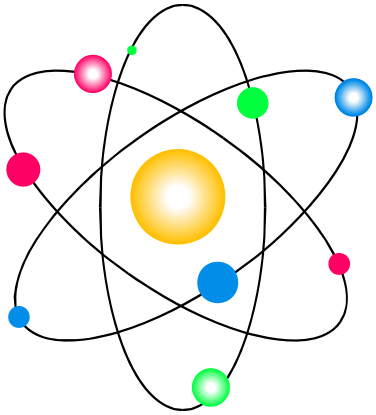
RADIOACTIVE MATERIALS REGULATORY GUIDE



PRODUCTION OF RADIOACTIVE MATERIAL USING A CYCLOTRON

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REGULATORY GUIDE FOR
PRODUCTION OF RADIOACTIVE MATERIAL USING A CYCLOTRON

PURPOSE

This guidance document has been excerpted from the US Nuclear Regulatory Commission Consolidated Guidance about Materials Licenses, NUREG-1556 Volume 21, which is *Program-Specific Guidance about Possession Licenses for Production of Radioactive Materials Using an Accelerator*. Minnesota Department of Health (MDH) has developed this document to address cyclotron facilities only. As such, some information may not be applicable. Licensees distributing radiopharmaceuticals should also refer to Minnesota Department of Health Nuclear Medicine Regulatory Guide.

This guidance document should be used for activities that take place once radioactive materials are produced by the cyclotron, which include material in the target and associated activation products, to the transfer or distribution of material to another license for preparation of the final product (e.g., radioactive drugs). This document does not include information for the operation of the cyclotron, as Minnesota Department of Health does not regulate its operation. Also, other types of accelerators (e.g., linear accelerators) are not covered in this document.

Radiochemicals are those materials that either require further manipulation to be suitable for human use or are not intended for human use. Examples include raw materials received from a supplier not licensed under 4731.3395 (chemical grade materials). For the purposes of this guidance document, "radiopharmaceutical" and "radioactive drug" will be used interchangeably in this guidance document, and reference to one is not meant to exclude the other.

Guidance for the distribution of Positron Emission Tomography (PET) radioactive drugs to medical use licensees is included in the Minnesota Department of Health Nuclear Pharmacy Regulatory Guide. This report provides guidance to applicants that produce radioactive materials using a cyclotron. The body of this document contains the standard requirements and guidance for the possession and distribution of radioactive material (e.g., radiochemicals) that is produced by a cyclotron, which is located at the applicant’s facility.

As a guidance document intended to assist a wide variety of applicants, this report contains a considerable amount of information about how licensees may choose to implement their programs to meet Minnesota Department of Health regulatory requirements. The information in this document is not intended to impose any conditions beyond those required by the regulations in Chapter 4731. This report provides specific guidance on what information should be submitted in an application to satisfy Minnesota Department of Health requirements.

Appendices A through L contain additional information on various radiation safety topics.

AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

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

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

FILING AN APPLICATION

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

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

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

Submit one copy of your application to:

Minnesota Department of Health
Radioactive Materials Unit
P.O. Box 64975
St. Paul, MN 55164-0975

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

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

Item 1: License Action Type

Check box A for a new license request.

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

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

Item 2: Name and Mailing Address of Applicant

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

radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent.

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

Applicants must provide a specific address for each location where radioactive material will be used or stored, or dispatched. Specify the street address, city, and state or other descriptive address (such as on Highway 10, 5 miles east of the intersection of Highway 10 and State Route 234, Anytown, State) for each permanent storage or use facility. A Post Office Box address is insufficient because Minnesota Department of Health needs a specific address to allow an Minnesota Department of Health inspector to find the use and/or storage location.

Timely Notification of Transfer of Control
Licensees must provide full information and obtain Minnesota Department of Health's prior written consent before transferring control of the license, directly or indirectly. Transfers of control may be the results of mergers, contractual agreements, buyouts, or majority stock transfers. Although it is not Minnesota Department of Health's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain prior Minnesota Department of Health written consent. This is to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid Minnesota Department of Health licenses.
- Materials are properly handled and secured.
- Persons using these materials are competent and committed to implementing appropriate radiological controls.
- A clear chain of custody is established to identify who is responsible for final disposal of radiography devices.

Public health and safety are not compromised by the use of such materials.

Item 4: Person to be Contacted About This Application

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

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

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

Item 5: Radioactive Material

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

For activation radionuclides, the applicant could request authorization to possess and use radioactive

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

Each authorized radioisotope is listed on an Minnesota Department of Health license by its element name, form, and the maximum amount the licensee may possess at any one time (maximum possession limit).

Unsealed and/or Sealed Radioactive Material

Each authorized radioisotope is listed on the Minnesota Department of Health license by its element name, form, and the maximum amount the licensee may possess at any one time (maximum possession limit). The applicant should list each requested radioisotope by its element name and its mass number (e.g., Fluorine-18) in item 5. It is necessary to specify whether the material will be acquired and used in unsealed or sealed form. The name of the specific chemical compound that contains the radioisotope is not generally required.

For unsealed radioactive material, it is also necessary to specify whether requested radioisotopes will be handled in volatile or non-volatile form, since additional safety precautions are required when handling and using material in a volatile form. Applicants requesting authorization to manipulate volatile radioactive material must describe appropriate facilities, engineering controls, and radiation safety procedures for handling of such material.

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

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

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

The applicant must also request authorization to possess depleted uranium if it will be used for shielding. Depleted uranium is exempt from the requirements for a license to the extent that the material is used as a shipping container. However, a specific license or authorization from the Minnesota Department of Health is needed to possess and use the depleted uranium as a shield during the time that the licensee

uses or stores the generator at its facility. The applicant must specify the total amount of depleted uranium, in kilograms, that will be needed.

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

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

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

TIMELY NOTIFICATION OF BANKRUPTCY PROCEEDINGS

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

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

RECORDKEEPING FOR DECOMMISSIONING AND FINANCIAL ASSURANCE

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

Licensees using authorized sealed sources generally use the licensed sources in a manner that would preclude releases into the environment or contamination of work areas. However, the licensee’s leak tests should demonstrate that there has been no leakage from the sealed sources while the sealed sources were in the licensee’s possession. Leakage of the sealed source in excess of the regulatory limits might warrant further Minnesota Department of Health review of decommissioning procedures.

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

Applicants requesting licensed material with a half-life in excess of 120 days should determine whether financial assurance is necessary. In addition, applicants requesting more than one radionuclide must use the sum-of-the-ratios method to determine if financial assurance is needed.

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

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

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

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

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

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

SAMPLE FORMAT FOR PROVIDING INFORMATION ABOUT REQUESTED RADIOISOTOPES			
Radioisotope	**Chemical/ Physical Form**	**Maximum Possession Limit**	**Proposed Use**
Oxygen-15	Any	1 Curie	Production and possession of a radiochemical for medical research.
Carbon-11	Any	1 Curie	Production and possession of a radiochemical for medical research.
Fluorine-18	Any	20 Curies	Production and possession of a radiochemical for transfer or distribution as

			a radiopharmaceutical to authorized licensees.
Any radioactive material with atomic numbers 3 through 83	Activated Components associated with equipment and/or shielding/building	Not to exceed 20 millicuries per radionuclide. Total not to exceed 1 curie, except as noted	Possession and storage incident to production activities

For cyclotron-produced radionuclides, applicants should state that radioactive materials will be possessed and stored incident to their production by a cyclotron in accordance with the regulations. For sealed sources that are not produced, specify their proposed use (e.g., calibration of instruments).

Distribution and Redistribution of Sealed and Unsealed Materials

Distribution activities are normally classified as either "distribution" or "redistribution." "Distribution" applies to those radioactive drugs and radiochemicals initially prepared by the pharmacy. "Redistribution" refers to those materials received from another person, authorized pursuant to 4731.3390, 3395, or 3400, depending on the product distributed. The distribution of radioactive materials to other persons requires specific approval from the Minnesota Department of Health, either by Minnesota Department of Health rules or by a license authorizing the activity. A person licensed pursuant to 4731.3395 must prepare the initial distribution of radioactive drugs for medical use.

The redistribution of *in vitro* kits and sealed sources containing radioactive material for medical use is authorized pursuant to 4731.3390 and 4731.3400, respectively, if the materials are not repackaged and the labels are not altered. The *in vitro* kits and sealed sources for medical use intended for redistribution must be initially distributed by a person licensed pursuant to 4731.3390 or 4731.3400, respectively. The transfer of radioactive materials for non-medical use, including radiochemicals, and sealed calibration and reference sources, is authorized pursuant to 4731.3105.

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

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

Provide the following as applicable:

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

For redistribution to specific licensees:

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

quantities, or NRC's or an Agreement State's regulations that authorize a general license (e.g., 4731.3245).
- Confirm that the labeling on redistributed prepackaged units for *in vitro* tests will conform to the requirements of 4731.2300 and 2330.

Preparation of Radiopharmaceuticals
The bulk of radiopharmacy activities involve the preparation of radiopharmaceuticals for commercial distribution to medical users. The applicant should indicate the types of radiopharmaceutical preparation activities it intends to perform.

To be qualified to produce PET radioactive drugs for medical use. The applicant must meeting one of the following criteria:

- Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);
- Registered or licensed with Minnesota as a drug manufacturer; or
- Licensed as a pharmacy by the Minnesota Board of Pharmacy.

Sealed Sources for Calibration and Checks
The applicant should describe the intended use of sealed sources. This will normally be for calibration and checks performed only on the applicant's instruments and equipment. Any sources intended for use in a specific instrument calibration device should be identified, along with the manufacturer and model number of the device. Supply specific information concerning the use of sealed sources for reference and calibration.

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

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

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

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

- The need for accurate detection, identification, and measurement of radioactivity in various types of effluents (gas, liquid, solid) containing varying amounts of different radionuclides and for evaluation of these effluents against Minnesota Department of Health regulatory requirements and limitations;
- The need for radioactive effluent treatment by filtration, absorption, adsorption, holdup;
- The need for the selection, evaluation, design, maintenance, and use of radioactive effluent treatment systems;

- The need for the selection, evaluation, and maintenance of radiation measurement and analysis equipment; and/or
- A potential for the contamination of facilities, equipment, and personnel, accompanied by the need to control such contamination (including airborne contamination), decontaminate personnel and equipment, and evaluate possible internal dose.

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

The minimum training and experience criteria for RSOs and Authorized Users should include a bachelor's degree in a physical science, or equivalent, and previous experience handling and supervising similar activities. If these individuals are already identified for other materials and uses, they may already be authorized for the quantities, materials, and radiation safety considerations associated with the PET radioactive drug production process. In order to demonstrate that these individuals are qualified by their training and experience to use these materials for the purposes requested, these individuals must describe their additional training and experience for the quantities, materials, and radiation safety considerations that differ substantially from the current authorization(s).

If the applicant is producing the PET radioactive drugs in a pharmacy, the applicant must be an Authorized Nuclear Pharmacist. The applicant should refer to the current version of Minnesota Department of Health Nuclear Pharmacy Regulatory Guide for guidance on the minimum training and experience requirements for an Authorized Nuclear Pharmacist and optional use of Minnesota Department of Health Form 313C (ANP) to document the individuals' training and experience.

- Identify the individuals responsible for the Radiation Safety Program and describe their training and experience using similar quantities, materials, and uses of radioactive materials.
- Describe the RSO's additional training and experience if the quantities, materials, and radiation safety considerations differ substantially from existing authorizations.
- Describe the authorized individuals' additional training and experience if the quantities, materials, and radiation safety considerations differ substantially from existing authorizations.
- If producing the PET radioactive drugs in a pharmacy identify at least one individual who meets the requirements of an Authorized Nuclear Pharmacist and document that his or her training and experience meets the requirements in 4731.4413 for a new Authorized Nuclear Pharmacist 4731.4414 for an experienced Authorized Nuclear Pharmacist. Minnesota Department of Health Form 313C (ANP) may be used to document this information for new Authorized Nuclear Pharmacists.

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

Management Responsibilities

Minnesota Department of Health recognizes that effective Radiation Safety Program management is vital to achieving safe operations that are in compliance with the regulations.

