Yes ☐No

C. Methods for controlling access to radiographic areas. ☐N/A ☐Yes ☐No

D. Methods and occasions for locking & securing radiographic exposure devices, storage containers, and sealed sources. ☐N/A ☐Yes ☐No

E. Personnel monitoring and the use of personnel monitoring equipment. ☐N/A ☐Yes ☐No

F. Transporting sealed sources to field locations, including the packaging and storage of exposure devices and containers in vehicles and control of the sealed sources during transport. ☐N/A ☐Yes ☐No

G. Minimizing exposure of persons in the event of an accident. ☐N/A ☐Yes ☐No

h. Procedure for notifying proper person in the event of an accident. ☐N/A ☐Yes ☐No

I. Maintenance of records. ☐N/A ☐Yes ☐No

J. Inspection and maintenance of radiographic exposure devices and storage containers. ☐N/A ☐Yes ☐No

K. Steps that must be taken by radiography personnel if a pocket dosimeter is found to be off-scale. ☐N/A ☐Yes ☐No

L. The procedure for reporting defects and noncompliance as required by 4731.4150, subp. 1, I. ☐N/A ☐Yes ☐No

Comments:

REMARKS:

7. TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS:

A. Instructions to workers. [4731.1020, subp. 1] ☐ Yes ☐ No

B. Radiographers and Radiographer Assistant(s) received copies and demonstrated understanding of 4731.4360 and Chapter 4731 where applicable. [4731.4140] ☐ Yes ☐ No

C. Radiographer Assistant(s) under direct supervision of Radiographer. [4731.4140] ☐ Yes ☐ No

D. Approved training program. ☐ Yes ☐ No

E. Deficiencies in implementation of training program. ☐ N/A ☐ Yes ☐ No

F. Radiographers completed on-the-job training. [4731.4140] ☐ N/A ☐ Yes ☐ No

G. Training provided by:

H. Test results reviewed by inspector. ☐ N/A ☐ Yes ☐ No

I. Written tests completed by all radiographers. [4731.4140] ☐ N/A ☐ Yes ☐ No

J. Radiographer and Radiographer assistant ID cards reviewed by inspector. ☐ N/A ☐ Yes ☐ No

K. Retraining program required. ☐ N/A ☐ Yes ☐ No

L. Retraining program implemented. ☐ N/A ☐ Yes ☐ No

M. Records maintained. ☐ N/A ☐ Yes ☐ No

Comments:

REMARKS:

8. **PERSONNEL RADIATION MONITORING:**

A. Film or TLD supplier: Frequency:

B. Supplier NVLAP approved. [4731.2200, subp. 3, A] ☐ Yes ☐ No

C. Processor's reports reviewed by:

D. Licensee uses MDH forms or equivalent. [4731.2520] ☐ Yes ☐ No

E. MDH inspector reviewed personnel monitoring records for period

through

F. Maximum annual whole body dose:

G. Average annual whole body dose:

H. Dose(s) exceeded regulatory limits. [4731.2200] ☐ Yes ☐ No

I. Each individual assigned a pocket dosimeter,

alarm ratemeter, and film badge. ☐ Yes ☐ No

J. Pocket Dosimeters

(1) Range:

(2) Recharged at start of shift. [4731.4170,subp. 2] ☐ Yes ☐ No

(3) Dosimeter dose recorded daily. [4731.4170, subp. 2] ☐ Yes ☐ No

(4) Annual response check. ☐ Yes ☐ No

(5) Readings comparable with film badge/TLD. ☐ Yes ☐ No

DOSIMETER MANUFACTURER	MODEL NO.	SERIAL NO.	CALIBRATION DATES

K. Alarm Ratemeters

(1) Checked at the start of each shift. [4731.4170, subp. 7,A] ☐ Yes ☐ No

(2) Record of function check. [4731.4170, subp. 7, D] ☐ Yes ☐ No

(3) Alarm preset at 500 mR/hr. [4731.4170, subp. 7, B] ☐ Yes ☐ No

(4) Calibration at intervals not to exceed one (1) year. [4731.4170, subp. 7, D] ☐ Yes ☐ No

(5) Records of annual calibration. 4731.4170, subp. 7, D] ☐ Yes ☐ No

ALARM RATEMETER MANUFACTURER	MODEL NO.	SERIAL NO.	CALIBRATION DATES

9. NOTIFICATION AND REPORTS:

A. Licensee provides notifications and reports to individuals. [4731.1030] ☐ N/A ☐ Yes ☐ No

B. Licensee in compliance regarding reporting of theft or loss. [4731.2600] ☐ N/A ☐ Yes ☐ No

C. Licensee in compliance regarding notification of incidents. [4731.2610] ☐ N/A ☐ Yes ☐ No

D. Licensee in compliance regarding reporting of overexposures and excessive levels and concentrations.[4731.2620] ☐ N/A ☐ Yes ☐ No

E. Termination reports furnished, if requested by workers. [4731.1030, subp. 4] ☐ N/A ☐ Yes ☐ No

REMARKS:

10. POSTING AND LABELING:

A. Radiation Areas posted. [4731.2310, subp. 1] ☐ N/A ☐ Yes ☐ No

B. High Radiation Areas posted. [4731.2310, subp. 2] ☐ N/A ☐ Yes ☐ No

C. Use or storage areas posted "Caution Radioactive Material." [4731.2310, subp. 5] ☐ N/A ☐ Yes ☐ No

D. Containers or devices labeled. [4731.2330] ☐ N/A ☐ Yes ☐ No

E. Notice to Workers posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

F. Notice to Employees posted. [4731.1010] ☐ Yes ☐ No

REMARKS:

11. FACILITIES, MATERIALS, AND EQUIPMENT:

A. Facilities described in license application. ☐ Yes ☐ No

B. Facilities are as described. ☐ Yes ☐ No

C. Storage and use of radioactive material.

(1) Adequate method to prevent unauthorized individuals from entering restricted area. [4731.4190] ☐ Yes ☐ No

(2) Sources stored in unrestricted areas secured from unauthorized removal. [4731.2290] ☐ N/A ☐ Yes ☐ No

(3) Material not in storage and in unrestricted area secured against unauthorized removal. [4731.2290, subp. 2] ☐ N/A ☐ Yes ☐ No

D. Fixed facility ☐ N/A

(1) Entrance control as required. ☐ Yes ☐ No

(2) Exit control as required. ☐ Yes ☐ No

(3) Visible and audible signals to warn

of the presence of radiation. [4731.4100, Subp. 1, B] ☐ Yes ☐ No

(4) Alarm tested at beginning of each day of use. [4731.4100, subp. 2] ☐ Yes ☐ No

(5) Record of alarm system test. [4731.4100, subp. 2, C] ☐ Yes ☐ No

REMARKS:

12. LOCKING AND STORAGE OF SOURCES OF RADIATION:

A. Sources locked in device. [4731.4050] ☐ N/A ☐ Yes ☐ No

B. Devices secured to prevent tampering or unauthorized removal. [4731.4050, subp. 1, A] ☐ N/A ☐ Yes ☐ No

REMARKS:

13. MATERIALS AND EQUIPMENT:

A. Describe any special equipment used by the licensee (e.g., shields, collimators, etc.)

B. Radiation exposure devices and storage containers meet radiation level limits. [4731.4040] ☐ N/A ☐ Yes ☐ No

C. During radiographic operations, sources are locked in shielded position each time the source is returned to that position. [4731.4050, subp 1, C] ☐ N/A ☐ Yes ☐ No

REMARKS:

14. RADIOACTIVE MATERIAL INVENTORY:

A. Quarterly inventories conducted. [4731.4080, subp. 1] ☐ Yes ☐ No

B. Inventories contain all required information. [4731.4250, subp.2] ☐ Yes ☐ No

C. Records retained for four (4) years. [4731.4250 subp. 1] ☐ Yes ☐ No

D. Last by-product material inventory on:

CAMERA MODEL	CAMERA S/N	SOURCE S/N	ISOTOPE	QUANTITY	AS OF

REMARKS:

15. INSPECTION AND MAINTENANCE OF DEVICES, CONTAINERS, AND CHANGERS:

A. Included in Operating and Emergency Procedures. [4731.4150, subp. 1, G] ☐ Yes ☐ No

B. Equipment check prior to use each day. [4731.4090, subp. 1] ☐ Yes ☐ No

C. Equipment inspection and maintenance at three (3) month interval. [4731.4090, subp. 2] ☐ Yes ☐ No

D. Record of results maintained. [4731.4090, subp. 2, D] ☐ Yes ☐ No

REMARKS:

16. UTILIZATION LOG:

A. Utilization log maintained. [4731.4260] ☐ Yes ☐ No

B. Utilization log contains required information. [4731.4260, subp. 1] ☐ Yes ☐ No

REMARKS:

17. INTERNAL AUDITS OR INSPECTIONS:

A. Audits required. [4731.2010,subp.3] ☐ Yes ☐ No

B. Audits or inspections conducted. ☐ Yes ☐ No

(1) Audits conducted by:

(2) Frequency:

(3) Scope of audit:

(4) Records reviewed ☐ Yes ☐ No

C. Inspection program of the job performance of each radiographer and assistant implemented. [4731.4140, subp. 4] ☐ N/A ☐ Yes ☐ No

(1) Observation of radiographer or radiographer assistant during actual radiographic operation. [4731.4140 subp. 4,(1)] ☐ N/A ☐ Yes ☐ No

(2) Radiographer or radiographer assistant has demonstrated understanding of subjects in 4731.4140, subp. 1, F, before participating in radiographic operations if longer than six months since last participation. [4731.4140, subp. 4, (2)] ☐ N/A ☐ Yes ☐ No

D. Records maintained. [4731.2500 and 4731.4140, subp.5] ☐ Yes ☐ No

E. Records reviewed. ☐ Yes ☐ No

REMARKS:

18. TRANSPORTATION (4731.0402) AND 49 CFR 171-178:

A. Licensee makes shipments of RAM. ☐ Yes ☐ No

B. Shipments are:

☐ Delivered to common carriers.

☐ Transported in licensee's own private vehicles.

☐ No shipment since last inspection.

NOTE: Complete only if shipment made since last inspection

C. Shipments:

(1) Authorized packages used. ☐ N/A ☐ Yes ☐ No

(2) DOT-7A performance test records on file. [173.415(a)] ☐ N/A ☐ Yes ☐ No

(3) Type B packages are approved [173.416] ☐ N/A ☐ Yes ☐ No

(4) Licensee has Certificates of Compliance on file with Agency. [4731.0406, subp.3] ☐ N/A ☐ Yes ☐ No

(5) Licensee has QA program approved by Agency. [4731.0406, subp.2] ☐ N/A ☐ Yes ☐ No

(6) For special form sources, performance test records on file. [173.476(a)] ☐ N/A ☐ Yes ☐ No

(7) Packages properly labeled. [172.403(b)] ☐ N/A ☐ Yes ☐ No

(8) Packages properly marked. [172.301(a)] ☐ N/A ☐ Yes ☐ No

(9) Proper shipping papers prepared. [172.200] ☐ N/A ☐ Yes ☐ No

(10) Shipping paper contains emergency response telephone number that is maintained while hazardous materials is being transported. [172.201(d)] ☐ N/A ☐ Yes ☐ No

(11) Shipping papers readily accessible during transport. [177.817(e)] ☐ N/A ☐ Yes ☐ No

(12) Shipping papers retained for 375 days or a record of shipments maintained [177.817(f)] ☐ N/A ☐ Yes ☐ No

(a) The record includes shipping name, identification number, quantity transported, and date of shipment.. ☐ N/A ☐ Yes ☐ No

(13) Vehicles placarded, as required [172.504(a)] ☐ N/A ☐ Yes ☐ No

(14) Cargo blocked and braced. [177.842(d)] ☐ N/A ☐ Yes ☐ No

(15) Incidents reported to DOT. [171.15] ☐ N/A ☐ Yes ☐ No

Comments:

REMARKS:

19. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL:

A. Procedure for opening packages. [4731.2350, subp. 1 & 5] ☐ N/A ☐ Yes ☐ No

B. Damaged incoming packages monitored for

radioactive contamination. [4731.2350, Subp. 2, C] ☐ N/A ☐ Yes ☐ No

C. Incoming packages monitored for radiation levels. [4731.2350, subp. 2, A or C and 4731.2350, subp. 3] ☐ N/A ☐ Yes ☐ No

D. Records of receipt surveys. [4731.2510, subp. 1] ☐ N/A ☐ Yes ☐ No

E. Shipment of sources since last inspection. ☐ Yes ☐ No

F. Receipt of sources since last inspection. ☐ Yes ☐ No

G. Records of receipt, transfer, & disposal of radioactive material. [4731.0210, subp. 1] ☐ N/A ☐ Yes ☐ No

REMARKS:

20. RADIATION SURVEYS:

A. Area or facility surveys to show compliance with 4731.2020 & 4731.2200 ☐ N/A ☐ Yes ☐ No

B. Survey records maintained. [4731.2510] ☐ N/A ☐ Yes ☐ No

C. Survey after each exposure includes guide tube and circumference of device. [4731.4180, subp. 1, B] ☐ N/A ☐ Yes ☐ No

D. Survey of storage area when device is placed in storage. [4731.4180, subp. 1, C] ☐ N/A ☐ Yes ☐ No

E. Records maintained of final survey when device is placed in storage. [4731.4180, subp. 2] ☐ N/A ☐ Yes ☐ No

F. Procedures evaluated at least yearly to ensure compliance with 4731.2090. ☐ N/A ☐ Yes ☐ No

G. Records retained for two years. [4731.2510, subp. 1] ☐ N/A ☐ Yes ☐ No

REMARKS:

21. **SURVEY INSTRUMENTS:**

INSTRUMENT MANUFACTURER	MODEL NO.	SERIAL NO.	CALIBRATION DATES

A. Capability of radiation survey instruments adequate for program -- 2 mR/hr through 1 R/hr. [4731.4060, subp. 1] ☐ Yes ☐ No

B. Calibrated and operable survey meters used. [4731.4060, subp. 2] ☐ N/A ☐ Yes ☐ No

C. Calibration performed at six (6) month intervals. [4731.4060, subp. 2, A] ☐ N/A ☐ Yes ☐ No

D. Calibrated by authorized person ☐ N/A ☐ Yes ☐ No

E. Records of calibration maintained. ☐ N/A ☐ Yes ☐ No

REMARKS:

22. **LEAK TESTS:**

SOURCE NUMBER	LEAK TEST DATES

DEPLETED URANIUM LEAK TESTS	
Device Serial Number	Leak Test Dates

A. Leak tests performed by authorized person. [4731.4070, subp. 1] ☐ N/A ☐ Yes ☐ No

B. Leak tests at six (6) month intervals. ☐ N/A ☐ Yes ☐ No

C. Records of leak tests maintained. [4731.4070, subp. 2, D & 4731.4240] ☐ N/A ☐ Yes ☐ No

REMARKS:

23. BULLETINS AND INFORMATION NOTICES:

A. Bulletins and Information Notices are received by the licensee. ☐ N/A ☐ Yes ☐ No

B. Licensee took action in response to Bulletins and Information Notices. ☐ N/A ☐ Yes ☐ No

REMARKS:

24. ENVIRONMENTAL MONITORING PROGRAM:

A. An environmental monitoring program is required. ☐ Yes ☐ No

B. Environmental monitoring program has been implemented. ☐ N/A ☐ Yes ☐ No

REMARKS:

25. **RECORD KEEPING FOR DECOMMISSIONING:**

A. Decommissioning funding plan required. ☐ Yes ☐ No

B. Plan submitted. [4731.3080] ☐ N/A ☐ Yes ☐ No

REMARKS:

26. **INDEPENDENT MEASUREMENTS:**

A. Independent measurements made by inspector. ☐ Yes ☐ No

B. Survey instrument: **Victoreen 190 Serial Number 856**

C. Last date of calibration:

D. Describe measurements and compare with Licensee's readings.

REMARKS:

26. SUMMARY - LIST OF VIOLATIONS:

MINNESOTA DEPARTMENT OF HEALTH
SERVICE FIELD INSPECTION REPORT

Date of this inspection:

License No.:

Licensee (Name and Address):

Address letter to:

cc:

Licensee Contact:

Telephone No.:

Last Amendment No.:

Date of Amendment:

Priority: ☐ 5

Category: ☐ 3225

Date of last inspection:

Location of Field Site:

Type of inspection:

☐ Announced ☐ Routine ☐ Initial
☐ Unannounced ☐ Special ☐ Reactive

Summary of findings and action:

☐ No Violation, letter issued
☐ Violation(s), letter issued
☐ Action on previous Violation(s)

Inspector:

☐ Timothy Donakowski
☐ John Goepferd
☐ George F. Johns, Jr.
☐ Sue McClanahan
☐ Craig Verke
☐ Katherine Johnson
☐ Other:

Next inspection date:

Frequency: ☐ Routine ☐ Accelerated

Inspector Signature:	Date:
Approval Signature:	Date:

Revised 6/23/04

KEY: A = Acceptable V = Violation U = Unresolved NI = Not Inspected

INDIVIDUALS INTERVIEWED DURING INSPECTION

X	NAME	TITLE
☐		
☐		
☐		
☐		

☒ Indicates which individuals were at the exit briefing

1. SECURITY OF RADIOACTIVE MATERIAL:

A. Device(s) are secured except when under direct surveillance. ☐A ☐V ☐U ☐NI

B. When secured and not under direct surveillance, device(s) and storage container(s) are secured to prevent tampering and removal. ☐A ☐V ☐U ☐NI