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

To ensure adequate management involvement, a management representative must sign the submitted application, acknowledging management's commitments and responsibility for the following:

- Radiation safety, security and control of radioactive materials, and compliance with regulations;
- Completeness and accuracy of the radiation safety records and all information provided to Minnesota Department of Health;
- Knowledge about the contents of the license and application;
- Compliance with current Minnesota Department of Health and Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures;
- Commitment to provide adequate resources (including space, equipment, personnel, time, and, if needed, contractors) to the Radiation Safety Program to ensure that the public and workers are protected from radiation hazards and that compliance with regulations is maintained;
- Selection and assignment of a qualified individual to serve as the Radiation Safety Officer (RSO) for licensed activities;
- Prohibition against discrimination of employees engaged in protected activities;
- Commitment to provide information to employees regarding the employee protection and deliberate misconduct;
- Commitment to obtain Minnesota Department of Health's prior written consent before transferring control of the license; and
- Notification to Minnesota Department of Health in writing, immediately following filing of petition for voluntary or involuntary bankruptcy (4731.3075).

Radiation Safety Officer (RSO)

RSOs must have training and specific experience with the types and quantities of licensed material to be authorized on the license. The person responsible for implementing the Radiation Safety Program is the RSO. This individual may also be called the Radiation Protection Officer. The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are possessed and used in a safe manner. Minnesota Department of Health requires the name of the RSO to be listed on the license to ensure that licensee management has identified a responsible, qualified person and that the named individual knows of his or her designation as RSO.

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

- Radiation Protection Principles;
- Characteristics of Ionizing Radiation;
- Units of Radiation Dose and Quantities;
- Radiation Detection Instrumentation;
- Biological Hazards of Exposure to Radiation (appropriate to types and forms of licensed material to be possessed and used);
- Minnesota Department of Health Regulatory Requirements and Standards; and
- Handling of Radioactive Materials in Relation to Production Activities (e.g., maintenance and repair of the cyclotron).

The amount of training and experience will depend on the type, form, quantity, and proposed use of the licensed material requested. For instance, in addition to a college degree, RSOs at cyclotron facilities

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

- Name of the proposed RSO; and
- Information demonstrating that the proposed RSO is qualified by training and experience.

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

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

The duties and responsibilities of a Radiation Safety Officer are outlined in Appendix A.

Individuals Authorized to Handle Licensed Material

Individuals authorized to handle licensed material must have adequate training and experience with the types and quantities of licensed material that they propose to possess and handle. Applicants must name at least one individual who is qualified to handle the requested licensed materials. For a production license, handling of licensed materials includes, for example, the processing of radiochemicals and the handling or manipulation of activated targets and/or components. An individual who is authorized to handle licensed material is a person whose training and experience have been reviewed and approved by Minnesota Department of Health, who is named on the license, and who uses or directly supervises the use of licensed material. This individual's primary responsibility is to ensure that radioactive materials are handled safely and according to regulatory requirements. The individual is also responsible for ensuring that procedures and engineering controls are used to keep occupational doses and doses to members of the public as low as reasonably achievable.

Individuals authorized to handle licensed material must have adequate and appropriate training to provide reasonable assurance that they will:

- handle licensed material safely;
- prevent the spread of contamination.
- maintain security of licensed material;
- control access to licensed material; and
- respond appropriately to events or accidents involving licensed material.

To demonstrate adequate training and experience at a cyclotron facility, the authorized individual should have:

- a college degree at the bachelor level, or
- equivalent training and experience in physical, chemical, or biological sciences or in engineering; and
- training and experience commensurate with the scope of proposed activities such as handling of

activated targets and activated products associated with cyclotron activities.

The training should include the following subjects:

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

The amount of training and experience will depend on the type, form, quantity, and proposed use of the licensed material requested. For instance, in addition to a college degree or equivalent experience, an authorized individual at a production facility who may handle Curie quantities of radioactive material should have at least 40 hours of radiation safety training specific to his or her job duties as well as a minimum of six months of experience with similar types, forms, quantities, and uses of radioactive material before the individual is qualified to be authorized to handle licensed material.

In general, authorized individuals should demonstrate training and experience with the type and quantity of material they propose to handle. For example, an individual with training and experience only with sealed radioactive sources might not be qualified to use or supervise the use of unsealed licensed material. In addition, someone with experience using only trace quantities of radioactive materials may not understand the risks of working with much larger (e.g., 10 or 100 times larger) quantities of the same substance.

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

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

Provide the following:

- Name of each proposed individual with the types and quantities of licensed material to be possessed and handled; and
- Information demonstrating that each proposed individual is qualified by training and experience to possess and handle the requested licensed materials.

Applicants should provide information about the proposed authorized individual’s training and experience relative to the licensed material and uses requested in the application. Do not include private, personal information (e.g., home address, home telephone number, social security number, date of birth, and radiation dose information). Applicants should not submit information such as unrelated lists of publications, research grants, committee and society memberships, and personal privacy information. Submittal of superfluous material may delay the review process.

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

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

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

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

Training may be in the form of lecture, demonstrations, videotape, or self-study, and it should emphasize practical subjects important to the safe possession and use of licensed material. If training is not conducted by an instructor, a method should be adopted whereby a trainee can ask questions and discuss topics relating to occupational radiation exposure. The guidance in Appendix B may be used to develop a training program. The program should consider all topics pertinent for each group of workers as well as the method and frequency of training. The licensee should determine whether the training succeeded in conveying the desired information and adjust the training program as necessary. This assessment may be performed by a written test or observation of the individual in the performance of assigned duties. Remedial training for missed test questions or other areas of apparent weakness should be conducted or additional formal training planned to cover deficient areas.

The person conducting the training should be a qualified individual (e.g., a person who meets the qualifications for RSO or authorized user on the license and is familiar with the licensee's program).

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

Personnel Involved in Hazardous Materials Package Preparation and Transport

Applicants must train personnel involved in the preparation and transport of hazardous material packages in the applicable US Department of Transportation (DOT) regulations[1]. Licensees who prepare packages of radioactive materials or transport their own packages must provide training to their employees who perform those functions. The training must include:

- General awareness and familiarization training designed to provide familiarity with DOT requirements, and the ability of the employee to recognize and identify hazardous materials.
- Function-specific training concerning the DOT requirements applicable to the functions the employee performs, (e.g., if the employee's duties require affixing DOT radioactive labels to packages, the employee must receive training in the Department of Transportation's regulations governing package labeling).

[1] The licensee is not responsible for providing DOT-required hazardous materials training to common carriers who transport radioactive materials packages.

- Safety training concerning the emergency response information discussed above; measures to protect the employee and other employees from the hazards associated with the hazardous materials to which they may be exposed to in the workplace; and methods of avoiding accidents, such as the proper procedures for handling packages containing hazardous materials.

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

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

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

Item 9: Facilities and Equipment

Facilities and equipment must be adequate to protect health and minimize danger to life or property. Licensee must minimize the possibility of contamination and keep exposures to workers and the public as low as reasonable achievable (ALARA). Applicants must demonstrate that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and their employees, keep exposures to radiation and radioactive materials ALARA, and minimize the danger to life and property from the uses of the types and quantities of radioactive materials to be used.

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

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

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

These records are required to be maintained in an identifiable location. Facilities are required to meet Minnesota Department of Health criteria prior to release. Therefore, careful facility design is important to prevent contamination, or facilitate decontamination, reducing the costs needed for decommissioning.

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

- A description of the cyclotron, which includes the name of the manufacturer, model, cyclotron energy, maximum current, type of targets, and type of shielding materials (including whether the cyclotron is self-shielded). This information will assist the license reviewer in understanding the
  - types of materials that could be produced;
  - activation products that could be produced; and

    - the maximum quantity of radioactive material that could be produced;
- A description of the areas assigned for the production, which includes transfer of produced material, storage, preparation, shipping, security, and measurement of radioactive materials;
- A description and diagrams that show the locations of delivery lines, shielded areas and equipment (e.g., hot cells, waste), the proximity of radiation sources to unrestricted areas, and other items related to radiation safety;
- A diagram and a description of the ventilation system, including representative equipment such as hot cells, glove boxes, or fume hoods. Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved. Confirm that such systems will be employed for the use or storage of radioactive materials that have the probability of becoming airborne; and
- Verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of 4731.2090, and are within the ALARA constraints for air emissions established in 4731.2010.

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

- The scale. Use the same scale (preferably 1/4 inch = 1 foot) for all drawings.
- Descriptions of the area(s) assigned for the receipt, storage, preparation, and measurement of radioactive materials and the location(s) for radioactive waste storage.
- The type, thickness, and density of shielding materials within the facility area (including the floor and roof). Sufficient detail in the diagram to indicate the proximity of radiation sources to unrestricted areas, and other items related to radiation safety.
- A description of the nature of the areas adjacent to the installation, and the distance to these areas.
- Types of posting and their locations.
- The locations of entranceways and other points of access into the installation.
- Security controls to prevent unauthorized access.
- The results of radiation-level calculations or actual radiation measurements adjacent to, above, and below the installation.
- A general description of the ventilation system, including representative equipment such as glove boxes or fume hoods. Pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems should be described in terms of the minimum performance to be achieved. Confirm that such systems will be employed for the use or storage of radioactive materials with the probability of becoming airborne, such as compounding radioiodine capsules and dispensing radioiodine solutions.

Radiation Monitoring Equipment

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

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

For the purposes of this document, radiation-monitoring instruments are defined as any device used to measure the radiological conditions at a licensed facility. Some of the instruments that may be used to perform the above functions include:

- Portable or stationary count rate meters
- Portable or stationary dose rate or exposure rate meters

- Single or multi-channel analyzers
- Liquid Scintillation Counters (LSC)
- Gamma counters
- Proportional counters
- Solid state detectors
- Hand and foot contamination monitors

The choice of instrument should be appropriate for the type of radiation to be measured and for the type of measurement to be taken (count rate, dose rate, etc.). Applicants should discuss the types of instruments to be used for each type of survey to be performed and the availability of a sufficient quantity of these instruments at their facility.

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

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

Appendix D contains additional information concerning instrumentation.

Dosage Measurement Systems

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

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

Guidance is not provided in this document on the measurement of alpha-emitting radionuclides. For photon-emitters, activity measurement is a straightforward determination; however, for beta-emitters, a correction factor is often necessary to accurately determine the activity. There are inherent technical difficulties to overcome in the determination and application of beta-correction factors. These difficulties include dependence on geometry, lack of an industry standard for materials used in the manufacture of both vials and syringes, and lack of a National Institute of Standards and Technology (NIST) traceable standard for all radionuclides currently in use. If radiopharmacies intend to *initially* distribute, i.e., measure, prepare, and label, beta-emitting radionuclides, the applicant must provide the calculation to demonstrate its ability to accurately dispense such materials. If the applicant intends to use beta-correction factors supplied by the instrument manufacturer, or other entity, it should include a means for ensuring the accuracy of the supplied factor.

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

atomic-numbered material to minimize the production of bremsstrahlung, followed by a high-atomic-numbered material thick enough to attenuate the bremsstrahlung intensity.

For each dose measurement system, specific periodic tests must be performed, as appropriate to the system, to ensure correct operation.

TEST	PURPOSE	TYPICAL TEST FREQUENCY
Geometry Dependence	For the range of volumes and product containers	Upon installation or after repair
Accuracy	For the range of energies to be measured	Upon installation, at intervals not to exceed 12 months, or after repair
Linearity	For the range of activities to be measured	Upon installation, quarterly, or after repair
Constancy	To ensure continued proper operation of the system	Each day of use

Appendix E contains a model procedure for dose calibrator testing.

The applicant should ensure that it possesses a sufficient number of such instruments to allow for periods when instruments are out of service for repair and calibration. The applicant must also describe the types of systems (measurement or combination of measurement and calculation) it intends to use for the measurement of alpha-, beta-, and photon-emitting radioactive drugs.

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

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

Item 10: Radiation Safety Program

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

Material Receipt and Accountability
Licensees must ensure the security and accountability of licensed material.

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

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

Licensees must secure and control licensed material and should have a means of promptly detecting losses of licensed material. Licensees are required to secure radioactive materials from unauthorized removal or access while in storage and to control and maintain constant surveillance over licensed material that is not in storage.

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

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

Material accountability records typically contain the following information:

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

See the section on Waste Disposal for more information.

Documents containing information about locations where licensed material is used or stored are among the records important to decommissioning and required by 4731.3080. See also the section on "Financial Assurance and Recordkeeping for Decommissioning."

Provide the following statements:

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

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

AND

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

Occupational Dose

Each licensee shall evaluate the potential occupational exposures of all workers and monitor occupational exposure to radiation when required. The licensee should perform an evaluation of the dose, which may be received from licensed and non-licensed (e.g., cyclotron operation) activities, the individual is likely to receive prior to allowing the individual to receive the dose (prospective evaluation). When performing the prospective evaluation, only a dose that could be received at the facilities of the applicant or licensee performing the evaluation needs to be considered. These estimates can be based on any combination of work location, radiation monitoring, survey results, monitoring results of individuals in similar work situations, or other estimates to produce a "best estimate" of the actual dose received. For individuals who have received doses at other facilities in the current year, the previous dose need not be considered in the prospective evaluation if monitoring was not required at the other facilities. This evaluation need not be made for every individual; evaluations can be made for employees with similar job functions or work areas.

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

Licensees shall monitor worker exposures for:

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

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

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

0.1 rem (1.0 mSv) deep-dose equivalent;
0.15 rem (1.5 mSv) eye dose equivalent;
0.5 rem (5 mSv) shallow-dose equivalent to the skin; and
0.5 rem (5 mSv) shallow-dose equivalent to any extremity.

Declared pregnant women who are likely to receive an annual dose from occupational exposures in excess of 0.1 rem (1.0 mSv) deep-dose equivalent, although the dose limit applies to the entire gestation period

Internal exposure monitoring is required for:

Adults likely to receive in one year an intake in excess of ten percent of the applicable annual limit on intake (ALI) for ingestion and inhalation; and

Minors and declared pregnant women likely to receive in one year a committed effective does equivalent in excess of 0.1 rem (1.0 mSv)

If an individual is likely to receive in one year a dose greater than ten percent of any applicable limit, monitoring for occupational exposure is required. When working at an Minnesota Department of Health-licensed facility, in addition to exposure to material regulated by Minnesota Department of Health, a worker may be exposed to radiation from registered sources (e.g., radiation emitted by cyclotrons). An occupational dose includes the dose received by individuals in the course of their employment, including exposure to radiation and to radioactive material from licensed and registered sources of radiation, whether in the possession of the licensee or other person. Therefore, authorized individuals and other radiation workers at a production facility are generally likely to receive ten percent of the limits for an occupational dose.

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

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

Public Dose

Licensees must do the following:

- Ensure that licensed material will be used, transported, stored, and disposed of in such a way that members of the public will not receive more than 100 mrem (1 mSv) (TEDE) in one year from licensed activities;
- Ensure that air emissions of radioactive material to the environment will not result in exposures to individual members of the public in excess of 0.1 mSv (10 mrem) (TEDE) in one year from those emissions;
- Ensure that the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour, from licensed operations; and
- Prevent unauthorized access, removal, or use of licensed material.

Member of the public" is defined as "any individual except when that individual is receiving an occupational dose." "Public dose" is defined as "the dose received by a member of the public from exposure to radiation and/or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee." Public dose excludes doses received from background radiation, sanitary sewerage discharges from licensees, and medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individual's assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) the individual is in when the dose is received.

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

- Airborne radioactive material;
- Waterborne radioactive material; and
- External radiation exposure.

The licensee should review these major pathways and decide which are applicable to its operations. The licensee must ensure that the TEDE from all exposure pathways arising from licensed activities does not exceed 1.0 mSv (100 mrem) to the maximally exposed member of the public. In addition, the licensee must control air emissions, such that the individual member of the public likely to receive the highest TEDE does not exceed the constraint level of 10 mrem (0.1 mSv) per year from those emissions. If exceeded, the licensee must report this, in accordance with 4731.2620, and take prompt actions to

ensure against recurrence.

Licensees should design a monitoring program to ensure compliance with 4731.2010 and 4731.2095. The extent and frequency of monitoring will depend upon each licensee's needs. Licensees must be able to provide documentation demonstrating, by measurement or calculation, that the TEDE to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit and the dose constraint.

Safe Handling of Radionuclides

Operating procedures for activities that can potentially impact radioactive material or occupational dose must be developed, documented, implemented and maintained. Licensees are responsible for the security and safe possession and use of all licensed material from the time it is produced at the facility until it is used, transferred/delivered, and/or disposed of. Licensees must develop written procedures to ensure safe possession and use of licensed material, and the procedures should also include operational and administrative guidelines. The written procedures should provide reasonable assurance that only appropriately trained personnel will handle and use licensed material without undue hazard to workers or members of the public.

Minimizing of Contamination

Applicants for new licenses must describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the fullest extent practicable, the generation of radioactive waste.

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

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

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

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

Sealed sources and devices that are approved by NRC or an Agreement State and located and used according to their SSDR certificates usually pose little risk of contamination. Leak tests performed as specified in the SSDR certificate should identify defective sources. Leaking sources should be

immediately withdrawn from use and decontaminated, repaired, or disposed of according to Minnesota Department of Health requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts.

General Safety Procedures

The written procedures should include the following elements:

- Contamination controls
- Waste disposal practices
- Personnel and area monitoring (including limits and frequency of personnel monitoring)
- Use of protective clothing and equipment (including use of appropriate shielding and frequent glove changes to minimize exposure to the individual and to avoid spread of contamination)
- Safe handling of radioactive materials (including special procedures for higher risk activities)
- Posting and labeling
- Recording requirements
- Reporting requirements
- Responsibilities

Applicants should also develop product- and radioisotope-specific procedures based on the respective hazards associated with the products and radioisotopes. General safety guidelines are described in Appendix G. Applicants should use these guidelines to develop procedures for the safe use of radioisotopes.

Licensees should determine if they have areas that require posting in accordance with 4731.2310, unless they meet the exemptions listed in 4731.2320. Also, containers of licensed material (including radioactive waste) must be labeled in accordance with 4731.2330, unless they meet the exemptions in 4731.2340.

Emergency Procedures

Accidents and emergencies can happen during any operation with radioisotopes, including their receipt, transportation, use, transfer, and disposal. Such incidents can result in contamination or release of material to the environment and unintended radiation exposure to workers and members of the public. In addition, loss or theft of licensed material, and fires involving radioactive material can adversely affect the safety of personnel and members of the public. Applicants should therefore develop and implement procedures to minimize the potential impact of these incidents on personnel, members of the public, and the environment.

Applicants should establish written procedures to handle events ranging from a minor spill to a major accident that may require intervention by outside emergency response personnel. For cyclotron facilities, written procedures should be included for specific accident scenarios such as target failures, spills or releases outside a containment enclosure, delivery line failures, malfunction of air supply or exhaust systems, and high radiation levels in exhaust monitors or systems. These procedures should include provisions for immediate response, after-hours notification, handling of each type of emergency, equipment, and the appropriate roles of users and the radiation safety staff. Except for minor spills or releases of radioactivity that can be controlled and cleaned up by the user, the licensee staff should have a clear understanding of their limitations in an emergency, along with step-by-step instructions and clear guidelines for whom to contact.

Licensees should have a sufficient number of appropriate and calibrated survey instruments readily available. Emergency spill kits should be strategically placed in well-marked locations for use by all users and the radiation safety staff. All equipment should be periodically inspected for proper operation and replenished as necessary. Appendix G includes model emergency procedures. Applicants may adopt these procedures or develop their own, incorporating the safety features included in these model procedures.

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

The applicant should submit a statement that "Procedures will be revised only if:

- the changes are reviewed and approved by the licensee management and the RSO in writing;
- the licensee staff is provided training in the revised procedures prior to implementation;
- the changes are in compliance with Minnesota Department of Health rules and the license; and
- the changes do not degrade the effectiveness of the program."

Radiation Monitoring

Licensees must possess radiation monitoring instruments to evaluate possible radiation hazards that may be present. Instruments used for quantitative radiation measurements must be calibrated at intervals not to exceed 12 months for the radiation measured. Licensees must possess calibrated radiation detection/measurement instruments to perform, as necessary, the following:

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

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

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

The choice of instrument should be appropriate for the type of radiation to be measured, and for the type of measurement to be taken (count rate, dose rate, etc.). Applications should include descriptions of the instrumentation available for use and the instrumentation that applicants intend to purchase prior to starting licensed activities. The description should include type of instrument and probe, and the instrument’s intended purpose.

Instruments used for qualitative surveys are only intended to detect contamination in the laboratory. Such instruments should be checked for operational response with an appropriate check source containing radioactive material and can be calibrated with an electronic pulser instead of a radioactive source. However, these instruments cannot be used for measurement of surface contamination or radiation levels without performing a calibration with appropriate radioactive sources.

Instrument calibrations should be performed by the instrument manufacturer or a person specifically authorized by the NRC or an Agreement State, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey instrument calibrations should submit procedures for review. Applicants should be aware that calibrations often require possession and use of a calibration source or device. Instruments for counting smear wipes to detect contamination and/or leakage need calibration sources that may be listed on the production license.

Surveys

Licensees are required by 4731.2200 to make surveys of potential radiological hazards in their workplace. Minnesota Department of Health requires testing to determine whether there is any radioactive leakage from sealed sources. Records of surveys and leak tests results must be maintained. Surveys are evaluations of radiological conditions and potential hazards. These evaluations may be measurements (e.g., radiation levels measured with survey instruments or results of wipe tests for contamination), calculation, or a combination of measurements and calculations. The selection and proper use of appropriate instruments is one of the most important factors in ensuring that surveys accurately assess the radiological conditions for both licensed and non-licensed (e.g., cyclotron operation) activities and the licensed facility. In order to meet regulatory requirements for surveying, measurements of radiological quantities should be understood in terms of their properties (i.e., alpha, beta, or gamma) and compared to the appropriate limits.

Radiation surveys are used to detect and evaluate contamination of:

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

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

4731.2200 states that surveys are required when it is reasonable under the circumstances to evaluate a radiological hazard as well as when necessary for the licensee to comply with the regulations. Many different types of surveys may need to be performed due to the particular use of licensed materials. The most important are as follows:

- Surveys for radioactive contamination that could be present on surfaces of floors, walls, laboratory furniture, workstations, and equipment;
- Measurements of radioactive material concentrations in air for areas where radioactive materials are handled or processed in unsealed form, and where operations could expose workers to the inhalation of radioactive material, or where licensed material is, or could be, released to unrestricted areas;
- Measurements of radioactive material concentrations in water that is released to the environment or to the sanitary sewer; and
- Surveys of external radiation exposure levels in both restricted and unrestricted areas.

The frequency of routine surveys depends on the nature, quantity, and use of radioactive materials, as well as the specific protective facilities, equipment, and procedures that are designed to protect the worker from external and internal exposure. Also, the frequency of the survey depends on the type of survey, such as those listed above.

Not all instruments can measure a given type of radiation. The presence of other radiation may interfere with a detector's ability to measure the radiation of interest. Correct use of radiation detection and measurements is an important aspect of any Radiation Safety Program

Chapter 4731 does not specify limits for surface contamination. Each applicant should propose and justify what removable surface contamination limits will be allowable before decontamination will be performed in each work area. Contamination checks are required before distributing licensed material.

Leak Testing of Sealed Sources and Foils

A license will require performance of leak tests of sealed/plated foil sources at intervals as approved by NRC or an Agreement State and specified by the SSDR certificate. The measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample be capable of detecting 0.005 microcuries (185 Bq) of radioactivity.

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

Leak tests are not required if:

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

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

Maintenance

Maintenance of equipment and facilities for the production and use of radioactive materials (e.g., cyclotrons and chemistry synthesis units) is necessary. Maintenance should be planned and carried out as frequently as needed, using ALARA principles. Individuals performing maintenance should be trained in the procedures they implement. Procedures should be written to account for the skills of the implementing personnel. Ordinarily, individuals handling unshielded materials should have up to forty hours of classroom and on-the-job training in radiation safety. Instructors should be more extensively qualified than the staff they teach.

Maintenance of equipment and facilities is necessary in order to produce a quality product safely and efficiently and to ensure a safe environment for staff and the public. Producing radioactive materials is an additional hazard, requiring attention to detail when incorporating maintenance information into procedures. Licensee staff should ensure that materials in the process stream are properly shielded, located, and protected to minimize the hazard to maintenance staff. Maintenance staff should be aware of the hazards and the procedures to minimize their exposure to radioactive materials that are possessed and used to control the production process. As examples:

- The staff should survey the cyclotron working area prior to entry into the cyclotron vault or opening of cyclotron self-shields; and
- A maintenance procedure should direct the shutdown and lockout of the cyclotron before beginning work in the area.