Comments:

REMARKS:

2. SECURITY AND POSTING OF RADIATION AREAS:

A. Direct surveillance of the operation to protect against unauthorized entry. ☐A ☐V ☐U ☐NI

B. Posting of Radiation and High Radiation Areas, as required. 4731.2310, subps. 1 & 2 ☐A V☐ ☐U ☐NI

Comments:

REMARKS:

3. PERSONNEL MONITORING:

A. Personnel dosimetry worn. ☐A ☐V ☐U ☐NI

B. Direct reading pocket dosimeter(s) or electronic dosimeters worn. ☐A ☐V ☐U ☐NI

KEY: A = Acceptable V = Violation U = Unresolved NI = Not Inspected

DOSIMETER MANUFACTURER	MODEL NO.	SERIAL NO.	CALIBRATION DATE

C. Range of pocket dosimeter(s) is at least 0 - 200 mR. ☐A ☐V ☐U ☐NI

D. Pocket dosimeter(s) recharged at start of each work shift. ☐A ☐V ☐U ☐NI

Comments:

REMARKS:

4. EXPOSURE DEVICE AND SOURCE:

DEVICE MANUFACTURER	MODEL NO.	SERIAL NO.

A. Conforms to license requirements. ☐A ☐V ☐U ☐NI

B. Labeled with chemical symbol and mass number of the radionuclide in the device. [4731.4030, sub.2, B] ☐A ☐V ☐U ☐NI

SOURCE ISOTOPE	ACTIVITY	DATE DETERMINED	SOURCE MODEL	SERIAL NUMBER

Comments:

REMARKS:

5. RADIATION SURVEYS AND INSTRUMENTS:

A. Survey instrument(s) being used at site ☐A ☐V ☐U ☐NI

KEY: A = Acceptable V = Violation U = Unresolved NI = Not Inspected

INSTRUMENT MANUFACTURER	MODEL NO.	SERIAL NO.	CALIBRATION DATE

B. Operable and calibrated within past year. ☐A ☐V ☐U ☐NI

C. Capable of measuring 2 mR/hr through 1 R/hr. ☐A ☐V ☐U ☐NI

D. Physical radiation survey after each installation or relocation. ☐A ☐V ☐U ☐NI

Comments:

REMARKS:

6. **OPERATING AND EMERGENCY PROCEDURES:**

Copies of operating & emergency Procedures available. ☐A ☐V ☐U ☐NI

Demonstrated understanding of:

A. Handling and use of licensed sealed sources and devices to prevent exposure to radiation doses in excess of limits. ☐A ☐V ☐U ☐NI

B. Methods and occasions for conducting radiation surveys. ☐A ☐V ☐U ☐NI

C. Methods for controlling access. ☐A ☐V ☐U ☐NI

D. Personnel monitoring and the use of personnel monitoring equipment. ☐A ☐V ☐U ☐NI

E. Transporting sources to locations, including the packaging and storage of devices and control of the sources during transport. ☐A ☐V ☐U ☐NI

F. Minimizing exposure of persons in the event of an accident. ☐A ☐V ☐U ☐NI

KEY: A = Acceptable V = Violation U = Unresolved NI = Not Inspected

G.	Procedure for notifying proper person in the event of an accident.	☐A	☐V	☐U	☐NI
H.	Maintenance of records.	☐A	☐V	☐U	☐NI
I.	Steps that must be taken by personnel if a pocket dosimeter is found to be off-scale.	☐A	☐V	☐U	☐NI
J.	The procedure for reporting defects and noncompliance as required by Part 21.	☐A	☐V	☐U	☐NI

Comments:

REMARKS:

7. TRANSPORTATION (4731.0402) AND 49 CFR 171-178

A.	Package properly marked.	☐A	☐V	☐U	☐NI
B.	Proper shipping papers prepared.	☐A	☐V	☐U	☐NI
C.	Shipping paper contains emergency response telephone number that is maintained while hazardous materials is being transported. [172.201(d)]	☐A	☐V	☐U	☐NI
D.	Shipping papers readily accessible.	☐A	☐V	☐U	☐NI
E.	Cargo blocked and braced.	☐A	☐V	☐U	☐NI

Comments:

REMARKS:

8. RECORDS:

A.	Survey records.	☐A	☐V	☐U	☐NI
B.	Leak tests.	☐A	☐V	☐U	☐NI

Comments:

REMARKS:

9. CONFIRMATORY MEASUREMENTS:

KEY:	A = Acceptable	V = Violation	U = Unresolved	NI = Not Inspected

A. Independent Survey Performed by Inspector ☐ Yes ☐ No

B. Survey instrument: **Victoreen 190 Serial Number 856**

C. Last date of calibration:

D. MDH measurement:

10. SUMMARY OF VIOLATIONS:

MINNESOTA DEPARTMENT OF HEALTH

SOURCE AND SPECIAL NUCLEAR MATERIAL INSPECTION REPORT

Date of this inspection:

License No.:

Licensee (Name and Address):

Address letter to:

cc:

Licensee Contact:

Telephone No.:

Last Amendment No.:

Date of Amendment:

Priority: ☐ 5

Category: ☐ 3620 ☐ other

Date of last inspection:

Type of inspection:

☐ Announced ☐ Unannounced

☐ Routine ☐ Special

☐ Initial ☐ Reactive

Summary of findings and action:

☐ No Violation, letter issued
☐ Violation(s), letter issued
☐ Action on previous Violation(s)

Inspector:

☐ Timothy Donakowski
☐ John Goepferd
☐ George F. Johns, Jr.
☐ Sue McClanahan
☐ Craig Verke
☐ Katherine Johnson
☐ Other:

Next inspection date:

Frequency: ☐ Routine ☐ Accelerated

Inspector Signature:	Date:
Approval Signature:	Date:

Revised 6/23/04

INDIVIDUALS INTERVIEWED DURING INSPECTION

*	NAME	TITLE
☐		
☐		
☐		
☐		

☒ Indicates which individuals were at the exit briefing

1. INSPECTION HISTORY ☐ N/A Initial Inspection

A. Last inspection conducted on:

B. Violations were identified. ☐ N/A ☐ Yes ☐ No

C. Response letter dated:

D. Violations identified during previous inspection:

REQUIREMENT	VIOLATION	CORRECTED	STATUS

E. If any violation(s) identified during the last inspection were not corrected, explain.

2. LICENSE CONDITIONS:

A. All license conditions reviewed. ☐ Yes ☐ No

B. Licensed activities were conducted in Accordance with License Conditions except As noted elsewhere in this report. ☐ Yes ☐ No

3. ORGANIZATION:

A. Briefly describe the organizational structure.

B. Structure meets license requirements. ☐ Yes ☐ No

C. Radiation Safety Officer (RSO)

(1) Authorized on license. [4731.4405, subp. 1, B] ☐ N/A ☐ Yes ☐ No

(2) Fulfills duties of RSO. [4731.4405, subp. 1, F] ☐ N/A ☐ Yes ☐ No

(3) Has sufficient authority. [4731.4405, subp. 1, G] ☐ N/A ☐ Yes ☐ No

D. Radiation safety Committee (RSC) ☐ N/A ☐ Yes ☐ No

(1) RSC approved use of radioactive material and Reviews use at RSC meetings. [4731.4405, subp. 1, G] ☐ N/A ☐ Yes ☐ No

(2) RSC reviews use of radioactive material in annual program Review [4731.4405, subp.1, F; 4731.2010, subp. 3] ☐ N/A ☐ Yes ☐ No

(3) RSC has implemented corrective actions **(LC)** ☐ N/A ☐ Yes ☐ No

E. Authorized Users.

(1) Radioactive materials used under supervision of an authorized user **(LC)** ☐ N/A ☐ Yes ☐ No

REMARKS:

4. SCOPE OF PROGRAM

A. Multiple authorized locations of use. ☐ N/A ☐ Yes ☐ No

B. Are all locations listed on license? **(LC)** ☐ N/A ☐ Yes ☐ No

C. Were on-site inspections performed at each location? In no, explain ☐ N/A ☐ Yes ☐ No

D. Describe scope of program (staff size, type of equipment, uses involving licensed material, frequency of use, etc.) ☐ N/A ☐ Yes ☐ No

REMARKS:

5. OPERATIONS:

A. Procedures are posted **(LC)** ☐ N/A ☐ Yes ☐ No

B. Procedures are identical or more restrictive than those submitted with license **(LC)** ☐ N/A ☐ Yes ☐ No

C. Procedures are approved by RSC **(LC)** ☐ N/A ☐ Yes ☐ No

D. Radiation survey of device and patient is performed to ensure source is returned to shielded position [4731.4427] ☐ N/A ☐ Yes ☐ No