Maintenance procedures should be prepared with the use of engineering controls first, using ALARA principles and administrative controls, as needed.

Transportation

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

Licensees should consider the safety of all individuals who may handle or come into contact with the packages containing licensed material. Therefore, the primary considerations in packaging licensed material should be to ensure that package integrity is not compromised during transport and that radiation levels (including removable contamination levels) at the package surfaces not only meet the regulatory requirements but are ALARA.

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

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

All domestic shipping paper and label information must be stated in the International System of Units (SI) only **OR** must be in SI units first, with English units in parenthesis.

The authorization used by most licensees to transport, or offer for transport, packages of radioactive material and specifies certain conditions is provided by a general license. Transporting licensed materials originating at some facilities involves quantities of radioactive material that require a Type B package. The manufacturer (or service licensee) who is subject to the provisions of 4731.0406 or 4731.0407, as appropriate, is responsible for proper packaging of the radioactive materials and compliance with Minnesota Department of Health and DOT regulations. If a licensee plans to make shipments of licensed materials in Type B packages on its own, the licensee must be registered as a user of the package and have an NRC-approved quality assurance (QA) plan, two of the requirements under the 4731.0406 general license.

The licensee should commit to transporting radioactive materials in accordance with US Department of Transportation (DOT) requirements. Licensees should also develop and maintain their own radiation safety procedures for transporting licensed material within their own facilities if it does not involve the use of public highways.

Radioactive Drug Labeling for Distribution

The licensee must label each transport radiation shield to show the radiation symbol as described in 4731.2000. The label must also include the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER,

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

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

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

Radioactive Drug Shielding for Distribution

The applicant must provide appropriate transport radiation shields for the primary container of each radioactive drug that it intends to distribute. The shielding must be adequate for the types and quantities of radioactive materials that the applicant intends to distribute. Typically, transport radiation shields have included two-piece, shielded syringe and vial containers (or "pigs"). Licensees have used lead and tungsten shields for gamma-emitting materials and plexiglass inserts for beta-emitters. The applicant should select appropriate shielding materials and dimensions to not only ensure that occupational doses are ALARA, but also that the transport radiation shield can be easily handled.

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

- Indicate the radionuclide and the maximum activity for each type of container (e.g., vial, syringe).
- Describe the type and thickness of the transport radiation shield provided for each type of container.
- Indicate the maximum radiation level to be expected at the surface of each transport radiation shield when the radioactive drug container is filled with the maximum activity.[2]

Audit Program

Licensees must review the content and implementation of their Radiation Safety Programs at least annually. It is in the best interest of licensees to have a strong audit program to ensure:

- Compliance with Minnesota Department of Health and DOT regulations and the terms and conditions of the license;
- Occupational doses and doses to members of the public are ALARA and dose reduction efforts have been considered; and
- Operating procedures are in place for activities that could potentially affect radioactive material or occupational dose.

An audit program that promptly identifies potential violations of regulatory requirements and takes prompt,

[2] It is not acceptable to state that the applicant will comply with DOT regulations. The dose rate limits that DOT imposes apply to the surface of the package, not the surface of the transport radiation shield.

comprehensive steps to correct them, meets Minnesota Department of Health's expectations. Elements of an effective audit program are described below.

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

- efforts to maintain doses ALARA;
- compliance with Minnesota Department of Health requirements;
- ability to identify and correct deficiencies in their Radiation Safety Program;
- management of the Radiation Safety Program including the role of senior management and the RSO; and

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

Auditor Qualifications.
Auditors should have training and experience similar to that of an individual authorized for the types, forms, uses, and quantities of radioactive material used in the areas audited. Auditors should not be selected from the staff of areas to be audited or their management. Ideally, auditors are third parties, from independent organizations.

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

Audit Techniques
While documentation should be reviewed during any audit of a Radiation Safety Program, emphasis should be placed on actual observations of work in progress. Applicants should consider performing unannounced audits of radioactive material users to observe work in progress and determine if, for example, operating and emergency procedures are available and are being followed. Radiation safety audits should include activities conducted during all shifts. Some details of typical audit techniques follow:

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

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

- **Training, Retraining, and Instructions to Workers.** Ensure that workers have received the training required 4731.1020. Be sure that, before being permitted to use radioactive material, the user has received training and has a copy of the licensee's operating and emergency procedures. Note whether refresher training is conducted in accordance with licensee commitments and that all shift workers are included. By interview and/or observation of selected workers, ensure that each has a copy of the licensee's procedures and can implement them properly. Special attention should be directed to the adequacy of training and observation of new employees performing their radioactive material duties.

- **Facilities.** Verify that the facilities are as described in the license documents**.**

- **Materials.** Verify that the license authorizes the quantities and types of radioactive material that the licensee possesses**.**

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

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

- **Radiation Surveys.** Verify that the licensee has appropriate, operable and calibrated survey instruments available, that the instruments are calibrated (at the required frequency) in accordance with license conditions and survey records are in accordance with 4731.2620. Calibration records must be retained for three years after the record is made. Check that radiation levels in areas adjacent to use areas are within regulatory limits. Verify compliance with 4731.2090 for dose limits to the public. Records of surveys must be retained for three years after the record is made.

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

- **Transfer of Radioactive Material (Includes Waste Disposal).** Ensure that transfers are performed in accordance with 4731.3105. Records of surveys, receipt, and transfer must be maintained in accordance with 4731.2510 and 4731.3115.

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

- **Personnel Radiation Protection.** Evaluate the licensee's determination that unmonitored personnel are not likely to receive more than ten percent of the allowable limits. Alternatively, if personnel dosimetry is provided and required, verify that it complies with 4731.2200 and licensee commitments. Review personnel monitoring records; compare exposures of individuals doing similar work; determine reasons for significant differences in exposures. The licensee is also responsible for ensuring that dosimetry results are assigned accurately and should consider that the assigned deep-dose equivalent and shallow-dose equivalent must be for the part of the body receiving the highest exposure. Therefore, if possible, whole body and extremity dosimeters should be placed in the areas that receive the highest exposure. An evaluation should be performed to determine if the maximum dose to a part of the whole body or an extremity may be substantially higher than the dose measured by the dosimeter. If the evaluation indicates that the maximum dose to a part of the whole body or extremity is higher than that measured by the dosimeter, the higher dose will be used as the dose of record. If any worker declared her

pregnancy in writing, evaluate compliance with 4731.2080. Check whether records are maintained.

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

- **Notification and Reports.** Check for compliance with the notification and reporting requirements. Ensure that the licensee is aware of the telephone number for Minnesota Department of Health.

- **Posting and Labeling.** Check for compliance with the posting and labeling requirements of 4731.1010, 4731.2310, and 4731.2320.

- **Recordkeeping for Decommissioning.** Check to determine compliance with 4731.3080.

- **Bulletins and Information Notices.** Check to determine if such notifications as bulletins, information notices, and newsletters are received from Minnesota Department of Health. Check whether appropriate actions were taken in response to Minnesota Department of Health information notices.

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

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

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

Problems or Deficiencies Noted

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

Records to be Maintained

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

The licensee's program for auditing its Radiation Safety Program will be reviewed during inspection.

Item 11: Waste Management

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

The applicant should discuss the methods for management and disposal of radioactive waste. The program should include procedures for handling of waste, safe and secure storage, waste characterization, waste minimization, and disposal of radioactive waste. Appropriate training should be provided to waste handlers. The application should include, where appropriate for the types of waste involved, provisions for monitoring and segregating waste materials (e.g., radioactive from non-radioactive, short from long half-life, liquid from solid waste).

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

Transfer to an Authorized Recipient

Waste may be transferred to a recipient (usually a waste disposal service company or the original supplier) who is properly licensed to receive such waste in accordance with 4731.2400. Each shipment must comply with all applicable Minnesota Department of Health and DOT requirements.

Licensees should implement procedures to reduce the volume of radioactive waste for final disposal in an authorized low-level radioactive waste (LLW) disposal facility. These procedures include volume reduction by segregating, consolidating, compacting, or allowing certain waste to decay in storage. Waste compaction or other treatments can reduce the volume of radioactive waste, but such processes may pose additional radiological hazards (e.g., airborne radioactivity) to workers, members of the public, and the environment. Safety procedures to address these concerns should be implemented.

Decay in Storage

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

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

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

Release into Air and Water
Release of radioactive material into air and water must conform to the requirements described in 4731.2095. The applicant should discuss the monitoring and control mechanisms in place to ensure compliance with the requirements. Applicants are reminded of the "constraint" on air emissions of radioactive material required by 4731.2010, which effectively reduces the limits specified in 4731.2095 for release of gaseous effluents by a factor of ten. Applicants considering release of radioactive material into air and water should review NRC Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," dated July 1993, which deals with the application of ALARA in controlling gaseous and liquid effluents and references documents with acceptable methods of effluent monitoring

Licensees considering disposal by release to the sanitary sewerage system must comply with the requirements of 4731.2420. Licensees are responsible for demonstrating that licensed materials discharged into the sewerage system are readily soluble or biologically readily dispersible in water. NRC IN-94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR 20," dated January 1994, provides the criteria for evaluating solubility of liquid waste. Liquid scintillation media and ash are examples of material that may or may not be readily dispersible. Licensees should carefully consider the possibility of re-concentration of radioisotopes that are released into the sewerage system.

Applicants should provide procedures that will ensure that all releases of radioactive waste into the sanitary sewerage system meet the criteria stated in 4731.2420 and do not exceed the monthly and annual limits specified in the regulations. Licensees are required to maintain accurate records of all releases of licensed material into the sanitary sewerage system. A model procedure for disposal of radioactive waste via a sanitary sewer is described in Appendix I.

If liquid releases are made to a private sewerage treatment system, septic system, or leach field, the sludges or other solids from these systems may become contaminated with radioactive material. Applicants should describe the monitoring planned for these systems in Item 8.10.7 of the application. Contaminated sludges should be disposed of as radioactive waste using one of the methods described in this section. Applicants may obtain approval of alternative disposal methods through application to the Minnesota Department of Health as described in 4731.2410.

Incineration
Applicants who wish to treat or dispose of licensed material by incineration must comply with the requirements of 4731.2430. A model procedure for incineration of waste is described in Appendix K. Applicants who are considering disposal of radioactive material by incineration should review Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," dated July 1993. Regulatory Guide 8.37 deals with the application of ALARA in controlling gaseous and liquid effluents and references documents containing acceptable methods of effluent monitoring.

Volume Waste Reduction
Waste volume reduction operations (e.g., compaction) that could create a radiological hazard to licensee employees or the general public should be described in detail in the application.

Other Methods Specifically Approved by Minnesota Department of Health Pursuant to 4731.2410
Applicants may also request alternate methods for the disposal of radioactive waste generated at their facilities. Such requests must describe the waste-containing licensed material, including the physical and chemical properties that may be important to assess risks associated with the waste, and the proposed manner and conditions of waste disposal. Additionally, the applicant must submit its analysis and evaluation of pertinent information on the nature of the environment, nature and location of other affected facilities, and procedures to ensure that radiation doses are maintained ALARA and within regulatory limits.

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

Additional Considerations

The application should describe the ALARA considerations taken before disposal of radioactive materials. Discuss the potential for unmonitored or unanticipated release of radioactive materials to work areas and from release points (i.e., hoods and incinerator stacks). To be in compliance with the ALARA philosophy stated in 4731.2010, radioactive material waste stream concentrations should be a fraction (generally 10% to 20%) of the limits specified in 4721.2750, Subpart 4. Furthermore, due to the variability of inventory control programs for monitoring disposal and releases of licensed material possessed or possessed and in use, a program for physically measuring releases should be in place whenever releases exceed the specified ALARA action point.

Because of the difficulties and costs associated with disposal of sealed sources, applicants should pre-plan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement. Sealed source manufacturers and suppliers that accept return of sealed sources should consider this when developing their waste management programs.

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

Item 12: License Fees

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

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

Item 13: Certification

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

AMENDMENTS TO LICENSE

After you are issued a license, you must conduct your program in accordance with

- the statements, representations, and procedures contained in your application,
- the terms and conditions of the license, and
- the Minnesota Department of Health Radioactive Materials Rules, Chapter 4731.

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

The licensee may not place into effect any amendment until receiving written verification from Minnesota Department of Health that the amendment has been approved.

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

RENEWAL OF LICENSE

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

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

IMPLEMENTATION

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

INSPECTIONS

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

APPENDIX A
DUTIES AND RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER

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

- Ensure that licensed material possessed by the licensee is limited to the types and quantities of licensed material listed on the license;
- Maintain documentation that demonstrates that the dose to individual members of the public does not exceed the limit specified in 4731.2090;
- Ensure security of radioactive material;
- Post documents as required by 4731.1010;
- Ensure that licensed material is transported in accordance with applicable Minnesota Department of Health and DOT requirements;
- Ensure that radiation exposures are ALARA;
- Oversee all activities (licensed and non-licensed) involving radioactive material, including monitoring and surveys of all areas in which radioactive material is possessed or possessed and used;
- Act as liaison with Minnesota Department of Health and other regulatory authorities;
- Provide necessary information on all aspects of radiation protection to personnel at all levels of responsibility and any other applicable rules;
- Oversee proper transfer and delivery of radioactive material, and conduct radiation surveys for all shipments of radioactive material arriving at or leaving from the institution, as well as packaging and labeling all radioactive material leaving the institution;
- Distribute and process personnel radiation monitoring equipment, monitor personnel radiation exposure records for trends and high exposures, notify individuals and their supervisors of radiation exposures approaching established limits, and recommend appropriate remedial action;
- Conduct training programs and otherwise instruct personnel in the proper procedures for handling radioactive material prior to possession or possession and use, both at periodic intervals (refresher training), and as required by changes in procedures, equipment, or regulations;
- Supervise and coordinate the radioactive waste disposal program, including effluent monitoring and recordkeeping on waste storage and disposal records;
- Oversee the storage of radioactive material not in current use, including waste;
- Perform or arrange for leak tests on all sealed sources and calibration of radiation survey instruments;
- Maintain an inventory of all radioisotopes possessed under the license and limit the quantity to the amounts authorized by the license;
- Immediately terminate any unsafe condition or activity that is found to be a threat to public health and safety or property;
- Supervise decontamination and recovery operations;
- Maintain other records not specifically designated above (e.g., records of production, transfers, and surveys);
- Hold periodic meetings with, and provide reports to, licensee management;
- Ensure that all users are properly trained;
- Perform periodic audits of the Radiation Safety Program to ensure that the licensee is complying with: all applicable Minnesota Department of Health rules, the terms and conditions of the license (e.g., leak tests, inventories, possession or possession and use limited to trained, approved users), the content and implementation of the Radiation Safety Program to achieve occupational doses and doses to members of the public that are ALARA in accordance with 4731.2010, and the requirement that all records be properly maintained;
- Ensure that the results of audits, identification of deficiencies, and recommendations for change are documented (and maintained for at least three years) and provided to management for review and ensure that prompt action is taken to correct deficiencies;

- Ensure that the audit results and corrective actions are communicated to all personnel who possess or possess and use licensed material;
- Ensure that all incidents, accidents, and personnel exposure to radiation in excess of ALARA or Minnesota Department of Health exposure limits are investigated and reported to Minnesota Department of Health within the required time limits; and
- Maintain an understanding of, and up-to-date copies of, Minnesota Department of Health rules, the license, and revised licensee procedures, and ensure that the license is amended whenever there are changes in licensed activities, responsible individuals, or information or commitments provided to Minnesota Department of Health during the licensing process.

APPENDIX B
RADIATION SAFETY TRAINING

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

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

Frequency of Training

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

General Information

Radiation safety:

- Radiation vs. contamination;
- Internal vs. external exposure;
- Biological effects of radiation;
- ALARA concept;
- Use of time, distance, and shielding to minimize exposure;
- Contact dose rates and dose rates at a distance from high-activity sources;
- Dose reduction responsibilities.

Regulatory requirements

- RSO;
- Material control and accountability;
- Personnel dosimetry;
- Radiation Safety Program audits;
- Transfer and disposal;
- Recordkeeping;
- Surveys;
- Postings;
- Labeling of containers;
- Handling and reporting of incidents or events;
- Licensing and inspection by Minnesota Department of Health;
- Need for complete and accurate information;
- Employee protection;
- Deliberate misconduct.

License Specific Program Elements

- Authorized individuals and supervised individuals.
- Worker-specific production activities (e.g., maintenance of the cyclotron).
- Shipping.
- Moving/transferring radioisotopes to different areas or licensees.
- Applicable regulations and license conditions.
- Areas where radioactive material is used or stored.
- Potential hazards associated with radioactive material in each area where the individuals will work.
- Appropriate radiation safety procedures.
- Licensee's in-house work rules (for instructions on laboratory safety and uses of
- radioisotopes.
- Each individual's obligation to report unsafe conditions to the RSO.
- Appropriate response to spills, emergencies, or other unsafe conditions.
- Worker's right to be informed of occupational radiation exposure results, if applicable.
- Locations where the licensee has posted or made available:
    - notices,
    - copies of pertinent regulations, and
    - copies of pertinent licenses and license conditions (including applications and applicable correspondence).

Emergency Procedures

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

Survey Program

- survey instrument accessibility;
- who is responsible;
- types, contamination, and areas;
- frequency;
- levels of contamination;
- personnel, hands, shoes;
- records.

Waste

- liquid;
- solids;
- sanitary sewer;
- burial (transfer to low-level waste repository);
- storage;
- decay-in-storage;
- waste storage surveys;
- incineration;
- records.

Dosimetry

- whole body;
- extremities;
- lost or replacement badges and dose assessment;

- records.

Instrumentation

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

Procedures for Receiving Packages Containing Radioactive Materials *(if applicable)*

- normal;
- off-duty;
- notification of user and RSO;
- security;
- exposure levels;
- possession limit;
- receipt of damaged packages.

Sealed sources

- leak-test requirements;
- inventory requirements;
- exempt quantities;
- records.

Inspection and Audit Findings

For Laboratory Safety and Use of Radioisotopes

- Control procedures for obtaining permission to possess or possess and use radioactive materials at the facility; give limitations on quantity to be handled per user, or allowed per experiment.
- Protective clothing and what laboratory apparel to wear and what equipment to use.
- Limitations and conditions relative to handling unsealed licensed material and what laboratory equipment to use when working with such material. For example, discuss which licensed materials and what procedures should be confined to radiochemical fume hoods or glove boxes. Explain what shielding or remote handling equipment is to be used when beta and/or gamma-emitting licensed materials are handled.
- Routine survey and monitoring procedures to be followed for contamination control. Include where and how contaminated articles and glassware are to be handled and stored.
- Emergency procedures concerning spills, fires, release of material, and/or accidental contamination of personnel.
- Decontamination procedures to use and whom to contact in case of an emergency.
- Instructions concerning transfer of licensed materials between rooms, halls, or corridors, if applicable.
- Requirements for storage, labeling of containers, and identification of areas where licensed materials are possessed or possessed and used.
- Personnel monitoring devices to use, where to obtain them, and exchange procedures and exposure results.
- Waste disposal procedures to follow, limitations for disposal of liquid or solid wastes, and procedures to use for waste storage. If the program involves experiments with animals, procedures for cleaning animal quarters and handling animal excreta and carcasses for disposal.
- Records to be maintained on possession, use, and disposal of licensed materials.
- Prohibitions of pipetting by mouth, eating, smoking, and drinking in areas where licensed materials are possessed or possessed and used.

APPENDIX C
FACILITIES AND EQUIPMENT

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

- Restricted areas are defined as areas to which access is limited by the licensee to protect individuals against undue risks from exposure to radiation and radioactive materials. The application should contain detailed descriptions and diagrams of the facilities, including information about the shielding properties of the construction materials used. Scaled drawings and sketches should be submitted showing the relationship between restricted areas and unrestricted areas and the location of all pertinent safety-related equipment. Drawings should show the uses of adjacent areas, including those beside, above, and below, and a recitation of the various shielding materials in the separating surfaces.
- A site diagram should indicate buildings and areas and their uses such as research, production, or waste storage.
- Bench top or open work areas may be used for sealed sources, for small quantities of solid materials in a form not likely to become airborne or dispersed, and for small quantities of liquids of such low volatility as not to cause airborne contamination or toxicity problems. Trays and/or absorbent surface covers to catch and retain spilled liquids should be used on these open work surfaces and inside the closed systems discussed below. Surfaces should be smooth and nonporous, to facilitate decontamination.
- Radioactive materials that are handled or used in unsealed forms should be confined to control the release of material and to prevent the spread of contamination. Gaseous, volatile, and fine particulate solid materials should be handled in closed or isolated systems such as fume hoods, glove boxes, or hot cells with controlled, and possibly filtered, exhaust systems.
- Chemical-type fume hoods provide a working area with controlled inward airflow from the room to the hood exhaust system. Hoods are used for gases, for unsealed volatile licensed materials, and for processes such as evaporation that may release gases and vapors. Fume hoods provide emergency ventilation and exhaust for unplanned releases, such as accidental spills and ruptures, as well as routine exhaust of effluents. Filters may be necessary for the exhaust stream unless monitoring and/or calculations demonstrate that any planned or likely effluent will be in accordance with the limits found in 4731.2750.
- Glove boxes are sealed boxes with transparent viewing windows, sealable ports and/or doors for transferring materials and equipment, and gloves sealed to the box through which licensed materials are handled. Glove boxes are used for the containment during storage and use of liquids and solids that can become airborne particulates or aerosols. Glove boxes can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.
- Hot cells are generally sealed shielded compartments with transparent viewing windows, sealable ports and/or doors for handling high gamma/photon emitting radioactive materials. Generally, remote manipulator arms are used within the hot cell to manipulate/handle license materials. Also, hot cells can be used for gases, for unsealed volatile licensed materials, and for processes such as evaporation that may release gases, fine particulates, and vapors. Hot cells can be closed or exhausted, with filtration systems if appropriate, to prevent contamination.
- Sink faucets should be designed, where possible, for operation by foot, knee, or elbow rather than by hand.
- Plumbing and duct work should be designed to avoid radioactive contamination build-up. This build-up of contamination can create external radiation exposure hazards and problems for decommissioning.
- Shielding consisting of lead, tungsten or other high-density material in the form of bricks, panels, L-shields, storage containers, or other shapes may be used on bench tops, in fume hoods, or in glove boxes to reduce radiation exposure from gamma-emitting radioactive materials. Shielded shipping containers are frequently used for continued storage after receipt of materials. Other shielding used may consist of high-density plastic for beta-emitting radioactive materials.

- Optimal shielding requirements will depend on the intensity and energy of the radiation; the type, quality and configuration of the local shielding in place; and the duration of personnel exposure in conducting the operation.
- The proper ventilation system is very important at production facilities. Systems should be designed to ensure adequate performance for each area in terms of flow rates and directions. When describing ventilation systems, applicants should provide a detailed description of the ventilation system, which includes location of air intakes for the building and any surrounding buildings, airflow rates, pressures, and any filtration equipment that is used within the system.
- Particular sinks should be designated for disposal of liquid radioactive waste to the sanitary sewerage system. In some cases, depending on the number of users and the distance between areas of use, more than one sink may need to be designated.
- Labeled waste containers should be used. These containers may be shielded as necessary, placed near the waste-generating areas, placed away from areas frequently occupied by personnel, and secured from unauthorized removal. Additionally, these containers should be effectively enclosed to prevent airborne contamination from deposited radioactive materials.
- Remote handling tools, such as forceps or extension handles, should be used to provide distance in the handling of radioactive materials (ALARA). In addition, shielded handling devices, such as shielded syringes, can be used to protect workers from materials that cannot be handled remotely.
- Pipetting should be done using appropriate devices. Pipetting by mouth should be strictly forbidden.
- Where appropriate, ventilation systems should be designed such that, in the event of an accident, they can be shut down and isolated to contain radioactivity. For a cyclotron facility, generally the ventilation system should be designed so that the cyclotron(s) has the most negative pressure and a higher air flow within the restricted areas of the facility. This is done to help avoid airborne contamination from possible high activity releases such as target ruptures or other failures within the cyclotron during operation.
- Designated areas should be provided for coats and personal belongings, to avoid contamination.
- Areas with low background radiation levels should be designated for personnel dosimetry storage when not in use.
- Areas of use should be well-lighted to avoid spills and other accidents that could result in contamination build-up.
- Observation of activities conducted behind shielding with remote tools (or with extended arms and hands, within limits consistent with permissible occupational exposures) can be accomplished by mirrors, through shielded (e.g., leaded glass) windows, through transparent plastic beta shields, or by remote video monitoring.
- The combination of containment, shielding, and handling devices proposed for any use of radioactive materials should be appropriate to the type and quantity of materials to be used and to the type and duration of the operations to be conducted.