E. Records of radiation surveys maintained for three years [4731.4427, C] ☐ N/A ☐ Yes ☐ No

F. Device operator trained in emergency procedures is physically present or available by telephone ☐ N/A ☐ Yes ☐ No

during treatment (LC)

G. Medical physicist or RSO and authorized user available for prompt assistance in emergency **(LC)** ☐ N/A ☐ Yes ☐ No

H. Written operating procedures are provided to nurses prior to device use **(LC)** ☐ N/A ☐ Yes ☐ No

REMARKS

6. TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS:

A. Instructions to workers. [4731.1020, subp. 1] ☐ N/A ☐ Yes ☐ No

B. Training program required. ☐ N/A ☐ Yes ☐ No

(1) If required, briefly describe program

(2) Training program implemented. ☐ N/A ☐ Yes ☐ No

(3) Retraining program required. ☐ N/A ☐ Yes ☐ No

(4) Retraining program implemented. ☐ N/A ☐ Yes ☐ No

(5) Records maintained. ☐ N/A ☐ Yes ☐ No

REMARKS

7. RADIOLOGICAL PROTECTION PROCEDURES:

A. Radioactive material used in accordance with approved procedures. ☐ N/A ☐ Yes ☐ No

B. Individual's understanding of procedures appeared adequate:

(1) In general rules for safe use of RAM. ☐ N/A ☐ Yes ☐ No

(2) In emergency procedures. ☐ N/A ☐ Yes ☐ No

C. Changes in procedures since last inspection. ☐ N/A ☐ Yes ☐ No

(1) Changes authorized. ☐ N/A ☐ Yes ☐ No

REMARKS:

8. **PERSONNEL RADIATION MONITORING – EXTERNAL:** ☐ N/A

A. Film or TLD supplier: Frequency:

B. Supplier NVLAP approved. [4731.2200, subp.1] ☐ N/A ☐ Yes ☐ No

C. Processor's reports reviewed by:

D. Licensee uses MDH forms or equivalent. [4731.2520] ☐ N/A ☐ Yes ☐ No

E. MDH inspector reviewed personnel monitoring records for period

through

F. Maximum annual whole body dose: mrem

G. Maximum annual extremity dose: mrem

H. Dose(s) exceeded regulatory limits. [4731.2020] ☐ N/A ☐ Yes ☐ No

I. Pocket dosimeters used. ☐ N/A

(1) Type used:

(2) Frequency of recharging:

(3) Readings comparable with film badge/TLD. ☐ N/A ☐ Yes ☐ No

REMARKS:

9. **PERSONNEL RADIATION MONITORING – INTERNAL:** ☐ N/A

A. Potential for exposure of individuals to airborne RAM exists. ☐ N/A ☐ Yes ☐ No

B. Monitoring for airborne radioactivity conducted to show compliance. [4731.2010, subp.4] ☐ N/A ☐ Yes ☐ No

C. Records maintained. [4731.2510] ☐ N/A ☐ Yes ☐ No

D. Briefly describe licensee's program for monitoring airborne radioactivity.

E. Bioassay program required. ☐ N/A ☐ Yes ☐ No

F. Bioassay program implemented as described in license application. ☐ N/A ☐ Yes ☐ No

G. Ventilation checks completed annually ☐ N/A ☐ Yes ☐ No

REMARKS:

10. INTERNAL AUDITS OR INSPECTIONS:

A. Audits required. [4731.2010, subp. 3] ☐ Yes ☐ No

B. Audits or inspections conducted. ☐ Yes ☐ No

(1) Audits conducted by:

(2) Frequency:

(3) Scope of audit:

C. Records maintained. [4731.4525; 4731.2500] ☐ N/A ☐ Yes ☐ No

D. Records reviewed. [4731.4405] ☐ N/A ☐ Yes ☐ No

REMARKS:

11. NOTIFICATION AND REPORTS

A. Licensee provides notifications and reports to individuals. [4731.1020, subp. 1] ☐ N/A ☐ Yes ☐ No

B. Licensee in compliance regarding reporting of theft or loss.

[4731.2600] ☐ N/A ☐ Yes ☐ No

C. Licensee in compliance regarding notification of incidents. [4731.2610 ☐ N/A ☐ Yes ☐ No

D. Licensee in compliance regarding reporting of overexposures and excessive levels and concentrations. [4731.2610] ☐ N/A ☐ Yes ☐ No

E. Termination reports furnished, if requested by workers. [4731.2620] ☐ N/A ☐ Yes ☐ No

REMARKS:

12. POSTING AND LABELING:

A. Radiation Areas posted. [4731.2310, subp.4] ☐ N/A ☐ Yes ☐ No

B. High Radiation Areas posted. [4731.2110, subp.2] ☐ N/A ☐ Yes ☐ No

C. Use or storage areas posted "Caution Radioactive Material." [4731.2310, subp. 5] ☐ N/A ☐ Yes ☐ No

D. Containers or devices labeled. [4731.2330] ☐ N/A ☐ Yes ☐ No

E. Notice to Workers posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

F. Notice to Employees posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

REMARKS:

13. FACILITIES, MATERIALS, AND EQUIPMENT:

A. Facilities described in license application. ☐ N/A ☐ Yes ☐ No

B. Facilities are as described. ☐ N/A ☐ Yes ☐ No

C. Storage and use of radioactive material.

(1) Adequate method to prevent unauthorized individuals from entering restricted area. ☐ N/A ☐ Yes ☐ No

(2) Sources stored in unrestricted areas secured from unauthorized removal. [4731.2290, subp. 1 & 2] ☐ N/A ☐ Yes ☐ No

(3) Material not in storage and in unrestricted area secured against unauthorized removal. [4731.2290, subp. 1 & 2] ☐ N/A ☐ Yes ☐ No

(4) Physical inventories conducted at intervals not to exceed six (6) months. **[LC]** ☐ N/A ☐ Yes ☐ No

(5) Records retained for five (5) years. **[LC]** ☐ N/A ☐ Yes ☐ No

D. Survey instrument(s)

(1) Possession and use of operable survey instruments required. ☐ Yes ☐ No

INSTRUMENT MANUFACTURER	MODEL NO.	SERIAL NO.	CALIBRATION DATE

(2) Capability of radiation survey instruments adequate for program. ☐ N/A ☐ Yes ☐ No

(3) Calibration performed, as required. [4731.2200, subp. 2] ☐ N/A ☐ Yes ☐ No

(4) Records maintained. ☐ N/A ☐ Yes ☐ No

REMARKS:

14. EMERGENCY PROCEDURES:

A. Procedures are posted in conspicuous location **(LC)** ☐ N/A ☐ Yes ☐ No

B. Licensee has responded to emergencies ☐ N/A ☐ Yes ☐ No

If yes, were authorized user or RSO notified ☐ N/A ☐ Yes ☐ No

If yes, was MDH notified **(LC)** ☐ N/A ☐ Yes ☐ No

C. Spill kits available **(LC)** ☐ N/A ☐ Yes ☐ No

REMARKS

15. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL:

A. Describe receipt of packages of radioactive material. ☐ N/A

B. Procedure for opening packages. [4731.2350, subp.1 and 5] ☐ N/A ☐ Yes ☐ No

C. Incoming packages monitored for radioactive contamination. [4731.2350, subp. 2, A or C and 4731.2350. subp. 3] ☐ N/A ☐ Yes ☐ No

D. Incoming packages monitored for radiation levels. [4731.2350, subp. 2, A or C and 4731.2350, subp. 3] ☐ N/A ☐ Yes ☐ No

E. Transfers performed as required. [4731.0815] ☐ N/A ☐ Yes ☐ No

F. Records of receipt surveys. [4731.2510, subp.1] ☐ N/A ☐ Yes ☐ No

G. Records of receipt, transfer, & disposal of radioactive material. [4731.0210] ☐ N/A ☐ Yes ☐ No

REMARKS:

16. SURVEYS:

A. Briefly describe survey requirements (both direct reading and surveys for removable contamination).

B. Records of surveys. [4731.2510, subp.1] ☐ N/A ☐ Yes ☐ No

C. Leak tests required. ☐ N/A ☐ Yes ☐ No

D. Leak tests performed. ☐ N/A ☐ Yes ☐ No

REMARKS:

17. TRANSPORTATION (4731.0402) AND 49 CFR 171-178

A. Licensee makes shipments of RAM. ☐ Yes ☐ No

B. Shipments are:

☐ Delivered to common carriers.

☐ Transported in licensee's own private vehicles.

☐ No shipment since last inspection.