APPENDIX D
INSTRUMENT CALIBRATION PROGRAM

The specifications in the following table will help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facility.

TYPICAL SURVEY INSTRUMENTS INSTRUMENTS USED TO MEASURE RADIOLOGICAL CONDITIONS AT LICENSED FACILITIES			
Detectors	**Range**	**Energy Range/Range**	**Efficiency**
REM Meter	Neutron	mrem – rem	Low
Exposure Rate Meters (e.g., ion chambers)	Gamma, X-ray	µR/hr – R/hr	N/A
Count Rate Meters			
Zinc Sulfide*	Alpha	All energies	Moderate
GM	Beta	All energies (dependent of window thickness)	Moderate
	Gamma	All energies	< 1 %
NaI Scintillator	Gamma	All energies (dependent on crystal thickness)	Moderate
Gas Flow Proportional	Alpha	All energies	Moderate
Plastic Scintillator	Beta	C-14 or higher (dependent on window thickness)	Moderate

STATIONARY INSTRUMENTS USED TO MEASURE WIPE, BIOASSAY, AND EFFLUENT SURVEYS			
Detectors	**Radiation**	**Energy Range**	**Efficiency**
LSC*	Alpha	All energies	High
	Beta	All energies	High
	Gamma	Low energy	Moderate
Gamma Counter (NaI)*	Gamma	All energies	High
Gas Proportional	Alpha	All energies	High
	Beta	All energies	Moderate
	Gamma	All energies	< 1%

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

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

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

Appropriate on-the-job-training should consist of the following:
- Observing authorized personnel performing survey instrument calibration; and
- Conducting survey meter calibrations under the supervision and in the physical presence of an individual authorized to perform calibrations.

Facilities and Equipment for Calibration of Dose Rate or Exposure Rate Instruments
- To reduce doses received by individuals not calibrating instruments, calibrations should be conducted in an isolated area of the facility or at times when no one else is present;
- Individuals conducting calibrations will wear assigned dosimetry; and
- Individuals conducting calibrations will use a calibrated and operable survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Model Procedure for Calibrating Survey Instruments
- A radioactive sealed source(s) used for calibrating survey instruments should:
- Approximate a point source;
- Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified to be within ± 5% accuracy by the National Institute of Standards and Technology (NIST);
- Approximate the same energy and type of radiation as the environment in which the
- calibrated device will be employed; and
- For dose rate and exposure rate instruments, the source should be strong enough to give an exposure rate of at least about 30 mR/hr (7.7×10^{-6} coulombs/kilogram/hour) at 100 cm. For example:
    - 85 mCi (3.1 gigabecquerels) of Cesium-137; or
    - 21 mCi (7.8×10^{2} Megabecquerels) of Cobalt-60.

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

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

- Meters with a digital display device shall be calibrated the same as meters with a linear scale.

Note:

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

Surface Contamination Measurement Instruments[3]

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

Model Procedures for Calibrating Liquid Scintillation Counters, Gamma Counters, Gas Flow Proportional Counters, and Multi-channel Analyzers

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

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

Calibration

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

Calibration Records

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

- The owner or user of the instrument;
- A description of the instrument, including the manufacturer's name, model number, serial number, and type of detector;
- A description of the calibration source, including the exposure rate at a specified distance or activity on a specified date;
- For each calibration point, the calculated exposure rate or count rate, the indicated exposure rate or count rate, the deduced correction factor (the calculated exposure rate or count rate divided by the indicated exposure rate or count rate), and the scale selected on the instrument;
- For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular);
- For instruments with internal detectors, the angle between the radiation flux field and a specified surface of the instrument;

[3] ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration."

- For detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure;
- The exposure rate or count rate from a check source, if used; and
- The name of the person who performed the calibration and the date it was performed.

The following information should be attached to the instrument as a calibration sticker or tag:

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

Air Sampler Calibration

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

The publication entitled "Air Sampling Instruments" found in the 9th Edition, American Conference of Governmental Industrial Hygienists, 2001, provides guidance on total air sample volume calibration methods acceptable to Minnesota Department of Health staff, as supplemented below.

Frequency of Calibration

- A licensee committed to a routine or emergency air sampling program should perform an acceptable calibration of all airflow or volume metering devices at least annually (see NRC Regulatory Guide 8.25).
- Special calibrations should be performed at any time there is reason to believe that the operating characteristics of a metering device have been changed, by repair or alteration, or whenever system performance is observed to have changed significantly.
- Routine instrument maintenance should be performed as recommended by the manufacturer.
- Primary or secondary standard instruments used to calibrate air sampling instruments should be inspected frequently for consistency of performance.

Error Limit For Measurement of Air Sample Volume

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

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

E_C: The error in determining the calibration factor. (An acceptable estimate is the percentage error associated with the standard instrument used in the calibration).[4]

[4] The calibration factor should be based on two kinds of determinations. First, correction factors should be determined at several flow rates distributed over the full-scale range. Each flow rate correction factor should be determined while adjusting flow rates

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

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

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

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

$$E_V = [ES^2 + EC^2 + Et^2]^{1/2}$$

The most probable value of the cumulative error EV, in the determination of total volume, should be less than 20%.

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

$$E_V = [4^2 + 2^2 + 1^2]^{1/2} = 4.58\% \text{ or approximately } 5\%$$

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

$$Vs = V1 * (P1/760) * (273/T1)$$

where:

Vs = volume at standard conditions (760 mm & ^{0}C)

V1 = volume measured at conditions P1 and T1

T1 = temperature of V1 in K

P1 = pressure of V1 in mm Hg

Documentation of Calibration of Air Metering Devices

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

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upscale and again while adjusting flow rates downscale, and the two sets of data should be compared. Second, subsequent calibrations should compare the new correction factors to those determined during the previous calibration. If observed differences are significant compared to the overall volume error limit of 20%, an additional error term should be included in the calculation above.

APPENDIX E
MODEL DOSE CALIBRATOR TESTING PROGRAM

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

MODEL PROCEDURE

1. Test for the following at the indicated frequency. Consider repair, replacement, or arithmetic correction if the dose calibrator falls outside the suggested tolerances.

1.1 Constancy, at least once each day prior to assay of patient dosages (a safe margin is considered to be below + 10%).

1.2 Linearity at installation and at least quarterly thereafter (a safe margin is considered to be below + 10%).

1.3 Geometry dependence at installation (a safe margin is considered to be below +10%).

1.4 Accuracy, at installation and at least annually thereafter (a safe margin is considered to be below +10%).

2. After repair, adjustment, or relocation of the dose calibrator, such that proper function of the ionization chamber or electronics would likely be in doubt, repeat the above tests as appropriate.

3. Constancy means reproducibility in measuring a constant source over a long period of time. Assay at least one relatively long-lived source such as Cesium-137, Cobalt-60, Cobalt-57, or Radium-226 using a reproducible geometry each day before using the calibrator. Consider using two or more sources with different photon energies and activities.

Use the following procedure:

3.1 Assay each reference source using the appropriate dose calibrator setting (i.e., use the Cesium-137 setting to assay Cesium-137).

3.2 Measure background at the same setting, and subtract or confirm the proper operation of the automatic background circuit if it is used.

3.3 For each source used, either plot or log (i.e., record in the dose calibrator log book) the background level for each setting checked and the net activity of each constancy source.

3.4 Using one of the sources, repeat the above procedure for all commonly used radioisotope settings. Plot or log the results.

3.5 Establish an action level or tolerance for each recorded measurement at which the individual performing the test will automatically notify the authorized nuclear pharmacist or the radiation safety officer of a suspected malfunction of the calibrator. These action levels should be written in the log book or posted on the calibrator. The dose calibrator should be repaired or replaced if the error exceeds 10%.

4. The linearity of a dose calibrator should be ascertained over the range of its use between the maximum activity in a vial and 30 microcuries. *Linearity* means that the calibrator is able to indicate the correct activity over the range of use of that calibrator. This example uses a vial of

Technetium-99^{m} that has the anticipated maximum activity to be assayed (e.g., the first elution from a new generator) and assumes your predetermined safety margin is ±5%.

4.1 **Time Decay Method**

4.1.1 Inspect the instrument to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).

4.1.2 Assay the Technetium-99^{m} vial in the dose calibrator and subtract background to obtain net activity in millicuries.

4.1.3 Repeat step 4.1.2 at time intervals of 6, 24, 30, and 48 hours after the initial assay.

4.1.4 Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

Assay Time[5] (hours)	Correction Factor
0	31.6
6	15.8
24	2.00
30	1.00
48	0.126

4.1.5 Plot both the measured net activity and the calculated activity versus time.

4.1.6 On the graph, the measured net activity plotted should be within ±5% of the calculated activity if the instrument is linear and functioning properly. If variations greater than 5% are noted, adjust the instrument, have it repaired, or use arithmetic correction factors to correct the readings obtained in daily operations.

4.1.7 If instrument linearity cannot be corrected, for routine assays it will be necessary to use either a portion of the eluate that can be accurately measured or the graph constructed in step 4.1.5 to relate measured activities to calculated activities.

4.2 **Shield Method**

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

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

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

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

4.2.2 Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

4.2.3 Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

4.2.4 Continue for all sleeves.

4.2.5 Complete the following decay method linearity test steps:

4.2.5.1 Repeat the assay at about noon, and again at about 4:00 p.m. Continue on subsequent days until the assayed activity is less than 30 microcuries. For dose calibrators on which the range is selected with a switch, select the range normally used for the measurement.

4.2.5.2 Convert the time and date information recorded to hours elapsed since the first assay.

4.2.5.3 On a sheet of semi log graph paper, label the logarithmic vertical axis in millicuries and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the manufacturer, model number, and serial number of the dose calibrator. Plot the data.

4.2.5.4 Draw a best fit straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.
(A-observed - A-line)/(A-line) = deviation

4.2.5.5 If the worst deviation is more than +0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow conversion from activity indicated by the dose calibrator to true activity.

4.2.6 From the graph made in step 4.2.5.3, find the decay time associated with the activity indicated with sleeve 1 in place. This is the equivalent decay time for sleeve 1. Record that time with the data recorded in step 4.2.2.

4.2.7 Find the decay time associated with the activity indicated with sleeve 2 in place. This is the equivalent decay time for sleeve 2. Record that time with the data recorded in step 4.2.3.

4.2.8 Continue for all sleeves.

4.2.9 The table of sleeve numbers and equivalent decay times constitutes the calibration of the sleeve set.

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

4.2.10 Assay the Technetium-99^{m} syringe or vial in the dose calibrator, and subtract background to obtain the net activity in millicuries. Record the net activity.

4.2.11 Steps 4.2.12 through 4.2.14 below must be completed within 6 minutes.

4.2.12 Put the base and sleeve 1 in the dose calibrator with the vial. Record the sleeve number and indicated activity.

4.2.13 Remove sleeve 1 and put in sleeve 2. Record the sleeve number and indicated activity.

4.2.14 Continue for all sleeves.

4.2.15 On a sheet of semi log graph paper, label the logarithmic vertical axis in millicuries, and label the linear horizontal axis in hours elapsed. At the top of the graph, note the date and the model number and serial number of the dose calibrator.

4.2.16 Plot the data using the equivalent decay time associated with each sleeve.

4.2.17 Draw a best fit straight line through the data points. For the point farthest from the line, calculate its deviation from the value on the line.
(A-observed - A-line)/A-line = deviation.

4.2.18 If the worst deviation is more than ±0.05, the dose calibrator should be repaired or adjusted. If this cannot be done, it will be necessary to make a correction table or graph that will allow conversion from activity indicated by the dose calibrator to "true activity."

5. *Geometry independence* means that the indicated activity does not change with volume or configuration. The test for geometry independence should be conducted using syringes and vials that are representative of the entire range of size, shape, and constructions normally used for injections and a vial similar in size, shape, and construction to the radiopharmaceutical kit vials normally used. The following example assumes that injections are done with 3-cc plastic syringes, that radiopharmaceutical kits are made in 30-cc glass vials, and that the predetermined safety margin is ±5%.

5.1 In a small beaker or vial, mix 2 cc of a solution of technetium-99^{m} with an activity concentration between 1 and 10 mCi/ml. Set out a second small beaker or vial with non-radioactive saline. Tap water may be used.

5.2 Draw 0.5 cc of the Technetium-99^{m} solution into the syringe and assay it. Record the volume and millicuries.

5.3 Remove the syringe from the calibrator, draw an additional 0.5 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

5.4 Repeat the process until a volume of 2.0-cc has been assayed. The entire process must be completed within 10 minutes.

5.5 Select as a standard the volume closest to that normally used for injections. For all other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, graph the data and draw horizontal error lines above and below the chosen standard volume.

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

5.7 To test the geometry dependence for a 30-cc glass vial, draw 1.0 cc of the Technetium99^{m} solution into a syringe and then inject it into the vial. Assay the vial. Record the volume and millicuries indicated.

5.8 Remove the vial from the calibrator and, using a clean syringe, inject 2.0 cc of non-radioactive saline or tap water, and assay again. Record the volume and millicuries indicated.

5.9 Repeat the process until a volume of 19.0-cc has been assayed. The entire process must be completed within 10 minutes.

5.10 Select as a standard the volume closest to that normally used for mixing radiopharmaceutical kits. For all other volumes, divide the standard millicuries by the millicuries indicated for each volume. The quotient is a volume correction factor. Alternatively, the data may be graphed, with horizontal 5% error lines drawn above and below the chosen standard volume.

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

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

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

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

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

6.3 Repeat the procedure for other calibrated reference sources.

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

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

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

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

APPENDIX F
RADIATION SURVEYS

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

Provide one of the following:

A description of the instrumentation (as described above) that will be used to perform required surveys, and a statement that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix G."

OR

A description of alternative equipment and/or procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration and calibration frequency of survey equipment will be performed.[6]
AND

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

Alternative responses will be reviewed by Minnesota Department of Health staff.

Training

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

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

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

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

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

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, survey samples should be analyzed in a low-background area.

[6] Calibrations may be performed by licensees specifically authorized to provide this service. It is not necessary to have a copy of the instrument manufacturer's license, but calibration vendors other than the instrument manufacturer should be verified to ensure they have authorization to calibrate instruments for others.

- A gamma counter system with a single or multi-channel analyzer can be used to count samples containing gamma-emitters (e.g., cesium-137, cobalt-60).
- A liquid scintillation or gas-flow proportional counting system can be used to count samples containing alpha-emitters, beta-emitters, and gamma-emitters (if efficiency is great enough to achieve the required sensitivity for measurements).

MODEL PROCEDURE

This model provides acceptable procedures for area surveys. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of 4731.2020, 4731.2200, and 4731.4426. Guidance for developing alternate trigger levels for contamination in restricted areas is included below.

Radiation Dose Rate Surveys
Perform surveys of dose rates in locations where:

- Workers are exposed to radiation levels that might result in radiation doses in excess of 10 percent of the occupational dose limits; or
- An individual is working in an environment with a dose rate of 2.5 mrem/hour (0.025 mSv) or more.[7]

4731.2090 requires that the TEDE to an individual member of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, and that the dose in any unrestricted area from external sources does not exceed 0.002 rem (20 mSv) in any one hour. Appropriate surveys will be conducted to assure that the requirements of 4731.2090 are met.

Perform radiation level surveys with a survey meter sufficiently sensitive to detect 0.1 milliroentgen (mR) per hour in the following areas, at the frequency specified:

- Survey at the end of each day of use all preparation, assay and administration areas when using radiopharmaceuticals requiring a written directive.
- Survey weekly all radionuclide use, storage, and waste storage areas.
- Survey monthly all laboratory areas where only small quantities of gamma-emitting radioactive material are used (< 200 µCi at a time).
- Survey quarterly all sealed source storage areas.

If trigger levels are exceeded, follow internal procedures for responding and investigating what caused the trigger to be tripped. Example trigger levels for restricted and unrestricted areas are presented in the following table.

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

[7] 2.5 mrem/hr = $\frac{5 \text{ rem/year}}{2{,}000 \text{ hour/year}}$

Contamination Surveys
Perform contamination surveys using instruments suitable for removable and fixed contamination to identify areas of contamination that might result in doses to workers or to the public. Removable contamination can be detected and measured by conducting a wipe test of the surface, counted in an appropriate counting instrument, such as a liquid scintillation counter, a sodium iodide or germanium gamma counter, or a proportional alpha/beta counter.

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

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

Use methods for conducting surveys for removable contamination that are sufficiently sensitive to detect contamination for those radionuclides in use and for which the most restrictive limits apply. Removable contamination survey samples should be measured in a low-background area. The following areas and frequencies should be followed:

- Removable contamination surveys daily for isotope production areas, radiopharmaceutical preparation, and assay areas.
- Removable contamination surveys weekly for radionuclide storage and radionuclide waste storage areas.

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

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

Contamination in Unrestricted Areas
Contamination found in unrestricted areas should be immediately decontaminated to background levels.

When equipment or facilities that are potentially contaminated are to be released for unrestricted use, surface contamination surveys should be conducted for both removable and fixed contamination before these facilities or equipment are released from restricted to unrestricted use.

A standardized method for smear testing of a relatively uniform area should be used to aid in comparing contamination at different times and places. A smear taken from an area of about 100 cm^2 is acceptable to indicate levels of removable contamination.

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

Recommended Action Levels in dpm/100 cm^2 for Removable Contamination	
	C-11, N-13 O-15, F-18
Unrestricted areas, personal clothing	*200*
Restricted areas, protective clothing used only in restricted areas, skin	*2000*

Contents of Survey Records
Survey records should include the following:

- A diagram of the area surveyed or a list of items and equipment surveyed
- Specific locations on the survey diagram where wipes test were taken
- Radiation or contamination levels with appropriate units
- Date of survey
- Manufacturer's name, model number, and serial number of each instrument used
- Name or initials of the person making the evaluation and recording the results.

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

Air Monitoring in the Workplace
Air monitoring can be used to do the following:

- Determine whether the confinement of radioactive materials is effective;
- Measure airborne radioactive material concentrations in the workplace;
- Estimate worker intakes of radioactive material;
- Determine posting requirements;
- Determine what protective equipment and measures are appropriate; and
- Warn of significantly elevated levels of airborne radioactive materials.

Airborne Effluent Release Monitoring
Airborne radioactive effluents should be released from monitored release points (e.g., monitored stacks, discharges, vents) to provide accurate measurements to estimate public exposure. Licensees should verify the performance of effluent monitoring systems by calibrations at intervals not to exceed 12 months to ensure their reliability.

NRC Regulatory Guide 4.20, "Constraints on Release of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," dated December 1996, provides guidance on methods acceptable to Minnesota Department of Health for compliance with the constraint on air emissions to the environment.

NRC Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," dated July 1993, provides guidance on designing an acceptable program for establishing and maintaining ALARA levels for gaseous and liquid effluents at materials facilities. For unmonitored release points, the licensee should estimate the magnitude of the unmonitored effluents. These unmonitored releases will occur any time unsealed material is handled outside a fume hood or other device that will control the releases. The licensee should include these estimates when demonstrating compliance with dose limits and ALARA goals. Unmonitored releases may be estimated based on the quantity of material used in these areas or

the number of procedures performed or other appropriate methods. The unmonitored effluents should not exceed 30 percent of the total estimated effluent releases or 10 percent of the permissible air effluent concentrations found in Column 1 of Table 2 in 4731.2750, Subpart 7, whichever is greater.

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

Liquid Effluent Release Monitoring

The licensee should evaluate the concentrations of radioactive material in water that is released to the environment and to the sanitary sewer. The licensee must show that these releases meet the limits in 4731.2090 and 4731.2420, respectively. The topic of sanitary sewer releases is more fully discussed in Appendix K.

APPENDIX G
SAFE POSSESSION AND USE OF RADIOACTIVE MATERIALS

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

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

The applicant should submit a statement that "Procedures will be revised only if:

- The changes are reviewed and approved by the licensee management and the RSO in writing;
- The changes are in compliance with Minnesota Department of Health rules and the license;
- The changes do not degrade the effectiveness of the program; and
- The licensee staff is provided training in the revised procedures prior to implementation."

General Topics for Safe Possession and Use of Radioactive Materials

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

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

Radionuclide-Specific Procedures

Licensees should develop written procedures for use of different radionuclides so that users know the types of shielding, protective clothing, survey instruments, surveys, and decontamination activities that are required. For example:

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

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

Model Procedures for Handling Emergencies
The following are acceptable procedures for responding to emergencies:

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

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

- Disposable gloves;
- Housekeeping gloves;
- Disposable lab coats;
- Disposable head coverings;
- Disposable shoe covers;
- Roll of absorbent paper with plastic backing;
- Masking tape;
- Plastic trash bags with twist ties;
- “Radioactive Material” labeling tape;
- Marking pen;
- Pre-strung “Radioactive Material” labeling tags;
- Box of wipes;
- Instructions for “Emergency Procedures”;
- Clipboard with a copy of the Radioactive Spill Report Form for the facility;
- Pen or Pencil; and
- Appropriate calibrated survey instruments including batteries (for survey meters).

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

Minor Spills of Liquids and Solids
Instructions to Workers:

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

Follow-up actions:

- Follow up on the decontamination activities and document the results;
- As appropriate, determine cause and corrective actions needed; and
- If necessary, notify Minnesota Department of Health.

***Major Spills of Liquids and Solids*Error! Bookmark not defined.**
Instructions to Workers:

- Clear the area. If appropriate, survey all persons not involved in the spill and vacate the room;
- Prevent the spread of contamination by covering the spill with absorbent paper (paper should be dampened if solids are spilled), but do not attempt to clean it up. To prevent the spread of contamination, limit the movement of all personnel who may be contaminated;
- Shield the source only if it can be done without further contamination or significant increase in radiation exposure;
- Close the room and lock or otherwise secure the area to prevent entry. Post the room with a sign to warn anyone trying to enter that a spill of radioactive material has occurred;
- Notify the RSO immediately;
- Survey all personnel who could possibly have been contaminated. Decontaminate personnel by removing contaminated clothing and flushing contaminated skin with lukewarm water and then washing with a mild soap;
- Allow no one to return to work in the area unless approved by the RSO;
- Cooperate with RSO/RSO staff (e.g., investigation of root cause); and
- Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, requested documentation).

Follow-up actions:
- Confirm decontamination of personnel. If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration;
- Supervise decontamination activities and document the results. Documentation should include location of surveys and decontamination results;
- Determine cause and needed corrective actions; and
- If necessary, notify Minnesota Department of Health.

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

Incidents Involving Radioactive Dusts, Mists, Fumes, Organic Vapors, and Gases
Instructions to Workers:

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

- Follow the instructions of the RSO/RSO staff (e.g., decontamination techniques, surveys, or requested documentation).

  Follow-up actions:
  - Supervise decontamination activities;
  - Perform air sample surveys in the area before permitting resumption of work with licensed materials;
  - Provide written directions to potentially contaminated individuals about providing and collecting urine, breath, blood, or fecal samples, etc;
  - Consider the need for a medical exam and/or whole body count before permitting involved individuals to return to work with licensed material;
  - Determine cause and corrective actions needed;
  - Document incident; and
  - If necessary, notify Minnesota Department of Health.

Minor Fires
Instructions to Workers:

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

  Follow-up actions:
  - Notify emergency medical personnel of any injured individuals who may be contaminated. Provide radiation safety assistance (e.g., monitoring) as needed or requested;
  - Supervise decontamination activities at the facility;
  - If decontamination of personnel was not fully successful, consider inducing perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination that was released by the perspiration;
  - Consult with fire safety officials to ensure that there is no likelihood of fire restarting and that it is safe to re-enter the building;
  - Determine cause and needed corrective actions;
  - Document incident; and
  - If necessary, notify Minnesota Department of Health.

Fires, Explosions, or Major Emergencies
Instructions to Workers:

- Notify all persons in the area to leave immediately;
- Notify the fire department or 911;
- Notify the RSO and other facility safety personnel;
- Ensure that injured personnel receive medical attention;

- Upon arrival of firefighters, inform them where radioactive materials are stored or where radioisotopes were being used; inform them of the present location of the licensed material and the best possible entrance route to the radiation area, as well as any precautions to avoid exposure or risk of creating radioactive contamination by use of high pressure water;
- Allow no one to return to work in the area unless approved by the RSO; and
- Follow the instructions of the RSO (e.g., decontamination techniques, surveys, requested documentation).

Follow-up actions:

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

APPENDIX H
LEAK TEST PROCEDURES

If applicable, the licensee should state:

- We will perform contamination checks on all manufactured sealed sources prior to distribution.
- Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSDR certificate.
- Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State to provide leak test kits to other licensees.