NOTE: Complete only if shipment made since last inspection

C. Shipments:

(1) Authorized packages used. ☐ N/A ☐ Yes ☐ No

(2) Package type used:

(3) DOT-7A performance test records on file. [173.415(a)] ☐ N/A ☐ Yes ☐ No

(4) Type B packages are approved [173.416] ☐ N/A ☐ Yes ☐ No

(5) Licensee has COCs on file with Agency. [4731.0406, subp.3] ☐ N/A ☐ Yes ☐ No

(6) Licensee has QA program approved by Agency. [4731.0406, subp. 2] ☐ N/A ☐ Yes ☐ No

(7) Packages properly labeled. [172.403(b)] ☐ N/A ☐ Yes ☐ No

(8) Packages properly marked. [172.301(a)] ☐ N/A ☐ Yes ☐ No

(10) Proper shipping papers prepared. [172.200] ☐ N/A ☐ Yes ☐ No

11) Shipping paper contains emergency response telephone number that is maintained while hazardous materials is being transported. [172.201(d)] ☐ N/A ☐ Yes ☐ No

(12) Shipping papers readily accessible during transport. [177.817(e)] ☐ N/A ☐ Yes ☐ No

(13) Vehicles placarded, as required. [172.504(a)] ☐ N/A ☐ Yes ☐ No

(14) Cargo blocked and braced. [177.842(d)] ☐ N/A ☐ Yes ☐ No

(15) Incidents reported to DOT. [171.15] ☐ N/A ☐ Yes ☐ No

REMARKS:

18. **WASTE DISPOSAL:**

A. Describe waste disposal methods - Liquid and Solids.

B. Radioactive material disposed of as authorized. [4731.2400] ☐ N/A ☐ Yes ☐ No

C. Transfer of low-level waste for disposal [4731.2510, subp.2, C] ☐ N/A ☐ Yes ☐ No

REMARKS:

19. ENVIRONMENTAL MONITORING PROGRAM:

A. An environmental monitoring program is required. ☐ N/A ☐ Yes ☐ No

B. Environmental monitoring program has been implemented. ☐ N/A ☐ Yes ☐ No

REMARKS:

20. BULLETINS AND INFORMATION NOTICES:

A. Bulletins and Information Notices are received by the licensee. ☐ N/A ☐ Yes ☐ No

B. Licensee took action in response to Bulletins and Information Notices. ☐ N/A ☐ Yes ☐ No

REMARKS:

21. FINANCIAL ASSURANCE AND RECORD KEEPING FOR DECOMMISSIONING:

A. Decommissioning funding plan required. ☐ N/A ☐ Yes ☐ No

B. Plan submitted. [4731.0580] ☐ N/A ☐ Yes ☐ No

22. INDEPENDENT MEASUREMENTS

A. Independent measurements made by inspector. ☐ Yes ☐ No

B. Survey instrument: **Victoreen 190 Serial Number 856**

C. Last date of calibration:

D. Describe measurements and compare with Licensee's readings.

REMARKS:

23. SUMMARY - LIST OF VIOLATIONS:

MINNESOTA DEPARTMENT OF HEALTH

TELETHERAPY INSPECTION REPORT

Date of this inspection:

License No.:

Licensee (Name and Address):

Address letter to:

cc:

Licensee Contact:

Telephone No.:

Last Amendment No.:

Date of Amendment:

Priority: ☐ 5

Category: ☐ 2300

Date of last inspection:

Type of inspection:
☐ Announced ☐ Unannounced
☐ Routine ☐ Special
☐ Initial ☐ Reactive

Summary of findings and action:

☐ No Violation, letter issued
☐ Violation(s), letter issued
☐ Action on previous Violation(s)

Inspector:

☐ Timothy Donakowski
☐ John Goepferd
☐ George F. Johns, Jr.
☐ Sue McClanahan
☐ Craig Verke
☐ Katherine Johnson
☐ Other:

Next inspection date:

Frequency: ☐ Routine ☐ Accelerated

Inspector Signature:	Date:
Approval Signature:	Date:

Revised 6/23/04

INDIVIDUALS INTERVIEWED DURING INSPECTION

	NAME	TITLE
☐		
☐		
☐		
☐		
☐		
☐		
☐		

* Indicates which individuals were at the exit briefing

1. INSPECTION HISTORY: ☐ N/A Initial Inspection

A. Last inspection conducted on:

B. Violations were identified. ☐ N/A ☐ Yes ☐ No

C. Response letter dated:

D. Violations identified during previous inspection:

REQUIREMENT	VIOLATION	CORRECTED	STATUS

E. If any violation(s) identified during the last inspection were not corrected, explain.

2. LICENSE CONDITIONS:

A. All license conditions reviewed. ☐ Yes ☐ No

B. Licensed activities were conducted in accordance with License Conditions except as noted elsewhere in this report. ☐ Yes ☐ No

3. ORGANIZATION:

A. Briefly describe the Organization

B. Radiation Safety Officer (RSO)

(1) Appointed. [4731.4405, subp. 1, B] ☐ N/A ☐ Yes ☐ No

(2) Fulfills duties of RSO. [4731.4405, subp. 1, F] ☐ N/A ☐ Yes ☐ No

(3) Has sufficient authority. [4731.4405, subp. 1, G] ☐ N/A ☐ Yes ☐ No

C. Radiation Safety Committee (RSC)

(1) RSC approved use and reviews use at RSC meetings [4731.4405, subp. 1, F] ☐ N/A ☐ Yes ☐ No

(2) Committee reviews use in annual program audit [4731.2010] ☐ N/A ☐ Yes ☐ No

(3) RSC has implemented corrective actions. ☐ N/A ☐ Yes ☐ No

D. Authorized Users - Device used under supervision of an authorized user **(LC)** ☐ N/A ☐ Yes ☐ No

REMARKS:

4. **SCOPE OF PROGRAM:**

A. Briefly describe scope of program, including types of equipment, uses involving licensed material, frequency of use, etc.

B. Radiation safety program changes. [4731.4405, subp. 2] ☐ N/A ☐ Yes ☐ No

REMARKS:

5. **OPERATING AND EMERGENCY PROCEDURES:**

A. Procedures are posted. [4731.4466, C & D] ☐ N/A ☐ Yes ☐ No

B. Procedures are as submitted with license. ☐ N/A ☐ Yes ☐ No

C. Device used in accordance with the manufacturer's radiation safety and operating instructions.

[4731.4463, A] ☐ N/A ☐ Yes ☐ No

D. At least one individual trained in safe use and emergency procedures is physically present while device in use ☐ N/A ☐ Yes ☐ No

E. Authorized user and either medical physicist or RSO is physically present while device in use **(LC)** ☐ N/A ☐ Yes ☐ No

F. Only patient is in treatment room during device use. [4731.4466. B (2)] ☐ N/A ☐ Yes ☐ No

G. Emergency Actions

(1) Procedures are located at the console unit [4731.4466, C] ☐ N/A ☐ Yes ☐ No

(2) Procedures contain names and telephone numbers of authorized users and the RSO. [4731.4466, B, 4 c] ☐ N/A ☐ Yes ☐ No

(3) Licensee has responded to emergencies ☐ N/A ☐ Yes ☐ No

If yes, were authorized user and medical physicist or RSO notified ☐ N/A ☐ Yes ☐ No

If yes, was MDH notified **(LC)** ☐ N/A ☐ Yes ☐ No

(4) Emergency response equipment available [4731.4466, F] ☐ N/A ☐ Yes ☐ No

6. TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS:

A. Instructions to workers. [4731.1020, subp. 1] ☐ N/A ☐ Yes ☐ No

B. Periodic retraining (interval <12 months) is provided to device operators. [4731.4466, E] ☐ N/A ☐ Yes ☐ No

C. Operator training on proper use of device.[4731.4466, E] ☐ N/A ☐ Yes ☐ No

D. Operators, physicians, and medical physicists have been given emergency training including dry run **(LC)** ☐ N/A ☐ Yes ☐ No

E. Records maintained. [4731.4466, G] ☐ N/A ☐ Yes ☐ No

REMARKS:

7. RADIOLOGICAL PROTECTION PROCEDURES:

A. Radiation Levels in unrestricted areas are within limits [4731.2100, subp. 2] ☐ N/A ☐ Yes ☐ No

B. Radiation levels in unrestricted areas are monitored after source installation or replacement. [4731.4469 or 4731.4471] ☐ N/A ☐ Yes ☐ No

Date of initial source installation or last source exchange:

Date of radiation survey:

C. Personnel monitoring is provided to appropriate individuals [4731.2020, 4731.2070 and 4731.2080] ☐ N/A ☐ Yes ☐ No

REMARKS:

8. PERSONNEL RADIATION MONITORING – EXTERNAL:

A. Film or TLD supplier: Frequency:

B. Supplier NVLAP approved. [4731.2200, subp. 3] ☐ N/A ☐ Yes ☐ No

C. Processor's reports reviewed by:

D. Licensee uses MDH forms or equivalent [4731.2520, subp. 4] ☐ N/A ☐ Yes ☐ No

E. MDH inspector reviewed personnel monitoring records for period

through

F. Maximum annual whole body dose:

G. Dose(s) exceeded regulatory limits. [4731.2020] ☐ N/A ☐ Yes ☐ No

H. Licensee has implemented an ALARA program. [4731.2010] ☐ N/A ☐ Yes ☐ No

(1) Annual review by radiation safety committee. [4731.4405, subp. 1, F] ☐ N/A ☐ Yes ☐ No

(2) Written description of ALARA program available. [4731.4405] ☐ N/A ☐ Yes ☐ No

REMARKS:

9. NOTIFICATION AND REPORTS:

A. Licensee provides notifications and reports to individuals. [4731.1030] ☐ N/A ☐ Yes ☐ No

B. Licensee in compliance regarding reporting theft or loss. [4731.2600] ☐ N/A ☐ Yes ☐ No

C. Licensee in compliance regarding overexposures notification of incidents.[4731.2610] ☐ N/A ☐ Yes ☐ No

D. Licensee in compliance regarding reporting of and excessive levels and concentrations. [4731.2620] ☐ N/A ☐ Yes ☐ No

E. Termination reports furnished, if requested by workers. [4731.1030, subp. 4] ☐ N/A ☐ Yes ☐ No

REMARKS:

10. POSTING AND LABELING:

A. Radiation Areas posted. [4731.2310, subp 1] ☐ N/A ☐ Yes ☐ No

B. High Radiation Areas posted. [4731.2310, subp. 2] ☐ N/A ☐ Yes ☐ No

C. Use or storage areas posted "Caution Radioactive Material." [4731.2310, subp. 5] ☐ N/A ☐ Yes ☐ No

D. Notice to Workers posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

E. Notice to Employees posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

F. Device(s) are properly labeled ☐ N/A ☐ Yes ☐ No

REMARKS:

11. FACILITIES, MATERIALS, AND EQUIPMENT:

A. Facilities described in license application. ☐ N/A ☐ Yes ☐ No

B. Facilities are as described. ☐ N/A ☐ Yes ☐ No

C. Storage and use of radioactive material.

(1) Licensee secures stored radioactive material to prevent unauthorized removal or access. [4731.2290, subp. 1 & 2] ☐ N/A ☐ Yes ☐ No

(2) Licensee controls and maintains surveillance of radioactive material in use to prevent unauthorized removal or access. [4731.2290, subp. 1 & 2] ☐ N/A ☐ Yes ☐ No

12. GENERAL REQUIREMENTS FOR TELETHERAPY UNITS:

A. Dedicated treatment rooms are equipped with continuous viewing and intercom systems. [4731.4467, E] ☐ N/A ☐ Yes ☐ No

B. Electrical interlock systems are Installed at each entry.

[4731.4467, C] ☐ N/A ☐ Yes ☐ No

C. Once activated door interlock must be reset. [4731.4467,C, 3] ☐ N/A ☐ Yes ☐ No

D. Back-up system is available to observe patient's during treatment **(LC)** ☐ N/A ☐ Yes ☐ No

If no, are treatments suspended ☐ N/A ☐ Yes ☐ No

E. Has separate backup power supply separate from power supply [4731.4474, subp. 3, A (1)] ☐ N/A ☐ Yes ☐ No

F. Allows only persons approved to be present during treatments [4731.4466, B, (2)] ☐ N/A ☐ Yes ☐ No

G. Prevent more than one radiation producing device in treatment room [4731.4466, B (3)] ☐ N/A ☐ Yes ☐ No

H. Radiation monitor to ensure radiation levels at ambient levels [7431.4467, D] ☐ N/A ☐ Yes ☐ No

I. Emergency response equipment available near treatment room [4731.4467, H] ☐ N/A ☐ Yes ☐ No

J. Calibrated dosimetry system in place [4731.4468, subp. 1] ☐ N/A ☐ Yes ☐ No

K. Locks off console if any safety checks fail [4731.4472, subp. 5] ☐ N/A ☐ Yes ☐ No

L. Written procedures for spot checks established by authorized medical physicist [4731.4472, subp.2] ☐ N/A ☐ Yes ☐ No

M. Spot check results reviewed by authorized medical physicist [4731.4472, subp. 3] ☐ N/A ☐ Yes ☐ No

N. Records maintained [4731.4472, subp. 6] ☐ N/A ☐ Yes ☐ No

REMARKS:

13. **PERIODIC SPOT CHECKS COMPLETED MONTHLY & AFTER ANY SOURCE CHANGE:** ☐ N/A ☐ Yes ☐ No

A. Test of electrical interlocks. [4731.4472, subp. 4, A] ☐ N/A ☐ Yes ☐ No

B. Beam "on-off", electrical and mechanical stops. [4731.4472, subp. 4, B] ☐ N/A ☐ Yes ☐ No

C. Beam condition indicator lights. [4731.4472, subp.4, C] ☐ N/A ☐ Yes ☐ No

D. Viewing and intercom systems. [4731.4472, 4472. subp. 4, D] ☐ N/A ☐ Yes ☐ No

E. Treatment doors. [4731.4472,subp. 4, E] ☐ N/A ☐ Yes ☐ No

F. Electrically assisted doors with teletherapy unit turned off. [4731.4472, subp. 4, F] ☐ N/A ☐ Yes ☐ No

G. Back-up battery (source retraction) is tested monthly for operation ☐ N/A ☐ Yes ☐ No

H. Records maintained [4731.4472, subp. 6] ☐ N/A ☐ Yes ☐ No

14. PERIODIC SPOT CHECKS:

A. Dosimetry system output tested [4731.4468, subp. 2] ☐ N/A ☐ Yes ☐ No

B. Timer accuracy, constancy and linearity. [4731.4472, subp. 1, A] ☐ N/A ☐ Yes ☐ No

C. "On-off" error. [4731.4472, subp. 1, B] ☐ N/A ☐ Yes ☐ No

D. Accuracy of all distance measuring and localization devices. [4731.4472, subp. 1, D] ☐ N/A ☐ Yes ☐ No

E. Coincidence radiation and light localization device [4731.4472, subp. 1, C] ☐ N/A ☐ Yes ☐ No

F. Difference between measured output and anticipated output [4731.4472, subp. 1, F] ☐ N/A ☐ Yes ☐ No

G. Records maintained [4731.4472, subp. 6] ☐ N/A ☐ Yes ☐ No

15. FULL CALIBRATION FOR TELETHERAPY:

A. Required before first medical use [4731.4469, subp. 1, A] ☐ N/A ☐ Yes ☐ No

B. Required if spot checks indicate output differs by more than 5 % [4731.4469, subp. 1, B (1) ☐ N/A ☐ Yes ☐ No

C. Required following source replacement or installation in new location [4731.4469, subp. 1, B (2)] ☐ N/A ☐ Yes ☐ No

D. Following any repair including removal of source [4731.4469, subp. 1, B (3)] ☐ N/A ☐ Yes ☐ No

E. At invervals not to exceed one year [4731.4469, subp. 1, C] ☐ N/A ☐ Yes ☐ No

F. Required determinations in 4731.4469, subp. 2 ☐ N/A ☐ Yes ☐ No

G. Full calibration done using published protocols [4731.4469, subp. 4] ☐ N/A ☐ Yes ☐ No

H. Corrections in outputs done at required intervals [4731.4469, subp. 5] ☐ N/A ☐ Yes ☐ No

I. Full calibration measurements performed by authorized medical physicist [4731.4469, subp. 6] ☐ N/A ☐ Yes ☐ No

J. Only qualified or authorized individuals perform calibrations ☐ N/A ☐ Yes ☐ No

Date of initial source installation or last source exchange:

K. Records maintained [4731.4469, subp. 7] ☐ N/A ☐ Yes ☐ No

16. FIVE YEAR CALIBRATION FOR TELETHERAPY:

A. Fully inspected and serviced in 5 years [4731.4477, subp. 1] ☐ N/A ☐ Yes ☐ No

B. Inspections and service performed by licensed individuals [4731.4477, subp. 2] ☐ N/A ☐ Yes ☐ No

C. Records are maintained [4731.4477, subp 3] ☐ N/A ☐ Yes ☐ No

17. RADIATION DETECTION EQUIPMENT:

A. Permanent radiation monitor is installed in dedicated treatment room. [4731.2220] ☐ N/A ☐ Yes ☐ No

MAKE	MODEL

B. Visible notice when source is exposed or partially exposed. [4731.2200,subp.1, A, (2)] ☐ N/A ☐ Yes ☐ No

C. Visible to someone entering room. [4731.2220, subp. 1, A, (2)] ☐ N/A ☐ Yes ☐ No

18. PORTABLE SURVEY INSTRUMENTS:

A. Survey meters required by 4731.2200, subp. 1. ☐ N/A ☐ Yes ☐ No

B. Survey meters are calibrated before first use, annually and following repair [4731.4421] ☐ N/A ☐ Yes ☐ No

C. Meter checked with dedicated check source daily before use [not required] ☐ N/A ☐ Yes ☐ No

MAKE	MODEL	S/N	CALIBRATION DATE

19. MAINTENANCE:

A. Only authorized individuals perform maintenance, repair and inspection. [4731.4465, A] ☐ N/A ☐ Yes ☐ No

Name of organization/individual:

C. Manufacturer's schedule for service is followed **(LC)** ☐ N/A ☐ Yes ☐ No

Date of last service:

20. RADIOACTIVE SOURCES:

(1) Approved source(s) are used/possessed ☐ N/A ☐ Yes ☐ No

(2) Leak tests are performed semi-annually. [4731.2200, subp. 1] ☐ N/A ☐ Yes ☐ No

Date of last test(s): ☐ N/A ☐ Yes ☐ No

(3) Source installation and replacement by authorized individuals only ☐ N/A ☐ Yes ☐ No

21. CALIBRATION/DOSIMETRY SYSTEM:

Dosimetry system calibrated by NIST or AAPM lab every two years. [4731.4468, subp1] ☐ N/A ☐ Yes ☐ No

Name of calibration lab:

Last date of calibration:

REMARKS

22. **INTERNAL AUDITS OR INSPECTIONS:**

A. Audits required. [4731.2010, subp. 3] ☐ N/A ☐ Yes ☐ No

B. Audits or inspections conducted. ☐ N/A ☐ Yes ☐ No

(1) Audits conducted by:

(2) Frequency:

(3) Scope of audit:

C. Records maintained. [4731.2500] ☐ N/A ☐ Yes ☐ No

D. Records reviewed. [4731.2010, subp.3] ☐ N/A ☐ Yes ☐ No

23. **MEDICAL EVENTS:**

A. Medical events have occurred. ☐ N/A ☐ Yes ☐ No

B. Licensee in compliance with reporting requirements for medical events. [4731.4525, subp. 1 or subp. 3] ☐ N/A ☐ Yes ☐ No

C. Appropriate action taken to prevent recurrence. ☐ N/A ☐ Yes ☐ No

D. Records maintained. [4731.4525, and 4731.0200] ☐ N/A ☐ Yes ☐ No

24. **WASTE DISPOSAL:**

A. Sources transferred to authorized individuals [4731.2400] ☐ N/A ☐ Yes ☐ No

25. **BULLETINS AND INFORMATION NOTICES:**

A. Bulletins and Information Notices are received by the licensee. ☐ N/A ☐ Yes ☐ No

B. Licensee took action in response to Bulletins and Information Notices. ☐ N/A ☐ Yes ☐ No

26. **INDEPENDENT MEASUREMENTS:**

A. Independent measurements made by inspector. ☐ N/A ☐ Yes ☐ No

B. Survey instrument: **Victoreen 190 Serial Number 856**

C. Last date of calibration:

D. Describe measurements and compare with Licensee's readings.

27. **SUMMARY OF VIOLATIONS:**

MINNESOTA DEPARTMENT OF HEALTH

VETERINARY MEDICINE INSPECTION REPORT

Date of this inspection:

License No.:

Licensee (Name and Address):

Address letter to:

cc:

Licensee Contact:

Telephone No.:

Last Amendment No.:

Date of Amendment:

Priority: ☐ 5

Category: ☐ 2400

Date of last inspection:

Type of inspection: ☐ Announced ☐ Routine ☐ Initial
☐ Unannounced ☐ Special ☐ Reactive

Summary of findings and action:

☐ No Violation, letter issued
☐ Violation(s), letter issued
☐ Action on previous Violation(s)

Inspector:

☐ Timothy Donakowski
☐ John Goepferd
☐ George F. Johns, Jr.
☐ Sue McClanahan
☐ Craig Verke
☐ Katherine Johnson
☐ Other:

Next inspection date:

Frequency: ☐ Routine ☐ Accelerated

Inspector Signature:	Date:
Approval Signature:	Date:

Revised 6/23/04

INDIVIDUALS INTERVIEWED DURING INSPECTION

*	NAME	TITLE
☐		
☐		
☐		
☐		
☐		
☐		
☐		
☐		
☐		

☒ Indicates which individuals were at the exit briefing

1. INSPECTION HISTORY ☐ N/A Initial Inspection

A. Last inspection conducted on:

B. Violations were identified. ☐ N/A ☐ Yes ☐ No

C. Response letter dated:

D. Violations identified during previous inspection:

REQUIREMENT	VIOLATION	CORRECTED	STATUS

E. If any violation(s) identified during the last inspection were not corrected, explain.

2. LICENSE CONDITIONS:

A. All license conditions reviewed. ☐ N/A ☐ Yes ☐ No

B. Licensed activities were conducted in accordance with License Conditions except as noted elsewhere in this report. ☐ N/A ☐ Yes ☐ No

3. **ORGANIZATION:**

A. Briefly describe the organizational structure.

B. Structure meets license requirements. ☐ Yes ☐ No

C. Licensee required to have a Radiation Safety Committee (RSC) ☐ Yes ☐ No

(1) If Yes, RSC fulfills requirements. ☐ N/A ☐ Yes ☐ No

(2) Records of RSC activities maintained. ☐ N/A ☐ Yes ☐ No

D. Radiation Safety Officer (RSO)

(1) Authorized on license. ☐ Yes ☐ No

(2) Fulfills duties of RSO. ☐ Yes ☐ No

REMARKS:

4. **SCOPE OF PROGRAM:**

A. Multiple authorized locations of use. ☐ Yes ☐ No

B. List locations inspected.

C. Briefly describe scope of program, including types of equipment, uses involving licensed material, frequency of use, etc.

REMARKS:

5. **OPERATING PROCEDURES:**

A. Procedures are posted **(LC)** ☐ N/A ☐ Yes ☐ No

B. Procedures are identical or more restrictive than those submitted with license **(LC)** ☐ N/A ☐ Yes ☐ No

C. Procedures are approved by RSC **(LC)** ☐ N/A ☐ Yes ☐ No

D. Radiation survey of device and patient is performed to ensure source is returned to shielded position [4731.4427] ☐ N/A ☐ Yes ☐ No

E. Records of radiation surveys maintained for Three years [4731.4427, C] ☐ N/A ☐ Yes ☐ No

F. Operator trained in emergency procedures is physically present or available by telephone during treatment **(LC)** ☐ N/A ☐ Yes ☐ No

G. Medical physicist or RSO and authorized user available for prompt assistance in emergency. **(LC)** ☐ N/A ☐ Yes ☐ No

H. Written operating procedures are provided to staff prior to procedure. (LC) ☐ N/A ☐ Yes ☐ No

REMARKS:

6. **EMERGENCY PROCEDURES:**

A. Procedures are posted in conspicuous location **(LC)** ☐ N/A ☐ Yes ☐ No

B. Individuals will carry radiation monitor if room monitor is non-functional **(LC)** ☐ N/A ☐ Yes ☐ No

C. Licensee has responded to emergencies. if yes, were authorized user and medical physicist or RSO notified. ☐ N/A ☐ Yes ☐ No

D. Emergency survey equipment available **(LC)** ☐ N/A ☐ Yes ☐ No

7. **TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS:**

A. Instructions to workers. [4731.1020, subp. 1] ☐ N/A ☐ Yes ☐ No

B. Training program required. ☐ N/A ☐ Yes ☐ No

(1) If required, briefly describe program

(2) Training program implemented. ☐ N/A ☐ Yes ☐ No

(3) Retraining program required. ☐ N/A ☐ Yes ☐ No

(4) Retraining program implemented. ☐ N/A ☐ Yes ☐ No

(5) Records maintained. ☐ N/A ☐ Yes ☐ No

C. Briefly describe the instructions given to pet owners.

D. Are they adequate **(LC)** ☐ N/A ☐ Yes ☐ No

REMARKS:

8. **RADIOLOGICAL PROTECTION PROCEDURES:**

A. Radioactive material used in accordance with approved procedures. ☐ N/A ☐ Yes ☐ No

B. Individual's understanding of procedures appeared adequate:

(1) In general rules for safe use of RAM. ☐ N/A ☐ Yes ☐ No

(2) In emergency procedures. ☐ N/A ☐ Yes ☐ No

C. Changes in procedures since last inspection. ☐ N/A ☐ Yes ☐ No

(1) Changes authorized. ☐ N/A ☐ Yes ☐ No

REMARKS:

PERSONNEL RADIATION MONITORING – EXTERNAL: ☐ N/A

A. Film or TLD supplier: Frequency:

B. Supplier NVLAP approved. [4731.2200, subp. 3, A] ☐ N/A ☐ Yes ☐ No

C. Processor's reports reviewed by:

D. Licensee uses MDH forms or equivalent. [4731.2520] ☐ N/A ☐ Yes ☐ No

E. MDH inspector reviewed personnel monitoring records for period

through

F. Maximum annual whole body dose: mrem

G. Maximum annual extremity dose: mrem

H. Dose(s) exceeded regulatory limits. [4731.2200] ☐ N/A ☐ Yes ☐ No

I. Pocket dosimeters used. ☐ N/A

(1) Type used:

(2) Frequency of recharging:

(3) Readings comparable with film badge/TLD. ☐ N/A ☐ Yes ☐ No

REMARKS:

10. PERSONNEL RADIATION MONITORING - INTERNAL ☐ N/A

A. Potential for exposure of individuals to airborne RAM exists. ☐ N/A ☐ Yes ☐ No

B. Monitoring for airborne radioactivity conducted to show compliance. [4731.2010, subp. 4] ☐ N/A ☐ Yes ☐ No

C. Records maintained. [4731.2510, subp. 2, C] ☐ N/A ☐ Yes ☐ No

D. Briefly describe licensee's program for monitoring airborne radioactivity.

E. Bioassay program required. ☐ N/A ☐ Yes ☐ No

F. Bioassay program implemented as described in license application. ☐ N/A ☐ Yes ☐ No

REMARKS:

11. NOTIFICATION AND REPORTS:

A. Licensee provides notifications and reports to individuals. [4731.1030] ☐ N/A ☐ Yes ☐ No

B. Licensee in compliance regarding reporting of theft or loss. [4731.2600] ☐ N/A ☐ Yes ☐ No

C. Licensee in compliance regarding notification of incidents. [4731.2610] ☐ N/A ☐ Yes ☐ No

D. Licensee in compliance regarding reporting of overexposures and excessive levels and concentrations. [4731.2620] ☐ N/A ☐ Yes ☐ No

E. Termination reports furnished, if requested by workers. [4731.1030, subp. 4)] ☐ N/A ☐ Yes ☐ No

REMARKS:

12. POSTING AND LABELING

A. Radiation Areas posted. [4731.2310, subp. 1] ☐ N/A ☐ Yes ☐ No

B. High Radiation Areas posted. [4731.2310, subp. 2] ☐ N/A ☐ Yes ☐ No

C. Use or storage areas posted "Caution Radioactive Material." [4731.2310, subp. 5] ☐ N/A ☐ Yes ☐ No

D. Containers or devices labeled. [4731.2330] ☐ N/A ☐ Yes ☐ No

E. Notice to Workers posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

F. Notice to Employees posted. [4731.1010] ☐ N/A ☐ Yes ☐ No

13. FACILITIES, MATERIALS, AND EQUIPMENT

A. Facilities described in license application. ☐ N/A ☐ Yes ☐ No

B. Facilities are as described. ☐ N/A ☐ Yes ☐ No

C. Storage and use of radioactive material.

(1) Adequate method to prevent unauthorized individuals from entering restricted area. ☐ N/A ☐ Yes ☐ No

(2) Sources stored in unrestricted areas secured from unauthorized removal. [4731.2290, subp. 1& 2] ☐ N/A ☐ Yes ☐ No

(3) Material not in storage and in unrestricted area secured against unauthorized removal. [4731.2290, subp. 1& 2] ☐ N/A ☐ Yes ☐ No

(4) Physical inventories conducted at intervals not to exceed six (6) months. **[LC]** ☐ N/A ☐ Yes ☐ No

(5) Records retained for five (5) years. **[LC]** ☐ N/A ☐ Yes ☐ No

D. Survey instrument(s)

(1) Possession and use of operable survey instruments required. ☐ N/A ☐ Yes ☐ No

INSTRUMENT MANUFACTURER	MODEL NO.	SERIAL NO.	CALIBRATION DATE

(2) Capability of radiation survey instruments adequate for program. ☐ N/A ☐ Yes ☐ No

(3) Calibration performed, as required. [4731.2202, subp. 2] ☐ N/A ☐ Yes ☐ No

(4) Records maintained. ☐ N/A ☐ Yes ☐ No

REMARKS:

14. INTERNAL AUDITS OR INSPECTIONS:

A. Audits required. [4731.2010, subp. 3] ☐ Yes ☐ No

B. Audits or inspections conducted. ☐ Yes ☐ No

(1) Audits conducted by:

(2) Frequency:

(3) Scope of audit:

C. Records maintained.

D. Records reviewed. ☐ Yes ☐ No

REMARKS:

15. **TRANSPORTATION (4731.0402) AND 49 CFR 171-178:**

A. Licensee makes shipments of RAM. ☐ N/A ☐ Yes ☐ No

B. Shipments are:

☐ Delivered to common carriers.

☐ Transported in licensee's own private vehicles.

☐ No shipment since last inspection.

REMARKS:

16. **RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL:**

A. Describe receipt of packages of radioactive material. ☐ N/A

B. Procedure for opening packages. [4731.2350, subp. 1; 4731.2350, subp. 5] ☐ N/A ☐ Yes ☐ No

C. Incoming packages monitored for radioactive contamination. [4731.2350, subp. 2 A or C; 4731.2350 subp. 3] ☐ N/A ☐ Yes ☐ No

D. Incoming packages monitored for radiation levels. [4731.2350, subp. 2 A or C; 4731.2350, subp. 3] ☐ N/A ☐ Yes ☐ No

E. Transfers performed as required. [4731.0815] ☐ N/A ☐ Yes ☐ No

F. Records of receipt surveys. [4731.2510, subp. 1] ☐ N/A ☐ Yes ☐ No

G. Records of receipt, transfer, & disposal of radioactive material. [4731.0210] ☐ N/A ☐ Yes ☐ No

REMARKS:

17. WASTE DISPOSAL

A. Describe waste disposal methods - Liquid and Solids.

B. Radioactive material disposed of as authorized. [4731.2400] ☐ N/A ☐ Yes ☐ No

C. Disposal to sanitary sewerage system within limits. [4731.2420] ☐ N/A ☐ Yes ☐ No

D. Disposal by incineration, as specified in [4731.2430 or 4731.2410; 4731.2240] ☐ N/A ☐ Yes ☐ No

E. Waste disposal by decay in storage. [4731.4429] ☐ N/A ☐ Yes ☐ No

F. Record of disposal by decay in storage. [4731.4508] ☐ N/A ☐ Yes ☐ No

G. Transfer of low-level waste for disposal [4731.2450 ☐ N/A ☐ Yes ☐ No

H. Survey of waste before disposal. [4731.2200] ☐ N/A ☐ Yes ☐ No

I. Records of waste surveys. [4731.2510] ☐ N/A ☐ Yes ☐ No

REMARKS:

18. SURVEYS:

A. Briefly describe survey requirements (both direct reading and surveys for removable contamination).

A. Ambient dose rate surveys. [4731.4476, A] ☐ N/A ☐ Yes ☐ No

C. Contamination surveys conducted. [4731.2200, subp.1] ☐ N/A ☐ Yes ☐ No

D. Action levels established. [4731.4426] ☐ N/A ☐ Yes ☐ No

E. Dose rate survey records in mR/hr. [4731.4505] ☐ N/A ☐ Yes ☐ No

F. Contamination survey records maintained in dpm/100 cm^2. [4731.4505; 4731.4426] ☐ N/A ☐ Yes ☐ No

G. Leak tests required. ☐ N/A ☐ Yes ☐ No

H. Leak tests performed. ☐ N/A ☐ Yes ☐ No

REMARKS:

19. BULLETINS AND INFORMATION NOTICES:

A. Bulletins and Information Notices are received by the licensee. ☐ N/A ☐ Yes ☐ No

B. Licensee took action in response to Bulletins and Information Notices. ☐ N/A ☐ Yes ☐ No

REMARKS:

20. ENVIRONMENTAL MONITORING PROGRAM:

A. An environmental monitoring program is required. ☐ N/A ☐ Yes ☐ No

B. Environmental monitoring program has been implemented. ☐ N/A ☐ Yes ☐ No

REMARKS:

21. **FINANCIAL ASSURANCE AND RECORD KEEPING FOR DECOMMISSIONING:**

A. Decommissioning funding plan required. ☐ N/A ☐ Yes ☐ No

B. Plan submitted. [4731.0580] ☐ N/A ☐ Yes ☐ No

REMARKS:

22. **INDEPENDENT MEASUREMENTS:**

A. Independent measurements made by inspector. ☐ N/A ☐ Yes ☐ No

B. Survey instrument: **Victoreen 190 Serial Number 856**

C. Last date of calibration:

D. Describe measurements and compare with Licensee's readings.

REMARKS:

23. **SUMMARY OF VIOLATIONS:**