As an alternative, the licensee can state: "We will implement the model leak test program, which is attached to this application."

Training

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

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

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

Appropriate on-the-job-training consists of:

- Observing authorized personnel collecting and analyzing leak test samples; and
- Collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak tests.

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests should be analyzed in a low-background area.
- Use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed.
- Analyze the leak test sample using an instrument that is appropriate for the type of radiation to be measured (e.g., NaI (Tl) well counter system for gamma-emitters, liquid scintillation for beta-emitters, gas-flow proportional counters for alpha-emitters).

If the sensitivity of the counting system is unknown, the minimum detectable activity (MDA) should be determined. The MDA may be determined using the following formula:

$$MDA = \frac{2.71 + 4.65\sqrt{(B_R \times t)}}{t \times E} = \text{Minimum Detectable Activity}$$

where:

MDA	=	minimum detectable activity in disintegrations per minute (dpm)
background	=	background count rate in counts per minute (cpm)
T	=	background counting time in minutes
E	=	detector efficiency in counts per disintegration

For example:

where:

background	=	200 counts per minute (cpm)
E	=	0.1 counts per disintegration (10% efficiency)
T	=	2 minutes

$$MDA = \frac{2.71 + 4.65\ \sqrt{(200\ cpm \times 2\ minutes)}}{2 \times 0.1} = \frac{2.71 + 4.65\sqrt{(400)}}{0.2}$$

$$MDA = \frac{2.71 + 4.65\ (20)}{0.2} = \frac{2.71 + 93}{0.2} = \frac{95.71}{0.2}$$

$$MDA = \frac{478.55\ disintegrations}{minute}$$

$$becquerels = \frac{1\ disintegration}{second}$$

$$Bq = \frac{478.55\ disintegrations}{minute} \times \frac{minute}{60\ seconds} = 7.976\ Bq$$

Frequency for Conducting Leak Tests of Sealed Sources

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

Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as sealed source serial number, radionuclide, and activity.
- If available, use a survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 0.005 microcuries (185 Bq) of the radionuclide.
- Using the selected instrument, count and record the background count rate.
- Check the instrument's counting efficiency using a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should

be within + 5% of the stated value and traceable to a primary radiation standard such as those maintained by NIST.

- Calculate efficiency.

For example:

$$\frac{\text{[(cpm from standard) - (cpm from background]}}{\text{activity of standard in Bq}} = \text{Efficiency in cpm/Bq}$$

Where:

cpm	=	counts per minute
background	=	background
Bq	=	becquerel

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

For example:

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

- Sign and date the list of sources, data and calculations. In accordance with 4731.2510, records must be retained for three years. If the wipe test activity is 185Bq (0.005 microcurie) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly, and also notify Minnesota Department of Health.

APPENDIX I
PERSONNEL EXPOSURE MONITORING PROGRAM

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

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

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

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

The As Low As Reasonably Achievable "ALARA" Program

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

External Exposure

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

There are three dose limits included in 4731.2020 that apply to external exposure:

Deep dose to the whole body	=	5 rem (0.05 Sv)
Shallow dose to the skin or extremities	=	50 rem (0.5 Sv)
Dose to the lens of the eye	=	15 rem (0.15 Sv)

The (DDE) to the whole body is considered to be at a tissue depth of 1 cm (1000 mg/cm2), shallow-dose equivalent to the skin or extremities at 0.007 cm (7 mg/cm2), and eye dose equivalent at 0.3 cm (300 mg/cm2). In evaluating the eye dose equivalent, it is acceptable to take credit for the shielding provided by protective lenses.

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

- Adults likely to receive, in one year, from sources external to the body, a dose in excess of 10 percent of the occupational dose limits in 4731.2020. Monitoring devices are accordingly required for adults with an annual dose in excess of
    - 0.5 rem (0.005 Sv) DDE
    - 1.5 rem (0.015 Sv) eye dose equivalent
    - 5 rem (0.05 Sv) shallow-dose equivalent to the skin
    - 5 rem (0.05 Sv) shallow-dose equivalent to any extremity.
- Minors who are likely to receive an annual dose in excess of
    - rem (1.0 mSv) DDE
    - 0.15 rem (1.5 mSv) eye dose equivalent
    - 0.5 rem (5 mSv) shallow-dose equivalent to the skin
    - 0.5 rem (5 mSv) shallow-dose equivalent to any extremity.
- Declared pregnant women likely to receive an annual dose in excess of 0.1 rem (1.0 mSv) DDE during the entire pregnancy.
- Individuals entering a high or a very high radiation area.

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

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

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

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

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

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

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

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

Investigational Levels – External Dose Monitoring

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

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

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

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

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

- Personnel dose less than Investigational Level I.

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

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

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

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

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

- Re-establishment of Investigational Level II to a level above that listed in the table.

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

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

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

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

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

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

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

APPENDIX J
DEMONSTRATING THAT MEMBERS OF THE PUBLIC WILL NOT EXCEED ALLOWABLE LIMITS

This appendix describes methods for determining radiation doses to members of the public.[8]

Licensees must ensure that:

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

Doses to Members of the Public

INCLUDES doses from:

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

DOES NOT INCLUDE doses from:

- Sanitary sewerage discharges from licensees
- Natural background radiation
- Medical administration of radioactive material
- Participation in medical research

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

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

- Demonstrating by measurement or calculation that the TEDE to the individual likely to receive the highest dose at the boundary of the unrestricted area does not exceed 100 mrem (1 mSv);
- Demonstrating that the annual average concentration of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area does not exceed the values specified in 4731.2750, Subpart 7; and if an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 2 mrem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year; and
- Demonstrating that air emissions of radioactive materials do not result in doses greater than the constraint limit of 10 mrem (0.1mSv) TEDE.

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

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

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

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

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

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

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

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

The following provides the steps on how to calculate the annual dose to an individual member of the public:

- Identify all potential sources of external and internal exposure to members of the public
- Identify all locations of use, transport, or storage of radioactive material
- Perform surveys of all locations of use, transport, or storage of radioactive material
- Identify from survey data, at each location, maximum levels of dose rates
- Calculate predicted occupancy factors at points of maximum dose rates
- Multiply the maximum annual dose by the occupancy factors to get the annual dose
- Multiply the dose rates by the number of hours in a year to produce the maximum annual dose

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

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

Records

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

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

APPENDIX K
WASTE DISPOSAL

General Discussion

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

Model Procedure for Decay-In-Storage (DIS)

- Licensees can minimize the need for storage space if the waste is segregated according to physical half-life.
- Only waste with a physical half-life of less than or equal to 120 days may be disposed of by DIS.
- Waste with a half-life of greater than 65 days but less than or equal to 120 days should be segregated at the source of generation from waste which has a half-life of less than or equal to 65 days.
- Waste should be stored in suitable well-marked containers, the containers should provide adequate shielding, and the waste's physical form should be compatible with the waste container.
- Liquid and solid wastes should be stored separately.
- Filled containers should be sealed. Sealed containers should be identified with labels affixed or attached to them.
- The identification label should include the date when the container was sealed, the longest-lived radioisotope in the container, total activity, and the initials of the individual who sealed the container. The container may then be transferred to the DIS area. When large quantities are held for DIS, sufficient quantities may be present even after 10 half-lives so that persons performing surveys should be aware of the potential for measurable radiation.
- Prior to disposal as ordinary trash, each container should be monitored as follows:
  - Check the radiation detection survey meter for proper operation with a radiation source;
  - Survey the contents of each container in a low background area;
  - Remove any shielding from around the container;
  - Monitor all surfaces of the container;
  - Discard the contents as ordinary trash only if the surveys of the contents indicate no residual radioactivity (i.e., surface readings are indistinguishable from background readings); and
  - If the surveys indicate residual radioactivity, return the container to the DIS area and contact the RSO for further instructions.
- If the surveys indicate no residual radioactivity, record the date when the container was sealed, the disposal date, type of waste (used or unused material, gloves, etc.).

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

Records for Decay-in-storage

The licensee shall retain a record of each disposal for three years. The record must include:

- the date of the disposal,
- the date on which the radioactive material was placed in storage,
- the radionuclides disposed with the longest half-life;
- the manufacturer's name, model number, and serial number of the survey instrument used, or a unique meter identification that can be cross-referenced to a specific manufacturer, model, and serial number;
- the background dose rate,
- the radiation dose rate measured at the surface of each waste container, and
- the name of the individual who performed the disposal.

Model Procedure for Disposal of Liquids Into Sanitary Sewer

- Confirm that the sewer system is a public system, not a private sanitary sewer, septic system, or leach field.
- Confirm that the liquid waste being discharged is readily soluble (or is easily dispersible biological material) in water.
- Calculate the amount of each radioisotope that can be discharged by using the information from prior, similar discharges and the information in 4731.2750.
- Make sure that the amount of each radioisotope does not exceed the monthly and annual discharge limits specified in 4731.2420 and 10 4731.2750, Subpart 7 (records for individual users/laboratories).
- If more than one radioisotope is released, the sum of the ratios of the average monthly discharge of a radioisotope to the corresponding limit in 4731.2750, Subpart 7 should not exceed unity.
- Make sure the total quantity of licensed material released into the sanitary sewerage system in a year does not exceed 185 GBq (5 Ci) of H-3 (tritium), 37 GBq (1 Ci) of C-14, and 37Gbq (1 Ci) of all other radioisotopes combined.
- Record the date, radioisotope(s), estimated activity of each radioisotope, location where the material is discharged, and the initials of the individual discharging the waste.
- Liquid waste should be discharged only via designated sinks or toilets.
- Discharge liquid waste slowly to minimize splashing, with water running to dilute it and to ensure that the material moves out of the sink into the sewer system.
- Survey the sink and surrounding work surfaces to confirm that no residual material or contamination remains in the sink or on work surfaces. Decontaminate as appropriate.
- Prior to leaving the area, decontaminate all areas or surfaces if found to be contaminated.
- For all releases to the sanitary sewer from the licensed facility, maintain records of each radioisotope and the quantity and concentration that is released into the sewer system in order to demonstrate compliance with the regulatory limits for total quantity released and concentrations released by the licensed facility.

APPENDIX L
DOT REQUIREMENTS FOR TRANSPORTATION OF TYPE A OR TYPE B QUANTITIES

- The major areas in the DOT regulations that are most relevant for transportation of Type A or Type B quantities of licensed material are:
- Table of Hazardous Materials and Special Provisions 49 CFR 172.101: Purpose and use of hazardous materials table;
- Shipping Papers 49 CFR 172.200-204: Applicability, general entries, description of hazardous material on shipping papers, additional description requirements, shipper's certification;
- Package Marking 49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324: Applicability, general marking requirements for non-bulk packaging, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging;
- Package Labeling 49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440: General labeling requirements, prohibited labeling, Class 7 (radioactive) material, placement of labels, label specifications, radioactive white-I label, radioactive yellow-II label, radioactive yellow-III label;
- Placarding of Vehicles 49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556: Applicability of placarding requirements, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, general specifications for placards, RADIOACTIVE placard;
- Emergency Response Information 49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604: Applicability and general requirements, emergency response information, emergency response telephone number;
- Training 49 CFR 172.702, 49 CFR 172.704: Applicability and responsibility for training and testing, training requirements;
- Shippers – General Requirements for Shipments and Packaging 49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.411, 49 CFR 173.412, 49 CFR 173.413, 49 CFR 173.415, 49 CFR 173.416, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.471, 49 CFR 173.475, 49 CFR 173.476: Definitions, general design requirements, industrial packages, additional design requirements for Type A packages, requirements for Type B packages, authorized Type A packages, authorized Type B packages, requirements for determining A1 and A2 values for radionuclides and for the listing of radionuclides on shipping papers and labels, table of A1 and A2 values for radionuclides, radiation level limitations, requirements for NRC-approved packages, quality control requirements prior to each shipment of Class 7 (radioactive) materials, approval of special form Class 7 (radioactive) materials; and
- Carriage by Public Highway 49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842: Driver training, shipping papers, general requirements (packages secured in a vehicle), Class 7 (radioactive) material.

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

SUMMARY OF REVISIONS

REVISION	SECTION	DESCRIPTION
02/17/09	Appendix F	Survey records - Added requirements in 4731.2510
02/17/09	Appendix K	Records for Decay-in-storage - Added requirements in 4731.2405